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Web-Based Intervention to Reduce Substance Abuse and Depressive Symptoms in Mexico: Development and Usability Test

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Abstract

Background: The development of Web-based interventions for substance abuse in Latin America is a new field of interest with great potential for expansion to other Spanish-speaking countries.

Objective: This paper describes a project aimed to develop and evaluate the usability of the Web-based Help Program for Drug Abuse and Depression (Programa de Ayuda para Abuso de Drogas y Depresión, PAADD, in Spanish) and also to construct a systematic frame of reference for the development of future Web-based programs.

Methods: The PAADD aims to reduce substance use and depressive symptoms with cognitive behavioral techniques translated into Web applications, aided by the participation of a counselor to provide support and guidance. This Web-based intervention includes 4 steps: (1) My Starting Point, (2) Where Do I Want to Be? (3) Strategies for Change, and (4) Maintaining Change. The development of the program was an interactive multistage process. The first stage defined the core structure and contents, which were validated in stage 2 by a group of 8 experts in addiction treatment. Programming of the applications took place in stage 3, taking into account 3 types of end users: administrators, counselors, and substance users. Stage 4 consisted of functionality testing. In stage 5, a total of 9 health professionals and 20 drug users currently in treatment voluntarily interacted with the program in a usability test, providing feedback about adjustments needed to improve users' experience.

Results: The main finding of stage 2 was the consensus of the health professionals about the cognitive behavioral strategies and techniques included in PAADD being appropriate for changing substance use behaviors. In stage 5, the health professionals found the functionalities easy to learn; their suggestions were related to the page layout, inclusion of confirmation messages at the end of activities, avoiding "read more" links, and providing feedback about every activity. On the other hand, the users said the information presented within the modules was easy to follow and suggested more dynamic features with concrete instructions and feedback.

Conclusions: The resulting Web-based program may have advantages over traditional face-to-face therapies owing to its low cost, wide accessibility, anonymity, and independence of time and distance factors. The detailed description of the process of designing a Web-based program is an important contribution to others interested in this field. The potential benefits must be verified in specific studies.

KEYWORDS

substance abuse; depressive symptoms; Internet; cognitive behavioral therapy; usability

Introduction

Internet-Based Cognitive Behavioral Interventions for Drug Use

The drug treatments with the greatest empirical validity are those involving cognitive behavioral interventions (CBIs) [1]. Some authors argue that the success of such interventions is related to the use of specific techniques, such as exploration of the positive and negative consequences of substance use (decisional balance); self-monitoring, or diary of use, where situations of high risk for drug use can also be identified; elaboration of strategies to anticipate and face situations of risk and craving; and training in social abilities [2-4].

A recent meta-analysis of the effectiveness of Internet-based interventions based on cognitive behavioral therapy demonstrated a large effect size (0.83, n=3960) as compared with other modalities, including psychoeducation (0.46, n=6796) [5]. On the other hand, it has been reported that the principles and techniques of CBIs focused on reduction in alcohol and tobacco use lend themselves more easily to adaption to an Internet-based format [6].

Web-based interventions allow complex treatments to be delivered with consistency and minimal demands on staff time and training resources. Moreover, computerized programs may be less threatening, provide greater anonymity [7,8], and reduce the effects of stigma, allowing individuals to seek information in relative privacy [9]. The expansion of the Internet offers new treatment opportunities for a large number of individuals at a relatively low cost; they may be particularly useful in rural or remote settings, where access to psychotherapy for substance use disorders may be limited, and they may thus help to broaden the availability of treatment [10-15]. Current Web-based programs differ in the level of therapist support provided and the use of tools that require or not a response from the user. The level of support can vary from nonassistance (self-help) to having some level of therapist contact by email or telephone; the latter has shown results superior to those of total self-help programs [5,16-18].

During the last decade, several Web-based interventions have been developed and validated in the mental health field [5]. Those for substance abuse, however, have focused mainly on alcohol [19-21] and tobacco [22,23]. There are few validated Web-based interventions to address drug abuse [24-27] and even fewer that address substance abuse and depression together even though comorbidity is highly frequent [28,29].

Internet Use and Web-Based Treatment in Latin America

Web-based interventions developed in Latin America are very limited and focus on smoking [30], heavy drinking [31,32], and depression [33,34]. Given the 560 million people worldwide who speak Spanish, 40 million of whom live in the United States, there is a pressing need for Web-based interventions in this language [35].

Approximately 3.3 billion people around the world use the Internet, among them 345 million in Latin America, with a growth of 1808.4% in the past 15 years [36]. According to the Mexican Internet Association [37], there are approximately 53.9 million Internet users in the country, 46% of whom are aged 13-24 years. Although there are no specific studies of the use of the Internet for health care, it has been documented that health-related pages occupy the eleventh place among Web searches as a whole [38].

There are few publications that describe the process of developing a Web-based intervention, the selection of strategies required, or the limitations involved in starting it up [39]. Such information could help to provide better interpretations of data on the effectiveness of Web-based programs, aid in the design of outreach strategies to target populations, and suggest avenues for further research [40]. It could also testify to the complexity of designing such programs in a Latin American context, where they have seldom been attempted and where there is still a degree of resistance to their use.

The purposes of this paper are therefore to describe the development process of the Web-based Help Program for Drug Abuse and Depression (Programa de Ayuda para Abuso de Drogas y Depresión, PAADD, in Spanish) [41] in Mexico and to describe its final structure and functioning, which includes the participation of a counselor.

Methods

Stages of Development

The PAADD was developed in an interactive multistage process that involved design, testing, and redesign tasks, following international recommendations for the development of eHealth strategies and ethical standards for Web-based interventions [42].

Stage 1. Conceptual Design

The aims of this phase were to define the structure and contents of the program. After a search of the literature on treatment in Mexico for problems of substance use and depression, 3 sources were chosen: (1) self-help manual ¿Cómo dejar de consumir drogas? (How to Stop Using Drugs) [43]; (2) Web-based

program Ayuda para Depresión (ADep, Help for Depression) [33,34]; and (3) Web-based program Beber Menos (Drink Less) [31].

The basic structure of the intervention and the specific techniques of behavior modification were taken from the self-help manual How to Stop Using Drugs [43], a brief CBI.

The Web-based program ADep [33,34] is a CBI-based self-help program addressed to women but also used by men. It was designed for the general population to reduce depressive symptoms or their severity in those already suffering from depression. It provided the basis for the cognitive restructuring component to change negative thoughts associated with substance use, as well as relaxation exercises; it does not address substance abuse.

The Web-based program Beber Menos [31] is part of a multisite project coordinated by the World Health Organization. This self-help program is directed at persons with hazardous or harmful alcohol use and served as a model for the functionalities.

On the basis of the literature review of Web-based interventions, the specific characteristics of the PAADD were defined as follows:

1. The PAADD is a stand-alone intervention directed at persons with risky levels of drug use and not at those with drug dependence.

2. It offers strategies to address substance abuse and depressive symptoms together.

3. It includes 4 steps to establish a baseline and a treatment goal, in addition to strategies to change the pattern of use, stay focused on the goal, and prevent relapses.

4. It offers contact from a counselor, which previous studies have shown produces favorable results [44,45]

Stage 2. Validation of Content

Once the outline and the core contents for each step were planned, these were shared with a focus group of 8 experts in addiction treatment from the public mental health care system in the Mexico City metropolitan area. Participants were asked to comment on the proposed techniques and the possible impact of the program and to provide suggestions for improvement and implementation.

These experts expressed the opinion that the CBI strategies and techniques for changing substance use behaviors were appropriate. Their comments were useful for fine-tuning the inclusion criteria: (1) medium risk level of drug use according to the Alcohol, Smoking and Substance Involvement Screening Test [46] and (2) moderate depressive symptomatology assessed with the Patient Health Questionnaire (PHQ-9) [47] administered in a first face-to-face session. They suggested including different easy-to-use applications including workable user reports to record the amount of drugs consumed and sending users reminders to finish their activities. They also offered observations on the functions of the counselor, suggesting in particular that there be an initial face-to-face meeting in order to forge a therapeutic alliance, explaining that the PAADD is not a treatment in real time but that the counselor would provide written feedback. It was also suggested that training be offered to the counselor in skills such as empathy and motivational interviewing–based reflective listening. Finally, they offered recommendations regarding the vocabulary used so that the program would also be accessible to users with a low educational level.

Stage 3. Structure of the PAADD

The PAADD was structured into 4 successive steps. The home page is shown in Figure 1. Table 1 indicates the CBI strategies used in each step, such as self-control, functional analysis of consumption, and exercises to identify risk situations and transform negative thoughts associated with depressive symptoms; Figures 2-5 show some examples of the content and functions of each step. Users receive feedback from the counselor via a message system to motivate them to complete all the exercises.

Table 1. Overall structure of the Web-Based Help Program for Drug Abuse and Depression (Programa de Ayuda para Abuso de Drogas y Depresión, PAADD, in Spanish).

Step	Cognitive behavioral strategies
Step 1: My Starting Point	Establishment of baseline
	Identification of pattern of use
	Depressive symptoms
	Identification of negative thoughts
	Decisional balance
	Motivation and reasons to change
Step 2: Where Do I Want to Be?	Goal setting
Step 3: Strategies for Change	Self-monitoring
	Functional analysis of substance use
	Developing an action plan
	Psychoeducation
	Relaxation exercises
	Stopping unwanted thoughts
	Cognitive restructuring—link to ADep[a] [31]
	Positive reinforcement
Step 4: Maintaining Change	Social skills for resisting pressure
	Seeking social support
	Assertiveness
	Monitoring results
	Adopting behaviors incompatible with substance use
	Relapse prevention

[a]ADep: Ayuda para Depresión (Help for Depression).

Figure 1. Help Program for Drug Abuse and Depression (Programa de Ayuda para Abuso de Drogas y Depresión, PAADD)''s welcome page. Illustration of the stages and tools comprised in the program.

Programa de Ayuda para el Abuso de Drogas y Depresión

paddl

SALIR

Paso 1   Comentarios

- Analizar tu consumo de drogas
- Reconocer los pensamientos que te dificultan dejar de usarlas
- Establecer una meta respecto a tu consumo y un plan para alcanzarla
- Aprender estrategias que te permitan pensar y actuar de manera más conveniente para modificar tu consumo
- Utilizar estrategias para mantener, a lo largo del tiempo, tu meta de dejar las drogas y evitar recaídas

Si tienes dudas o necesitas el apoyo de tu orientador recibirás respuesta en un plazo máximo de 24 horas.

El siguiente diagrama muestra los pasos que integran el programa y el proceso que seguirás en el PAADD.

Para empezar el análisis de tu consumo continuaremos con el Paso 1.

1 MI PUNTO DE PARTIDA   Exploración del consumo   Estado de ánimo y pensamientos negativos   Motivación para cambiar

Razones para cambiar

2

¿A DÓNDE QUIERO LLEGAR?

Diario de consumo   3 ESTRATEGIAS PARA EL CAMBIO

Situaciones de riesgo

Ansiedad y deseo

Establecer objetivos y metas

Pensamientos negativos   4 MANTENIENDO EL CAMBIO   Manejo de la presión para consumir

Pros y contras de mi consumo

Reconocimiento de logros   Compartir mi decisión

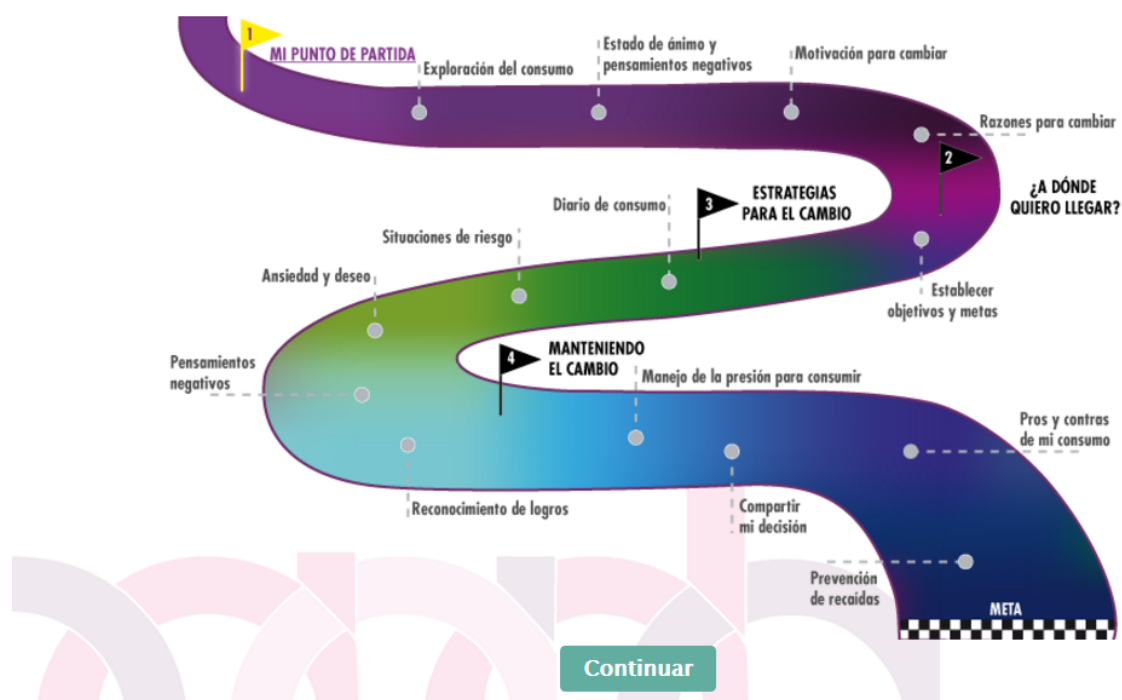Prevención de recaídas   META

Continuar

XSL•FO
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Figure 2. Timeline followback in step 1. Tool used to record drug use during the previous week and the amount of money expended.

Figure 3. Decisional balance in step 1. Tool to identify advantages and disadvantages of drug use.

Figure 4. Goal setting in step 2. Tool to set a consumption goal for the following week.

Figure 5. Cognitive restructuring in step 3. Tool to analyze negative thoughts associated with drug use.

Step 1: My Starting Point

The aim of this module is to promote the awareness of personal drug use and its risks in order to increase the motivation to change. This module includes assessment instruments and behavioral strategies to establish a baseline. At the end, users receive a printable report and are asked if they are committed to participating in a process of change. A positive answer directs them to step 2; a negative answer redirects them to a feedback page to prompt reflection about the consequences of drug use.

Step 2: Where Do I Want to Be?

The purpose of this step is to set treatment goals. Users are provided with various tools, such as the recommendation to define a goal (simple, specific, realistic), to establish a reduction plan (to focus on 1 drug at a time, to plan ahead, to remember that any reduction in use is a step forward), and to set a time limit to achieve the goal. At the end of this step the user receives a printable feedback page.

Step 3: Strategies for Change

Step 3 is aimed at achieving behavioral change in accordance with the goals established in step 2. Users are advised to log in every day, record daily drug use, review the progress graph, and do an activity to achieve the change. They are offered tools to perform a functional analysis of substance use behavior, to develop action plans to face risk situations, to apply emotional control techniques to cope with anxiety, to generate positive self-reinforcement, and for cognitive restructuring of negative thoughts.

Step 4: Maintaining Change

The objective of step 4 is to reinforce changes in drug use behavior and avoid relapses. It offers strategies for recognition of success (self-reinforcement), for facing pressure to use drugs (assertiveness), and for seeking social support, among others. The counselor makes the decision to enable this step in accordance with the results from step 3.

The program is designed to be completed in 8 weeks, but this period can be extended if necessary depending on the evaluation of the counselor, who might suggest specific activities that the participant may have skipped, according to the progress and needs of each user. The role of the counselor also includes monitoring the completion of the activities as well as providing written feedback and encouragement within; all these functions

are performed through a messaging system within the program within 24 hours after a user logs in. This is a minimal contact scheme that differs from conducting therapy sessions via the Internet and represents an opportunity to optimize time because one counselor can monitor 2 or more patients simultaneously.

The structure of the Web-based intervention was outlined as a diagram in order to establish the sequence of the steps involved. The PAADD was constructed by a commercial programming company as a Web application accessible through computers, laptops, or tablets with any browser; although it is not a mobile application, it can also be accessed with a mobile phone. It took into account 3 types of end users: administrators, counselors, and substance users. Functionality and usability tests were performed on the completed application.

Stage 4. Functionality Test

The purpose of this process was to ensure that the PAADD met the technical requirements set out in the functional design and to identify programming glitches. The test specifically verified the following:

- The program worked according to specifications.
- The database responded to the input and output specifications of expected information.
- The system followed the sequence identified in the functional design.

These functionalities were tested by members of the research team (n=7), who interacted with the program and verified each one, following a checklist. Errors found were corrected and a second test was performed. This functionality testing was then followed by a usability test.

Stage 5. Usability Test

Usability is defined as the ability of a software or program to be understood, learned, used, and be attractive to the end user under specific conditions of use [48]. The objectives of this phase were (1) to test the usability of the PAADD and (2) to identify the sections that needed adjustment to improve users' experience.

Participants

A total of 9 health professionals from Mexico City, State of Mexico, and the states Morelos, and Baja California agreed to participate. Inclusion criteria were that (1) they worked in an addiction treatment center; (2) they had at least a year of experience working in substance abuse treatment using cognitive behavioral strategies; (3) they had experience using the Internet; and (4) they were regular email users. Each was asked to invite patients under treatment (n=20) to give their opinion of the PAADD. The inclusion criteria for the patient group were that (1) they were adults; (2) they had received a minimum of 4 treatment sessions for abuse of psychoactive substances during the previous 6 months; (3) they could read and write; (4) they had experience using the Internet; and (5) they were regular email users.

Evaluation Instruments

All participants (both health professionals and patients) responded to a questionnaire about their Internet usage and received an instruction guide for usability test. The checklist for the health professionals focused on evaluating the role of the counselor (usefulness of strategies, contents, and message system), whereas that for patients focused on their perspective about language and ease of use.

Procedure

This procedure was approved by the Research Ethics Committee of the Ramón de la Fuente Muñiz National Institute of Psychiatry. All participants were volunteers and signed an informed consent form with the understanding that the data might be used in research. All information obtained in this program is confidential and available only to members of the research team. The questionnaires, forms, and other documents were identified by a numeric code that avoids the identification of participants.

The usability test was based on a selection of tasks and pages according to the guidelines proposed by Dumas and Loring [49]: (1) frequently used tasks; (2) tasks that are basic to the general program; (3) tasks that are critical because they affect other parts of the design, even though they may not be frequently used; (4) tasks in which problems are anticipated; (5) tasks that test the structure and components of the design; and (6) the time available for the evaluation.

The tests carried out by the health professionals consisted of navigating the PAADD, following a list of specific actions, and reporting on their experience. The tests by patients were carried out at the centers where they were receiving treatment. A member of the research team accompanied them and recorded their commentaries and suggestions.

Results

Results of the usability test are presented here separately by type of participant.

Characteristics of the Health Professionals

The group included 5 women and 3 men with an average age of 30.25 years (SD 5.33). All participants had a master's degree in psychology of addiction and had an average of 5 years of experience using the CBI approach to treat persons with problems of substance abuse. All participants were regular users of the Internet, with an average daily use of 6.1 hours, the majority from their home and workplace.

Professionals' Suggestions

The main suggestions from the health professionals focused on the content and format but not on the structure of the program, for instance, recommendations to change the color scheme, page layout, font size, arrangement of functions, inclusion of confirmation messages at the end of activities, avoiding the use of technical language and "read more" links, providing short introductory texts for every task, and creating more visible help buttons with specific explanations and tips. They found the functionalities easy to learn, although they indicated that some were not intuitive at first glance. They suggested providing feedback about every activity and including more activities and exercises within the program, as well as more tips on how to end substance abuse. They also suggested the possibility of

including testimonials from persons who had benefited from the program (see Table 2).

Characteristics of the Users

The user group included 16 men and 4 women, 60% of them single, with an average age of 29.6 (SD 9.1) years. In this group 70% (14/20) had completed high school, 15% (3/20) an undergraduate degree, and 15% (3/20) elementary school; 65% (13/20) were employed, 20% (4/20) did not work, and 15% (3/20) were students. All participants were regular users of the Internet, with an average daily use of 3 hours, the majority from home (85%) and the rest using their cell phone and/or at Internet cafes.

Users' Suggestions

Users suggested a more dynamic design with images and colors, clearer, more concrete instructions, inclusion of empathetic, reflective feedback, and also a chart showing the names and appearance of different drugs. The majority said it was important to be able to modify the weekly goal and clarify the sequence of activities in the program (see Table 3).

The observations and suggestions of users and health professionals were compiled into a document that served as a guide for development of a new version of the PAADD, which was in turn put through an evaluation process.

Table 2. Observations and suggestions from health professionals.

Step	Positive aspects	Negative aspects	Suggestions
Step 1	Includes counselor from first contact. The format of the instruments facilitates response. Providing a summary of results of the initial evaluation favors a decision to change.	It is necessary to clarify some instructions and the sequence of the instruments. Feedback is very brief. Cannot log fractional amounts of substances used.	Indicate what each instrument evaluates. Provide motivational, reflective, and personal feedback. Include a list of common names for drugs. Allow logging of open responses. Include interactive applications, examples, and vignettes.
Step 2	Gives users the responsibility to set their own goals. Weekly goal report helps the user not to forget it. Information provided helps users to plan their weekly goals.	The sequence of activities is not clear. The setting of goals does not consider multiple use.	Provide simpler instructions. Compare habitual use with the weekly goal. Allow setting of goals for more than 1 drug.
Step 3	The graph of use allows users to observe their changes. The diary of drug use allows the identification of risk situations. The summary of drug use situations allows for the analysis of factors that interfere with the goal.	The sequence of activities is not clear. Complex texts. There is no indication to show the end of the activities.	Make the sequence of activities explicit. Include clear, concise texts with interactive elements such as vignettes and images. Include a brief explanation of the significance of the graphs. Add a phrase to show when an activity is finished.
Step 4	The exercises included are strategically important to maintain the change in drug use. They are easy to do.	Needs automatic feedback on finishing exercises. Needs an indication of the end of an activity.	Add a phrase to show when an activity is finished.

Table 3. Observations and suggestions from drug users in treatment.

Step	Positive aspects	Negative aspects	Suggestions
Step 1	The initial information and the informed consent help to understand what the program is about. The feedback for every questionnaire is very useful. The report lets you see the combined results of the evaluation.	The design of the program is very serious. The exercises on advantages and disadvantages of drug use are complex. The instructions for some questionnaires are not clear. There is technical language in the instructions, exercises, and feedback.	Use a dynamic design that includes images, vignettes, and more color. Provide clear and simple instructions. Give reflective and empathetic feedback to help interpret the result. Include examples of different forms and names of drugs. Highlight the link to the page on risks associated with drug use.
Step 2	Feedback on setting goals helps to remember them.	The instructions are complex. The sequence of activities is not clear.	Include more than 1 drug in the log of goals. Allow a change in goal. Compare the weekly goal with habitual use logged in step 1.
Step 3	The initial screen shows a general overview of the activities of this step. The drug use diary lets you identify the factors that encourage use. The graphs show progress in reducing drug use and situations of use and nonuse.	The instructions are complex. The diary does not allow logging of fractional amounts of substances used. Interpretation of the graphs is not clear. Texts are long. Needs an indication of when all the activities are finished.	Provide clear and concise instructions and interactive examples of the activity log. Provide more concrete texts. Include a brief explanation of the meaning of the graphs. Make the sequence of activities explicit. Include a phrase that shows the end of the activity.
Step 4	The activities are easy to do.	Activities do not provide feedback, and there is no indicator of when they are finished.	Give automatic reminders in case the weekly goal is not met. Indicate a time period for each activity.

Discussion

Main Findings

This paper describes the development and results of the usability test of PAADD, a Web-based intervention with the participation of a counselor, the first of its kind in Latin America that is designed to reduce substance use and depressive symptoms. The development of the program was systematic and rigorous. It began with a review of the literature on brief interventions and incorporated the opinions of experts in addiction treatment as well as 2 types of end users, following a procedure similar to that reported by Morrison et al [50]. The result of the process was a Web-based program that contains the key elements of a CBI, with a user-friendly design, simple instructions, and intuitive and time-efficient functions.

The translation of cognitive behavioral strategies to the concrete activities of the PAADD was complex and time consuming. Van Voorhees et al [51] note that a focus on detail is necessary to achieve good results in this type of process. Likewise, a multidisciplinary approach considering different points of view leads to more satisfactory results [52]. The detailed description of the process of designing a Web-based program is an important contribution, given that there is no specific method for the creation of this intervention modality [50]. This study can therefore serve as a guide to others interested in this field.

Acceptance and Usability Test

An important characteristic of the PAADD is that it includes the participation of counselors who provide feedback according to the motivational interviewing techniques. This element is intended to strengthen adherence, as it has been shown that the inclusion of health professionals has a positive influence on retention and motivation of participants in such programs [53,54].

In the usability test, drug users commented that the PAADD was professional and clear. Many felt that the information presented within the modules was relatively easy to follow, comprehensive, and of good quality. A few participants reported at times feeling impatient to receive the next module. The majority of users commented positively on the content of the program and felt that they could benefit from it. In their view, it helped principally with improved self-awareness of their pattern of drug use. They reported that the PAADD encouraged them to think about self-management techniques, how to monitor their thoughts and feelings, and how to regulate their behavior and consumption patterns. These observations suggest that the design process was successful; it resulted in a program that is easily usable by persons who wish to end their substance use and who present depressive symptomatology.

The PAADD may have advantages over traditional face-to-face therapies because of its low cost, wide accessibility, anonymity, and independence of time and distance factors. It may be a good alternative for persons not receiving treatment owing to factors such as physical distance from available services, lack of qualified providers, socioeconomic condition, and stigma, although these potential benefits will have to be verified in specific studies.

Future Directions

In future efforts it will also be important to consider that the initial investment for the design of a Web-based intervention can be high and that it is necessary to perform a cost-benefit analysis to document the viability of the project. It should also be kept in mind that technologies are developing rapidly; in order to provide increased availability and accessibility, it is necessary to plan from the beginning the possibility of using the program on diverse types of devices, such as mobile phones and tablets, and not just on computers.

Because PAADD is not an open-access program, it will also be necessary to design a dissemination strategy that would include training of counselors and to promote the use of PAADD in specialized treatment centers. This will allow to document adoption and implementation in real-life scenarios.

Limitations

The lack of forums or chat functionalities for users to interact with each other may be a limitation in this program because having contact with others in the same situation can be a source of support. It is also possible that the small number of users participating in the usability test limited the number of opinions regarding improvements to the program. Such limitations have been reported in similar studies [53,54].

Conclusions

Data from the usability test indicate that the PAADD has the necessary features to support users in their process of reducing drug use. If this is corroborated in effectiveness studies, the program could be used as an alternative to treatment as usual.

Acknowledgments

Conflicts of Interest

None declared.

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Abbreviations

ADep: Ayuda para Depresión (Help for Depression)
CBI: cognitive behavioral intervention
PAADD: Programa de Ayuda para Abuso de Drogas y Depresión (Web-based Help Program for Drug Abuse and Depression)
PHQ-9: Patient Health Questionnaire

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Exploring the Use of Information and Communication Technology by People With Mood Disorder: A Systematic Review and Metasynthesis

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Abstract

Background: There is a growing body of evidence relating to how information and communication technology (ICT) can be used to support people with physical health conditions. Less is known regarding mental health, and in particular, mood disorder.

Objective: To conduct a metasynthesis of all qualitative studies exploring the use of ICTs by people with mood disorder.

Methods: Searches were run in eight electronic databases using a systematic search strategy. Qualitative and mixed-method studies published in English between 2007 and 2014 were included. Thematic synthesis was used to interpret and synthesis the results of the included studies.

Results: Thirty-four studies were included in the synthesis. The methodological design of the studies was qualitative or mixed-methods. A global assessment of study quality identified 22 studies as strong and 12 weak with most having a typology of findings either at topical or thematic survey levels of data transformation. A typology of ICT use by people with mood disorder was created as a result of synthesis.

Conclusions: The systematic review and metasynthesis clearly identified a gap in the research literature as no studies were identified, which specifically researched how people with mood disorder use mobile ICT. Further qualitative research is recommended to understand the meaning this type of technology holds for people. Such research might provide valuable information on how people use mobile technology in their lives in general and also, more specifically, how they are being used to help with their mood disorders.

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Introduction

Mood disorder is a diagnostic category containing, among others, diagnoses such as major depression and bipolar depression [1]. For some, having a mood disorder can be a lifelong problem and the need to support people with such long-term conditions is a major challenge facing health care providers. In order to effectively manage their health and wellbeing, people with a mood disorders may have to master a range of skills and make lifestyle changes, either independently or with the support of others, such as family, friends, third sector services, and mental health and social care professionals [2].

In mental health care systems designed primarily to treat acute episodes of care, the rise in long-term conditions has threatened the sustainability of services and ultimately failed to meet the needs of patients with ongoing care management and the delivery of psychosocial interventions [3]. Developments in information and communication technology (ICT) (such as the use of the Internet or computer technology and electronic systems) have begun to provide new ways for people to manage their health. ICT interventions have become affordable, accessible, and versatile such as through the use of Web-based self-help resources [4]. Psychological interventions have been effectively delivered through ICTs [5] while having the ability to reach rural areas within diverse populations and settings [6].

ICTs are increasingly being used for direct patient care [7]. eHealth is the umbrella term used for a broad range of health informatics applications that facilitate the management and delivery of health-related care, including the dissemination of health-related information, storage, and exchange of clinical data, interprofessional communication, computer-based support, patient-provider interaction, education, health service management, health communities, and telemedicine, among other functions [8].

In mental health care, eHealth technologies can facilitate the delivery of a wide range of effective treatments for a variety of clinical problems. They have widened the choices available to patients for selecting an approach best suited to manage their long-term condition [7]. Such choices include: computerized cognitive behavioral therapy (cCBT) [9]; computerized bibliotherapy, and Web-based self-help resources/patient information websites [10]; online counselling [11]; patient forums, blogs, social media/social networking sites (SNSs) [12], and online self-management groups [13].

More recently, a shift has occurred toward making technologies more portable or mobile, evidenced by the recent rise in smartphone and tablet ownership and usage [14]. Consequently, mHealth has become important for the delivery of health and health services. Improvements in reliability and broadband coverage means greater and faster Internet access for these mobile technologies. As a result, mobile devices have changed the way that consumers manage their health and engage with the health care system [15].

Evidence suggests that mHealth can facilitate the provision of effective interventions and support the self-management of long-term conditions [15]. Self-management is an interactive, dynamic, and daily set of activities by which people manage their long-term condition through overlapping skills, tasks, and processes. [16].

However, despite its growing popularity over the last decade, systematic research on the use of mHealth as a means of improving health outcomes remains scarce [17,18]. Many mHealth development studies to date, mostly outcome studies and randomized control trials (RCT), have failed to include patients or end users in a meaningful way or considered them only in limited ways in the design process [5,14,19-22]. This oversight has contributed to technology redundancy and abandonment rates [23]. Qualitative research that provides a more in-depth understanding of users' views and experiences of how eHealth and mHealth affects their lives [23,24] is of vital importance if we are to understand how people use or benefit from technology and what drives them to engage, or not, with these technologies.

With the fast accumulation of qualitative studies in practice disciplines that specifically reflect experiences and subjective perspectives there is a need to bring together evidence from these studies [25]. We therefore conducted a systematic review in order to collect and synthesize all qualitative evidence exploring the use of ICTs and/or mobile information and communication technologies (mICTs) by people with mood disorder. We sought to answer the following review questions:

1. Why do people with mood disorders use (m)ICTs?

2. What are (m)ICTs being used for by people with mood disorders?

3. What are the perceived benefits and challenges of using (m)ICTs by people with mood disorders?

4. In what ways are (m)ICTs being used for self-management by people with mood disorders?

5. What role, if any, do (m)ICTs play in terms of social relationships for people with mood disorders?

Methods

Rationale

A protocol for the review was published in PROSPERO (ID=CRD42014008841). The systematic review and metasynthesis drew on methods proposed by Sandelowski and Barroso [26], Thomas and Harden [27], and Barnett-Page and Thomas [28]. Qualitative research synthesis is an approach developed to make use of this proliferation of qualitative findings driven from the growth of empirical research and evidence-based practice in the 1990s [26].

Search Strategy

Due to potential difficulties in finding qualitative research [27], a sensitive systematic search strategy was created to maximize the likelihood of finding all relevant studies. The strategy consisted of two search strings combining thesaurus terms, free-text terms, and broad-based terms: one for ICTs/mICTs and one for qualitative methods (See Textbox 1 for an example of a search). Initially there were also terms for mood disorders, however, the pilot searches identified the inclusion of this string as being too specific limiting the aggregative capabilities of the search strategy. The systematic review would therefore categorize and catalogue all qualitative health research related to ICTs with mood disorder being the category focused upon for synthesis.

Textbox 1. Example search of Cumulative Index to Nursing and Allied Health.

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1. (MH "World Wide Web Applications+") (MH "Computers, Hand-Held") (MH "Macintosh Microcomputers") (MH "Multimedia") OR (MH "Social Media") (MH "Telemedicine+") OR (MH "Telepsychiatry") OR (MH "Telehealth+") (MH "Computers, Portable+") (MH "Computer Input Devices+")OR TI App OR TX Mobile phone*OR TX Mobile Internet OR TX Sony OR TX HTC OR TX Nokia OR TX Samsung OR TX Wireless OR TI 5G OR TI 4G OR TI 3G OR TX Touch screen OR TX Context-aware system* OR TX Cel* Phone* OR TX User-centered design OR TX Mobile app* OR TX Internet treatment OR TX Virtual realit* OR TX Internet delivered OR TX Mobile technolog* OR TX Electronic health OR TX Mobile health OR TX iPad* OR TI Apple OR TX mHealth OR TX eHealth OR TX Android OR TX Blackberry OR TX Windows mobile* OR TX Windows phone* OR TX Smartphone* OR TX iPhone* OR TI Mobile*

2. (MH "Phenomenological Research") OR (MH "Observational Methods+") OR (MH "Patient Attitudes") OR (MH "Ethnographic Research") OR (MH "Constant Comparative Method") OR (MH "Purposive Sample") OR (MH "Qualitative Studies+") OR (MH "Focus Groups") OR TX Theoretical sample OR TX Qualitative research OR TX Theoretical saturation OR TX Mixed methodolog*

3. 1 AND 2

4. Limit 3 to published 2007-2014

Searches were run in eight electronic databases: Medline, Embase, Cumulative Index to Nursing and Allied Health, the psychological literature database, Applied Social Sciences Index and Abstracts, British Nursing Index, Social Sciences Citation Index, and Cochrane Library. The results from each database were exported into Endnote X7 where duplicates were removed electronically and manually. The title and abstracts of the remaining articles were exported into a Microsoft Word document and numbered ready for screening.

Additionally, to optimize qualitative article retrieval the following methods were used: footnote searching; citation searching; journal run; area scanning; and author searching. In addition, experts and key authors were contacted to identify unpublished and ongoing studies. Due to research on the mobile aspect of ICTs being an emerging field, it was envisaged that grey literature might be a valuable source of primary data. Grey literature covers a wide range of material including: reports, government publications, fact sheets, newsletters, conference proceedings, policy documents, and protocols. We therefore searched the following sources for grey literature: The New York Academy of Medicine's Grey Literature report and Open Grey and Grey Source Index. The Journal of Medical Internet Research and Biomedcentral Psychiatry were hand searched from 2007 to present day.

Eligibility and Screening

One reviewer screened all of the titles and abstracts for inclusion in accordance with the following inclusion criteria: study used widely accepted qualitative methods to elicit in-depth experiences with findings appearing well supported by raw data (eg, participant quotes); study sample included people with mood disorders; study sample included the use of (m)ICTs; time period of 2007 to 2014 (2007 saw the release of the first 'smartphone', ie, Apple's iPhone); and English language.

To optimize the validity of the search a systematic sampling strategy was adopted, whereby 10% of results were coscreened (HF & SM/LM) to facilitate consistency of approach [29]. All questionable citations from the full search results were discussed in order to reach consensus on disposal. Full texts were retrieved for those publications that were deemed to meet inclusion criteria and those that could not be adequately assessed for inclusion with the information provided in the abstract. Two authors independently assessed the full texts for inclusion and then met to discuss their decisions. Where they could not come to a consensus, a third author was consulted.

Quality Appraisal

There is a lack of agreement about the approach to quality appraisal in qualitative research [26,30]. Therefore, due to the scarcity of data on the topic being studied, papers were not excluded based on quality, instead all papers were included and their quality appraised. A global assessment of study quality was undertaken assessing studies as being either strong or weak. Strong studies would likely include elements of respondent validation, triangulation of data, transparency, reflexivity, clear descriptions of methodology, methods of data collection, analysis, and an overall fit in regards to the research questions and the design of the project [31]. Reports were both individually and comparatively appraised. A typology designed by Sandelowski and Barroso [32] for classifying findings was used. Rather than comparing differences in quality between studies the typology was used to identify the level of data transformation.

Synthesis

The synthesis stage used thematic synthesis, an approach that combines elements of meta-ethnography and grounded theory providing the opportunity to synthesis methodologically heterogeneous studies [27,28]. The thematic synthesis followed a three-step process described in Textbox 2.

Textbox 2. Thematic synthesis steps.

Step 1

Free sentence-by-sentence coding: the verbatim findings of each selected study were entered into NVivo 10. Codes were developed initially free from hierarchical structure but as the translation of concepts developed from one study to another new codes were either added to existing ones or new codes created.

Step2

Organization of free codes in hierarchical order under a range of descriptive themes: free codes were organized into related areas to create descriptive themes; then similarities and differences between codes were studied, facilitating the organization of the codes into related groups and the formation of a hierarchical tree structure of descriptive themes.

Step 3

Development of analytical themes: descriptive themes were analyzed and then organized into more abstract analytical themes, producing a synthesis that went beyond the data in the original studies and addressed the research questions.

In order to keep the synthesis as close to the data as possible the research questions were initially set to one side facilitating an inductive process. Codes were applied as part of an iterative process with constant comparison with other codes (Step 1). This process was repeated for all the codes until higher order categories were constructed and all codes accounted for (Step 2). The review questions were then brought to the fore and used as a framework to guide the analytical process, which focused and transformed the descriptive themes into the final synthesis (Step 3). The categorization process was examined by the reviewing team where, through discussion, changes, and adaptions were made where necessary until consensus was reached and no further changes were required. The reviewing team scrutinized the synthesis at an analytical level through a cyclical process until a final synthesis was achieved.

Results

Search findings

The search identified 12,926 titles; 67 publications were retrieved in full (Figure 1). The methodological designs of the studies were qualitative or mixed-methods using focus groups, interviews, or forum/message boards as the methods for generating data. Studies originated mainly from Europe, the United States, or Australia and New Zealand.

Only one paper was identified from the systematic review of qualitative papers and therefore, synthesis of mICTs and mood disorders was not possible due to lack of data. However, the review mapped and categorized all qualitative papers in the domain of health and ICT research. This facilitated

methodological development in order to find a solution regarding how to use imperfect data. Rather than lose the potentially valuable qualitative data of relevance to the project, the 67 full-text papers were rescreened. The aggregative and sensitive systematic search strategy offered a flexible approach toward the data. This provided the researchers with the ability to use the existing data to explore how people with mood disorders used ICTs 'of relevance' to mobile technology. This would include, but not be limited to, ICTs such as websites, online therapy, online support groups, forums, blogs, and so on, essentially, ICTs that could be accessed from mICTs but were not necessarily made explicit within the text. Thirty-four studies were included in the synthesis after the full-text articles had been rescreened; a summary of their results can be found in Multimedia Appendix 1.

The results of the appraisal process are shown in Table 1 with 22 studies identified as being strong and 12 weak, with most having a typology of findings either at the topical or thematic survey levels of data transformation. Therefore, with over a third of the studies being weak in quality, the appraised strength of the studies weighed upon, in a measured manner, our interpretation of the study findings.

The synthesis created three analytical themes and a number of respective analytical subthemes to describe people's use of ICTs. This is presented as a typology of findings (Textbox 3).

The research questions were then used as a template, explicating the typology of findings to understand how the descriptive themes interrelated with their analytical themes, thus helping to answer the questions asked of the data. The results are presented below.

Table 1. Appraisal of qualitative papers in metasynthesis.

Global assessment of study quality	n (%)
Weak	12 (35)
Strong	22 (65)
Typology of findings	
No findings	4 (12)
Topical survey	11 (32)
Thematic survey	14 (41)
Conceptual thematic description	5 (15)
Interpretive explanation	0 (0)
Total	34 (100)

Textbox 3. Typology of findings.

Movement and change

- Change processes
- Engagement
- Motivational aspects of use
- Recovery
- Taking action
- Values

Providing a source of community

- Communication
- Intrapersonal effects
- Safe places
- Sharing
- Social aspects

The person and technology

- Acceptance of technology
- Design features
- Functionality
- Personal time
- Safety
- Technical mastery
- Technical issues
- Usability

Figure 1. PRISMA diagram of screened articles of relevance to mood disorders and mICT .
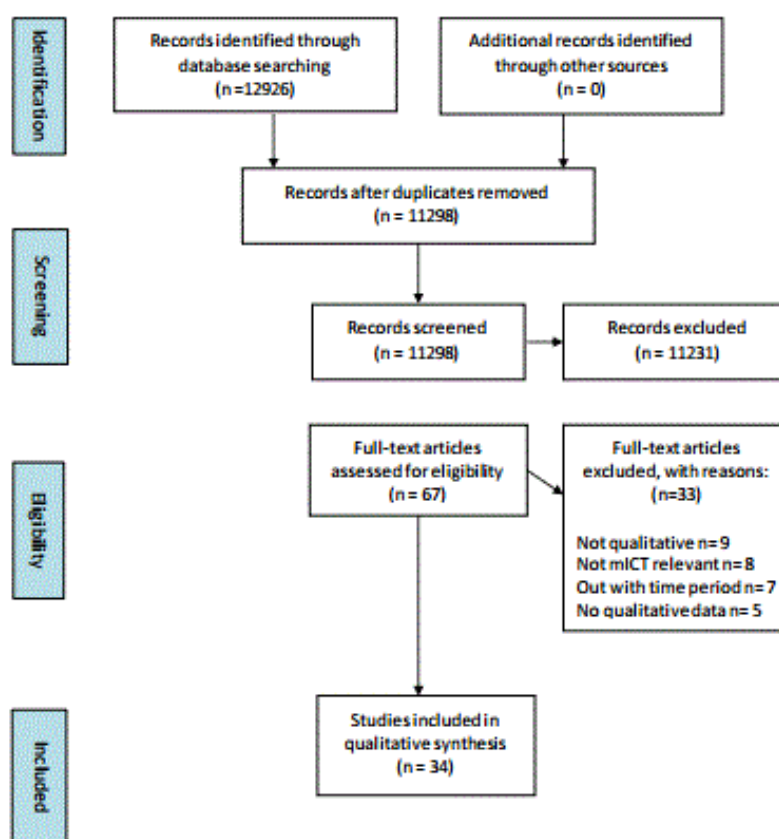
Why do People With Mood Disorders use (Mobile) Information and Communication Technologies?

Considerable overlap was found in terms of why people used ICTs and the perceived benefits this technology gave them. Two studies [33,34] provided data regarding motivation to use ICTs. For those involved in Internet-based treatment, the interactive nature of ICTs appeared to increase their motivation to engage with treatment and, in so doing, possibly help in their recovery [34].

Three studies showed how users of ICTs liked the option of being able to choose where to use technology (ie, at work or in the convenience of their own homes) [35-37]. Having easy access to information from around the world, at any time in the day, through use of the Internet was regarded as useful in comparison to using books [37,38].

The use of websites to support relatives of people with depression appeared to decrease feelings of stigma in both by enabling people to draw strength from talking more openly about their situation [37]. Young people were concerned about feelings of embarrassment if other people realized they had depression increasing a sense of helplessness [38-40]. Fear of being judged by others due to having a mental health issue was a particular problem faced by some young users of ICTs and it became a specific reason for using the technology [39,41]. Fear of school peers finding out and potential links to bullying opted users to engage with ICTs in the privacy of their own homes

[41]. People who felt shame due to experiencing emotional problems would put a lot of effort into hiding their symptoms so having a website where people could discuss their emotional problems anonymously was considered a good thing and often would be the first time sharing their experiences [40]. The use of websites to support relatives of people with depression appeared to decrease feelings of stigma and support their mental health [41]. Using Web-based assessment tools appeared to facilitate dialogue between patients and clinicians. For instance, patients felt it was easier to talk to their general practitioner as they had thought about things beforehand and would be more confident in receiving a diagnosis [36]. Of significant importance to using ICTs was the concept of privacy [37,42-44]. Web-based programs were considered, by some, as providing the most private way to seek help for psychological issues [35].

ICTs appeared to provide people with options regarding how they used technology with choice over temporal, location, treatment, privacy, and disclosure aspects of their care needs [33,38,39,41,45]. The credibility of ICTs appeared an important factor when deciding upon usage [35]. For example, having testimonials from other users displayed on Web pages regarding credibility, and knowledge that the ICT was designed on research appeared to raise confidence in technology [35,46]. ICTs were also regarded as cost-effective solutions to access-to-care problems faced by people living in remote localities, by both patients and health professionals [47]. Participants reported being aware of long waiting times for

specialist health services and, with the alternative being expensive private treatment, the low cost nature of ICTs made them attractive [34,37,42]. Modifying aspects of ICTs with a user-centered design appeared to facilitate use to some extent by reducing technical challenges and helped people feel more competent and autonomous [48,49].

What are (Mobile) Information and Communication Technologies Being Used for by People With Mood Disorders?

The use and view of ICTs as a resource appeared to be an important factor in people's lives. ICTs could open up access to information, support, and treatment in a highly accessible, interactive, and instant way [37,38,42,50,51]. The Internet was also considered empowering [45] and provided a resource for learning [46,48,52]. Holding certain values appeared to suggest people were going to commit to using and completing therapeutic work via ICTs more than others, for example, having a sense of what one should, or should not do, appeared to influence some people's commitment to complete Web-based programs regardless of how tedious or frustrating they were [53]. ICTs appeared to be used as a resource for people to communicate and exchange information and stories with others [38,43,45]. They appeared to facilitate disclosure of personal information regarding people's mental health [40], indicating a need by people to talk about their issues [34].

What are the Perceived Benefits and Challenges of Using (Mobile) Information and Communication Technologies by People With Mood Disorders?

There was significant overlap in terms of why people use ICTs and the benefits provided. As these benefits have already been identified and discussed in the previous two sections, this section focuses on the challenges of using technology. Certain forms of technology and their functionalities produced usage difficulties [42]. That is, people were put off using ICTs if software was slow, had broken hyperlinks, was unnecessarily complex or impersonal, and if use required additional software [47,50,54]. For some people, there were concerns regarding the safety of using ICTs for treatment purposes due to queries regarding the levels of confidentiality the technology could provide [47,52,55]. Being able to use ICTs anonymously appeared to be an important aspect in managing confidentiality and a factor when assessing the appropriateness of using a Web-based intervention [37,40,43]. Indeed, there were people who preferred not to share personal information unless it was face-to-face due to the importance they placed on confidentiality [38].

Some people made a conscious decision not to use ICTs. Reasons included having no interest in certain forms of technology, not being technologically savvy, and being too unwell to use technology (for example, reduced energy and motivation due to an acute depressive phase) [38,41,56]. There were also practical reasons for not using ICTs, such as, having no need to use it, not identifying with content, inhibitive cost, or having no Internet connection [42,48]. Users needed to believe and trust in the ICTs they were using [48,52]. There were concerns regarding information reliability and quality on

the Internet, and doubts as to whether people had the ability to discriminate trustworthy information themselves [45]. Of note, was the generally limited mention of negative outcomes in the reviewed studies.

In What Ways are (Mobile) Information and Communication Technologies Being Used for Self-Management Purposes by People With Mood Disorders?

The use of ICTs appeared to support people to acquire relevant knowledge in regards to their mood problems providing a sense of recognition in situations that might be difficult to accept or unfamiliar, thus helping them feel supported [34]. ICTs were used, by some, to acquire information about treatment, diseases, drug information, and the experiences of others [44,45]. Some people read information specifically targeted toward health professionals as they deemed it to be the most comprehensive and up-to-date sources of information [45]. Seeing relevance in material appeared to be a factor in the process of acquiring new self-knowledge. This was achieved through learning together by reflecting and restructuring new knowledge to suit one's own needs [34]. ICTs appeared to be being used for help-seeking through the acquirement of self-help information, the development of skills, and also as a means to seek help through online support groups and forums [38,40,45,57,58]. Sitting down at a computer at regular times working on a self-help programs appeared to be of benefit; people reported experiencing an empowering effect, a change of perspective, increased personal agency, and a way of keeping new learning at the forefront of their minds [46]. A programs to help monitor depression (on a mobile phone) appeared to hold potential as a motivational tool to support people to look after themselves [42]. Self-help books were viewed as having a number of disadvantages such as being hard to read, noninteractive, and difficult to engage with; where available, people preferred Web-based versions [50,59]. ICTs appeared to provide people with informational support and the ability to delve as deeply as they wished into certain topics, such as medication management, counselling services, negative thinking, and poor concentration [40,52]. The Internet appeared to be considered a key component in providing greater access to health information by patients and receiving benefits from engaging in self-help [34,40,45,46,52].

ICTs appeared to help provide a sense of control in people's lives by providing them with the opportunity to find information about where to find help, assisted them with understanding when to seek help, and what support was available to them [38,52]. They helped prepare for meetings with health professionals, thus making treatment more collaborative [45]. Support from online forums was flexible and inexpensive [60]. Maintaining contact with friends and family was also feasible through diverse Web-based platforms [39].

Receiving support through ICTs appeared to be of benefit by people with mood disorders [49]. People required support in maintaining relationships and dealing with broken relationships while recovering from a mood disorder [50]. Methods of support, in preference to telephone calls or home visits by professionals, included the use of emails due to their unintrusive

nature [49,50]. People also appeared to benefit from support from friends, family members, and significant others to encourage and help them persist with using ICTs for their recovery [48]. Web-based programs potentially offered a means to lessen stigma toward mental health and encourage acceptance of conditions such as Bipolar Disorder [35,37,52,61]. Web-based programs supported people to feel validated and empowered increasing feelings of confidence and self-worth [36,46,57].

Learning time management techniques facilitated people to organize their time better helping them meet deadlines and prepare for exams [35,48]. Time was required to be set aside to use ICTs and having personal time in a private space was appreciated [37]. People taking responsibility for their treatment, had a sense of determination, curiosity, and attributed success to their own endeavors appeared to benefit more from treatment delivered through ICTs [53,62]. People were able to use ICTs to contact health professionals and source health information for themselves, which appeared to help them manage their own problems moving from a position of passivity to one of activity [34,38,53,62]. Being aware of one's motivational levels and having responsibility for maintaining motivation to use interventions delivered through ICTs appeared helpful [33]. Holding certain values would help people to complete Web-based programs and others found their own way of working with material to face and overcome challenges and seeing difficulties as potentially valuable lessons to be learned [53,62].

People's awareness sometimes appeared to change when using ICTs. For instance, becoming aware of holding high expectations toward technology and feeling disappointment if programs did not meet all their needs fostered a sense of consideration to revisit and work with material to see if it would be of benefit [62,63]. Web-based programs held the potential to help people become more aware of their negative thinking habits, promoting reflection, and challenging of thoughts moving people in a more positive direction toward self-acceptance [34,37,50,64]. Participant feedback in the design process of ICTs potentially influenced the goals of particular programs centering on raising awareness regarding the importance of managing depressive symptoms among their users [65]. The use of ICTs to access information and seek other people's opinions through online forums for example offered different viewpoints and helped people understand more about the difficulties they faced [37].

What Role, if any, do (Mobile) Information and Communication Technologies Play in Terms of Social Relationships for People With Mood Disorders?

Using ICTs for social support appeared to be of benefit to people and one of the predominant reasons for using the technology on a daily basis [42]. Meeting similar people in virtual environments created a sense of acknowledgement and recognition decreasing feelings of social isolation, loneliness, and alienation [37,48,52]. People could use ICTs as an opportunity for sharing their feelings, emotions, and personal stories [40]. The exchange of experiences and knowledge in a supportive environment appeared to help people; narrate their experiences, gain a sense of community, share tips, and provide a sense of comfort, strength, and hope in people [37,42-45].

Using ICTs made some users less inhibited, in terms of the personal information they shared, because they felt more secure about privacy being maintained and, therefore, found ICTs less discomforting than face-to-face interactions [37,38,40].

ICTs provided people with the capacity to use online social networks in order to communicate with people experiencing similar issues, to ask advice or discuss certain topics in a convenient and accessible manner [37,38,42]. ICTs also provided people with the opportunity to receive and give peer support [37,44,50,66]. Peer support appeared to help people engage with Web-based interventions, overcome procrastination and motivational issues, and helped them to understand their own problems in a way that gave potential for behavior change [44,50].

Discussion

Principal Findings

The aim of the study was to conduct a metasynthesis of all qualitative studies exploring the use of ICTs by people with mood disorder. The resultant metasynthesis created an analytical typology of findings and a descriptively themed framework, which conceptualized how people with mood disorder use and relate to their ICTs, and in so doing, answered the specific review questions. The metasynthesis identified that people with mood disorders use ICTs in similar ways and face similar technological paradoxes as other users [67]. However, the metasynthesis developed the understanding further, suggesting a continuum of use, in this instance, by people with mood disorder. How ICTs of relevance to mobile technology are used and harnessed by this particular client group are discussed below.

Our metasynthesis identified the factors influencing why people with mood disorders chose to use ICTs such as affordability, accessibility, and versatility. These factors align closely with previous studies on the delivery of health-related products evidenced through increasing Web-based self-help resources [4], effective delivery of psychological interventions [68], and their ability to reach rural areas within diverse populations and settings [6]. The body of eHealth research is expanding with studies across different patient groups, using different technologies/interventions, and focusing on different outcomes [69-73]. In their interpretive review of the literature on consumer eHealth, Hordern et al [74] identified five broad usage themes: (1) peer-to-peer online support groups and health-related virtual communities, (2) self-management/self-monitoring applications, (3) decision aids, (4) the personal health record, and (5) Internet use. The results of our metasynthesis reflected these uses but also highlight a number of intrinsic factors affecting people's use of ICTs. People were motivated to use ICTs to aid recovery, associated with the convenience afforded to them through using the technology. The privacy and choice of communication methods of ICTs were seen as facilitative and credible options often wrapped-up in cost-effective and user-center designed products. Seen as a resource, ICT use was empowering, facilitating people to self-care or self-manage. The Internet was considered a key component in providing greater access to health information by patients and for them to receive benefits from

engaging in self-help [34,40,45,46,52]. ICTs helped provide a sense of control in people's lives by providing them with the opportunity to access information to help themselves, bettered their understanding about when to seek help, and increased awareness of what help was available [38,52]. They facilitated people to prepare for meetings with their health professionals making treatment more collaborative. Receiving support through ICTs was seen to be of benefit by people with mood disorders [49]. ICTs potentially facilitated people to take the first step in managing their recovery after years of deliberation [34]. ICTs supported people to stay in contact with health professionals involved in their care and establish therapeutic relationships despite being separated by distance [38,47,49]. People were able to use ICTs to contact health professionals and source health information for themselves in order to manage their problems by converting intentions into actions [34,38,53,62].

People who took responsibility for their treatment, had a sense of determination, curiosity, and attributed success to their own endeavors appeared to benefit more from treatment delivered through ICTs [53,62]. ICTs that were stimulating to use and interacted well with peoples' senses and cognitive abilities enhanced engagement [46]; this was deemed vital in the context of online depression therapy [34]. With engagement came an enhanced sense of personal agency from interacting with ICTs and the completion of Web-based activities offered a sense of empowerment [37,46]. The functionality of ICTs was an important factor in their adoption and use [42]. For example, having functions to compare information from day-to-day to week-to-week, track information, format content, use Web-based diaries, forums, bookmarks, blogs, messages, control privacy settings, invitation functions, e-reminders, and options to reply directly to clinicians were important usage features [37,42-44,49,50]. ICTs with increased usability were desirable [38,42]. For example, having a user-interface that could be personally controlled, with an array of images, colors, information, and music options, could help engage the user [46]. In addition, being able to use ICTs in different locations (such as, work, home, or on public transport) appeared important factors when assessing usability by the user [37,42].

When designing ICTs and Web-based interventions importance was placed upon managing depressive symptoms in order to support people, through evidence-based interventions, with their practical and interpersonal issues caused by their conditions. [50,65]. Web-based programs supported users to work on solving problems through taking a structured approach using manageable steps [46,57]. If people focused on achieving manageable goals then it provided them with a sense of completion [50,53]. Web-based programs supported people to cognitively restructure, facilitating them to rethink stressful situations that challenged their negative thought patterns. Web-based programs also facilitated behavioral changes by breaking negative cycles of inactivity, self-incrimination, and withdrawal, which lead to secondary benefits as people become closer to those around them [34,35]. Peer support accessed through ICTs helped people to feel more positive and understand themselves better leading to behavior change and the confidence to negotiate changes in treatment [44]. Accessing Web-based medication information through ICT use prompted some people

to request additional drug information from their prescriber regarding risks and benefits of antidepressants and conversely, made others change the dose of drug or discontinue the prescription without seeking professional guidance first [45]. Having a sense of curiosity toward ICTs and a will to learn self-management techniques and, if an improvement in their health was noticed through using ICTs, then they were more likely to persist with an intervention [48,53]. ICTs supported people to stay in contact with health professionals involved in their care and to establish therapeutic relationships despite being separated by distance [38,47,49]. However, ICTs can be viewed to have paradoxical elements to them; social and economic paradoxes, which challenged people in their social and individual lives [67].

The findings of our metasynthesis indicate that usage difficulties were a key factor in reducing people's motivation to use ICTs. This aligns well with the findings of others, including Bessel et al [75] who identified that computer-based interventions have limitations, such as the reliance on users having access to computers at scheduled times and restricted and unreliable Internet access in remote and rural areas. Safety was a key concern raised from the synthesis with the concept of confidentiality and data security being paramount. This is clearly associated with the disadvantages of ICTs such as software errors, unreliable information, problems with privacy and unreliability, lack of regulation, social isolation, and in some forms of technology, the loss of vocal intonation and nonverbal communication [75]. Internet-delivered treatment programs such as open access websites are characterized by poor adherence with an average dropout rate of 31% [76,77].

There are many advantages for patients when using ICTs, such as being able to get in contact with health professionals quickly and easily, a reduction in travel and waiting times for face-to-face appointments, convenience, and affordability. The technology provides a medium for communication between health professionals and patients where information about the patients' disease, treatment, and therapeutic interventions can be discussed [7]. This is of particular importance for those with long-term conditions and our metasynthesis reinforces this point. In contrast to other forms of patient contact, ICTs provide the opportunity for asynchronous communication. eHealth holds the potential to enable patients to better manage their long-term health conditions through the use of technology [7].

Our metasynthesis identified that people used ICTs to acquire relevant knowledge in regards to their mental health issues. This can be linked to an increasing trend in society to adopt self-service models of interaction. There have been promising results for using computers to deliver self-management programs to patients with long-term conditions in health-supported settings showing potential for changing health behavior and improving clinical outcomes [78]. Since 2005, interest in the Internet as a vehicle to disseminate interventions designed to treat and prevent mental disorders, including those targeted at depression, has been increasing [11]. Passive psychoeducational information might be an effective intervention for depression when employed with reminders and involving minimal information [11]. In their systematic review, Griffiths et al [11] identified that the Internet was highly effective and facilitative when used to deliver mental

health interventions with or without practitioner guidance. Web-based CBT has also been shown to provide small benefits when used to help manage chronic pain [79]. However, in a recent meta-analysis of computerized cognitive behavioral therapy (cCBT) by So et al [9] only short-term reductions in symptoms were noted, long-term follow-up and functional improvement were not significant and there was a recommendation that the clinical usefulness of cCBT should be reconsidered downward in terms of methodological validity and practical implementation [9]. Therefore, further research is required to help understand peoples' self-service approach to accessing Web-based health information and their acceptability and use of Web-based therapeutic interventions [80].

Outcome data from RCTs and meta-analyses have identified the cost-effectiveness and clinical efficacy of mental health programs delivered via ICTs with comparable effect sizes to face-to-face treatment [14,81]. Web-based interventions have also highlighted positive effects on patient empowerment and self-efficacy including people with physical health conditions such as cancer [82,83]. Our metasynthesis suggests similar outcomes for people with mood disorder and that ICTs can provide opportunities for help seeking and support for such people. Yet, evidence points to the variable quality of information and apps available on the Internet [7,84-87]. There appear to be numerous health-related websites with limited availability of help, containing information that can be difficult to read and incomplete [85,86].

Our metasynthesis identified that people with mood disorder were using ICTs to give and receive social support. This corresponds with evidence from SNS use and associated indices of psychological well-being relating to a persons' sense of self-worth, self-esteem, satisfaction with life, and other psychological development measures [88]. The metasynthesis identified that people with mood disorder where using social networks in a similar way as suggested by Cohen [89] by providing platforms to give and receive social support in the form of informational support, instrumental support, and emotional support. The metasynthesis highlighted how ICTs facilitate people with mood disorder to communicate with others, corresponding to previous work undertaken regarding Web-based disinhibition. Suler [90] suggests that a number of factors can loosen psychological barriers allowing for inhibition to become reduced when on the Internet: invisibility, dissociative anonymity, synchronicity, dissociative imagination, solipsistic introjections, and minimizing authority. People use social networking sites (SNSs) for their sociability function to maintain relationships with on and offline friends over varying distances [91] attending to extended social networks and relationships [92,93]. Before the development of popular Web-based SNSs such as Facebook, Skinner and Zack [94] had already identified that barriers to communication were being overcome through using the Internet and as a result people were getting help in ways convenient to them.

Of particular importance was the lack of qualitative research being undertaken in this field as evidenced by only one paper retrieved specifically reporting on mICTs. To date, patients or end uses have not been sufficiently included in the design of software applications. The same applies to the selection of relevant and appropriate outcome measures in effectiveness studies such as RCTs. These omissions have contributed to redundancy and the abandonment of technology. n fact, there has been a presumption that those designing technology and undertaking research already know what the user wants in terms of software and hardware. Designers have, jumped ahead, and designed apps and websites, without first talking to end users about how they use and fit technology into both their existing lives and what would help them manage their lives. Qualitative research, which provides a more in-depth understanding of users' views and experiences is of vital importance if we are to understand how people use or benefit from technology and what drives them to engage, or not, with these technologies.

Recommendations

Research: research relating to how people with mood disorder used ICTs was lacking and in particular, their use of mICTs, not as participants in research studies, but as ubiquitous technology in their everyday lives. Qualitative research is required to help understand how mICTs fit into people's lives both in general but also more specifically in relation to their mood disorders.

Practice: clinical practice could be supported through understanding how people with mood disorder use mICTs to look after themselves providing clinicians with valuable information to help harness peoples' mICTs for use in their recovery and inform the future design of technology.

Strengths and Limitations

The review relied exclusively upon English language publications, which may not adequately reflect the user experiences and perceptions that were gathered in non-English speaking contexts. Another issue may relate to the quality of primary data sources and the quality of existing quality appraisal tools for metasyntheses. The researcher's stance was clearly set out in the study providing rationales for the choice of methodology and methods used. Transparency was achieved by clearly detailing the synthesis process and checks and balances were used to ensure rigor throughout. The study originally set out to synthesis all qualitative articles regarding people with mood disorder and mICT. Unfortunately, as only one article met the original inclusion criteria for mobile technology a synthesis of this material was not possible. However, our novel approach toward the search and retrieval of data allowed us to catalogue all qualitative data related to health and ICTs including data of relevance to mICTs. This process provided us with the opportunity to restructure our inclusion criteria and make use of the data that would have otherwise been neglected in other systematic reviews and metasyntheses.

Conclusion

The metasynthesis of people with mood disorders and their use of ICTs has provided a tentative understanding into their uses, challenges, and gratifications spanning the intrapersonal, interpersonal, and through into wider society. The typology of findings and analytical framework highlights the connections and interrelationships between analytical themes and subcategories; the intrinsic and extrinsic nature of use and the

embedded characteristics of the technology. Our metasynthesis has identified that people can use ICTs in novel ways to help them manage their lives and health. People use ICTs to support motivation, for their convenience, to help decrease feelings of stigma, their facilitative capabilities, enhance privacy, credibility, and cost effectiveness. ICTs support people to access the Internet to get what they need in a way that fits into their lives. ICTs are a resource for communication and promote user engagement. However, they are not without issue, with particular challenges of trust and confidentially requiring to be negotiated. That being said, when the challenges are navigated successfully, people are able access opportunities to manage their mood

disorder by acquiring relevant knowledge, engage in help-seeking behavior, receive support, gain a sense of control, learn time management techniques, take responsibility, and increase their awareness. ICTs also allow access to Web-based social networks where sharing with others can facilitate social support. Our typology of findings creates an empirical basis to help guide and harness the potential of (m)ICTs to support self-management, facilitate collaborative, person-centered care, and support the person actively recover from their mood disorder. Importantly, our metasynthesis has highlighted a gap in the evidence base, as no research has focused specifically on mICT use by people with mood disorder.

Authors' Contributions

H. Fulford undertook the metasynthesis and manuscript preparation with principal supervision from S. MacGillivray and additional supervision from L. McSwiggan and T. Kroll.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of results

[PDF File (Adobe PDF File), 65KB - mental_v3i3e30_app1.pdf]

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Abbreviations

cCBT: computerized cognitive behavioral therapy
BD: bipolar disorder
GP: general practitioner
mICTs: mobile information and communication technologies
ICTs: information and communication technologies
RCT: randomized control trials
SNS: social networking site

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Original Paper

Predicting Risk of Suicide Attempt Using History of Physical Illnesses From Electronic Medical Records

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Abstract

Background: Although physical illnesses, routinely documented in electronic medical records (EMR), have been found to be a contributing factor to suicides, no automated systems use this information to predict suicide risk.

Objective: The aim of this study is to quantify the impact of physical illnesses on suicide risk, and develop a predictive model that captures this relationship using EMR data.

Methods: We used history of physical illnesses (except chapter V: Mental and behavioral disorders) from EMR data over different time-periods to build a lookup table that contains the probability of suicide risk for each chapter of the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) codes. The lookup table was then used to predict the probability of suicide risk for any new assessment. Based on the different lengths of history of physical illnesses, we developed six different models to predict suicide risk. We tested the performance of developed models to predict 90-day risk using historical data over differing time-periods ranging from 3 to 48 months. A total of 16,858 assessments from 7399 mental health patients with at least one risk assessment was used for the validation of the developed model. The performance was measured using area under the receiver operating characteristic curve (AUC).

Results: The best predictive results were derived (AUC=0.71) using combined data across all time-periods, which significantly outperformed the clinical baseline derived from routine risk assessment (AUC=0.56). The proposed approach thus shows potential to be incorporated in the broader risk assessment processes used by clinicians.

Conclusions: This study provides a novel approach to exploit the history of physical illnesses extracted from EMR (ICD-10 codes without chapter V-mental and behavioral disorders) to predict suicide risk, and this model outperforms existing clinical assessments of suicide risk.

Introduction

Suicide is a prominent public health concern. All over the world each year, 2% of the population contemplate suicide [1]. In 2013, an average of 6.9 suicide deaths was recorded in Australia each day. It is estimated that by 2020 suicide will become the 10th most common cause of death in the world [2]. Therefore, suicide prevention is important and is an active research field. Because general practitioners are usually the first port of call for mental health problems, the suicide prevention process should be integrated within both hospital treatment and general medical practice [3].

In the last decades, large epidemiological studies have identified the number of previous suicide attempts, lethality of previous

attempts, psychiatric disorders, and social isolation as potential risk factors for suicide [4-9]. Besides identifying independent risk or protective factors, these epidemiologic studies also quantified the strength of their relative contribution. Despite the effort to combine these risk factors into risk scores and algorithms to predict suicide risk [10-12], the predictions often have sensitivity and specificity that are too poor to be clinically useful [13,14]. The failure of these approaches may be attributed to the complex nature of suicidal behavior, which consists of an evolving and multifactorial constellation of components that act together but vary from one individual to another. On the other hand, clinical assessment of suicide risk is primarily done based on the response of the patient, where current suicidal ideation and known risks are integrated. Although suicidality is a prominent risk factor for suicide attempts and completion, only approximately 30% of patients attempting suicide disclose their suicidal ideation [15-17] and the vast majority of individuals who express suicidal ideation never attempt suicide [18-20].

To improve the clinical assessment or predictive value of suicide risk, researchers have started to look at the broader source of available information, such as electronic medical records (EMR) [21] and clinical notes [22]. Recent papers showed that EMR can be used to predict various medical conditions including chronic obstructive pulmonary disease in asthma patients [23], genetic risk for type 2 diabetes [24], myocardial infarction [25], 5-years life expectancy of elderly population [26], and 30-day life expectancy of cancer hospitalized cancer patients [27]. In our previous work [21], we have developed a statistical risk stratification model to predict attempt of suicide risk based on EMR data and the model performance was found to be better than clinical predictions based on an 18-point risk assessment instrument. However, this model was complex and does not generalize to facilitate limited routine data collection. Moreover, because EMR contains a wide variety of information, there is a strong possibility that combinations of them can be infinite. Poulin et al [22] have developed linguistics-driven prediction models to estimate the risk of suicide using unstructured clinical notes taken from a national sample of US Veterans Administration medical records. From the clinical notes, they generated datasets of single keywords and multiword phrases, and constructed prediction models using a machine-learning algorithm based on a genetic programming framework. Although their result showed an accuracy of 65% or more, it was based on a small veteran population and the method was too complex to derive any symptomatic link with the suicide risk factors.

Recently, Qin et al [28] analyzed the relationship between suicidal death and physical illness, which was the first detailed analysis where physical illness was categorized based on the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) chapters. The results of the study showed that the frequency of hospitalization elevates the risk of suicide deaths and this relationship was significant. However, the study is different from this study in terms of population groups and length of history of physical illness used for analyzing the cohort.

In this study, using machine learning to analyze EMR, we aim to find the effect of physical illnesses for the at-risk population,

considering patients who have received at least one suicide risk assessment but who did not attempt suicide. We hypothesize that the relationship between physical illnesses alone and suicide risk can be exploited for quantitative assessment of suicidal risk using ICD-10 codes. This means that we do not use the "Mental and behavioural disorders" (Chapter V, ICD codes), relying purely on the physical illnesses. We developed a novel predictive model to obtain a suicide risk score using the history of physical illnesses derived from ICD-10 codes. Finally, we compared the performance of the physical-illness-based risk score with corresponding baseline clinical assessment.

Methods

Data

Data Description

The data was collected retrospectively from the EMRs, coded using ICD-10-AM, within Barwon Health, Australia [21]. This is a regional hospital serving an area of 350,000 residents. The data consisted of 7399 mental health patients who were 10-years or older and were underwent assessment for suicide risk between April 2009 and March 2012. There were 16,858 assessments, each of which was considered as an observational case, from which suicide risk could be predicted. In the follow-up period of 90 days after an assessment, the ground truth of suicide risk levels were determined through ICD-10 codes occurring during the period. In this study, we have divided the complete population into Control and Risk groups. The Control group consists of assessments of patients who never attempt suicide. Thus, the Risk group consists of assessments of patients who commit at least one suicide attempt.

Ethics approval was obtained from the Hospital and Research Ethics Committee at Barwon Health (number 12/83). Deakin University has reciprocal ethics authorization with Barwon Health. Although all patients has given written informed consent, patient information was anonymized and de-identified prior to analysis.

Clinical Risk Scoring

Suicide risk assessments were routinely performed by clinicians using an instrument developed internally. The instrument has been in use for 15 years. The checklist has the following 18 items: suicidal ideation, suicide plan, access to means, prior attempts, anger/hostility/impulsivity, current level of depression, anxiety, disorientation/disorganization, hopelessness, identifiable stressors, substance abuse, psychosis, medical status, withdrawal from others, expressed communication, psychiatric service history, coping strategies, and supportive others (connectedness).

Based on the ratings (from 1-3) for these 18 items, an overall rating of suicide risk ($RiskScore_{clinical}$) is determined on a scale from 0 (lowest) to 4 (highest). For the purpose of this study, the overall rating was used as the baseline for comparison. A total of 15,513 assessments had $RiskScore_{clinical}$ 0, which is approximately 92.02% (15513/16858) of total assessments used in this study.

Selection of ICD-10 Chapters and Calculating Frequency of Physical Illnesses

ICD-10 (2015 version) has 22 chapters to code all diseases recorded in EMR. The following shows the exclusion and inclusion chapter that were used.

Exclusion

We removed all codes from chapter V, that is all codes related to "Mental and behavioral disorders." We removed chapters XVI (Certain conditions originating in the perinatal period) and XVII (congenital malformations, deformations, and chromosomal abnormalities) codes altogether as these were absent in the studied population.

Inclusion

We merged chapters VII (Diseases of the eye and adnexa) and VIII (Diseases of the ear and mastoid process) due to minimal presence of these diagnostic codes. As a result, we finally have 18 chapter headings (ch=1,2,…,18) corresponding to 19 ICD-10 chapters.

Computing Frequency of Codes for Each Chapter

We first defined the time-period (*len*) over which the patient history EMR was included. Five different time-periods were used (Figure 1 and 2):

Figure 1. Equation 1.

$$\tau = \begin{cases} 1 & , & len = 0 - 3 Months \\ 2 & , & len = 0 - 6 Months \\ 3 & , & len = 0 - 12 Months \\ 4 & , & len = 0 - 24 Months \\ 5 & , & len = 0 - 48 Months \end{cases} \quad (1)$$

For each time-period, the ICD-10 codes for each assessment were aggregated under selected chapters, wherein each aggregated value represents the total number of occurrences of physical illnesses for the corresponding chapter. Therefore, for each assessment i we obtained a vector $f_i(\tau, ch)$, where $ch=1,2,…,18$ and $\tau=1,2,…,5$. Assessments with an entry of 0 for all 18 chapter headings, were counted as an assessment with no history of physical illnesses. For all assessments, we constructed the matrix $F_i(\tau, ch)$, as:

$$F_i(\tau, ch) f_i(\tau, ch)]^n{}_{i=1} \quad (2)$$

where, n is the total number of assessments.

In this study, we developed six models to predict suicide risk based on different length of history of physical illnesses. Five models used the frequency of physical illnesses for the designated time-period, that is, $F(\tau, ch)$, where $\tau=1,2,…,5$ and the sixth model horizontally concatenated frequency matrices from all five individual time periods, $F=[F_i(\tau, ch)]^5{}_{\tau=1}$.

Figure 2. Time periods used to extract the history of physical illnesses from EMR and the suicide risk prediction horizon.
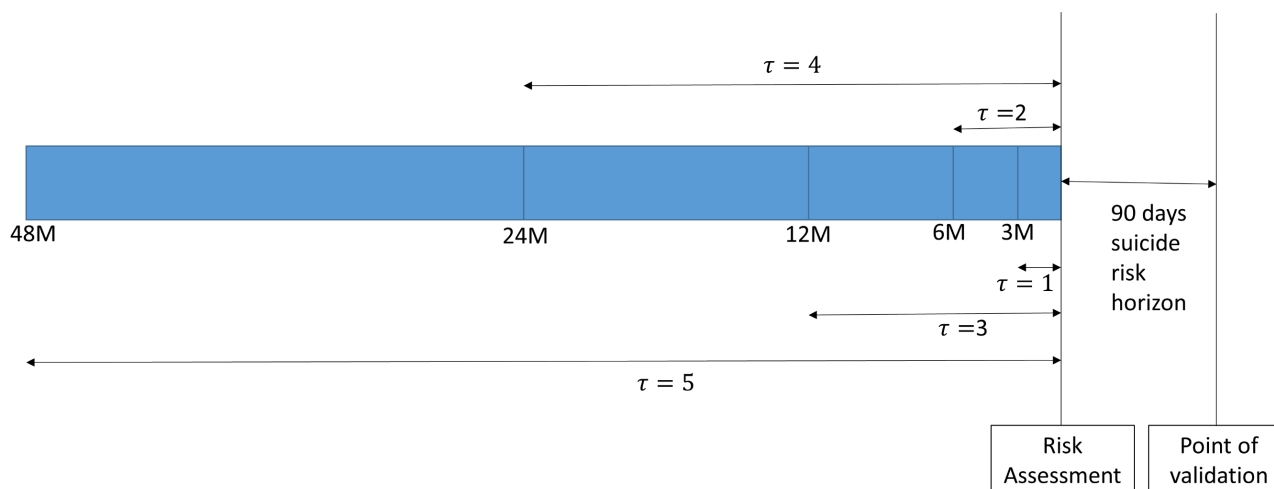
Creating the Suicide Risk Lookup Table

Definition

A probability lookup table PT is generated from the history of physical illnesses as:

$$PT=(pt_{t,ch,j}) \quad (3)$$

where $\tau=1,2,…5$ in the index of the time period used to extract history of physical illnesses, $ch=1,2,…,18$ is the index of the ICD-chapter and $j=1,2,…,5$ is index of the frequency bin. Each element of this table, $PT=(pt_{t,ch,j})$ is the suicide risk probability of the ch^{th} chapter defined using historical data from time period τ for the jth frequency bin. To calculate $PT=(pt_{t,ch,j})$, we

computed the histogram $Hist_j(F_i(\tau, ch))$, where j is the bin index and defined as in Figure 3:

Figure 3. Equation 4.

$$j = \begin{cases} 1 & , & 1 \le f_i(\tau, ch) \le 2 \\ 2 & , & 3 \le f_i(\tau, ch) \le 5 \\ 3 & , & 6 \le f_i(\tau, ch) \le 10 \\ 4 & , & 11 \le f_i(\tau, ch) \le 20 \\ 5 & , & f_i(\tau, ch) > 20 \end{cases} \quad (4)$$

To separate out the Control and Risk histogram, we introduced the notation $Hist_j^{Control}$ and $Hist_j^{Risk}$, which were defined as:

$$Hist_j^{Control}(\tau, ch)=Hist_j(F_i(\tau, ch)) \quad (5)$$

where, $i \in Control$ and $f_i(\tau, ch) \neq 0$

$Hist_j^{Risk}(\tau,ch)Hist_j(F_i(\tau,ch))$ (6)

where, $i \in Risk$ and $f_i(\tau,ch) \neq 0$

Figure 4. Equation 7.

Finally, the suicide risk probability of ch^{th} chapter for time period τ and bin index j was defined by equation 7 in Figure 4.

$$pt(\tau,ch,j) = \frac{Hist_j^{Risk}(\tau,ch)\big/\sum_j Hist_j^{Risk}(\tau,ch)}{\left(Hist_j^{Risk}(\tau,ch)\big/\sum_j Hist_j^{Risk}(\tau,ch)\right) + \left(Hist_j^{Control}(\tau,ch)\big/\sum_j Hist_j^{Conrol}(\tau,ch)\right)} \qquad (7)$$

Scoring Suicide Risk of an Assessment

The suicide risk score ($RiskScore_{Algorithm}$) for any assessment was inferred from the suicide risk lookup table *PT*. This was accomplished using following steps:

1. For a new assessment I and historical time-period τ, extract the frequency of physical illness $f_i(\tau, ch)$ from the EMR data for that assessment.

2. For each chapter *ch*
   - Calculate bin index from $f_i(\tau, ch)$ using equation 5.
   - Extract $P^{Risk}(\tau, ch)=pt_{\tau,ch,i}$ from the lookup table *PT*.
   - Use a Heaviside step function to convert $P^{Risk}(\tau, ch)$ into equations 8 and 9 (Figure 5).

3. Calculate suicide risk score $RiskScore_{Algorithm}(i)$ as in equation 10 (Figure 6).

Figure 5. Equations 8 and 9.

$$Vote_{Control}^{\tau}(ch) = \begin{cases} 1 & P^{Risk}(\tau,ch) < 0.45 \\ 0 & Otherwise \end{cases} \qquad (8)$$

$$Vote_{Risk}^{\tau}(ch) = \begin{cases} 1 & P^{Risk}(\tau,ch) > 0.55 \\ 0 & Otherwise \end{cases} \qquad (9)$$

Figure 6. Equation 10.

$$RiskScore_{Algorithm}(i) = \frac{\sum_{ch} Vote_{Risk}^{\tau}(ch)}{\sum_{ch} Vote_{Risk}^{\tau}(ch) + \sum_{ch} Vote_{Control}^{\tau}(ch)} \qquad (10)$$

Performance Evaluation

The performance of ICD-10 code history based suicide risk scores, clinically evaluated scores and their combination were measured using area under the receiver operating characteristic curve (AUC). For the clinical score ($RiskScore_{Clinical}$), the performance was evaluated by directly measuring the AUC of the entire assessments without dividing them in training or testing sets.

On the other hand, for $RiskScore_{Algorithm}$ we used 90% (13,962/15,513) of the assessments to generate reference lookup table that is, training set and the remaining 10% (1551/15,513) of the population was used as a test set to measure AUC. This process was repeated 10 times, where there were 10 different test sets and union of them encompass the original population, and the overall performance was presented by the average AUC that were obtained over those reiterations.

A similar approach (13,962/15,513, 90% training and 1551/15513, 10% test populations with 10 reiterations) was used for evaluating the performance of combination of clinical and ICD-10–based score. Multilinear regression was used to combine two variables. The training data set was used to train the regression model and output was generated using test set and the trained model. Finally, the AUC was computed using the output ($RiskScore_{Combined}$) of the model.

Results

This study included 2072 suicide risk cases and 14,786 control cases, comprising of 1080 male and 992 female suicide risk cases and 7215 male and 7571 female control cases. In the study population, the percentage of suicide risk and control cases over five different time ranges with a history of hospitalization were (1515/2072, 73.12% and 6674/14,786, 45.14%), (1659/2072, 80.07% and 7877/14,786, 53.27%, 1882/2072, 87.93% and 9241/14,786, 60.50%, 1910/2072, 92.18% and 10,794/14,786, 73.00% and 1987/2072, 95.90% and 12,285/14,786, 83.09% over the past 3, 6, 12, 24, and 48 months, respectively (Table 1). This indicates that the number of subjects having physical illness is higher in suicide risk population than the control population irrespective of the time range. In addition, although the percentage of population having no ICD codes decreased with increasing time range in both the control and risk groups, it was reduced to 4.10% (85/2072) in risk group in contrast to 16.91% (2501/14,786) in control group.

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Table 1. Distribution of physical illnesses according to ICD-10 category (without chapter V-Mental and behavioral disorders) in control and risk groups over five different time ranges.

	τ=1 (0-3 months)				τ=2 (0-6 months)				τ=3 (0-12 months)				τ=4 (0-24 months)				τ=5 (0-48 months)			
	Control		Risk		Control		Risk		Control		Risk		Control		Risk		Control		Risk	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
History of ICD codes																				
No	8112	54.86	557	26.88	6909	46.73	413	19.93	5545	37.50	250	12.07	3992	27.00	162	7.82	2501	16.91	85	4.10
Yes	6674	45.14	1515	73.12	7877	53.27	1659	80.07	9241	62.50	1822	87.93	10794	73.00	1910	92.18	12285	83.09	1987	95.90
Frequency of ICD codes																				
0	8112	54.86	557	26.88	6909	46.73	413	19.93	5545	37.50	250	12.07	3992	27.00	162	7.82	2501	16.91	85	4.10
1-2	2914	19.71	500	24.13	2925	19.78	430	20.75	2881	19.48	365	17.62	2733	18.48	238	11.49	2517	17.02	179	8.64
3-5	1641	11.1	319	15.40	1870	12.65	305	14.72	2044	13.82	277	13.37	2213	14.97	254	12.26	2379	16.09	216	10.42
6-10	1317	8.91	356	17.18	1666	11.27	315	15.20	1999	13.52	332	16.02	2286	15.46	336	16.22	2532	17.12	267	12.89
11-20	657	4.44	247	11.92	1028	6.95	366	17.66	1499	10.14	345	16.65	2089	14.13	386	18.63	2338	15.81	383	18.48
>20	145	0.98	93	4.49	388	2.62	243	11.73	818	5.53	503	24.28	1473	9.96	696	33.59	2519	17.04	942	45.46

Multiple ICD codes were more common among risk cases relative to the control cases (Table 1, Figure 7). For τ=1 (0-3 months) percentages of risk cases were always higher than control cases for ICD codes more than zero. This trend changed with the increasing time, length where distribution of control populations become approximately equal over all five frequency ranges used in this study (Figure 7, top panel). On the other hand, for risk population the frequency of ICD codes increased with time ranges and therefore, approximately 45.46% (942/2072) of the total population had ICD code frequency >20 (Figure 8, bottom panel).

The prevalence of physical illness of both suicide risk and control groups grouped according to ICD-10 categories (chapter headings) has been summarized in Table 2 and Figure 8. Except for ICD-10 chapters II (Neoplasms) and (VII, VIII) (Sensory organ disease), a significantly higher prevalence of physical illness was observed in suicide risk cases than in control cases. However, the percentages of populations in those two chapters were insignificant across all organs or systems of the body. Interestingly, the most prevalent physical illness found for both control and suicide risk groups across all time ranges was Factors influencing health status and contact with health services (ICD-10 Chapter XXI), where the percentage of population continually increased from 20.38% (3013/14,786) to 53.54% (7916/14,786) and 39.29% (814/2072) to 78.38% (1624/2072) for control and suicide risk groups, respectively (Table 2). Interestingly, a significant (454/2072, 21.91%) population showed prevalence of multiple ICD-10 chapters in suicide risk cases at shorter time ranges than control cases. For τ=1 and τ=2, ICD-10 chapter XXI were prevalent in more than 20.00%

(2957/14,786) of control cases in contrast with five chapters (XVIII, XIX, XX, XXI, XXII) in suicide risk cases. This indicates that comorbidity is more prevalent and observable in shorter time range in suicide risk cases than control cases (Figure 8).

The performance of proposed physical illnesses (without ICD-10 chapter V)-based suicide risk scoring model has been shown in Table 3. The AUC value using RiskScore was 0.64, 0.67, 0.68, 0.68, and 0.69 for individual time ranges. This sequential increment of ROC area values with increased length of history of physical illnesses shows longer history length provides better suicide risk assessment than the shorter one. The maximum AUC 0.71 was obtained using physical illnesses from all time ranges, which indicates that overlapping history of physical illnesses improves the performance of the model than using a physical illnesses from a single time-period. In addition, for all of the lengths of the history of physical illnesses the $RiskScore_{Algorithm}$ performed better than clinically assessed risk score $RiskScore_{Clinical}$ (AUC=0.56).

The performance of regression model output $RiskScore_{combined}$ has been shown in Table 3. Similar to physical illnesses based $RiskScore_{Algorithm}$, the AUC values increased with increasing length of history of physical illnesses (AUC=0.65, 0.67, 0.68, 0.69, and 0.70, respectively) and maximum AUC=0.72 was obtained for history of physical illnesses of all time ranges. Although AUC values of multilinear regression model was higher than physical illnesses based model, the improvement is marginal and statistically insignificant.

Table 2. Distribution of suicide risk and control cases associated with diagnostic groups according to ICD-10 category for five different time ranges.

	τ=1 (0-3M)				τ=2 (0-6M)				τ=3 (0-12M)				τ=4 (0-24M)				τ=5 (0-48M)			
	Control		Risk		Control		Risk		Control		Risk		Control		Risk		Control		Risk	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I Certain infectious and parasitic diseases																				
	440	2.98	73	3.52	638	4.31	115	5.55	944	6.38	157	7.58	1352	9.14	259	12.5	1816	12.28	346	16.7
II Neoplasms																				
	28	0.19	1	0.05	45	0.30	5	0.24	67	0.45	7	0.34	131	0.89	10	0.48	194	1.31	17	0.82
III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism																				
	142	0.96	22	1.06	190	1.28	25	1.21	269	1.82	47	2.27	417	2.82	78	3.76	577	3.90	100	4.83
IV Endocrine, nutritional and metabolic diseases																				
	724	4.90	165	7.96	994	6.72	252	12.16	1331	9.00	340	16.41	1740	11.77	420	20.27	2223	15.03	483	23.31
VI Diseases of the nervous system																				
	230	1.56	60	2.90	324	2.19	79	3.81	454	3.07	104	5.02	599	4.05	134	6.47	858	5.80	166	8.01
VII, VIII Sensory organ disease																				
	16	0.11	1	0.05	26	0.18	1	0.05	46	0.31	3	0.14	102	0.69	9	0.43	184	1.24	9	0.43
IX Diseases of the circulatory system																				
	748	5.06	120	5.79	1022	6.91	163	7.87	1347	9.11	220	10.62	1766	11.94	291	14.04	2329	15.75	426	20.56
X Diseases of the respiratory system																				
	548	3.71	53	2.56	700	4.73	88	4.25	898	6.07	142	6.85	1199	8.11	216	10.42	1533	10.37	282	13.61
XI Diseases of the digestive system																				
	534	3.61	154	7.43	790	5.34	227	10.96	1145	7.74	297	14.33	1650	11.16	384	18.53	2347	15.87	502	24.23
XII Diseases of the skin and subcutaneous tissue																				
	188	1.27	37	1.79	257	1.74	51	2.46	345	2.33	71	3.43	521	3.52	113	5.45	755	5.11	166	8.01
XIII Diseases of the musculoskeletal system and connective tissue																				
	428	2.89	138	6.66	699	4.73	171	8.25	1004	6.79	256	12.36	1412	9.55	361	17.42	2037	13.78	471	22.73
XIV Diseases of the genitourinary system																				
	444	3.00	57	2.75	598	4.04	86	4.15	844	5.71	113	5.45	1098	7.43	183	8.83	1389	9.39	237	11.44
XV Pregnancy, childbirth and the puerperium																				
	90	0.61	8	0.39	152	1.03	15	0.72	216	1.46	45	2.17	386	2.61	85	4.10	617	4.17	114	5.50
XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified																				
	2079	14.06	547	26.40	2804	18.96	759	36.63	3660	24.75	978	47.20	4690	31.72	1125	54.3	6041	40.86	1311	63.27
XIX Injury, poisoning and certain other consequences of external causes																				
	1677	11.34	574	27.70	2175	14.71	729	35.18	2934	19.84	946	45.66	4023	27.21	1095	52.85	5205	35.20	1254	60.52
XX External causes of morbidity and mortality																				
	1315	8.89	495	23.89	1867	12.63	668	32.24	2727	18.44	872	42.08	3912	26.46	1064	51.35	5169	34.96	1260	60.81
XXI Factors influencing health status and contact with health services																				
	3013	20.38	814	39.29	3911	26.45	1010	48.75	5053	34.17	1231	59.41	6476	43.80	1470	70.95	7916	53.54	1624	78.38
XXII Codes for special purposes																				
	989	6.69	455	21.96	1391	9.41	595	28.72	2086	14.11	808	39.00	3070	20.76	984	47.49	4106	27.77	1165	56.23

Table 3. AUC obtained using suicide risk scoring model based on physical illnesses, clinically assessed score and their combinations.

Length of history of physical illness	AUC		
	$RiskScore_{Algorithm}$	$RiskScore_{Clinical}$	$RiskScore_{Combined}$
0-3 months (τ=1)	0.64	0.56	0.65
0-6 months (τ=2)	0.67	0.56	0.67
0-12 months (τ=3)	0.68	0.56	0.68
0-24 months (τ=4)	0.68	0.56	0.69
0-48 months (τ=5)	0.69	0.56	0.70
Combined τ (1, 2, … 5)	0.71	0.56	0.72

Figure 7. Distribution of assessments with respect to frequencies of ICD-codes (without chapter V-Mental and behavioral disorders) and time periods. Different color represents the frequencies of ICD-codes.

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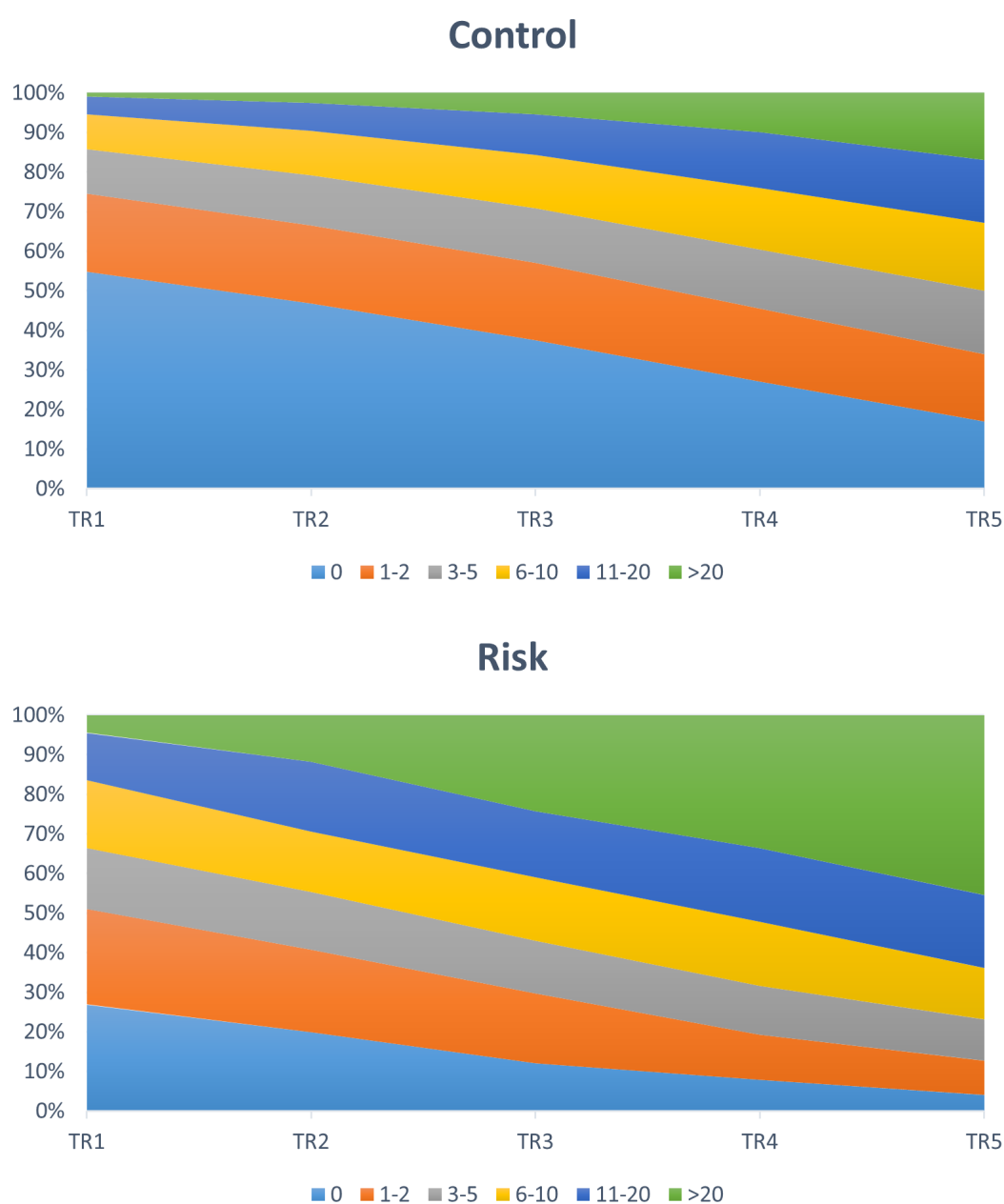
Figure 8. Cumulative percentage of cases in control and suicide risk groups over five time-periods grouped on ICD-10 category (Excluded chapters: chapter V-Mental and behavioral disorders, chapter XVI-Certain conditions originating in the perinatal period, and chapter XVII-Congenital malformations, deformations and chromosomal abnormalities).
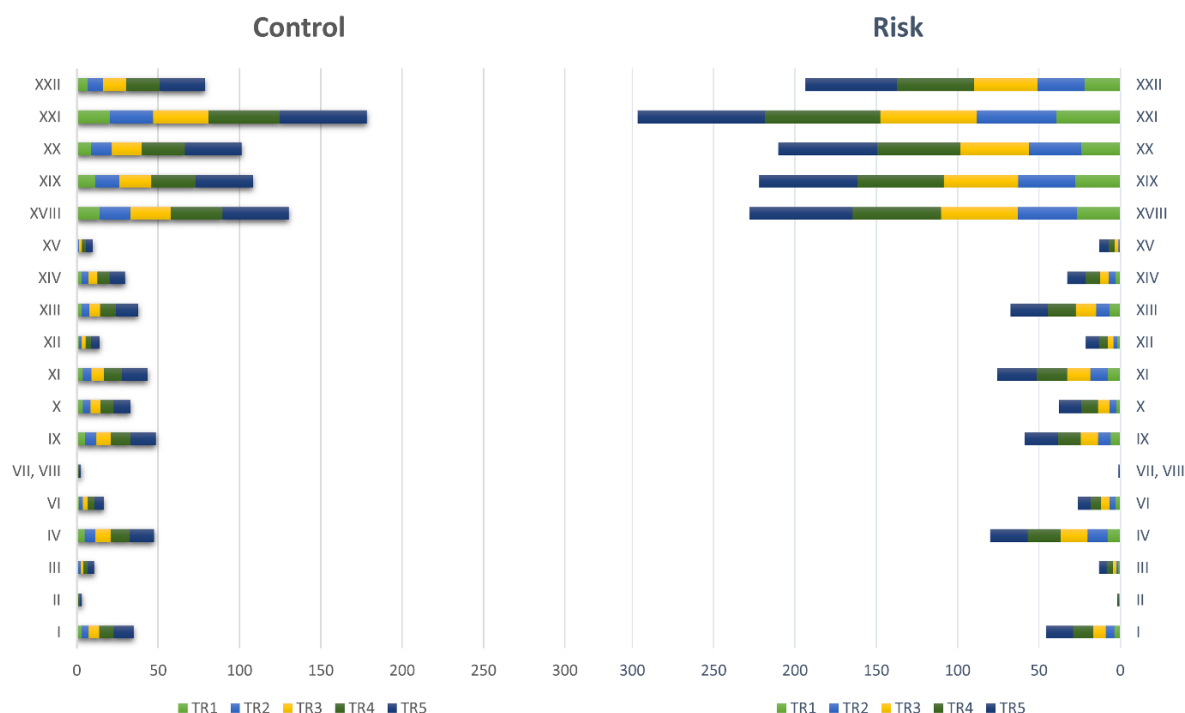
Discussion

Principal Findings

To our knowledge, this study is the first to only use the patient's history of physical illnesses (ICD-10 codes, without chapter V, Mental and behavioral disorders) to predict suicide risk. This study has demonstrated how to exploit the physical illnesses to predict suicide risk using EMR of a single regional hospital (Barwon Health). The ready availability of EMR shows promise that such tools can be integrated within hospital systems for effective decision support.

The findings of this study, based on all patients of Barwon Health who had the mandated suicide risk assessment between April 2009 and March 2012, showed that the percentage of the population having a history of physical illness were higher in risk group than the control. This supports previously reported findings that hospitalization for a physical illness significantly increases the risk of subsequent suicide [8,28]. Although this higher prevalence of physical illnesses in our risk group was found over five different time-periods ranging from 3 to 48 months, the difference in prevalence between two groups decreased with increasing time (Table 1, Figure 8). This indicates that time-period over which history is considered is a critical parameter in predicting risk.

The results of this study showed that the frequency of physical illness (11-20, >20) was higher in suicide risk population than control for all time periods, which is similar to the findings reported by Qin et al [28]. However, for smaller frequency values, the percentage of control cases exceeded the percentage

of suicide risk cases with increasing historical time-period. Although this findings are different from Qin et al [28] where they have used much longer time period than 48 months, this can be attributed to the cohort difference-they have reported 1.13% of suicide cases with physical illnesses frequency >20 in contrast to 0.27% of control; in our study for a 48-month period, we found these frequencies to be 45.46% (942/2072) and 17.04% (2519/14,786) for the risk and control group, respectively.

The performance of ICD-10 based (without chapter V) suicide risk score, $RiskScore_{Algorithm}$ performed better than 18-point risk checklist based clinical assessment ($RiskScore_{Clinical}$) for all time-periods used in this study. This indicates that 3 or more months of history of physical illnesses can better predict the suicide risk than clinical assessment. This supports the previous findings that additional information is required in designing a more effective and automated suicide risk assessment systems suitable for clinical settings [13,14]. $RiskScore_{Combined}$ showed a marginal improvement in suicide risk prediction than physical illnesses based score $RiskScore_{Algorithm}$ but substantial improvement over clinical assessment. Therefore, adding history of physical illnesses with regular clinical assessments can improve the performance of suicide risk prediction. Since physical illnesses based models were tested using 10-fold cross validation, the performance can be considered to be robust.

A limitation of this study is that we have considered only physical illnesses that resulted in hospitalization. However, this is an inherent and unavoidable limitation of any study based on hospital records. Therefore, the effect of mild illnesses that

resulted in no hospitalization or treated outside hospitals was not considered. Furthermore, we did not consider the effect of age or gender on the distribution of physical illnesses and developed a single model for scoring the suicide risk, which may provide some bias. The small number of suicide risk cases restricted us from stratifying by age or gender as this would result in a sparse lookup table.

This study has following clinical implications: (1) The results of this study shows that hospital clinicians who are not specialists in mental health can use our decision support tool for identifying patients at risk of attempt of suicide and this may improve patient care, (2) clinical assessors with mental health expertise can use patient's history of physical illnesses through our proposed tool to improve the prediction of risk of suicide attempt, especially for patients with a history of multiple hospitalizations, and (3) our tool can also assist primary care providers with access to EMR to recognize early signs of risk of suicide attempt and refer patients to specialty care.

Conclusion

In summary, this study provides a novel approach to exploit the history of physical illnesses extracted from EMR (ICD-10 codes without chapter V-Mental and behavioural disorders) to predict risk of suicide attempt. This model also outperforms existing clinical assessments of suicide risk.

Conflicts of Interest

None declared.

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Abbreviations

AUC: area under the receiver operating characteristic curve
EMR: electronic medical records
ICD-10: International Statistical Classification of Diseases and Related Health Problems, 10th Revision

Viewpoint

Technology-Based Early Warning Systems for Bipolar Disorder: A Conceptual Framework

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Abstract

Recognition and timely action around "warning signs" of illness exacerbation is central to the self-management of bipolar disorder. Due to its heterogeneity and fluctuating course, passive and active mobile technologies have been increasingly evaluated as adjunctive or standalone tools to predict and prevent risk of worsening of course in bipolar disorder. As predictive analytics approaches to big data from mobile health (mHealth) applications and ancillary sensors advance, it is likely that early warning systems will increasingly become available to patients. Such systems could reduce the amount of time spent experiencing symptoms and diminish the immense disability experienced by people with bipolar disorder. However, in addition to the challenges in validating such systems, we argue that early warning systems may not be without harms. Probabilistic warnings may be delivered to individuals who may not be able to interpret the warning, have limited information about what behaviors to change, or are unprepared to or cannot feasibly act due to time or logistic constraints. We propose five essential elements for early warning systems and provide a conceptual framework for designing, incorporating stakeholder input, and validating early warning systems for bipolar disorder with a focus on pragmatic considerations.

Introduction

The potential for technology to facilitate "early warning systems" for bipolar disorder has been described for several decades [1-3]. A number of reports have identified the existence of near-term precursors of mood episodes [4-6]. These factors can be internal to the patient's "warning signs" (eg, disruptions in sleep/wake cycles) or external factors or "triggers" (eg, life events) that are associated with increased risk for worsening course. It is apparent that warning signs are highly varied across individuals, although some data suggests they are consistent within the same individuals over time (so called relapse signatures) [7]. Due to the importance of early warning signs, skills in monitoring and developing action plans to respond to them are a core element of many of the psychosocial interventions for bipolar disorder [8].

A promise of high frequency data collection agents, such as mobile health (mHealth) technologies, is that potential warning signs and outcomes can be prospectively and concurrently monitored. Moreover, predictions about the near future could be more accurate if based in part on accumulating knowledge about a given patient, rather than upon more static risk factors that frequently fail to predict near-term trajectories for a given individual. A variety of passive and active technologies have been piloted in bipolar disorder to this end [9-12], and while the evidence base is limited and technologies seem better at monitoring depressive than manic symptoms [12], there is some

convergence of opinion that electronic self-monitoring will become increasingly used in the management of this illness.

Within a high frequency self-monitoring framework, an early warning system might gather high frequency data on both predictors (eg, sleep/wake cycle) and outcomes (eg, onset of mood episodes), identify when changes in sleep/wake cycles that previously heralded a mood episode occurrence, and subsequently deliver an alert or intervention targeted to the early warning sign in a timely fashion. Existing applications of early warning systems are already part of daily life (eg, credit card fraud monitoring). Despite the potential of early warning systems, there are a number of challenges to validation and also potential harms. Problems may arise, both if early warning systems produce incorrect predictions and lead to unnecessary distress or resource inefficiency, as well as if predictions are accurate but patients or other stakeholders are unprepared or ill-equipped to act on warnings. This paper proposes a framework for developing, validating, and implementing early warning systems with technologies that collect intensive longitudinal data in bipolar disorder.

Proposed Architecture of Early Warning Systems

We propose a conceptual framework for design elements of an early warning system. The following are the five elements of an early warning system (Table 1): (1) a *platform* or networked collection of platforms that enables frequent data collection (eg, mobile phones, sensors), (2) *inputs* that produce intensive longitudinal data (eg, repeated self reports, collection of behavioral data such as voice, sleep, activity) and *outcomes* that could either be externally monitored events, states, or other streams of intensive longitudinal data, (3) *predictive statistical analytic* methods that link inputs with outcomes, (4) *decision rules* that determine the thresholds and actions according to the prediction based on a time horizon between the timing of the input data and the outcome that are predicted, and (5) *preventative feedback*, which may vary by content, format, delivery method, and intended audience.

Table 1. Proposed components of an early warning system, selected techniques, and research gaps.

Component	Selected resources	Research gaps
Platform	Mobile phone apps; text messaging; home-based telehealth; wearables	Best practices for long-term adherence and engagement; effective integration of multiple platforms; user preferences and methods for granular control of transmitted information
Inputs and outcomes	Patient reports of mood and related risk factors; passive activity/location sensing; passive metadata sensing; serial physiological sensors	Predictive validity of near future and rare events; optimal data capture frequency and duration; interpretability of passive data for warning systems
Predictive analytics	Linear and non-linear models for intensive longitudinal data; machine learning; within-sample and out of sample validation techniques	Integration of within-person and between-person data to inform predictions; integration of high dimensional variable frequency data; utility of non-linear, complex models in practicable early warning systems; validation metric criteria
Decision rules	Clinically important thresholds; empirically defined thresholds based on classification models; recursive analyses to define earliest detectable change in risk at threshold	Developing interpretable decision rules based on multiple inputs or interactions; updating decision rules based on accumulating data within patients
Feedback	Multiple communication platforms with which to alert stakeholders; elements of evidence-based behavioral change content developed for risk factor self-management in bipolar disorder	Optimization of feedback messaging to enhance self-efficacy and health protective behavior; identification of potential patient and other stakeholder's experience of adverse impact of forewarnings; research methods for quantifying the impact of individual feedback strategies; impact of feedback messaging tailoring by mood state, patient preference, and/or severity of risk

Platform Considerations

In considering the elements in Table 1, there is evidence to support the feasibility and acceptability of data capture platforms that use computer [13], mobile texting [14], wearable technologies [15], and mobile phone apps in monitoring mood symptoms and other inputs in bipolar disorder [12]. Platforms may increasingly combine passive sensor and device metadata (eg, duration and timing of calls) with patient reported data. Advancements in software platforms for data collection are beyond the scope of this paper, but increasingly toolkits are available to generate apps that provide the interactive data collection framework on mobile devices such as with Apple Research Kit and Android Research Stack.

For the purpose of early warning systems, key requirements for platforms would be the availability of online statistical analysis as data is accumulated, which typically and essentially if data from other individual's are used in prediction models, would involve transmission of data from the device to a server for online analytics. Efficiency of transmission and interoperability of information sources gathered from the device or multiple devices remains a challenge that is especially pressing. Many of the electronic self-monitoring tools for bipolar disorder reviewed by Faurholt-Jepsen et al [12] were validated over periods of 3 months, which then necessitated that the predicted outcome occur during that span, resulting in a low probability of capturing multiple episode-level relapses for most patient populations. Ideally such systems were to be developed to capture more infrequent events over longer periods, and it is

unclear what platform-related factors contribute to longer-term engagement (>3 months) in data collection. There is some suggestion that long-term engagement might be enhanced through interventions that promote continued use and perceived benefit, as well as the use of an individual's own device rather than study phones.

Since data is being transferred, which could include personally identifying information (eg, phone numbers, location) as well as information about symptoms and other potentially sensitive information, mHealth platforms add a risk of loss of confidentiality. A recent review found that 75% of commercially available apps purported to assist with self-managing bipolar disorder did not include a privacy policy [16]. Given that consumer buy-in for early warning systems would especially necessitate "trustworthiness" since the intent is to provide meaningful information about future personal risks, data security procedures and risk from the device and/or sever to the cloud would need to be explained to users, including the potential consequences in loss of privacy if devices are lost [17]. When asked, patients express preferences for granular control over elements of transmitted data and so apps for enabling such control, beyond just informing patients of the types of data being transmitted, may further facilitate patient engagement in early warning system design [18].

Inputs and Outcomes

Potential inputs to early warning sign systems are far ranging and include behaviors (eg, social behaviors, substance use, changes in activity), sleep (eg, number of hours, quality), stressors, medication adherence, and affective states (eg, anxiety, irritability). These inputs measured with the device need to be validated as convergent with gold standard clinical ratings. To date, most validation studies in bipolar disorder using mobile devices have focused on the validity of mood ratings, and thus focus on the validity of measurement of the typical outcome of early warning systems rather than predictors. As reviewed recently, information technology strategies for self-monitoring indicate positive indication of the concurrent validity of aggregated momentary self-ratings of depressive mood states (although less consistently with manic symptoms) captured on mobile devices with clinician-rated data [12], with greater intra-variability than paper-and-pencil mood charts [19]. Further toward the path of an early warning system, integrated information from multiple sensors has accurately identified the presence of episodes among patients followed longitudinally [20]. It is unclear if patient reports of other inputs, such as stressors, medication adherence, or social function are associated with in-lab measures.

There are proof of concept data suggesting that passive sensor data obtained through actigraphy can individuate bipolar disorder from patients with depression and healthy controls [21]. In addition, geographic or vocal tone correlates with concurrent clinician rated mood symptoms and metadata from interactions on the device are also moderately associated with symptoms [11]. While mobile phones and their multiple embedded sensors offer new streams of data, such as call logs to understand social patterns in bipolar disorder patients,

understanding the clinical translation of such data is still an area of novel research and not fully understood.

Taken together, these early stage studies indicate that mobile devices could be feasibly used to monitor at least some of the potential inputs and symptom outcomes over time. Challenges for inputs and outcomes in early warning systems are that mHealth technologies create data that is complex and unique from typical panel-type data, explained in terms of its high volume, velocity, and variety [22]. The potential to collect large amounts of data must be balanced with adherence, missingness, interoperability, and validity concerns. Studies using mobile data collection have repeatedly shown that user adherence is not perfect and participants either completely stop using these devices or provide data less frequently than planned. Indeed, missing data has been attributed to a lower than anticipated accuracy in a pilot study of the prediction of relapse in bipolar disorder using actigraphy [23]. Adherence issues may require robust statistical models for imputation [22] and may also be modeled as an additional input. Other issues with collecting these new data steams the inter-stream and temporal correlation that will require partnerships with data science experts to fully utilize and best understand the potential of real-time self report, behavioral, and physiological data [24].

Moreover, some critically important outcomes and potential new data sources would seem highly relevant to early warning systems but have received little research. In particular, suicidal ideation and risk of self-harm has been effectively assessed over time in non-bipolar samples with attention to affective states prior to thoughts [25]. It is notable that patients may actually be more open and willing to disclose suicidal thoughts to a digital device than in person to a clinician. Some people now also report suicidal thoughts and symptoms of their mental illness to online forums and their digital messages provide a new source of data on suicide risk (eg, TalkLife), and a number of studies have linked risks of suicide from texts extracted from social media and blog posts [26]. Data collection in the context of an intervention that directly heralds suicidal behavior raises the need for a robust clinical response framework [27]. As detailed elsewhere, there are a number of ethical and privacy pitfalls in incorporating social media data into to clinical decision making [28], and providing patients with granular control over the inputs to early warning systems would seem to be especially applicable to social media.

Application of Prediction Models

Prediction models link input data and subsequent outcomes. A variety of emerging methods are used to model intensive longitudinal data and predictive analytics applied to these complex data that have varying rates and structures. Techniques such as data mining, machine learning, and probabilistic modeling have been employed to make predictions about the future. While a discussion of these individual techniques is beyond the scope of this paper (see [29]), effective early warning systems would require automating analyses and responsive updating predictions based upon incoming data.

Irrespective of the statistical technique applied, validation of an early warning sign system would center on the accuracy and preventative utility of prediction. There are several steps beyond

identifying a group-level association between T_{-1} predictor and T_{-0} outcome. In terms of raising the clinical utility of predictions, the standard for gauging the usefulness of prediction would additionally include (1) how accurate the prediction is for a given individual; (2) how interpretable the predictions are in the formation of decision rules; and (3) how much lead-time is provided in which alter the course of the predictor, if alterable.

Complex time series models have been applied to understanding the dynamics of mood course in bipolar disorder, focusing on the potential for non-linear chaotic or latent approaches to modeling state shifts in the context of intra-individual noise [30-33]. Here we focus on potentially more accessible linear models. In linear models, estimates generated from training data in ordinary least squares regression frequently result in overfitting, with validation samples highly likely to perform worse than the training set. Techniques such as penalized regression can reduce the likelihood of overfitting [34]. Given that most samples are likely to be small at proof-of-concept stages, validation with independent samples is typically impossible. Within sample alternatives to validation include leave-one out validation [35].

Such models gauge the accuracy of predictions in samples with and without predicted outcomes. However, this conflates potential individual differences in the predictor-outcome relationship. In repeated measures designs, case-crossover analyses can examine the association between predictors and outcomes within patients when outcomes occurred and earlier or later times when outcomes were present [36]. This approach could help to identify the within-person sensitivity of predictors.

As an example, Thompson et al [37] employed functional data analysis to identify prospective time-lagged relationships between changes in daily-assessed negative and positive affect and observed the emergence of suicidal ideation two to three weeks later. Here, changes in affect can be seen as potential early warning signs of increases in suicidal ideation. The authors found that accuracy of the association between negative affect and suicidal ideation observed two to three weeks later was quite accurate (88% sensitivity and 95% specificity), and more accurate than predictions that relied on baseline levels of suicidal ideation. In this way, indication of a time lagged relationship between inputs and outcomes suggests a potentially causal relationship and also provides a window of time between input and outcome in which to deliver feedback regarding an impending risk of suicidal ideation and possibly attempt to alter the early warning sign.

Creation of Decision Rules and Time Horizons

With validated data and prediction rules, a combination of clinical acumen, patient preferences, and data driven models will be necessary to create decision rules that can guide clinical interventions. While some of these decision rules may be more straightforward, such as a link between cessation of a medication and risk of switch into mania, others rules will be more complex. For example, considering insomnia as a symptom of bipolar disorder, applying the right intervention at the right time and for the right patient will likely be a personal, dynamic, and varied response with no clear-cut point or binary decision. Such decision rules can be developed empirically and a first step will require determining how sensitive and specific the input is in predicting subsequent outcomes, such as by use of a penalized regression technique. Accuracy can be judged by a metric (eg, area under the curve, AUC) generated by leave-one-out validation, and can be compared to baseline estimates of risk (eg, most recent suicidal ideation rating), and/or relative to prior windows of time that did not result in suicidal ideation, as in the case-crossover method. If sensitive and specific to the criteria listed above, sensitivity analyses to determine when prior to the outcome the earliest detectable increase in the outcome occurs (eg, examining the accuracy of prediction by censoring predictors within the span of 1-3 weeks prior to the outcome), based on an assumption is that time-varying predictors increase in accuracy the closer in time to the outcome. The identification of the time of earliest detection would be determined by comparison of accuracy when moving a stable window of information back in time to when the prediction accuracy falls below a clinical metric of accuracy (eg, AUC < 0.80) or a patient-preferred tolerance. To generate cut points, regression tree methods can then be used to identify the levels of the input that would be associated with the best fitting model (ie, with the largest AUC). These cut points can then be used to form decision rules and updated with machine learning algorithms in real-time, and made more precise to the individual weighting information from the individual, relying increasingly on individual data over that from other individuals' data. Multiple inputs and interactions among inputs may also create even more powerful models, yet with the tradeoff of greater complexity in implementation, and more importantly, diminishing interpretability toward targeted feedback, described next.

Feedback and Clinical Application

The empirical understanding of best practices in the feedback component of early warning systems is in its infancy. Since early warning systems will involve communication around a future probabilistic risk, there is substantial evidence to suggest that people may variably interpret or misinterpret risk communication [38]. As such, the content and form of the feedback aspect of early warning systems is critical, and one in which perspectives of providers and patient stakeholders are essential for understanding how best to communicate risk while mitigating potential adverse impacts, and maximizing tolerability, usefulness, and timeliness.

Feedback from early warning systems may be more effective if it extends beyond simply notifying patients, clinicians, and stakeholders of an impending risk. There is substantial evidence that to change behavior in response to a future risk, the arousal of fear or threat is insufficient and possibility counterproductive, particularly among people with low self-efficacy to make changes [39]. For example, an early warning system describing a risk for a near-term manic episode might arouse fear about the consequences of mania, but without specific instructions about how to avert the manic episode, respondents may discredit the message [40]. A related concern is that, if predictions derive from multiple sources of inputs including sensor data, it might be difficult to directly interpret; the drivers of risk may be somewhat of a "black box" and may not translate to a greater

understanding of the illness course or actionable steps to mitigate risk. Clinicians may face the same conundrums with acting on the content of warning messages as do patients, additionally with the concern of balancing time allotted to care for patients with current *known* risks versus future *possible* risks.

There are several potential approaches to enhancing the effectiveness of warnings derived from the broader health psychology literature [41]. Messages may have greater impact if they can winnow out actionable predictors that are meaningful to the individual, emphasizing one behavior change at a time. Once the target behavior is identified, messages may be more likely to lead to changes in behavior if they (1) focus on increasing self-efficacy to act and the benefits of acting rather than evoking fear about the risk of harm [42]; (2) identify strategies that require low effort or facilitate reducing effort such as through implementation intentions [43]; and (3) provide affirmations of the individual prior to requiring the processing of threat, if delivering information about the threat is necessary [44]. It is unknown how variation in mood state may impact the receptiveness of different warnings, but it is technically feasible for messages to be tailored to the mood state of the individual to maximize persuasiveness.

Designing the feedback element of early warning systems should involve the incorporation of stakeholder perspectives, both patients and clinicians, which can occur at multiple levels. At a broader level of intervention *design*, participatory design methods have been evaluated in mental health technology-focused projects [45]. Although it is unclear if participatory approaches yield greater uptake and impact than researcher-centered programs, participatory methods typically include design cycles in which user input is sought at the outset and after multiple phases of development, from inception to deployment. For early warning systems, patient input about the interpretability and timing of warnings along with content to accompany those warnings would be essential, as is clinician input about the liabilities associated with warnings. At the narrower level of the early warning system design, there are a number of methods for incorporating patient preferences and language into feedback. For example, patients may create their own messages to accompany warnings for future display [9]. In our prior work, patients generated statements that they would like to tell themselves or adaptive behaviors they could employ in depressed or manic mood states, which were then presented to them later through the device upon reporting such a state. Many other means providing user control via mHealth are possible, such as the frequency, timing, and communication channel of feedback, as well as delineating whether and which other people are also recipients.

Within early warning systems, there will be practical challenges to understanding the impact of various feedback strategies. As with all prevention research, it is challenging to determine whether specific elements of early warnings systems have an effect at the individual level, given that it is impossible to know if future threats would have occurred without such a warning. As such, understanding the patient and message variables of effective risk communication using prediction models may be best advanced in experimental studies with proxy measures of target behaviors rather than episodes, at least in initial development stages.

Discussion

Summary

Much work is required to make early warning systems accurate, useful, and safe for people with bipolar disorder and their care teams. Nonetheless, there have been dramatic advances in technology-based data capture, statistical prediction analysis, and risk communication that together form the ingredients of a variety of early warning systems for bipolar disorder. Many such systems have been proposed and are in the proof-of-concept stages of development, and soon will be available to consumers and clinicians. These systems may make it possible for patients to better understand and manage bipolar disorder, avoid or forestall illness exacerbations, and minimize disruptions in social and productive roles associated with illness exacerbations.

Conclusion

We have described a basic framework for designing interventions alongside patients and clinicians, and validating and evaluating such systems. In particular, we caution that early warning systems must empower patients to make changes rather than to simply sound alarms. We hope that this paper stimulates future development in this exciting area.

Conflicts of Interest

John Torous is editor-in-chief of JMIR Mental Health, but was not involved in the decision making process related to this paper. The peer-review process was handled by a different editor.

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Abbreviations

AUC: area under the curve
mHealth: mobile health

Original Paper

Are Mental Health Effects of Internet Use Attributable to the Web-Based Content or Perceived Consequences of Usage? A Longitudinal Study of European Adolescents

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Abstract

Background: Adolescents and young adults are among the most frequent Internet users, and accumulating evidence suggests that their Internet behaviors might affect their mental health. Internet use may impact mental health because certain Web-based content could be distressing. It is also possible that excessive use, regardless of content, produces negative consequences, such as neglect of protective offline activities.

Objective: The objective of this study was to assess how mental health is associated with (1) the time spent on the Internet, (2) the time spent on different Web-based activities (social media use, gaming, gambling, pornography use, school work, newsreading, and targeted information searches), and (3) the perceived consequences of engaging in those activities.

Methods: A random sample of 2286 adolescents was recruited from state schools in Estonia, Hungary, Italy, Lithuania, Spain, Sweden, and the United Kingdom. Questionnaire data comprising Internet behaviors and mental health variables were collected and analyzed cross-sectionally and were followed up after 4 months.

Results: Cross-sectionally, both the time spent on the Internet and the relative time spent on various activities predicted mental health ($P<.001$), explaining 1.4% and 2.8% variance, respectively. However, the consequences of engaging in those activities were more important predictors, explaining 11.1% variance. Only Web-based gaming, gambling, and targeted searches had mental

health effects that were not fully accounted for by perceived consequences. The longitudinal analyses showed that sleep loss due to Internet use (ß=.12, 95% CI=0.05-0.19, *P*=.001) and withdrawal (negative mood) when Internet could not be accessed (ß=.09, 95% CI=0.03-0.16, *P*<.01) were the only consequences that had a direct effect on mental health in the long term. Perceived positive consequences of Internet use did not seem to be associated with mental health at all.

Conclusions: The magnitude of Internet use is negatively associated with mental health in general, but specific Web-based activities differ in how consistently, how much, and in what direction they affect mental health. Consequences of Internet use (especially sleep loss and withdrawal when Internet cannot be accessed) seem to predict mental health outcomes to a greater extent than the specific activities themselves. Interventions aimed at reducing the negative mental health effects of Internet use could target its negative consequences instead of the Internet use itself.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 65120704; http://www.isrctn.com/ISRCTN65120704?q=&filters=recruitmentCountry:Lithuania&sort=&offset=5&totalResults=32&page=1&pageSize=10&searchType=basic-search (Archived by WebCite at http://www.webcitation/abcdefg)

KEYWORDS

Introduction

Depression and anxiety are two of the most prevalent psychiatric disorders among adolescents [1-3], and suicide, which is often closely related to these disorders, is the second leading cause of death in the world for 15- to 29-year olds (after traffic accidents) [4]. Over the past decade, there has been a growing interest and concern about how adolescents' mental health and emotional development are affected by their Internet use. Almost 80% of the European population are Internet users, with percentages above 90% in some countries [5], and with the increasing use of smartphones, more and more individuals have instant and continuous access to the Internet. Over 90% of 16- to 24-year olds in Europe regularly use the Internet at least weekly, a percentage that is higher than for any other age group [6]. Although it is difficult to measure exactly how much time is spent on the Internet, most young people access the Internet on a daily basis, and the Internet has become a well-integrated part of their lives. This has led to changes in how people live their lives and how they construct and maintain social relations and self-identities, seek information, and enjoy entertainment.

A major line of research has linked mental health problems to what has been termed problematic Internet use (or pathological or compulsive Internet use), which is often conceptualized as an impulse control disorder similar to gambling addiction and other behavioral addictions. The most used and validated measure of problematic Internet use, the Internet Addiction Test (IAT) [7], was constructed through an Internet use-specific reformulation of the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-4) diagnostic criteria for Pathological Gambling Disorder (for a review of problematic Internet use measurements, see [8]). As such, this screening instrument measures compulsive aspects of Internet use resulting in clinical impairment or distress (eg, feeling preoccupied with the Internet; inability to control or reduce Internet use; feeling moody or depressed when attempting to stop or reduce Internet use; staying online longer than intended; lying about excessive Internet use, and so forth). However, there is no standardized way of classifying problematic Internet use because measurements, cutoffs, and classification procedures vary

between studies [8-9]. These differences in diagnostic procedures aside, numerous studies have found problematic Internet use to correlate with DSM Axis I disorders, mainly depression but also social phobia and anxiety, substance use, attention-deficit hyperactivity disorder, and certain personality variables such as hostility [10-13]. The putative mechanism by which problematic Internet use affects mental health is partly related to the excessive time spent on Web-based activities, which results in a neglect of protective offline activities such as sleep, physical exercise, school attendance, and offline social activities, and partly related to symptoms of withdrawal when those activities cannot be accessed [9,14].

Studies show that the problematic aspects of certain individuals' Internet use are restricted to one or a few specific Web-based activities (eg, gaming or social media use), whereas other activities are nonproblematic [15-17]. Although there is some recent evidence that the factor structure of the IAT [7] is consistent across measuring problematic engagement in specific activities such as gambling and gaming [18], this has led to a differentiation between generalized problematic Internet use and specific forms of problematic Internet use. For example, as most Internet-use research has focused on problematic Web-based gaming, and as many studies have found an association between gaming and severe mental health symptomology, this is the only specific form of problematic Internet use that has been considered for inclusion in DSM-5, whereas generalized problematic Internet use and other specific forms have not [9,19].

It is thus important to differentiate between activities when investigating the mental health effects of Internet use. In some cases, it could be important because the activity in question is prone to becoming addictive, such as Web-based gambling (eg, Web-based poker, sports betting, casino spins) [20-23]. In other cases, it might be important because the content itself may impact mental health by producing specific emotional, cognitive, or behavioral reactions. For example, 1 study on social media use suggests that passive consumption of social content increases feelings of loneliness, whereas direct communication with friends does not [24]. Another example is performing information searches. Studies show that young people, including

those with mental health problems, often perform targeted searches related to their physical and mental health [25-27]. Depending on what information they find, this type of behavior could probably have both negative and positive outcomes. Website content that promotes self-destructive behaviors or self-harm may be of particular concern. Furthermore, adolescents perform increasing amounts of school work using the Internet, and as academic performance is usually associated with better mental health [28], using the Internet for such purposes might be predictive of positive mental health rather than what would be expected from a problematic Internet use perspective [29,30]. Other research has shown that certain types of games (eg, massively multiplayer online role-playing games) and certain motives for playing those games (in-game achievement, socializing, immersion, relaxation, and escapism) are predictive of mental health problems and problematic gaming [31-33]. Although the majority of previous research is correlational, it suggests that Internet use can impact mental health either through the activity or content that is used or through delayed consequences that follow the use of the Internet.

This study aimed to investigate how adolescents' mental health is predicted by time spent on the Internet and their level of engagement in 7 types of Internet activities: social media use, gaming, gambling, pornography viewing, newsreading or watching, activities related to school or work, and targeted information searches that are not related to school or work. Second, the study also tested whether these effects would be sustained or accounted for by perceived consequences of using those Web-based activities. We investigated the impact of both negative consequences (eg, withdrawal, sleep loss) and positive consequences (eg, enjoyment, finding new friends). In addition to performing these analyses on cross-sectional data, we also tested whether these effects would predict changes in mental health over a period of 4 months.

Methods

Study Design

Data were collected as a part of the Suicide Prevention through Internet and Media Based Mental Health Promotion (SUPREME) trial (Current Controlled Trials ISRCTN65120704). The study was carried out by collaborating mental health research centers in Estonia, Hungary, Italy, Lithuania, Spain, Sweden, and the United Kingdom. As part of this project, a randomized controlled longitudinal study was carried out in 2012-2013 to evaluate a Web-based mental health intervention website, which was tested in a randomly selected sample of adolescents in a selected area of these countries. Inclusion criteria of the schools were: (1) the school authority agrees to participate; (2) the school is a state school (ie, not private); (3) the school contains at least 100 pupils within the age range of 14-16; (4) the school has more than 2 teachers for pupils aged 15 years; (5) no more than 60% of pupils are of either gender. Participants were cluster randomized, based on school affiliation, into either a full-intervention condition (with access to the intervention website) or a minimal-intervention control group (without access to the intervention website), and were administered an evaluation questionnaire at baseline and

at 2 and 4 months of follow-up. The questionnaire included questions about their Internet habits, mental health and suicidal behaviors, and other variables relevant to the evaluation. This study did *not* aim to evaluate any effects of the Web-based intervention but instead explored Internet-related risk factors for mental health problems.

Participants

Subjects were registered pupils of state schools randomly selected from a predefined area in each country: West Viru County (Estonia), Budapest (Hungary), Molise (Italy), Vilnius city (Lithuania), Barcelona city (Spain), Stockholm County (Sweden), and eastern England (the United Kingdom). Eligible state schools in these areas were randomly arranged into a contact order, the order in which schools were contacted and asked to participate. If a school declined, the next school on the list was contacted. If a school accepted participation, a team of researchers went to the school and presented the background, aims, goals, and procedures of the study to the pupils verbally and through consent forms. As the study procedure included screening for suicidal adolescents, participation was not completely anonymous, but participants' identities were encrypted in the questionnaire. Written consent was obtained from all pupils who agreed to participate (as well as from one or both parents according to ethical regulations in the region). The study was approved by ethics committees in all participating countries.

The sampling procedure resulted in a total number of 2286 adolescents participating at baseline (Estonia=3 schools, 416 participants; Hungary=6 schools, 413 participants; Italy=3 schools, 311 participants; Lithuania=3 schools, 240 participants; Spain=3 schools, 182 participants; Sweden=9 schools, 337 participants; the United Kingdom=3 schools, 387 participants). Of the participants, 1571 (68.72%) were randomized to the full-intervention group and 715 (31.27%) to the minimal-intervention group. There was a notable dropout rate in the study. In the total sample, the number of subjects that discontinued participation comprised 467 pupils (20.42%) between T1 and T2 and 244 pupils (13.41%) between T2 and T3. Subjects were included in the longitudinal analyses if they had participated at least at T1 and T3, but participation at T2 was not necessary. This resulted in a longitudinal sample of 1544 subjects, with 56% women and a mean age of 15.8 years (standard deviation, SD=0.91 years).

Internet Use Measures

Measures of Internet behaviors and uses were constructed specifically for this study. This included items that measured the regularity of Internet use (eg, using the Internet once a month vs using it once a week) and the number of hours spent on the Internet on a typical week. Participants were also asked to rate how much time they spend on 7 different activities when using the Internet (socializing, gaming, school- or work-related activities, gambling, newsreading or watching, pornography, and targeted searches that are not related to school or work). Participants rated these activities on a 7-point scale (1=I spend very little or no time doing this; 7=I spend very much time doing this). The last set of items asked participants to rate the self-perceived consequences of engaging in said activities.

Participants were asked to rate the extent to which various consequences apply to them, but *only* in relation to those activities that he or she engaged in to a considerable degree (had previously rated as ≥4). The participants rated, on a 7-point scale (1=very seldom or never; 7=very often), the occurrence of the following consequences: "I find new friends"; "I have fun"; "I learn interesting things"; "I stay online longer than intended"; "I chose these activities instead of hanging out with friends (In real life)"; "I stay up late and lose sleep"; "I feel depressed or moody when I have no access to the above mentioned activities". Participants also rated how their Internet use affected their work performance or school grades (1=my work or grades suffer; 4=not affected at all; 7=my work or grades improve) and whether it was thought to contribute to their life meaning (1=less meaningful; 4=equally meaningful as without them; 7=more meaningful).

For the sake of clarity, we refer to some of these consequences as "positive" (finding new friends; having fun; learning interesting things) because they are outcomes of Internet use that do not necessarily imply addictive behavior and can be expected to lead to better mental health (if at all). We refer to other consequences as "negative" (staying on the Internet longer than intended; choosing Web-based activities instead of offline social activities; staying up and losing sleep; feeling moody when Web-based activities cannot be accessed) because they suggest symptoms of problematic Internet use and can therefore be expected to lead to poor mental health. For example, these negative consequences resemble those included in the IAT [7] and the Internet Gaming Disorder measurement recommendations by Petry et al [9]. Finally, some consequences are considered "bidirectional" (My work or grades improve/suffer; My life becomes less or more meaningful) because subjects could rate them either negatively or positively or indicate no change at all.

Mental Health Measures

Participants' levels of depression, anxiety, and stress were assessed by means of the 3 subscales constituting the 42-item version of the *Depression Anxiety Stress Scale* (*DASS-42*) [34]. Each subscale consists of 14 statements that are scored on a 4-point Likert scale according to how much the statement applied to the person over the past week. The scales are designed to measure negative emotional states of depression (dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest or involvement, anhedonia, and inertia), anxiety (autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect), and stress or tension (difficulty relaxing, nervous arousal, and being easily upset or agitated, irritable or over-reactive, and impatient). Studies that have investigated the psychometric properties of this scale have reported satisfactory outcomes on reliability and validity measures in healthy and clinical populations [34-37], also when administered over the Internet [38]. However, there have been reports that young adolescents distinguish less between the 3 factors as compared with adults, and correlations among them are typically high [39,40]. The scales demonstrated high internal consistency in the present sample, in terms of Cronbach alpha calculated on the baseline data (depression alpha=.93; anxiety alpha=.89; stress alpha=.91). As some

participants did not respond to all scale items, the final score on each scale was calculated by dividing the sum score by the number of items that they had responded. Only participants with 50% missing data or more were excluded. The scales correlated highly with each other (depression × anxiety: r=.76; depression × stress: r=.79; anxiety × stress: r=.78; all P values <.001), and the combined 42-item scale demonstrated high internal consistency (alpha=.96). Due to the relatively high intercorrelation between constructs, and to simplify analysis, the 3 scales were combined into a single measure of mental health.

Procedure

All study procedures took place at the respective schools in classrooms or computer rooms. The questionnaires were administered either in paper and pencil format or using a Web-based survey tool, if the school was able to provide computers for all pupils at time of data collection. The questionnaire contained items used to screen for suicidal adolescents (The Paykel Suicide Scale [41]), and the screening procedure took place within 24 hours after each wave of data collection. Therefore, participation was not completely anonymous; however, subjects' identities were encrypted using individual "participation codes," which were written on the questionnaire instead of the participants' name. The codes were linked to pupil's identities only to connect data longitudinally and to contact high-risk suicidal adolescents (emergency cases) to offer help. Subjects were defined as emergency cases if they responded that they had seriously contemplated, planned, or attempted suicide within the past 2 weeks. The exact procedure for dealing with risk cases varied between countries and was contingent on the regional ethical guidelines and available help resources. Emergency cases were excluded from the data analysis (n=23). The intervention tested in the SUPREME project was administered after baseline data collection and is described further in Multimedia Appendix 1.

Data Analysis

Two main analyses were performed in this study: 1 cross-sectional hierarchical multiple regression analysis and 1 longitudinal analysis. The measure of frequency of Internet use was omitted from analysis owing to a ceiling effect (90% of participants reported using the Internet at least once per day). The remaining predictor variables were thus the self-reported number of weekly hours online, the ratings of the 7 activities, and the ratings of the 9 consequences of Internet use. The composite DASS score was the dependent variable in these analyses (tests of statistical assumptions are described in Multimedia Appendix 1). In the cross-sectional regression, Internet behaviors at T1 were used to predict mental health at T1. The longitudinal regression analysis predicted change in overall DASS (the score difference between T1 and T3) by means of change in Internet behaviors. Only the longest follow-up was of interest in this study. Gender, age, and experimental condition were included as control variables in the first model. Time spent on the Internet was added in the second model, activity ratings were added in a third model, and the consequence ratings were added in a fourth model. Further, because participants were instructed to rate perceived

consequences only if they performed at least one online activity above the >3 threshold, a minority (n=82; 5%) of subjects whose scores had transcended above or below the threshold between T1 and T3, had incomplete data for the calculation of difference scores. However, sensitivity analyses indicated no statistically significant difference between these subjects and other cases, regarding the average amount of longitudinal change in DASS scores or mean online activity scores.

Results

Descriptive Results

DASS-42 scores could be calculated for 2220 participants. Total DASS scores ranged between 0-3 points, where higher scores indicate more mental health problems. The mean baseline scores for males, females and the total sample are presented in Table 1. Females scored significantly higher than males on all mental health measures (Table 1). In the total sample, 1848 participants (83.24%) had a mean DASS score below 1, and 314 (14.1%)

had a score between 1 and 1.99, and 58 (2.6%) had a score of 2 or above. There were small but significant differences between the countries in DASS scores ($F_{(6, 2213)}=9.28$, $\eta^2_{partial}=.02$, $P<.001$). The average change in DASS scores over the 4-month study period was −0.15 (SD=0.42), which indicates a decrease over time. Participants who dropped out of the study between T1 and T3 had somewhat higher baseline DASS scores than adhering participants (mean difference=0.10; $t_{(2218)}=4.068$; $P<.001$).

Table 1 also summarizes the average reported time spent on the Internet, activity ratings, and consequence ratings at baseline. The table summarizes that average number of hours spent on the Internet per week was 17.23, with large variation in the sample, and that men had spent slightly more hours on the Internet than women. It was most common for the adolescents to use the Internet for social purposes, followed by school or work, targeted searches, gaming, newsreading or watching, pornography viewing, and gambling, although there were notable gender differences regarding these activities.

Table 1. Descriptive results (means and standard deviations) for mental health and Internet use measures at baseline.

Variable[a]	Total	Women	Men	Gender difference[b]		
	M (SD)	M (SD)	M (SD)	t	P	d
Depression	0.52 (0.59)	0.62 (0.64)	0.40 (0.49)	9.15	<.001	0.40
Anxiety	0.48 (0.49)	0.54 (0.51)	0.40 (0.45)	7.02	<.001	0.30
Stress	0.72 (0.60)	0.83 (0.63)	0.57 (0.53)	10.39	<.001	0.37
DASS (total)	0.57 (0.52)	0.67 (0.54)	0.46 (0.45)	9.71	<.001	0.42
Time spent on the Internet	17.12 (17.72)	16.43 (17.04)	17.96 (18.50)	−1.99	.046	−0.09
Socializing	4.94 (1.73)	5.29 (1.62)	4.51 (1.77)	10.80	<.001	0.46
Gaming	3.05 (2.04)	2.03 (1.42)	4.33 (1.98)	−31.95	<.001	−1.33
School or work	3.71 (1.54)	4.01 (1.49)	3.34 (1.52)	10.44	<.001	0.45
Gambling	1.31 (0.98)	1.09 (0.51)	1.58 (1.30)	−12.06	<.001	−0.50
News	2.96 (1.66)	2.93 (1.63)	2.99 (1.69)	−0.83	.41	NS
Pornography	1.73 (1.48)	1.10 (0.55)	2.53 (1.86)	−25.42	<.001	−1.04
Targeted searches	3.28 (1.68)	3.28 (1.68)	3.29 (1.68)	−0.19	.85	NS
Finding friends	3.42 (1.79)	3.40 (1.81)	3.44 (1.76)	−0.45	.65	NS
Learning	4.07 (1.64)	4.02 (1.60)	4.12 (1.68)	−1.35	.18	NS
Having fun	4.66 (1.77)	4.49 (1.73)	4.88 (1.80)	−5.08	<.001	−0.22
Meaningfulness	4.12 (1.22)	4.10 (1.15)	4.14 (1.30)	−0.69	.49	NS
Impact on grades	3.95 (1.24)	3.95 (1.24)	3.93 (1.24)	0.37	.71	NS
Staying on the Internet longer	4.03 (1.86)	4.22 (1.84)	3.79 (1.86)	5.34	<.001	0.23
Prefers Web-based relations	2.14 (1.44)	1.99 (1.38)	2.31 (1.49)	−5.16	<.001	−0.22
Sleep loss	3.07 (1.97)	3.05 (1.98)	3.09 (1.95)	−0.51	.61	NS
Withdrawal (negative mood when inaccessible)	2.25 (1.52)	2.24 (1.54)	2.26 (1.49)	−0.22	.83	NS

[a]Mental health scores (depression, anxiety, stress, DASS total) range between 0 and 3. Time spent on the Internet is measured in hours. All other Internet-related measures range between 1 and 7.

[b]Gender differences were determined through independent samples t-tests; t-values, P values, and Cohen's d are presented.

Cross-Sectional Regression Analysis

The cross-sectional hierarchical multiple regression analysis was used to predict DASS scores at T1 by means of Internet use at T1. The first model comprising the control variables (gender, age, experimental condition) was highly significant ($F_{(3, 1683)}=26.40$, $P<.001$) and explained $R^2_{adj}=4.3\%$ of the variance in psychopathology. The second model (time spent on the Internet) contributed significantly to the prediction (F change$_{(1, 1682)}=26.05$, $P<.001$) by 1.4%, resulting in a total of $R^2_{adj}=5.7\%$ explained variance. The third model (relative time spent on activities) contributed significantly to the prediction (F change$_{(7, 1675)}=8.29$, $P<.001$) by 2.8%, resulting in a total of $R^2_{adj}=8.5\%$ explained variance. The fourth model (consequences of Internet use) contributed significantly to the prediction (F change$_{(9, 1666)}=26.80$, $P<.001$) by 11.1%. This resulted in a final total of $R^2_{adj}=19.6\%$ explained variance, 15.3% of which was accounted for by Internet-related factors. The adjusted R^2 continued to increase at each step in the analysis, indicating that the model was not overfitted. There was no indication of problematic collinearity as all variables had a tolerance above 0.5. The results of the regression analysis, including the standardized beta coefficients (ß) for each predictor in each model, are summarized in Table 2.

Table 2 summarizes that gender was the only significant control variable, whereas age and experimental condition were not. The self-reported average number of hours spent on the Internet was a significant predictor of higher DASS scores in models 2 and 3 but not when accounting for consequences of Internet use in the fourth model. The effect size (ß) of individual Web-based activities varied between .05 and .13. Using the Internet for social purposes was a significant predictor of DASS scores in model 3, but not in model 4, suggesting that the risk associated with socializing on the Internet was accounted for by the consequences measured in the study. Web-based gaming followed the opposite pattern, as this activity was not a significant predictor of DASS in model 3 but turned significant in the fourth model. The negative beta value indicates that Web-based gaming was a protective factor associated with mental health. Performing school or work activities on the Internet was also a significant protective factor for psychopathology in the third model but not when accounting for consequences of Internet use. Web-based gambling was a significant risk factor for higher DASS scores in both models 3 and 4. Consuming news content was not significantly associated with DASS in either model. Viewing pornographic content on the Internet was a significant risk factor only in model 3 but not model 4, thus accounted for by consequences of Internet use. Performing targeted searches on the Internet was significantly and strongly positively associated with DASS scores in both models 3 and 4, having the largest effect size of the activities. Regarding consequences of Internet use, finding new friends, learning interesting things, and having fun did not predict DASS scores in model 4. Thus, these "positive" consequences did not seem to act as protective factors. However, Internet use that was perceived to increase life meaning or improve school or work performance was a significant protective factor. The "negative" consequences were more powerful predictors of DASS scores. Although staying on the Internet longer than originally intended was not a significant predictor, the statements "I choose these activities instead of hanging out with friends," "I stay up late and lose sleep," and "I feel depressed or moody when I have no access to the above-mentioned activities" were highly significant risk factors, with effect sizes (ß) ranging between .12 and .22.

Table 2. Results from the cross-sectional hierarchical multiple regression analysis. Statistics are presented for each predictor variable in each model.

Entered in model no	Predictor variable	Model no[a]	Standardized Beta	95% CI	t	P	Tolerance
1	(Constant)	1			1.07	.29	
		2			0.41	.68	
		3			0.03	.97	
		4			−0.30	.77	
1	Exp. Condition[b]	1	.00	−0.05 to 0.04	−0.12	.90	1.00
		2	−.01	−0.05 to 0.04	−0.28	.78	1.00
		3	.00	−0.05 to 0.05	0.02	.98	0.99
		4	.02	−.03 to 0.06	0.80	.42	0.98
1	Gender[c]	1	−.21	−0.26 to −0.16	−8.80	<.001	1.00
		2	−.22	-0.26 to −0.17	−9.10	<.001	1.00
		3	−.26	−0.32 to −0.20	−8.03	<.001	0.52
		4	−.22	−0.28 to −0.16	−7.10	<.001	0.51
1	Age	1	−.03	−0.07 to 0.02	−1.04	.30	1.00
		2	−.01	−0.06 to 0.04	−0.39	.69	0.98
		3	.00	−0.05 to 0.05	−0.02	.99	0.97
		4	.01	−0.04 to 0.05	0.31	.76	0.92
2	Time spent on the Internet	2	.12	0.08-0.17	5.10	<.001	0.98
		3	.10	0.05-0.14	3.88	<.001	0.91
		4	.02	−0.03 to 0.07	0.93	.35	0.84
3	Socializing	3	.05	0.00-0.10	2.06	.04	0.90
		4	−.01	−0.06 to 0.03	−0.57	.57	0.78
3	Gaming	3	−.02	−0.07 to 0.04	−0.54	.59	0.64
		4	−.06	−0.12 to −0.01	−2.17	.03	0.57
3	School or work	3	−.05	−0.10 to 0.00	−2.02	.04	0.83
		4	−.03	−0.08 to 0.02	−1.22	.22	0.78
3	Gambling	3	.08	0.03-0.13	3.11	.002	0.89
		4	.05	0.01-0.10	2.30	.02	0.87
3	News	3	.01	−0.04 to 0.06	0.50	.62	0.85
		4	.03	−0.02 to 0.07	1.08	.28	0.82
3	Pornography	3	.07	0.01-0.12	2.46	.01	0.72
		4	.02	−0.03 to 0.07	0.78	.44	0.71
3	Targeted searches	3	.13	0.08-0.18	4.94	<.001	0.84
		4	.09	0.04-0.14	3.56	<.001	0.75
4	Finding friends	4	.03	−0.01 to 0.08	1.38	.17	0.79
4	Learning	4	.01	−0.04 to 0.06	0.34	.73	0.67
4	Having fun	4	−.05	−0.10 to 0.00	−1.80	.07	0.71
4	Meaningfulness	4	−.05	−0.10 to −0.01	−2.22	.03	0.90
4	Impact on grades	4	−.07	−0.11 to −0.02	−2.78	.005	0.88
4	Staying on the Internet longer	4	.01	−0.04 to 0.07	0.53	.60	0.66
4	Prefers Web-based relations	4	.12	0.07–0.17	4.74	<.001	0.79
4	Sleep loss	4	.13	0.08-0.19	4.95	<.001	0.65

Entered in model no	Predictor variable	Model no[a]	Standardized Beta	95% CI	t	P	Tolerance
4	Withdrawal (neg. mood when inaccessible)	4	0.22	0.17-0.27	8.80	<.001	0.76

[a]The model numbers designate which values were obtained when (1) only control variables were analyzed, (2) when time spent over the Internet was added to the model, (3) when Web-based activities were added to the model, and (4) when consequences of Internet use were added to the model.

[b]For experimental condition, the minimal-intervention condition constitutes the reference group.

[c]For gender, females constitute the reference group.

Longitudinal Regression Analysis

The longitudinal hierarchical multiple regression analysis was used to predict change in overall psychopathology (the score difference between T1 and T3) by means of change in Internet use. There was no indication of problematic levels of collinearity in the model, as all variables had a tolerance value above 0.7. The first model comprising the control variables (gender, age, experimental condition) was not significant ($F_{(3, 981)} < 1$, $P=.59$), and neither was the second model (time spent on the Internet; F change$_{(1, 980)} < 1$, $P=.95$). The third model (relative time spent on activities) contributed significantly to the prediction (F change$_{(7, 973)}=2.25$, $P<.03$) by $R^2_{adj}=0.7\%$ explained variance. This contribution was attributable to news viewing, where an increase in news viewing from T1 to T3 was associated with an increase in DASS scores (ß=.07, 95% CI=0.00-0.13, $P=.049$). All other Web-based activities were nonsignificant ($P \geq .19$) in this model. The fourth model (consequences of Internet use) contributed significantly to the prediction (F change$_{(9, 964)}=3.39$, $P<.001$) by 2.1%, resulting in a total of $R^2_{adj}=2.8\%$ explained variance. News consumption was rendered nonsignificant here ($P=.13$). The contribution of the fourth model was attributable to 2 of the negative consequences. The statements "I stay up late and lose sleep" (ß=.12, 95% CI=0.05-0.19, $P=.001$) and "I feel depressed or moody when I have no access to the above mentioned activities" (ß=.09, 95% CI=0.03-0.16, $P<.01$) were significant predictors in this model. All other predictors were

nonsignificant (change in life meaning: $P=.10$; other variables had P values above that).

Thus, Internet use that was reported to result in staying up late and losing sleep ("sleep loss") and to produce negative mood when it could not be accessed ("withdrawal") were the only variables that consistently predicted longitudinal change in mental health. To further investigate these negative consequences, 2 standard multiple regressions were calculated to predict longitudinal changes in each of these variables by means of changes in time spent on the Internet and the different Web-based activities. The regression model that predicted sleep loss was significant ($F_{(8, 1120)}=5.76$, $P<.001$, $R^2_{adj}=3.3\%$ explained variance) and so was the regression that predicted withdrawal ($F_{(8, 1125)}=11.17$, $P<.001$, $R^2_{adj}=6.7\%$ explained variance). The coefficients from these regressions are summarized in Table 3 and Table 4, respectively. Table 3 summarizes that the strongest predictor for increased sleep loss was a decrease in school or work activities, followed by increased gaming, targeted searching, pornography viewing, and online time in general. Social activities, gambling, and news viewing were not significantly related to change in sleep loss. Table 4 summarizes that the strongest predictors of change in withdrawal were gambling activities, followed by overall time spent on the Internet, pornography viewing, and gaming. Changes in social activities, school or work, news viewing, and targeted searches were not significantly associated with change in withdrawal.

Table 3. Results from the multiple regression analysis predicting changes in "sleep loss" by means of change in Internet use.

Predictor variable	Standardized beta	95% CI	t	P
Constant			0.82	.42
Time spent on the Internet	.07	0.01-0.13	2.25	.03
Socializing	.06	0.00-0.11	1.89	.06
Gaming	.08	0.02-0.14	2.59	.01
School or work	−.10	−0.16 to −0.04	−3.16	.002
Gambling	.01	−0.05 to 0.07	0.36	.72
News	.04	−0.02 to 0.10	1.20	.23
Pornography	.06	0.01-0.12	2.14	.03
Targeted search	.08	0.02-0.14	2.56	.01

Table 4. Results from the multiple regression analysis predicting changes in "withdrawal" by means of change in Internet use.

Predictor variable	Standardized beta	95% CI	t	P
Constant			3.47	.001
Time online	.12	0.06-0.17	3.93	<.001
Socializing	.03	−0.03 to 0.09	1.03	.31
Gaming	.08	0.02-0.13	2.56	.01
School or work	.00	−0.06 to 0.06	−0.03	.97
Gambling	.14	0.08-0.20	4.75	<.001
News	.04	−0.02 to 0.10	1.27	.20
Pornography	.10	0.04-0.16	3.38	.001
Targeted search	.02	−0.04 to 0.08	0.57	.57

Discussion

Cross-Sectional Findings

The purpose of this study was to identify Internet-related risk and protective factors for mental health problems and to test if the effects of time spent on the Internet and on various Web-based activities could be accounted for by a number of perceived consequences of those activities. This was investigated by examining the association between adolescents' general mental health (combined levels of depression, anxiety, and stress or tension) and those Internet-related behaviors, both cross-sectionally and longitudinally over a 4-month period.

The cross-sectional results showed that mental health was predicted by Internet-related behaviors at baseline (15.3% explained variance after adjusting for the number of predictors in the model). Individual effect sizes were rather small (standardized ß=.05-.22). Time spent on the Internet had a larger effect than most individual activities, but consequences of Internet use explained the largest variance in DASS scores (11.1%). Of these, 3 of the 4 negative consequences were the most important predictors (preference for Web-based activities over offline social activities, sleep loss, and withdrawal), whereas the positive consequences were nonsignificant. Internet use that was perceived to increase life meaning or improve school grades or work performance was associated with better mental health, but the effects were smaller than for the negative consequences.

Furthermore, the results showed that time spent on the Internet, social media use, pornography viewing, and school or work activities were only significant predictors when perceived consequences were not accounted for, which suggests that the mental health effects of these activities were explained by the consequences. Web-based gaming, gambling, and targeted searches, on the other hand, were significant predictors of mental health even when controlling for perceived consequences, suggesting that the content of these activities was relatively important in comparison with perceived consequences, with regard to mental health. Together, these results indicate that all Web-based activities measured in this study are predictive of mental health, but only some of them seem to have content-based effects large enough to be detected in a fully adjusted model. The other activities seemed to only affect mental

health by means of their perceived consequences, mainly the preference for Web-based interactions, sleep loss, and withdrawal. As these negative consequences are indicative of problematic Internet use [9,14], their relatively strong effect on mental health is expected from a problematic Internet use perspective. It should be noted, however, that perceived consequences may be different from actual consequences.

Longitudinal Findings

Previous studies have linked sleep loss and withdrawal symptoms to mental health problems and problematic Internet use [9,12,42-45]. The longitudinal analyses in this study similarly suggest that sleep loss and withdrawal (negative mood when content is inaccessible) predict changes in mental health over time (2.1% explained variance), and in fact, these were the only variables to do so in the long term. Longitudinal changes in time spent on the Internet and various activities did not predict change in mental health directly but instead had an indirect effect by predicting changes in sleep loss and withdrawal (3.3% and 6.7% explained variance, respectively). This suggests that time spent on the Internet and content viewed are predictive of mental health mainly because they predict negative perceived consequences, such as sleep loss and withdrawal. This interpretation is in line with the problematic Internet use approach and also supports the differentiation between generalized and specific forms of problematic Internet use (eg, [15-17]), as activities were indeed differently associated with negative consequences. It also suggests that interventions aimed at reducing the negative mental health effects of Internet use could target the negative consequences instead of the Internet use itself. For instance, instead of reducing the time spent on a certain activity, the intervention could focus on making sure that activity does not interfere with sleep. However, with certain types of Internet use, such as gambling, activity-specific interventions may be more effective.

General Discussion

The results of this study confirm that problematic (or unhealthy) Internet use cannot simply be equated to high-intensity or frequent Internet use. First, although time spent on the Internet was found to be negatively associated with mental health, some activities, such as school work, were positively associated. Second, time spent on the Internet was not an independent risk factor for mental health after accounting for the perceived

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consequences of Internet use, underlining that Internet use is not intrinsically harmful. Even when it comes to specific activities, for example, gaming, the relationship could be complex. Previous studies have established that gaming has a negative effect on mental health (eg, [12,29]), whereas in this study, the effects were positive. Most studies that have found negative gaming effects have typically only investigated problematic gaming. Thus, it seems possible that gaming has some protective properties when used to a certain extent, but negative consequences might overshadow those properties when used excessively. For instance, in this study, we found that despite its positive mental health effects, gaming significantly predicted sleep loss and withdrawal, which in turn were associated with mental health problems. In line with this, a recent European study on gaming among children aged 6-11 years, found that, once controlled for high usage predictors, gaming was not significantly associated with mental health problems but was instead associated with less peer relationship problems and prosocial deficits [46].

The causal link between general Internet use and mental health also seems complex. Previous authors have acknowledged the possibility that the risk associated with Internet use could reflect an already present disorder, which may have an effect on how the Internet is used [47-49]. Certain cognitive styles that constitute disposition toward using the Internet in certain ways may also influence mental health. For example, Brand et al [50] suggested that problematic Internet use is associated with expectations that the Internet can be used to positively influence mood, which in some cases might be a false assumption on behalf of the user. The disappointing reality of this may in turn worsen preexisting mental health problems. In this study, performing targeted searches (unrelated to school or work) was associated with higher DASS scores and had a larger effect size than any other Web-based activity. A possible explanation for this is that individuals who experience more distress are more prone to use the Internet as a tool for coping with their problems [27]. It could also reflect a general tendency to rely on Web-based sources to solve problems or concerns even when professional help would be more useful. However, because health issues are not the only possible target of Internet searches, future studies will have to explore this hypothesis further.

Furthermore, although Internet-related sleep loss was found to be a longitudinal predictor of mental health, there is an established bidirectional link between sleeping problems and depression [51] as well as mood and affective functioning in general [52]. It therefore seems likely that the relationship between Internet use–related sleep loss and mental health is also reciprocal. Therefore, interventions aimed at reducing problematic Internet use may be more successful if they include simultaneous treatment of comorbid disorders (including depression and sleep disorders). Similarly, a number of previous studies have found problematic gambling to be predictive of generalized problematic Internet use, suggesting that addictive gambling and Internet use have some common etiology [20-23,53]. Our results support this view, as gambling activities were the strongest predictor of perceived withdrawal, suggesting that treatment of problematic Internet use behaviors should also address any gambling problems. However, it is important that future studies examine in more detail which variables act as precursors of harmful Internet use (eg, personality, cognitive, emotional and motivational factors, and existing mental disorders) and which variables act as outcomes and mediators. As certain personality domains might constitute a predisposition toward risk factors such as withdrawal, future studies should investigate the mediating role of such nonpathological variables.

In this study, we found no effect of perceived positive consequences of Internet use on mental health, and it is possible that this is because they are actually rather motives for using the Internet. In other words, participants may have reported consequences they hoped for rather than what actually happened. Sagioglou and Greitemeyer [54] pointed out that self-reported outcomes of different Internet activities may have limited validity, especially when made temporally distant, in which case it may rather reflect what participants see as plausible motivations for their use. More accurate measures may be obtained when participants are asked to rate them immediately after using a Web-based application, which was not possible in this study. Future studies should consider treating positive consequences of Internet use as predictors of using certain Web-based content (in healthy or unhealthy ways) rather than as direct predictors of mental health.

Limitations

This study is limited by the nature of the measurements used to estimate the participant's Internet use. One issue of validity concerns the consequences of Internet use, which cannot be assumed to perfectly reflect the real outcomes. In addition to the difficulty of observing the impact of daily activities on one's own health and behaviors, this measure might also be particularly vulnerable to recall biases and expectancy effects. Hence, this study only intended to measure the perceived consequences. It is also difficult to know whether the perceived consequences are produced by the Internet behaviors or some third factor, such as comorbid disorders. Another limitation of this study is that we did not make in-depth measures of the Web-based content that participants use. Therefore, one should take caution when applying these results to uses of more specific content; for example, different types of games and social networking activities may have different effects on both perceived consequences and mental health. Furthermore, our measurements did not include any problematic Internet use diagnostic tool. It is possible that if we had included more negative consequences of Internet use, or specific problematic Internet use criteria, this would have explained a larger proportion of the effects of the Web-based activities. Finally, there was a notable dropout rate between baseline and follow-up measurements (34%), which reduced the statistical power in the longitudinal analyses compared with the cross-sectional analyses. Also, participation in this study was not completely anonymous, and participants with high suicidal risk were excluded from the data analysis, which could mean that some of the adolescents with the most severe psychopathology were not represented in the analyses.

Conclusions

Different Web-based activities or content can have specific effects on mental health, even when used in moderate levels

and when adjusting for the number of hours spent on the Internet. Web-based activities differ in how consistently, how much, and in what direction they affect mental health. Activities also differ regarding which negative consequences they produce, and those consequences (especially sleep loss and withdrawal) seem to predict mental health outcomes to a greater extent than the activities themselves. Therefore, it seems that time spent on the Internet and Web-based content are predictive of mental health mainly because they predict such negative consequences. These results underscore the importance of differentiating between generalized and specific forms of problematic Internet use. It also confirms that Internet use is not intrinsically harmful, but it depends on the activity that one engages in, and how it affects the individual. Change in mental health over time appears to be best predicted by changes in Internet-related sleep loss and withdrawal, and interventions to reduce harmful Internet use should therefore target such consequences. Positive consequences of Internet use may not predict mental health directly but might predict the propensity to engage in certain Web-based activities excessively or problematically. However, the causality between Internet use and mental health morbidity is complex and likely to be reciprocal, which means interventions or treatments of problematic Internet use might have to be multifaceted to be effective.

Acknowledgments

Conflicts of Interest

None declared.

Multimedia Appendix 1

[PDF File (Adobe PDF File), 40KB - mental_v3i3e31_app1.pdf]

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Abbreviations

DASS: Depression Anxiety Stress Scale
DSM: Diagnostic and Statistical Manual of Mental Disorders
IAT: Internet Addiction Test
SUPREME: Suicide prevention through Internet and media based mental health promotion

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mHealth for Schizophrenia: Patient Engagement With a Mobile Phone Intervention Following Hospital Discharge

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Abstract

Background: mHealth interventions that use mobile phones as instruments for illness management are gaining popularity. Research examining mobile phone based mHealth programs for people with psychosis has shown that these approaches are feasible, acceptable, and clinically promising. However, most mHealth initiatives involving people with schizophrenia have spanned periods ranging from a few days to several weeks and have typically involved participants who were clinically stable.

Objective: Our aim was to evaluate the viability of extended mHealth interventions for people with schizophrenia-spectrum disorders following hospital discharge. Specifically, we set out to examine the following: (1) Can individuals be engaged with a mobile phone intervention program during this high-risk period?, (2) Are age, gender, racial background, or hospitalization history associated with their engagement or persistence in using a mobile phone intervention over time?, and (3) Does engagement differ by characteristics of the mHealth intervention itself (ie, pre-programmed vs on-demand functions)?

Methods: We examined mHealth intervention use and demographic and clinical predictors of engagement in 342 individuals with schizophrenia-spectrum disorders who were given the FOCUS mobile phone intervention as part of a technology-assisted relapse prevention program during the 6-month high-risk period following hospitalization.

Results: On average, participants engaged with FOCUS for 82% of the weeks they had the mobile phone. People who used FOCUS more often continued using it over longer periods: 44% used the intervention over 5-6 months, on average 4.3 days a week. Gender, race, age, and number of past psychiatric hospitalizations were associated with engagement. Females used FOCUS on average 0.4 more days a week than males. White participants engaged on average 0.7 days more a week than African-Americans and responded to prompts on 0.7 days more a week than Hispanic participants. Younger participants (age 18-29) had 0.4 fewer days of on-demand use a week than individuals who were 30-45 years old and 0.5 fewer days a week than older participants (age

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46-60). Participants with fewer past hospitalizations (1-6) engaged on average 0.2 more days a week than those with seven or more. mHealth program functions were associated with engagement. Participants responded to prompts more often than they self-initiated on-demand tools, but both FOCUS functions were used regularly. Both types of intervention use declined over time (on-demand use had a steeper decline). Although mHealth use declined, the majority of individuals used both on-demand and system-prompted functions regularly throughout their participation. Therefore, neither function is extraneous.

Conclusions: The findings demonstrated that individuals with schizophrenia-spectrum disorders can actively engage with a clinically supported mobile phone intervention for up to 6 months following hospital discharge. mHealth may be useful in reaching a clinical population that is typically difficult to engage during high-risk periods.

Introduction

Patients, practitioners, and policy makers are increasingly enthusiastic about the use of mHealth approaches that can bring much needed resources (eg, information, assessment, and treatment) to people with chronic illnesses [1-3]. A recent meta-analysis of 12 studies conducted in the United States, Canada, United Kingdom, and India found that across countries the majority of people with schizophrenia-spectrum disorders own mobile phones, and many are interested in using them as tools to support the management of their illness [4]. Research examining mobile phone based mHealth programs for people with psychosis has shown that these approaches are feasible, acceptable, and clinically promising [5-10]. However, most mHealth initiatives involving people with schizophrenia have spanned periods ranging from a few days to several weeks and have typically involved participants who were clinically stable.

Schizophrenia has a prolonged and dynamic course typically consisting of periods of relative stability or remission interspersed with phases of symptomatic exacerbation that can last several months [11,12]. The months following hospital discharge are a particularly vulnerable period during which individuals are at increased risk for relapse and rehospitalization [13]. Whether people with schizophrenia are willing and able to engage in mHealth interventions during this high-risk period is unclear. On one hand, mHealth approaches are less constrained by clinic hours, location, or clinician availability and are therefore more flexible and accessible. On the other, mHealth programs require autonomous use and are limited in their personalization and adaptation capacities [14,15]. Consequently, patients might find mHealth interventions to be too effortful, formulaic, or repetitive and disengage.

With the current study, we set out to evaluate the viability of extended mHealth interventions for people with schizophrenia-spectrum disorders following hospital discharge. Specifically, we asked the following questions: (1) Can individuals be engaged with a mobile phone intervention program during this high-risk period?, (2) Are age, gender, racial background, and psychiatric hospitalization history associated with their engagement or persistence in using a mobile phone intervention over time?, and (3) Does engagement differ by characteristics of the mHealth intervention itself (ie, pre-programmed vs on-demand functions)? To address these questions, we examined mHealth intervention use and demographic and clinical predictors of engagement in 342 individuals who were given a mobile phone intervention for up to 6 months as part of a comprehensive technology-assisted relapse prevention program for people with psychosis following hospital discharge [16].

Methods

Procedures

The study was approved by the institutional review boards of the coordinating center, the participating sites, and the Committee for Protection of Human Subjects at Dartmouth College. Participants were drawn from a multisite Health Technology Program (HTP) implementation project that was conducted in partnership with 10 community mental health centers and outpatient clinics in eight US states between 2012 and 2015. HTP is described in detail elsewhere [16,17]. Briefly, the program offered individuals with psychotic disorders the opportunity to engage in a technology-assisted relapse prevention program for up to 6 months. As part of HTP, patients were offered an Android smartphone with the FOCUS [5,18] illness self-management program installed. Initially, a case manager introduced the mHealth intervention to patients and explained how to use the phone functions (eg, call, text, charge the battery) and FOCUS program (eg, respond to clinical assessment measures using the touchscreen, select on-demand tools). Once individuals demonstrated their proficiency, the case manager engaged them in a shared decision-making process to identify the three most relevant treatment targets from five possible FOCUS modules: medication adherence, mood regulation, sleep, social functioning, and coping with auditory hallucinations. Once treatment targets were selected, they were input into the mobile phone and patients could use FOCUS independently. Participants could call or meet with their case managers for technical support and troubleshooting. The FOCUS system prompted patients to engage in a brief assessment/intervention up to three times daily, focusing on their assigned treatment targets. In addition to pre-scheduled prompts, participants could access the treatment content for all five modules without restriction as part of the FOCUS on-demand functions. The mobile phone transmitted participant use data to a remote server regularly. Once data were uploaded, case managers at the different individual sites could view their assigned participants' FOCUS activity via a secure online dashboard. HTP case managers met with participants for relapse

prevention planning regularly, and data from the dashboard were available to inform these meetings. Brunette et al describe in detail the development of the Relapse Prevention Plan in which FOCUS was embedded [16].

Participants

Individuals were eligible to participate in HTP if they were diagnosed with a psychotic disorder, were 18-60 years old, and had been discharged from psychiatric hospitalization within the past 60 days. The HTP sample consisted of 368 individuals. Four individuals were offered the FOCUS intervention but declined. Two individuals received a mobile phone but lost or sold it before the FOCUS program was activated and so did not generate mHealth use data. One individual was not offered FOCUS because his living environment did not permit the use of a mobile phone. Five individuals dropped out of HTP shortly after their baseline assessment and did not receive a mobile phone. Another 14 individuals provided fewer than 7 days of mobile phone data and were not included in the analyses because weekly engagement measures could not be calculated for them. Our final mHealth user sample consists of 342 individuals. These participants had a mean age of 35 years (SD 11). The sample was 62.3% (213/342) male, 50.0% (171/342) white, 25.1% (86/342) African-American, 10.8% (37/342) Hispanic, and 14.0% (48/342) were Asian, American Indian, Native Hawaiian, or more than one race. The majority (75.7%, 259/342)were single.

Measures

Psychiatric diagnoses were based on medical records at the community mental health center or outpatient clinic where they received care and were confirmed by investigators at each site. Demographic information was collected during a baseline interview. Participants' FOCUS use "events" were logged automatically by the mobile phone and transmitted to a study server when the device had connectivity. Four engagement outcomes were calculated for each individual: Days of mHealth Use represents the number of days a participant used any FOCUS function during the week. Days Responding to Prompts represents the number of days a participant responded to system-initiated prompts during the week. Days of On-Demand Use represents the number of days a participant initiated FOCUS use during the week. Average Daily On-Demand Use tallied how often within a day individuals self-initiated FOCUS functions. In initial descriptive tables, weekly engagement measures were summarized at the individual level for the entire time they participated in the study. Weekly measures were then characterized over time in longitudinal analyses.

Overview of Analyses

The goal of longitudinal analyses was to estimate engagement over the course of the study. Participants, however, received the smartphone intervention for differing amounts of time and consequently had differing amounts of engagement data. Engagement data were missing for months without mobile phone data. Missing data may be a product of participants' discontinuing FOCUS use prior to the end of the 6-month relapse prevention program or because they enrolled in HTP

with less than 6 months left before the end of the project (these participants were informed that they may receive less than the full "dose" of the intervention when enrolling). For participants who dropped out prematurely, it is particularly important to take into account the relationship between available data and engagement. If a participant was less engaged with the mHealth intervention, they would be expected to be more likely to discontinue using it altogether. Therefore, modeling of engagement must assume missing data is informative on the engagement outcome values. Jointly modeling the longitudinal outcomes and the duration of available data allows an unbiased estimate of the association between predictors and the longitudinal outcome while appropriately accounting for missing data. In analyses including all participants (even those with less than 6 months of data), the results presented are from joint models. These models fit a longitudinal mixed-effects model for each engagement outcome simultaneously with a Cox proportional hazard model of duration of available data. Subgroup models among only those participants with 5-6 months of available data were performed via mixed-effects models. All longitudinal models included linear time terms, and quadratic time terms were retained if significant. To assess the effect of demographic factors and engagement, fixed effects were added to the time-trend models for each of the demographic factors of interest. Due to significant associations between age and gender (younger individuals were more likely to be male) and age and race (older individuals were more likely to be white), models for each demographic factor were fit separately. All longitudinal models include random individual-level intercept and slope terms to account for the correlation of outcomes over time within individuals.

Results

The majority of participants were able to use the mobile phone and FOCUS program safely and without difficulty. One participant reported getting paranoid about the mobile phone and breaking it. Another participant reported only using it on "airplane mode" to avoid being tracked. Three participants deleted the FOCUS program from the phone. Another 21 participants reported their mobile phone lost or stolen over the course of their participation and requested a replacement device. One participant accidentally downloaded malware that rendered the phone inoperative and it needed to be replaced. At least two devices were pawned by participants.

Table 1 summarizes participant demographics and engagement rates. Participants included in this analysis had a study mobile phone for varying timeframes ranging from 8 to 183 days (mean 126 days, SD 52). Most participants (73.6%, 252/342) used the intervention for 3-6 months. On average, participants used the FOCUS program for 82% of the weeks they had the device. On average, participants had 9.5 (SD 7.4) meetings with HTP case managers in which they engaged in FOCUS-related topics (eg, device set-up and training, treatment target selection, technical troubleshooting, modification of prompting schedules, encouragement to use FOCUS strategies in the context of daily life).

Table 1. Individual demographic and engagement outcomes.

Demographic and study variables	Values
Gender, n (%)	
Female	129 (37.7)
Male	213 (62.3)
Age, n (%)	
18-29	138 (40.3)
30-45	135 (39.5)
46-60	69 (20.2)
Race, n (%)	
White	171 (50.0)
African-American	86 (25.1)
Hispanic	37 (10.8)
Other (Asian, American Indian/Alaskan Native, Native Hawaiian, or more than one race)	48 (14.0)
Marital status, n (%)	
Married	23 (6.7)
Widowed/Divorced	57 (16.7)
Single/Never married	259 (75.7)
Months of mHealth use, n (%)	
<1	26 (7.6)
1+	28 (8.2)
2+	36 (10.5)
3+	36 (10.5)
4+	65 (19.0)
5+	151 (44.2)
Number of previous psychiatric hospitalizations, n (%)	
1-6	186 (55.2)
7+	151 (44.8)
Engagement measures, mean (SD)	
Days of mHealth Use per week	3.5 (1.9)
Days Responding to Prompts per week	2.9 (2.0)
Days of On-Demand Use per week	1.8 (1.4)
Daily On-Demand Use	1.2 (1.8)
Percentage of weeks used	82% (21%)
Percentage of weeks responding to prompts	72% (28%)
Percentage of weeks using on-demand functions	62% (28%)

Individuals who used FOCUS for 5-6 months of the relapse prevention program (44%) had higher average engagement throughout their participation than those who used FOCUS for less time. Their Days of mHealth Use were mean 4.3 (SD 1.8) per week; Days Responding to Prompts: mean 3.8 (SD 2.0) per week; Days of On-Demand Use: mean 1.9 (SD 1.5) per week; and Daily On-Demand Use: mean 1.3 (SD 1.8). In the Cox proportional hazard portion of the joint models, there was a significant association between level of engagement and likelihood of discontinuing use, with higher levels of engagement associated with lower risk of discontinuation. Greater number of psychiatric hospitalizations was also significantly associated with likelihood of discontinuing use, with a discontinuation hazard ratio of 1.4 (95% CI 1.1-1.8; P=.004) for 7+ hospitalizations compared to fewer hospitalizations.

The level of engagement with the mobile phone intervention declined over time (see Figure 1). The joint model results including all participants showed a curvilinear decline from an

average of 3.9 uses in the first week to 1.9 uses in week 24. Days Responding to Prompts declined linearly and Days of On-Demand Use declined more steeply initially followed by a leveling off of use. Mean Days Responding to Prompts in the first week was 3.1 and in week 24 was 1.6. Mean Days of On-Demand Use was also 3.1 in the first week and 1.4 in week 24. Daily On-Demand Use also declined steeply initially followed by a leveling off in the later weeks (1.4 in week 1 and 0.6 week 24).

If the analysis is restricted to only those participants who continued using FOCUS for 6 months, the declines in Days of mHealth Use and Days Responding to Prompts do not appear to be as steep. In this subset, engagement in week 24 remained high with a mean of 3.8 Days of mHealth Use, 3.5 Days Responding to Prompts, 1.5 Days of On-Demand Use, and 1.1 Daily On-Demand Use. Both prompted and on-demand features continued to be used throughout the study (see Figure 2).

Gender, race, age, and number of psychiatric hospitalizations were all found to be significantly associated with engagement outcomes (see Table 2). Females were significantly more engaged as measured by Days of mHealth Use, Days Responding to Prompts, and Daily On-Demand Use. On average, females used FOCUS on 0.42 days more per week than males and responded to prompts on 0.18 days more than males. On average, females also used on-demand features 1.61 times more

per day than males. No significant association was seen between gender and Days of On-Demand Use.

White participants were the most engaged. They had significantly more Days of mHealth Use (0.69 more per week), Days Responding to Prompts (0.72 more per week), and Days of On-Demand Use (0.17 more per week) than African-American participants. White participants had significantly more Days Responding to Prompts (0.74 more per week) and Days of On-Demand Use (0.33 more per week) but less Daily On-Demand Use (1.32 less uses per day) than Hispanic participants.

Participants were categorized into three age groups: 18-29, 30-45, and 46-60. Participants aged 30-45 were significantly more engaged than younger participants (18-29 years) when considering Days of On-Demand Use (0.42 days more weekly) and Daily On-Demand Use (0.16 uses more per day). Older participants (46-60) were significantly more engaged in Days of On-Demand Use (0.48 days more weekly) and Daily On-Demand Use (1.78 uses more per day) when compared to those 18-29. However, they were significantly less engaged in Days Responding to Prompts (0.41 days fewer).

Participants with 7 or more psychiatric hospitalizations were significantly less engaged than those with fewer hospitalizations when considering Days of mHealth Use (0.2 days fewer per week), but no difference was seen in Days Responding to Prompts, Days of On-Demand Use, or Daily On-Demand Use.

Table 2. Joint longitudinal model results for engagement over time.

	Days of mHealth use		Days responding to prompts		Days of on-demand use		Daily on-demand use	
	Parameter estimate	P	Parameter estimate	P	Parameter estimate	P	Parameter estimate	P
Intercept	4.04 (0.10)	<.001	3.13 (0.072)	<.001	3.34 (0.085)	<.001	1.59 (0.11)	<.001
Study week	-0.14 (0.014)	<.001	-0.062 (0.007)	<.001	-0.24 (0.011)	<.001	-0.19 (0.014)	<.001
Study week 2	0.0021 (0.0006)	<.001			0.0067 (0.0004)	<.001	0.0063 (0.0005)	<.001
Male vs female	-0.42 (0.14)	<.01	-0.18 (0.076)	<.05	-0.11 (0.076)	.15	-1.61 (0.066)	<.001
Race								
African-American vs white	-0.69 (0.13)	<.001	-0.72 (0.09)	<.001	-0.17 (0.082)	<.05	0.023 (0.068)	.73
Hispanic vs white	-0.29 (0.23)	.22	-0.74 (0.14)	<.001	-0.33 (0.079)	<.001	1.32 (0.11)	<.001
Other vs white	-0.46 (0.54)	.39	-0.95 (0.13)	<.001	-0.099 (0.094)	.29	-0.064 (0.12)	.58
Age								
30-45 vs 18-29	0.34 (0.18)	.06	-0.10 (0.15)	.51	0.42 (0.076)	<.001	0.16 (0.067)	<.05
46-60 vs 18-29	-0.27 (0.16)	.097	-0.41 (0.18)	<.05	0.48 (0.093)	<.001	1.78 (0.11)	<.001
Previous hospitalizations								
1-6 vs 7+	0.21 (0.10)	<.05	-0.026 (0.084)	.76	-0.063 (0.076)	.41	-0.013 (0.066)	.84

Figure 1. Model-based estimates of mHealth engagement over time.
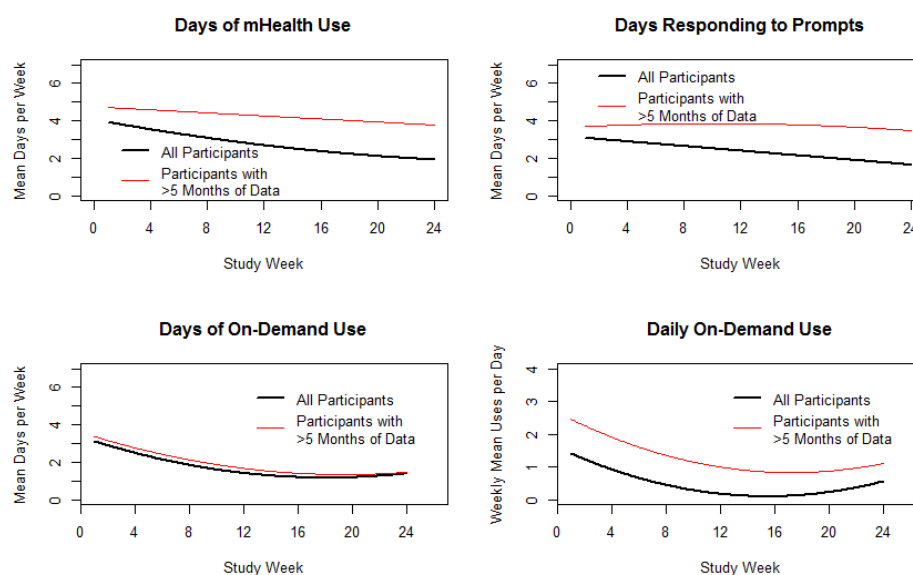
Figure 2. Proportion of engaged participants accessing on-demand features, prompted features, and both features, by study week.
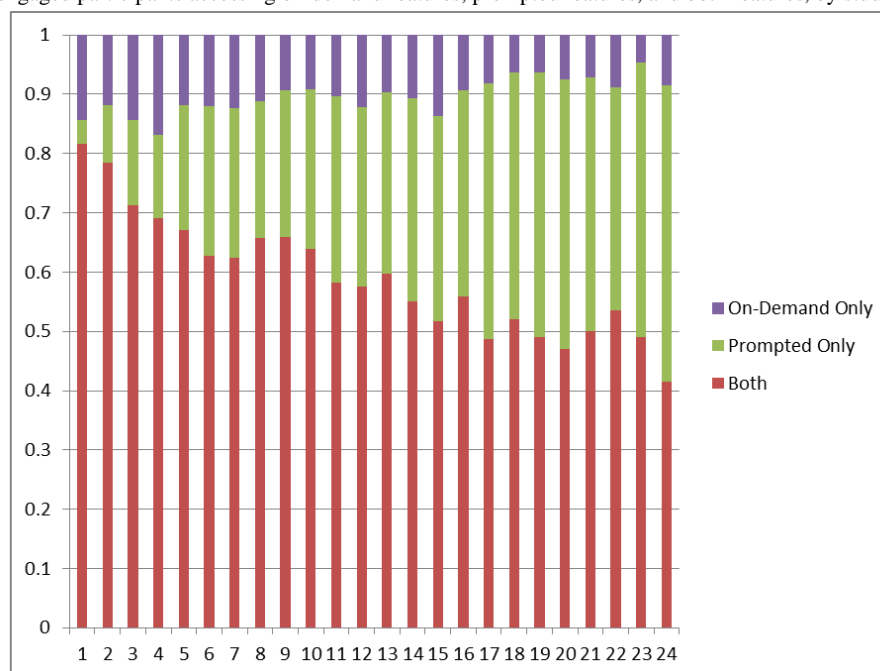
Discussion

Principal Findings

To our knowledge, this study reports on the largest and longest implementation of an mHealth program for people with schizophrenia-spectrum disorders to date and is the first to systematically examine predictors of mobile phone intervention engagement among individuals who were recently discharged from a psychiatric hospitalization [19]. Our findings suggest that most participants (74%) were willing and able to use the FOCUS program successfully during this high-risk period for 3-6 months, which refutes the oft-stated concern that people with schizophrenia who are not clinically stable cannot engage in mHealth interventions successfully. On average, participants engaged with the mHealth program every other day. On days

they engaged, they used on-demand (self-initiated) tools more than once a day.

Individuals' continued use of the intervention over time was associated with their level of day-to-day engagement; people who engaged with the mHealth program more often used it for more months. This point is worth noting because active users undoubtedly encountered the same intervention content repeatedly; it is informative to see that more frequent program use did not lead to participant disengagement, but the contrary. Intervention program, patient, or provider characteristics may have contributed to these results; FOCUS intervention modules consist of brief skills training, practical exercises, and encouragement to use illness management techniques. Participants may have viewed FOCUS as a coaching or "booster" tool that had continued value even after their initial

exposure to the content. Participants who were more engaged may have also had greater capacity to apply FOCUS strategies in their daily lives and reap the rewards, thus creating a reinforcing effect that would sustain their engagement. Finally, HTP case managers were charged with supporting their assigned participants' use of the FOCUS intervention. There may have been some variability in how diligent they were in reviewing their patients' mHealth use data via the dashboard and/or how active they were in encouraging daily and continuous use.

Several demographic and clinical variables were associated with engagement. Female participants were significantly more engaged and used the mHealth program on average one half-day more a week than males. White participants were more engaged and on average used the mHealth intervention almost one day more weekly than African-American participants and a third of a day more than Hispanic participants. Younger participants (age 18-29) were less engaged than older participants. Individuals with more severe psychopathology (as indicated by number of previous psychiatric hospitalizations) were less engaged than those with less severe psychopathology. Links between lower engagement in mental health treatment, male gender, minority background, younger age, and level of psychopathology have been found in the context of person-delivered care for people with schizophrenia [20]. Our data suggest that these patterns may apply to mHealth interventions as well. Despite having comparatively lower engagement, most younger participants, most male participants, most participants from minority backgrounds, and most participants with seven or more past hospitalizations typically used the FOCUS program multiple days a week over several months. While the mHealth intervention approach used in the study appears to be viable for these subgroups, attempting to optimize their engagement by developing adapted versions that can be tailored to subgroup needs may be warranted.

mHealth program functions were associated with engagement. Participants were exposed to FOCUS intervention content more often as a result of responding to system-initiated prompts than after initiating on-demand resources. Both types of intervention use declined over time (on-demand use had a steeper decline). This decline in use may be linked with patients feeling more capable of managing their illness and/or less likely to relapse (perhaps in part due to internalizing and practicing FOCUS self-management suggestions). Although mHealth use declined, the vast majority of individuals used both on-demand and system-prompted functions regularly throughout their participation, that is, neither function is extraneous. Thus, enabling both options in mHealth interventions for people with psychosis is recommended.

Limitations

The study had several limitations. First, participants were provided with a fully functional mobile phone and data plan,

which limits generalizability. While there was no contingent reinforcement or monetary incentive to use the FOCUS program, participants did gain access to other mobile phone resources (eg, Internet, games, texting) that might have indirectly influenced their FOCUS use. For example, a participant may have been more apt to notice and respond to FOCUS prompts if they took place when already using the phone to listen to music. We provided study participants with an Android smartphone to ensure the mHealth program worked reliably; the FOCUS system is a research tool that was not compatible with all commercial smartphone operating systems at the time of the study (eg, iOS, Windows). We also wanted to provide training, technical support, and troubleshooting solutions that would apply to all users. In the future, mHealth system that are compatible with a range of smartphone systems can be deployed, and clinical technology specialists who are embedded in health care systems may be able to provide technical and troubleshooting support to people using a wide array of devices [21]. Second, while we made every effort to document anomalies and unexpected events over the course of the study, there were likely technical (eg, prompting or data transmission failures, operating system updates that disabled the FOCUS program), and logistical barriers (eg, staff delays in replacing lost devices, delays in phones shipping to a study site) that went unidentified and unrecorded. In circumstances when these events hampered participants' ability to use the mHealth intervention or resulted in unlogged use, engagement may have been underestimated. Finally, the power to make inferences about specific racial (especially Hispanic and "other") or age groups is limited due to sample size and any relationships examined here should be confirmed in larger studies.

Conclusions

As interest in mHealth for mental health treatment grows [22-25], it is important to evaluate which approaches are viable for different clinical populations (and when) and to gain a better understanding of the variables that may facilitate or hinder patient engagement with these novel interventions. This study provides evidence that individuals with schizophrenia-spectrum disorders can actively engage with a clinically supported mobile phone intervention for up to 6 months following hospital discharge; that gender, race, age, and history of psychiatric hospitalization were associated with their level of engagement; and that system-initiated mHealth functions led to proportionally more exposure to treatment content than on-demand tools, but that both were used regularly. Taken together, our findings indicate that the FOCUS mobile phone program may be a useful method to reach a clinical population that is typically difficult to engage in clinic-based services during high-risk periods. Future work should examine whether the use of FOCUS and other mHealth interventions can lead to clinically meaningful outcomes such as reduction in relapses.

Acknowledgments

Conflicts of Interest

• DB-Z has an intervention content licensing agreement with Pear Therapeutics.
• MB receives research support from Alkermes.
• DR has been a consultant or received grants from Asubio, Bristol-Myers Squibb, Janssen, Otsuka, and Shire.
• EA has received research support from AssurEx, Avanir, Janssen, Novartis, Otsuka, Pfizer, Pine Rest Foundation, Priority Health, Network180, and Vanguard Research Group and serves on an advisory panel for the Vanguard Research Group.
• DM has received honoraria from Otsuka.
• PM is a stockholder in Pfizer.
• NS has served on advisory boards for Allergan, Alkermes, Forum (formerly EnVivo), Roche, and Sunovion and receives research support from Otskua.
• JK has been a consultant for or has received honoraria from Alkermes, Eli Lilly, EnVivo Pharmaceuticals (Forum), Forest, Genentech, H. Lundbeck, Intracellular Therapeutics, Janssen Pharmaceuticals, Johnson and Johnson, Otsuka, Reviva, Roche, Sunovion, and Teva and is a shareholder in Med-Avante, Inc., LB Pharmaceuticals, and Vanguard Research Group.

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Abbreviations

HTP: Health Techology Program

XSL•FO
RenderX

Original Paper

Effectiveness of Internet-Based Interventions for the Prevention of Mental Disorders: A Systematic Review and Meta-Analysis

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Related Article:

This is a corrected version. See correction statement: http://mental.jmir.org/2016/3/e41/

Abstract

Background: Mental disorders are highly prevalent and associated with considerable disease burden and personal and societal costs. However, they can be effectively reduced through prevention measures. The Internet as a medium appears to be an opportunity for scaling up preventive interventions to a population level.

Objective: The aim of this study was to systematically summarize the current state of research on Internet-based interventions for the prevention of mental disorders to give a comprehensive overview of this fast-growing field.

Methods: A systematic database search was conducted (CENTRAL, Medline, PsycINFO). Studies were selected according to defined eligibility criteria (adult population, Internet-based mental health intervention, including a control group, reporting onset or severity data, randomized controlled trial). Primary outcome was onset of mental disorder. Secondary outcome was symptom severity. Study quality was assessed using the Cochrane Risk of Bias Tool. Meta-analytical pooling of results took place if feasible.

Results: After removing duplicates, 1169 studies were screened of which 17 were eligible for inclusion. Most studies examined prevention of eating disorders or depression or anxiety. Two studies on posttraumatic stress disorder and 1 on panic disorder were also included. Overall study quality was moderate. Only 5 studies reported incidence data assessed by means of standardized clinical interviews (eg, SCID). Three of them found significant differences in onset with a number needed to treat of 9.3-41.3. Eleven studies found significant improvements in symptom severity with small-to-medium effect sizes (d=0.11- d=0.76) in favor of the intervention groups. The meta-analysis conducted for depression severity revealed a posttreatment pooled effect size of standardized mean difference (SMD) =−0.35 (95% CI, −0.57 to −0.12) for short-term follow-up, SMD = −0.22 (95% CI, −0.37 to −0.07) for medium-term follow-up, and SMD = −0.14 (95% CI, -0.36 to 0.07) for long-term follow-up in favor of the Internet-based psychological interventions when compared with waitlist or care as usual.

Conclusions: Internet-based interventions are a promising approach to prevention of mental disorders, enhancing existing methods. Study results are still limited due to inadequate diagnostic procedures. To be able to appropriately comment on effectiveness, future studies need to report incidence data assessed by means of standardized interviews. Public health policy should promote research to reduce health care costs over the long term, and health care providers should implement existing, demonstrably effective interventions into routine care.

Introduction

Mental disorders remain highly prevalent worldwide with lifetime prevalence rates varying between 12.0% in Nigeria and 47.4% in the United States [1]. In 2010, the largest contributor to years lived with disability were mental and behavioral disorders [2]. In addition to the high disease burden and premature mortality, mental disorders also represent a financial burden for both, people affected and society [3-5].

Because care and treatment options and results remain limited [5], the focus should be on the reduction of the incidence by prevention measures.

There are 3 different types of prevention. Universal prevention is focused on the general population (including those without special risk factors). The focus of selective prevention is on subgroups at risk of developing a (mental) disorder (increased risk compared with the average population), whereas indicated prevention targets subgroups who show subthreshold symptoms (ie, not fulfilling full diagnosis criteria) [6].

Regardless of the type of prevention, prevention measures should lead to a substantial reduction in the incidence of the target mental disorder. Consequently, for assessing the effectiveness of preventive interventions, an initial disorder-free target population is needed. In addition, current incidence data collected by means of standardized interviews (eg, Structured Clinical Interview for DSM Disorders [SCID], MINI) are required [7,8]. Together, this allows for calculating the incidence rate ratios (IRRs) and number needed to treat (NNT). The NNT indicates how many people would have to receive an intervention to prevent one new case of the target mental disorder ("effort"), whereas the IRR is an indicator of the "impact" of a preventive intervention [9].

Recent reviews and meta-analyses indicated that prevention of mental disorders is feasible and can lead to a substantial "impact," that is, reduction of incidence rates of mental disorders [9-13].

The Internet as medium for delivery has been identified as an appropriate way to scale up preventive interventions [14,15], needs less effort in provision, and has several additional advantages over traditional (ie, face-to-face) prevention settings. Internet- and mobile-based interventions (IMIs) are flexible (participants can integrate them easily in their daily lives and work at their own pace) and anonymity might be appealing for those fearing stigmatization [16]. Furthermore, in the setting of limited health care resources, IMIs have been found to be cost-effective [17-19]. A large number of people can be reached as a result of decreased personnel and infrastructure costs, especially those in remote areas without easy access to health care services [20]. Considering the worldwide rapid growth of Internet usage during the last decade [21], health care services and particularly mental health professionals could benefit from IMIs as an alternative or supplement to existing and traditional interventions [22].

There are few reviews and meta-analyses to date summarizing empirical findings on IMIs for the prevention of mental disorders. The literature yields reviews on prevention of eating disorders (EDs) [23,24], and substance-related and addictive disorders [25-27] in adult populations. Regarding ED, the review by Schlegl et al [24] integrated a wide range of intervention and prevention trials. Concerning prevention, they presented a mixture of relapse prevention (2 studies), treatment of subthreshold ED (2 studies), and primary prevention trials. Unfortunately, the wide range of studies and outcome parameters did not allow for meta-analytical pooling. Beintner et al [23] focused on a single ED prevention program for students called StudentBodies.

With regard to content, substance-related and addictive disorders prevention programs are often focused on health behaviors and health promotion, rather than on psychotherapeutic variables [28,29]. In summary, none of the previously mentioned reviews summarizes and evaluates the existing literature of Internet-based interventions for the prevention of mental disorders in general and with a clear reference to the previously mentioned statistical criteria (initial disorder-free target population, reporting of incidence data by means of standardized interviews). Consequently, health care providers and public health policy makers are unable to gain an overview of the effectiveness of IMIs for the prevention of mental disorders. This systematic review and meta-analysis fills this gap in research as understudied disorder groups, intervention types, and populations are detected. It aims to (1) describe existing studies on Internet-based preventive interventions, (2) assess the quality of included studies, (3) evaluate the intervention effectiveness, and (4) highlight understudied subfields of research (eg, certain disorder groups or intervention content).

Methods

Registration and Study Protocol

This systematic review has been registered in the PROSPERO register (registration number CRD42015026781). It was conducted according to the PRISMA guidelines [30]. A study protocol that describes trial details has been submitted on December 17, 2015 [31].

Eligibility Criteria

Population

Studies were eligible for inclusion if they (1) focus on an adult target population, who (2) were without a diagnosis of the target mental disorder at baseline (primary prevention intervention). (3) Mental disorders had to be assessed by means of standardized interviews (eg, SCID [32]), validated self-reports (eg, Beck Depression Inventory-II [33]) or clinician-rated scales (eg, HAM-D [34] with normed cutoff points or diagnosed by

health care professionals). Studies on the prevention of substance-related and addictive disorders have been excluded, as this represents a frequently-studied and already reviewed specific subgroup of prevention research [26,27].

Intervention

(4) Interventions needed to be based on psychological interventions. The definition of "psychological intervention" was taken from Kampling et al [35] and refers to cognitive behavioral therapy (CBT), psychodynamic psychotherapy, behavior therapy or behavior modification, systemic therapy, third wave cognitive behavioral therapies, humanistic therapies, integrative therapies, and other psychological-oriented interventions. (5) Interventions must be provided in an online setting, defined as online, Internet, Web, or mobile based. Interventions may vary concerning the amount of external guidance provided to participants. Self-help interventions will also be included. We excluded studies on the relapse prevention of mental disorder, as these treatment maintenance interventions differ substantially from preventive interventions focused on the first or recurrent onset of mental disorders [35].

Comparison

(6) Studies had to include a control group. This could be either (enhanced) usual care, wait-list control group, another intervention, or no treatment.

Outcomes

(7) Studies examining onset of disorder were included, defined as percentage of persons who developed the mental disorder under study from pre- to follow-up-assessment. In addition to data from standardized clinical interviews (eg, SCID-IV [7]), we included studies reporting only symptom severity scores, when validated rating scales with normed cutoff points (referencing onset of disorder or diagnosis) have been used. To be able to comment meaningfully on any postintervention reduction of incidence, studies had to (8) include a follow-up assessment at 3 months or longer after randomization.

Study Type

(9) Only randomized controlled trials (RCTs) that are available in full text will be eligible for this review. For an overview of the eligibility criteria, see Table 1.

Table 1. Eligibility criteria.

No.	Item	Inclusion	Exclusion
1	Population	Adults (≥ 18 years)	Children and adolescents (< 18 years)
2	Prevention	Universal, selective, or indicated prevention	Parts of the population already affected at baseline
3	Assessment	Instrument with standardized cut-offs for clinical significance or symptom severity (> moderate symptomatology)	Descriptive symptom-oriented instruments without standardized cut-offs
4	Prevented disorder	Mental disorder other than substance-related/addictive disorder	Other types of disorders; substance-related/addictive disorders
5	Intervention	Web-based, psychological, preventive	Not Web-based, no psychological principles, treatment rather than prevention
6	Control group	Waiting list, other treatment, placebo, care as usual	No control group
7	Outcomes	Onset, Number Needed to Treat, Incidence Rate Ratio, severity	Other outcomes (no statements possible about preventive effect)
8	Follow-up	At least 3 month follow-up assessment	No or < 3-month follow-up assessment
9	Study design	Randomized controlled trial	No randomized controlled trial (eg, cross-sectional studies, case studies, or case reports)

Search Strategy

A systematic database search was conducted. Databases included are The Cochrane Central Register of Controlled trials (CENTRAL), PsycINFO, and MEDLINE (search date August 17, 2015). A sensitive search strategy was developed and applied for each database [31]. The search was complemented by a review of reference lists from identified publications and a hand-search of the World Health Organization International Clinical Trials Registry Platform (ICTRP) to include ongoing trials.

When indicated, study authors have been contacted to obtain further information to clarify study characteristics. When study protocols were identified without subsequent publication of results, authors have been contacted to obtain missing or unpublished data and determine eligibility for inclusion in this review.

Study Selection

The selection of papers was conducted by 2 independent reviewers (LS, LR). In the first step, authors screened all titles and abstracts yielded by the database search. In the second step, the full texts of the selected articles were retrieved and screened in terms of the aforementioned eligibility criteria. Reference lists of all articles included in the study were screened in the same way. Disagreement at both screening levels was resolved by discussion. Concurrent validity of the 2 reviewers was examined. Figure 1 shows a PRISMA flow chart to illustrate the study selection process and reasons for exclusion [30].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart of included studies.
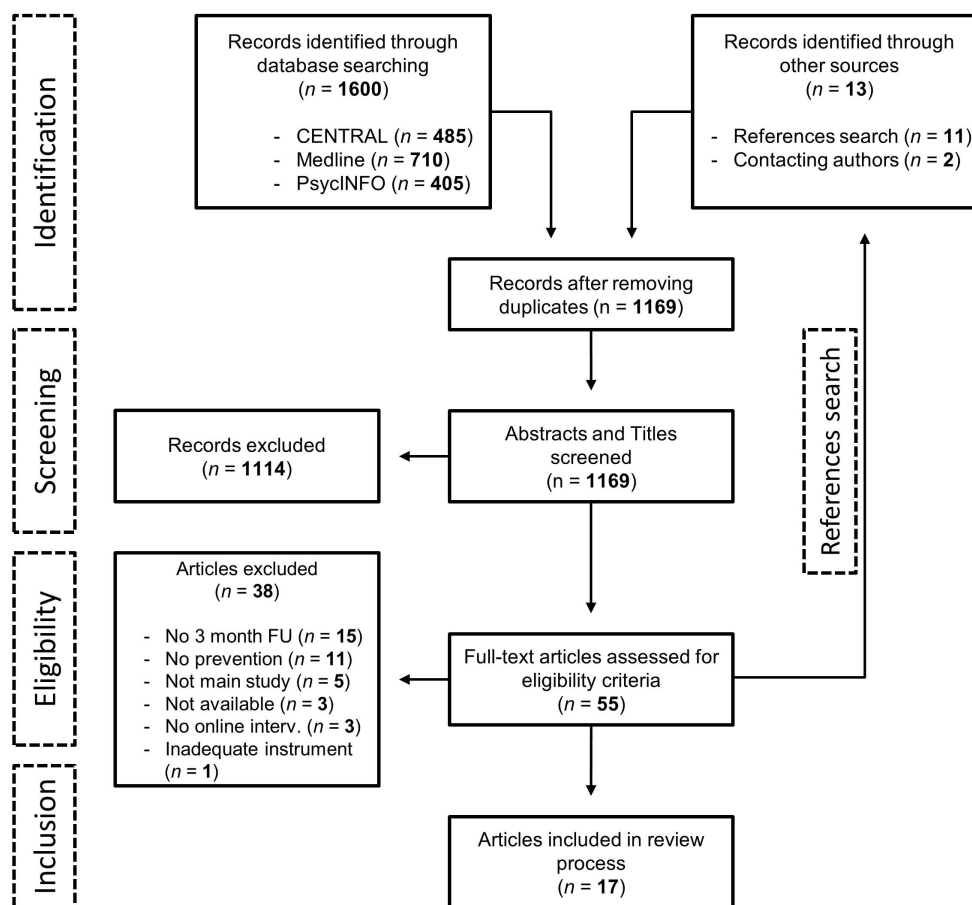
Data Extraction

The following data items were extracted for each study: (1) study identification items (first author, year of publication), (2) study design characteristics (sample size, control group, type of assessments, length of follow-up assessments), (3) intervention characteristics (name, type, duration, level of human support or guidance), (4) prevention characteristics (type, prevented disorder), (5) dropout rate, (6) target population (eg, risk group), and (7) clinical outcomes (onset and/or severity of disorder including means, variances, as well as effect sizes). In case of deficient or missing outcome data, authors were contacted and data were requested. To ensure accuracy, a second reviewer rechecked the extracted data.

Assessment of Methodological Quality

To evaluate the quality of evidence, the risk of bias was assessed for each study according to the Cochrane Collaboration's tool for assessing risk of bias in RCTs [36]. The assessment was rechecked by a second reviewer. As recommended, each study was reviewed for procedures in the following domains: (1) random sequence generation, (2) allocation concealment, (3) blinding (3a – of participants, 3b – of personnel, 3c – of outcome assessors), (4) incomplete outcome data (4a – dropout rate (≤ 20% for short-term follow-ups, ≤ 30% for long-term follow-ups), 4b – intention-to-treat analysis), (5) selective outcome reporting, and (6) other threats to validity (6a – similar groups at baseline, 6b – no or similar cointerventions between intervention and control groups, 6c – compliance, 6d – identical timing for

outcome assessment). Studies were rated as showing a "low" or "high" risk of bias according to the aforementioned criteria. For studies with at least 6 fulfilled criteria and no serious flaws, the risk of bias was evaluated as being low according to Furlan et al [36]. Less than 6 fulfilled criteria or serious flaws yielded a rating of "high" risk of bias. Of note, in the implementation of psychological interventions, blinding of health care providers (if a guided intervention was provided) or patients concerning the treatment is not possible. This results in a "high" risk of bias rating on this criterion. However, outcome assessors can remain unaware of the treatment allocation of patients.

Data Analysis

If onset data were available, IRR and NNT were calculated. When there were at least 5 studies with available severity data within one disorder (as primary and secondary outcome), a meta-analytically pooled effect size was calculated, and effect sizes were illustrated in forest plots. Meta-analyses were conducted using Review Manager 5.3 (Cochrane Collaboration, 2014). Standardized mean differences (SMDs) with 95% CIs were computed for all continuous outcomes. Random-effects meta-analyses were performed to compute overall estimates of treatment outcome. The I^2 statistic was used to examine study heterogeneity [37]. Consistent with Sterne et al [38], a funnel plot examining publication bias was not examined due to the limited number of included studies. Follow-up periods were subgrouped into short-term (post assessment), medium-term (≤ 6 month), and long-term (> 6 month) follow-ups. Subgroup

comparisons were not feasible due to the low number of studies included.

Results

Overview

The systematic database search yielded 1600 hits. After removing duplicates, screening titles, abstracts, and full text papers for inclusion, conducting a reference search, searching trial registers for eligible studies and contacting authors, a total of 17 studies met eligibility criteria and were included in the review. The selected studies targeted the prevention of EDs, depression, anxiety, post-traumatic stress disorder, generalized anxiety disorder (GAD), or a combination of these mental disorders [39-56].

Quality Assessment

Five of 17 studies were classified as having a high risk of bias and the remaining 12 studies were classified as having a low risk of bias (Table 2). Sequence generation (1) was mostly met; only 3 studies were categorized as unclear. Allocation concealment (2) was met in almost half of the included studies, otherwise categorized as unclear as it was not sufficiently specified. Blinding of participants (3a) was met in 2 studies with active control groups [42,50]. Blinding of personnel (3b) was set on "no" without exception. As blinding of personnel is not possible for most psychological interventions, it must be considered a possible source of bias. However, outcome assessors remained unaware of the treatment allocation (3c) in 4 studies [40,42,43,51].

Regarding dropout rate (4a), only 7 studies met the predetermined criterion (≤20% for short-term follow-ups, ≤ 30% for long-term follow-ups). Ten of the included studies reported the use of an intention-to-treat analysis (4b); the remaining studies were categorized as unclear. Two studies reported results incompletely [39,48]. (5) Particularly for Jacobi et al [39] this can be regarded as serious flaw, since results of a clinical interview (SCID) were not reported. About half of the studies reported similar groups at baseline (6a) in demographics

and outcome measures. Some studies reported differences in one demographic variable, which was subsequently used as a covariate [54]; alternatively, if the manuscript did not address this variable, the study was categorized as unclear. Two serious flaws were catalogued on this category because of disregarded baseline differences in outcome measures [43,53]. There were no cointerventions (6b) in any study. Compliance with interventions (6c) was rated acceptable in two thirds of the included studies. One study [50] received a serious flaw because of a very low compliance and significant between groups difference (combined with a relatively high dropout rate). (6d) Outcome assessment was timed similarly for all groups except for 2 studies [43,46] that used a cohort design.

To evaluate the risk of certain biases (selection, performance, detection, and attrition bias), the criteria can be grouped into randomization, blinding, outcome, and withdrawal criteria. Selection bias could only be ruled out in 3 studies [41,47,52] that fulfilled all 3 randomization criteria (1) sequence generation, (2) allocation concealment, (6a) similar groups.

Performance bias could be present in every study. As mentioned previously, blinding was only insufficiently possible for all studies. Hence, criteria concerning expectation and performance effects (3a – blinding of participants, 3b – blinding of personnel, 6b – no cointerventions, 6c – compliance) were never completely fulfilled.

Concerning detection bias, 3 studies [40,42,51] fulfilled both criteria of outcome assessment (3c – blinding of outcome assessors, 6d – identical timing for outcome assessments).

Three studies [45,47,54] fulfilled both criteria concerning withdrawals from studies (4a – dropout, 4b – ITT); the remaining studies could be affected by attrition bias.

Intervention Characteristics

Many studies administered measures of a variety of mental disorders. Hereinafter included studies are arranged by their main focus. For an overview of all included studies, see Table 3.

Table 2. Risk of bias assessment.

Study	Sequence generation[a]	Allocation concealment[c]	Blinding			Incomplete outcome data		Selective outcome reporting[i]	Other threats to validity				Risk of Bias[n]
			Participants[d]	Personnel[e]	Outcome assessors[f]	Dropout[g]	ITT[h]		Similar groups[j]	Cointerventions[k]	Compliance[l]	Timing[m]	
Bantum et al [46]	Yes[b]	Unclear	No	No	No	Yes	Unclear	Yes	No	Yes	Yes	No	High
Beatty et al [47]	Yes	Yes	Unclear	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Low
Christensen et al [48]	Yes	Yes	Unclear	No	No	No	Yes	No	No	Yes	Yes	Yes	Low
Christensen et al [55]	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Low
Imamura et al [49]	Yes	Yes	No	No	No	No	Yes	Yes	Unclear	Yes	No	Yes	Low
Jacobi et al [39]	Yes	Unclear	No	No	No	Yes	Unclear	No	Unclear	Yes	Yes	Yes	High[o]
Jacobi et al [40]	Yes	Unclear	No	No	Yes	No	Unclear	Yes	Unclear	Yes	Yes	Yes	Low
Mitchell et al [50]	Yes	Yes	Yes	No	No	No	Yes	Yes	Unclear	Yes	No	Yes	High[p]
Mouthaan et al [51]	Yes	Yes	No	No	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Low
Musiat et al [41]	Yes	Yes	No	No	No	No	Unclear	Yes	Yes	Yes	No	Yes	Low
Powell et al [52]	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Low
Proudfoot et al [53]	Yes	Yes	No	No	No	No	Yes	Yes	No	Yes	No	Yes	High[q]
Stice et al [42]	Yes	Unclear	Yes	No	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Low
Taylor et al [43]	Yes	Unclear	No	No	Yes	Yes	Unclear	Yes	No	Yes	Yes	No	High[r]
Thompson et al [54]	Unclear	Unclear	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low
Winzelberg et al [44]	Unclear	Unclear	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Low
Zabinski et al [45]	Unclear	Unclear	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Low

[a]Random unpredictable assignment sequence.

[b]Yes = Criterion has been met (low risk of bias); No = Criterion has not been met (high risk of bias)

[c]Assignment generated by an independent person who is not responsible for determining the eligibility of participants.

[d]Intervention and control group are indistinguishable for the participants.

[e]Intervention and control group are indistinguishable for the care providers.

[f]Intervention and control group are indistinguishable for the outcome assessors (for patient reported outcomes, it is adequate if patients are blinded).

[g]Dropout must be described and reasons must be given, for short term follow-ups (eg, 3 months) 20%, for long term follow-ups (eg, ≥ 6 months) 30% should not be exceeded.

[h]ITT: intention-to-treat; all randomized patients are reported and analyzed in the group they were allocated to by randomization.

[i]Results of all pre-specified outcomes have to be adequately and completely reported.

[j]Groups should not differ significantly at baseline regarding demographics and outcomes.

[k]There are no cointerventions or they are similar between intervention and control groups.

[l]Acceptable compliance with the intervention (eg, intensity, duration, number, frequency of sessions).

[m]Identical timing of outcome assessments for intervention and control groups.

[n]≥ 6 x "Yes" and no serious flaws indicates an overall low risk of bias; < 6 x "Yes" or serious flaws indicates an overall high risk of bias.

[o]Serious flaw: Results of diagnostic interviews not reported.

[p]Serious flaw: Very high dropout and very low compliance rate.

[q]Serious flaw: Baseline differences between groups, very low compliance.

[r]Serious flaw: Baseline differences between groups in several scales.

Table 3. Characteristics of included studies

Study	Prevention type	Prevented disorder	Targeted population	Program name	Intervention type (duration)	Conditions	Sample size (n)	Instrument	Follow-up months	Drop-out[a]	ITT[b]
Bantum et al [46]											
	Selective	Depression	Adult cancer survivors	Surviving and Thriving with Cancer (STC)	Assisted health behavior change program (6 weeks)	1. STC 2. Delayed treatment	n=352 (cohorts of n=20-25)	PHQ-9[c]	6	13.9%	Unclear
Beatty et al [47]											
	Selective	PTSD[d] Anxiety Depression	Adult cancer patients	Cancer Coping Online (CCO)	Self-guided web-based CBT[e] (6 weeks)	1. CCO 2. Information only	n_1=30 n_2=30	DASS[f] PSS[g]	4.5 7.5	8.3%	Yes
Christensen et al [48]											
	Indicated	GAD[h] Depression	Young adults with mild GAD symptoms	iChill	Active website (CBT) + email (10 weeks)	1. Active website 2. Active +phone 3. Active +email 4. Control website 5. Control +phone	n_1 = 111 n_2 = 110 n_3 = 113 n_4 = 113 n_5 = 111	GAD-7[i] MINI[j] CES-D[k]	6 12	52.69%	Yes
Christensen et al [55]											
	Indicated and selective	Depression	Adult Internet users with insomnia and subthreshold depression	SHUTi	Modular insomnia website (6 weeks)	1. SHUTi 2. Placebo website (HealthWatch)	n_1=574 n_2=575	PHQ-9 MINI	1.5 6	56.1%	Yes
Imamura et al [49]											
	Indicated	Depression	Workers with subthreshold depression	Internet CBT program (iCBT)	Guided stress management training (manga) (6 weeks)	1. iCBT 2. Information only	n_1=381 n_2=381	BDI-II[l] WHO-CIDI[m]	12	32.9%	Yes

Study	Prevention type	Prevented disorder	Targeted population	Program name	Intervention type (duration)	Conditions	Sample size (n)	Instrument	Follow-up months	Drop-out[a]	ITT[b]
Jacobi et al [39]											
	Selective	Eating disorders	Female university students	Student-Bodies (SB)	Structured CBT + discussion group (8 weeks)	1. SB 2. Waiting list	n_1=50 n_2=50	EDE-Q[n] SCID[o] EDI-2[p]	3	6.00%	Unclear
Jacobi et al [40]											
	Indicated	Eating disorders	Women with sub-threshold eating disorders	Student-Bodies+ (SB+)	Structured CBT + symptom checklist/ body image exercise (8 weeks)	1. SB+ 2. Waiting list	n_1=64 n_2=62	EDE-Q SCID	6	18.3%	Unclear
Mitchell et al [50]											
	Universal	Anxiety Depression	Adult Australian residents	Strength-Intervention	Self-guided text- and graphic-based interactive program (3 weeks)	1. Strength-Intervention 2. Placebo	n_1=48 n_2=54	DASS	3	78.4%	Yes
Mouthaan et al [51]											
	Indicated	PTSD Anxiety Depression	Injury patients	Trauma TIPS	Self-guided Internet-based CBT (30 min)	1. Trauma TIPS 2. Care as usual	n_1=151 n_2=149	HADS[q] CAPS[r] MINI	1 3 6 12	53.7%	Yes
Musiat et al [41]											
	Universal	Anxiety Depression Eating disorders	University students	Personality and Living of University Students (PLUS)	Automated transdiagnostic trait focused Web-based intervention (5x 20-40 min)	1. PLUS 2. Placebo	n_1=519 n_2=528	PHQ GAD-7 EDDS[s]	3	61.7%	Unclear

Study	Prevention type	Prevented disorder	Targeted population	Program name	Intervention type (duration)	Conditions	Sample size (n)	Instrument	Follow-up months	Drop-out[a]	ITT[b]
Powell et al [52]											
	Universal	GAD	Users of the UK National Health Service	MoodGYM	Self-directed CBT training (5 weeks)	1.MoodGYM 2. Waiting list	n_1=1534 n_2=1536	CES-D GAD-7	3	50.2%	Yes
Proudfoot et al [53]											
	Indicated	Anxiety Depression	Adults with mild to moderate anxiety or depression	my-Compass	Automated intervention + symptom self-monitoring (7 weeks)	1. My-Compass 2. Attention control 3. Waiting list	n_1=242 n_2=248 n_3=230	DASS	3	51.4%	Yes
Stice et al [42]											
	Selective	Eating disorders Depression	Female college student with body dissatisfaction	eBody Project (eBP)	Self-guided cognitive-behavioral program to change thin ideal (3 weeks)	1. eBP 2. BP 3. Video control 4. Brochure control	n_1=19 n_2=39 n_3=29 n_4=20	BDI[t] EDDI[u]	12 24	4.7%	Unclear
Taylor et al [43]											
	Selective	Eating disorders Depression	College women with high weight/ shape concerns	Student-Bodies (SB)	Structured CBT+ discussion group (8 weeks)	1. SB 2. Waiting list	n_1=244 n_2=236	CES-D EDE-I[v] EDE-Q	12 24 36	12.3%	Unclear
Thompson et al [54]											

Study	Prevention type	Prevented disorder	Targeted population	Program name	Intervention type (duration)	Conditions	Sample size (n)	Instrument	Follow-up months	Drop-out[a]	ITT[b]
	Indicated	Depression	Mild- to moderately depressed epilepsy patients	Using Practice and Learning to Increase favorable thoughts (UPLIFT)	Telephone- and Web-based mindfulness and cognitive therapy (8 weeks)	1. UPLIFT 2. Waiting list	n_1=64 n_2=64	BDI mBDI[w] NDDI-E[x] PHQ	2 4	15.6%	Yes
Winzelberg et al [44]											
	Selective	Eating disorders	Female university students	Student Bodies (SB)	Structured CBT+ discussion group	1. SB 2. Waiting list	n_1=31 n_2=29	EDE-Q	3	26.7%	Yes
Zabinski et al [45]											
	Selective	Eating disorders	College age women	Chat room	Private chat room for moderated discussion (8 weeks)	1. Chat room 2. Waiting list	n_1=30 n_2=30	EDE-Q	4.5	3.3%	Yes

[a]Dropout-rate from baseline to the longest available follow-up.

[b]ITT: Intention-to-treat-analysis

[c]PHQ: Personal Health Questionnaire depression scale

[d]PTSD: Posttraumatic Stress Disorder

[e]CBT: Cognitive Behavioral Therapy

[f]DASS: Depression Anxiety Stress Scale

[g]PSS: PTSD Symptom Scale

[h]GAD: Generalized Anxiety Disorder

[i]GAD-7: Generalized Anxiety Disorder questionnaire – 7

[j]MINI: Mini-International Neuropsychiatric Interview

[k]CES-D: Center for Epidemiological Studies Depression scale

[l]BDI-II: Beck Depression Inventory II

[m]CIDI: WHO Composite International Diagnostic Interview (Web-based, self-administered version)

[n]EDE-Q: Eating Disorder Examination Questionnaire

[o]SCID: Structured Clinical Interview for DSM Disorders

[p]EDI-2: Eating Disorder Inventory

[q]HADS: Hospital Anxiety and Depression Scale

[r]CAPS: Clinician-Administered PTSD Scale

[s]EDDS: Eating Disorders Diagnostic Scale

[t]BDI: Beck Depression Inventory

[u]EDDI: Eating Disorder Diagnostic Interview

[v]EDE-I: Eating Disorder Examination Interview

[w]mBDI: Modified Beck Depression Inventory

[x]NDDI-E: Neurological Disorders Depression Inventory in Epilepsy

Eating Disorders

The systematic search yielded 6 studies on eating disorders. Four evaluated the effectiveness of StudentBodies, an Internet-based intervention for young women at risk of developing an eating disorder or with subthreshold eating disorders. StudentBodies was originally developed and evaluated in the United States [43,44] and was later translated to the German language [39,40]. The program makes use of common CBT principles and includes a Web-based discussion group.

Also inspired by StudentBodies, Zabinski et al [45] developed a moderated synchronous group intervention for college-age women, called Chat Room. The main difference to StudentBodies is the integration of a synchronous communication chat room that enables participants to communicate more directly with each other.

Stice et al [42] developed and evaluated the eBody Project, an Internet-based version of a CBT-based eating disorder prevention group-program. eBody is a dissonance-based intervention encouraging young women to question the popular "thin" ideal.

Depression

The search yielded 3 prevention programs focused on the prevention of depression. Surviving and Thriving with Cancer [46] is an assisted Web-based education course aimed to foster positive health behaviors in cancer survivors. In addition to depression, intervention effects on health conditions as nutrition, exercise, and sleep were examined.

The guided Internet-based CBT program (iCBT) by Imamura et al [49] conveys stress management skills to employees of 2 information technology (IT) companies with subthreshold depression. The intervention aims to prevent major depression episodes. It includes common CBT elements such as self-monitoring or relaxation techniques.

Thompson et al [54] adapted a mindfulness-based prevention program (UPLIFT) for epilepsy patients with mild-to-moderate depressive symptoms [56]. The telephone- and Web-based intervention makes use of psychoeducative principles (eg, knowledge about depression, importance of reinforcement) and mindfulness-based tools (eg, monitoring of thoughts).

The 6-week Web-based insomnia program SHUTi by Christensen et al [55] aims at the high co-occurrence of insomnia and depression. Overall, 1149 participants were recruited via the social network platform Facebook and randomized to either a CBT-based insomnia intervention or a control website (HealthWatch).

Anxiety and Depression

Two studies focused on combined anxiety and depression. A self-guided intervention promoting well-being in a general population was tested by Mitchell et al [50]. In 3 weekly sessions, users completed either an interactive program focusing on strengths (intervention 1, based on positive psychology principles) or problem-solving skills (intervention 2). Users received feedback and email reminders.

MyCompass [53], a self-guided computer-delivered intervention, aims to foster self-management and self-monitoring skills in people with mild-to-moderate depression, anxiety, and stress symptoms. Content in the 12 modules was derived from CBT, interpersonal psychotherapy, problem-solving therapy, and positive psychology. Users are also provided with text messages or emails containing reminders and material on psychoeducation.

Post-Traumatic Stress Disorder

There were 2 studies that focused on post-traumatic stress. The self-guided Trauma TIPS [51] aims to prevent PTSD in injury patients. CBT techniques such as psychoeducation, stress management, and in vivo exposure are presented in the 30-minute program alongside contact information for professional help and a Web forum for peer support.

Cancer Coping Online, a self-guided Web-based CBT program for reducing distress in patients currently receiving cancer treatment, was evaluated by Beatty et al [47]. The 6-session program mainly focuses on coping strategies taught via text, audios, and worksheets. Besides posttraumatic stress (cancer-specific distress), levels of depression and anxiety (general distress) were evaluated.

Generalized Anxiety Disorder

The search yielded 2 studies on GAD. MoodGYM [52] is a fully automated Internet-based program that teaches CBT skills (eg, psychoeducation, relaxation, or mediation techniques) to improve mental well-being in a general population. Besides well-being, depression and GAD data were gathered. Because the mean depression score of the participants exceeded a clinical cutoff (and thus did not fulfill inclusion criteria), only GAD data were included in this review. Christensen et al [48] evaluated the program iChill, which aims to prevent GAD in young adults with mild GAD symptoms. iChill is an active website. The intervention makes use of multiple CBT tools as psychoeducation, relaxation, or toolkits. Telephone reminders for participants without therapeutic purpose were included in one trial arm.

Common Mental Health Disorders

Musiat et al [41] developed a transdiagnostic trait-focused program (PLUS) aiming to prevent common mental disorders. Investigated disorders were depression, GAD, EDs, and alcohol misuse. The CBT-based program focuses on the identification of strengths and the consolidation of coping strategies and includes computerized feedback.

Effectiveness

Primary Outcome Onset

Five studies reported incidence data allowing for the calculation of onset, IRR, and NNT (see Table 4). Christensen et al [48,55] did not observe significant group differences in onset. Imamura et al [49] reported a significant onset difference for the 12-month follow-up period (1.26% for the intervention group, 5.51% for the control group). Calculations yielded an IRR of 0.23 and a NNT of 23.48. Taylor et al [43] found an onset of 4.00% in the intervention group, compared with 6.60% in the control group. This yields an IRR of 0.63 and a NNT of 41.31. Thompson et al [54] found a 0% onset for the intervention group and a 10.70%

onset for the control group. In accordance to the Cochrane Handbook for Systematic Reviews [57], a correction of 0.5 was added to the zero incidence in the intervention group, resulting an IRR of 0.09. The NNT was 9.33.

Table 4. Incidence, onset, incidence rate ratio (IRR), number needed to be treated (NNT)

Study	Disorder	Number of onsets		Follow-up	IRR[c]	NNT[d]
		IG[a]	CG[b]			
Christensen et al [55]	Depression	N=9 N_{Total}= 224	N=13 N_{Total}= 280	6 months	0.87	160
Imamura et al [49]	Depression	n=3 N_{Total}= 239	n=15 N_{Total}= 272	12 months	0.23	23.5
Thompson et al [54]	Depression	n=0[e] N_{Total}= 52	n=6 N_{Total}= 56	2 months (pre–post)	0.09	9.3
Taylor et al [43]	Eating Disorders	n=8 N_{Total}= 193	n=13 N_{Total}= 198	12 months	0.63	41.3
Christensen et al [48]	GAD[f]	n=10 N_{Total}= 171	n=6 N_{Total}= 132	6 months	1.29	−76.8

[a]IG: intervention group

[b]CG: control group

[c]IRR: incidence rate ratios

[d]NNT: number needed to treat

[e]A correction of 0.5 was added to the zero incidence in the intervention group for IRR calculation.

[f]GAD: Generalized Anxiety Disorder

Secondary Outcome: Severity

Severity data were extracted for all included studies. Eleven studies found significant effects on symptom severity with small-to-large effect sizes (d=0.11 to d=0.76), indicating differential intervention effects on group, time, or interactions of both respectively [39-41,43,45,47,51-55].

For the meta-analysis of depression interventions, we included studies with depression as a primary and secondary outcome. In cases of multiple active groups, only the main intervention sample was analyzed [48,50]. Results for short-, medium-, and long-term follow-up are presented in Figure 2, Figure 3, and

Figure 4, respectively. In summary, pooled effect sizes, indicating a greater decrease in symptom severity for the intervention group, were small but significant.

For short-term follow-up, our calculations yielded an effect size of SMD = −0.35 (95% CI, −0.57 to −0.12, P=.002). Test of heterogeneity was significant (P<.001; I^2= 79%). Effect size for medium-term follow-up was SMD = −0.22 (95% CI, −0.37 to −0.07), P=.005. Heterogeneity was significant (P=.02; I^2= 57%). For long-term follow-up, an effect SMD = −0.14 (95% CI −0.36 to 0.07, P=.18) was found. Heterogeneity was not significant (P=.17; I^2= 38%). According to Higgins et al [58], overall level of heterogeneity was moderate to high.

Figure 2. The effects of preventive interventions on symptom severity of depression at short-term FU—comparison experimental versus control group.
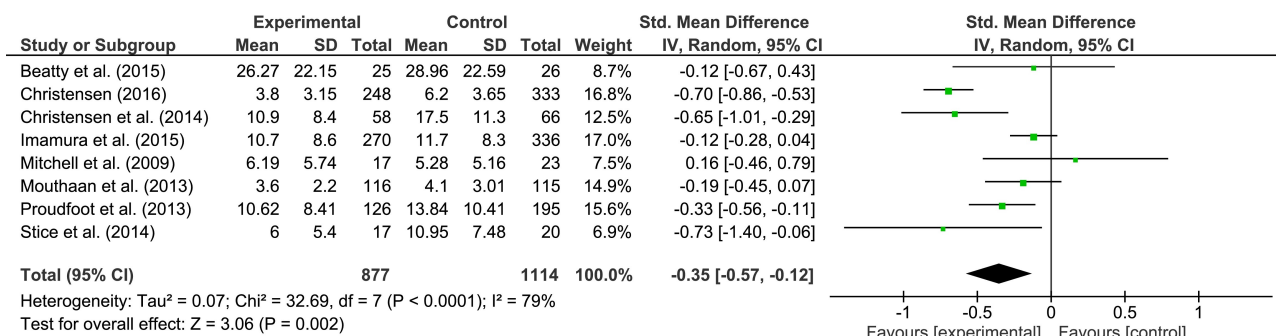
Figure 3. The effects of preventive interventions on symptom severity of depression at medium-term FU—comparison experimental versus control group.

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
Bantum et al. (2014)	6.1	4.02	147	7.1	4.14	156	16.1%	-0.24 [-0.47, -0.02]	
Beatty et al. (2015)	24.46	21.55	25	27.46	21.65	25	5.7%	-0.14 [-0.69, 0.42]	
Christensen (2016)	3.8	2.99	224	5.5	3.35	280	18.7%	-0.53 [-0.71, -0.35]	
Christensen et al. (2014)	11.8	8.9	54	14.4	11.3	55	9.8%	-0.25 [-0.63, 0.12]	
Imamura et al. (2015)	11.3	9.6	272	12.1	8.7	320	19.6%	-0.09 [-0.25, 0.07]	
Mitchell et al. (2009)	5.75	5.29	11	5.54	5.52	11	2.9%	0.04 [-0.80, 0.87]	
Mouthaan et al. (2013)	4.1	2.91	77	4.5	3.9	72	11.8%	-0.12 [-0.44, 0.21]	
Proudfoot et al. (2013)	11.68	9.86	100	12.59	9.53	197	15.4%	-0.09 [-0.33, 0.15]	
Total (95% CI)			**910**			**1116**	**100.0%**	**-0.22 [-0.37, -0.07]**	

Heterogeneity: Tau² = 0.02; Chi² = 16.13, df = 7 (P = 0.02); I² = 57%
Test for overall effect: Z = 2.81 (P = 0.005)
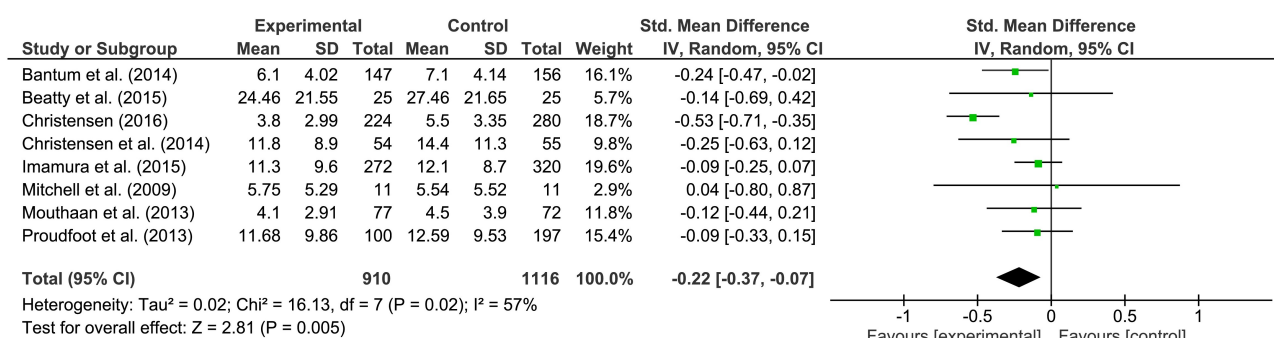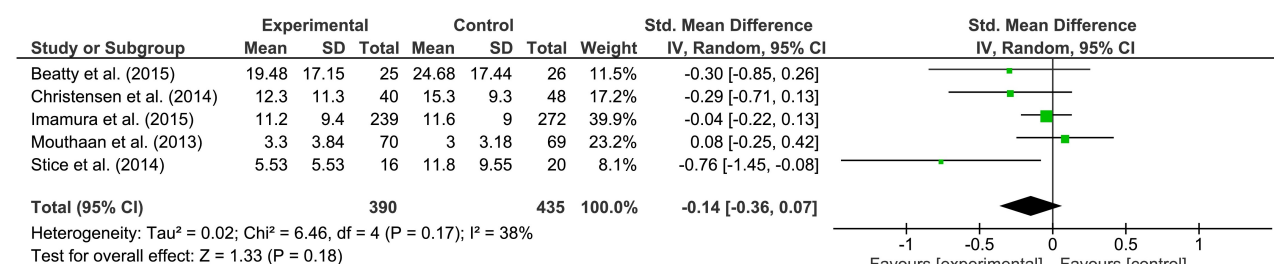
Favours [experimental]   Favours [control]

Figure 4. The effects of preventive interventions on symptom severity of depression at long-term FU—comparison experimental versus control group.

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
Beatty et al. (2015)	19.48	17.15	25	24.68	17.44	26	11.5%	-0.30 [-0.85, 0.26]	
Christensen et al. (2014)	12.3	11.3	40	15.3	9.3	48	17.2%	-0.29 [-0.71, 0.13]	
Imamura et al. (2015)	11.2	9.4	239	11.6	9	272	39.9%	-0.04 [-0.22, 0.13]	
Mouthaan et al. (2013)	3.3	3.84	70	3	3.18	69	23.2%	0.08 [-0.25, 0.42]	
Stice et al. (2014)	5.53	5.53	16	11.8	9.55	20	8.1%	-0.76 [-1.45, -0.08]	
Total (95% CI)			**390**			**435**	**100.0%**	**-0.14 [-0.36, 0.07]**	

Heterogeneity: Tau² = 0.02; Chi² = 6.46, df = 4 (P = 0.17); I² = 38%
Test for overall effect: Z = 1.33 (P = 0.18)

Favours [experimental]   Favours [control]

Ongoing Mental eHealth Prevention Trials

An ICTRP search for ongoing trials yielded 570 records for 560 trials (years 2005-2015). Sixty-two records were selected as likely being relevant. Most of those were planned studies on symptom severity as a secondary outcome and with different study purposes. Eleven records aimed to assess severity data and had an explicit preventive goal. Targeted conditions were mostly mood and anxiety disorders. Seven studies planned to use clinical interviews for diagnostics or to explicitly gather incidence data. Three studies of those studies were already published, one of them is included in this review [49] and 2 were excluded because of high symptom severity or diagnosis (inclusion criteria 2) at baseline [59,60]. Another planned study on depression had been withdrawn before enrolment because of missing funding (ClinicalTrials.gov, registration no. NCT01080105). Of the remaining 3 records, one study is planned on the prevention of psychosis for people with psychotic like experiences (Australian New Zealand Clinical Trials Registry, registration no. ACTRN12612000963820). The other one concerns the prevention of depression in people with complicated grief (UMIN Clinical Trials Registry, registration no. UMIN000007331). Our own research group also conducts a clinical trial on the prevention of depression in the risk-group of back pain patients with subthreshold depressive symptoms, which is registered at the German Clinical Trials Register (registration no. DRKS00007960). Inspection study protocols emerging from the data base search yielded ongoing trials for the prevention of depression [61-64] and PTBS [65].

Discussion

Principal Findings

This review and meta-analysis systematically summarizes previous research on Internet-based interventions for the prevention of mental disorders. It therefore exceeds the informative value of existing reviews (eg, [23,67]) in terms of the range of included disorders and gives an extensive overview of the actual state of research.

Seventeen RCTs were included in this review and described in detail. Results are in line with previous meta-analyses, showing that indicated and selective prevention is more common than universal prevention [13] and that CBT is a frequently (sometimes even exclusively) used Internet-based intervention type (eg, [24,66]).

Quality assessment suggests that 5 included studies have a high risk of bias. Some biases are inevitable (eg, blinding not possible for psychological interventions). Others, such as biases due to inappropriate randomization, can and should be avoided. Of note, 3 studies were classified as having high risk of bias solely due to a serious flaw. Reasons for study classification as having a serious flaw included baseline differences between intervention and control groups [43,53], very low compliance with the intervention [50,53], and a very high dropout rate [50]. Concerning study dropout, the Cochrane guideline [36] provides a rather conservative appraisal when applied to IMIs [67]. When evaluating treatment dropout, a more differentiated perspective can be beneficial. In a recent meta-analysis, van Ballegooijen et al found that IMIs regularly have lower completer rates of total interventions when compared with face-to-face treatments (65.1% vs. 84.7%), but are equal in the percentage of average completed sessions (face-to-face CBT: 83.9% vs. iCBT: 80.8%) [68]. Above that, participants do not necessarily have to

complete all sessions to benefit from IMIs. They may stop the treatment because they already obtained benefit, and therefore, these cases would represent a success, rather than a treatment dropout [69,70].

Three of 5 studies reporting incidence data provided evidence for a preventive effect of the investigated interventions [43,49,54]. One study failed to report the results of a diagnostic interview, which would have allowed calculating incidence rates [39]. The remaining studies by Christensen et al [48,55] did not find effects on reduction of new cases. However, secondary outcome measures of anxiety and depression symptoms showed positive effects. The included incidence studies differed in the length of follow up-periods. Thompson et al [54] only had a pre-post comparison. For the remaining studies, incidence reduction could be observed over a 12-month follow-up period [43,49], suggesting that preventive interventions have the potential for incidence reduction in the long term.

Nevertheless, severity data show positive effects of interventions in 11 of 17 studies with small-to-medium effect sizes. The best evidence was found for ED and depression. Beintner et al [23] previously conducted a meta-analytic review on most included ED studies, demonstrating mild-to-moderate effects on ED-related attitudes (d=0.15 to d=0.57). The only study not included in Beintners' review [42] found similar effects. The Internet-based intervention was superior in the reduction of ED symptoms compared with the 2 control conditions (d=0.33 and d=0.19) at the long-term follow-up (1 year).

Our meta-analysis on IMIs for depression showed an overall small but significant reduction in symptom severity. As mentioned before, this demonstrates an effect of IMIs on the treatment of subclinical depression; a subsequent reduction of incidence can only be assumed, as most included studies did not report incidence data. Because of moderate to high levels of heterogeneity, the actual effect size values should be interpreted with caution. Nevertheless, heterogeneity results from estimates showing the same direction of effect favoring interventions over control groups.

In summary, evidence was found for effectiveness of interventions for EDs, depression, and anxiety. Internet-based interventions can be considered effective in reduction of subthreshold symptomatology and may also be suitable for preventing the onset of mental disorders over the long term. Depression and anxiety are of particular clinical relevance against the background of prevalence rates: as mentioned, anxiety disorders, insomnia, and major depression are the most common mental disorders in the European Union [5]. Although many IMIs include modules on sleep or relaxation (eg, [47,50]), Christensen et al [57] reported the first prevention RCT explicitly targeting insomnia resulting in a reduction in depressive symptomatology.

Limitations

A number of potential limitations and challenges regarding this study should be acknowledged. As usual for reviews and meta-analyses, publication bias [71] must be assumed. This review included several studies reporting not expected or nonsignificant results; nevertheless, publication bias cannot be precluded. Furthermore, the search might have been confounded by language bias because only English and German papers were included. Fortunately, in contrast to publication bias, this only minimally impacts conclusions [72].

Another limitation concerns the inclusion of studies that reported mean scores only and did not clearly state that participants did not exceed clinical cutoffs at baseline (second exclusion criterion). This became evident after contacting authors to obtain raw data and subsequently computing incidence and onset rates if they had not already been reported. Four of those studies [73-76] had to be excluded because inspection of the raw data revealed that a considerable number of participants exceeded clinical cutoffs at baseline, even though the other eligibility criteria had been fulfilled. Unfortunately, only a few authors responded to our requests for additional information. Thus, it cannot be ruled out that this might also be the case for some included studies, that is, those which reported mean scores and did not provide raw data.

One major challenge of this broad review was the handling of variability between studies. Although heterogeneity was expected, and even welcomed to map out the broad scope of existing e-mental health prevention interventions, it must be taken into account when interpreting the findings. There are several sources of heterogeneity. First, this review was not restricted to one mental disorder but included a number of clinical conditions. Second, methods to determine the clinical status of participants, such as structured clinical interviews or self-report questionnaires, differed between studies. Third, intervention contents were different. As mentioned previously, most interventions were based on CBT, but other intervention types were included as well. Fourth, study design caused heterogeneity, due to different types of control groups, varying follow-up assessment periods and different sample sizes. For the meta-analysis, pooled effect sizes were calculated for depression and grouped into 3 follow-up periods. Nevertheless, different sample sizes can lead to overweighting of the larger size studies.

Future Research

To gain insight into requirements for future research, limitations of the presented studies should be considered. First, the 5 included incidence studies were planned with preventive goals and used standardized clinical interviews for valid diagnosis. The remaining studies were often planned for other purposes (eg, improving well-being), and mental disorder symptoms were gathered by means of self-report questionnaires. Therefore, additional incidence studies using valid diagnostic instruments are needed, especially in light of the ICTRP search results, which revealed that very few incidence studies are planned in the near future.

Second, the evidence base is limited to a handful of disorder groups specifically EDs, depression and anxiety. Research could expand to the missing subfields, for which Internet-based prevention could be applicable. It is noteworthy that one ongoing trial targets prevention of psychosis [77].

Third, this is the first exhaustive review on Internet-based prevention for mental disorders in adults. One could expand the scope to additional domains and populations, for instance to relapse prevention in mentally ill persons. As there are already several studies on this topic (eg, [78,79]), a systematic review would be beneficial to provide an overview of the current state of research. Another potential field of study could be Internet-based prevention of mental disorders in children and adolescents. There is already one review on this topic [66], which is limited to depression and anxiety, but could be expanded to include other mental disorders.

Fourth, most Internet-based interventions included in this review had no additional human support component (ie, unguided). Although this results in a reduction of initial costs, it is also accompanied by a reduction of effectiveness [80]. To date, there is no study investigating whether or not this reduced effectiveness translates into an increase in costs over the long term, due to (for example) increased health care utilization or work incapacity days.

Conclusions

Internet-based interventions can be effective in the primary prevention of mental disorders. The body of research is still limited to a few mental disorders (EDs, depression, anxiety disorders). Therefore, further high-quality studies are required, using standardized clinical interviews and gathering incidence data in long-term follow-ups. Because of the advantages of Internet-based interventions such as cost-effectiveness, availability, and flexibility [16,17], this can be a fruitful area for research. Content could be adapted for use with other disorders and populations. Furthermore, interventions that have been found to be effective in preventing certain mental disorders can and should be implemented into practice. Health care costs and personal, social, and financial burdens of the affected and society can consequently be reduced.

Conflicts of Interest

None declared.

Authors' Contributions

LS, LR, and HB were involved in the concept and design of the study. LS and LR had major contributions to data extraction and analysis. All authors had major contributions to the write-up and editing of the manuscript and read and approved the final manuscript.

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Abbreviations

CBT: cognitive behavioral therapy
CENTRAL: Cochrane Central Register of Controlled Trials
CG: control group
ED: eating disorder
GAD: generalized anxiety disorder
ICTRP: International Clinical Trials Registry Platform
IG: intervention group
IMI: Internet- and mobile-based intervention
IT: Information technology
IRR: incidence rate ratio
MD: mean difference
MeSH: Medical Subject Heading
NNT: number needed to be treated
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD: post-traumatic stress disorder
RCT: randomized controlled trial
SCID: structured clinical interview for DSM disorders

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<u>Original Paper</u>

Cultural Adaptation of Minimally Guided Interventions for Common Mental Disorders: A Systematic Review and Meta-Analysis

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Abstract

Background: Cultural adaptation of mental health care interventions is key, particularly when there is little or no therapist interaction. There is little published information on the methods of adaptation of bibliotherapy and e-mental health interventions.

Objective: To systematically search for evidence of the effectiveness of minimally guided interventions for the treatment of common mental disorders among culturally diverse people with common mental disorders; to analyze the extent and effects of cultural adaptation of minimally guided interventions for the treatment of common mental disorders.

Methods: We searched Embase, PubMed, the Cochrane Library, and PsycINFO for randomized controlled trials that tested the efficacy of minimally guided or self-help interventions for depression or anxiety among culturally diverse populations. We calculated pooled standardized mean differences using a random-effects model. In addition, we administered a questionnaire to the authors of primary studies to assess the cultural adaptation methods used in the included primary studies. We entered this information into a meta-regression to investigate effects of the extent of adaptation on intervention efficacy.

Results: We included eight randomized controlled trials (RCTs) out of the 4911 potentially eligible records identified by the search: four on e-mental health and four on bibliotherapy. The extent of cultural adaptation varied across the studies, with language translation and use of metaphors being the most frequently applied elements of adaptation. The pooled standardized mean difference for primary outcome measures of depression and anxiety was -0.81 (95% CI -0.10 to -0.62). Higher cultural adaptation scores were significantly associated with greater effect sizes (P=.04).

Conclusions: Our results support the results of previous systematic reviews on the cultural adaptation of face-to-face interventions: the extent of cultural adaptation has an effect on intervention efficacy. More research is warranted to explore how cultural adaptation may contribute to improve the acceptability and effectiveness of minimally guided psychological interventions for common mental disorders.

KEYWORDS

cultural adaptation; depression; anxiety; self-help; minimally guided intervention; e-mental health; bibliotherapy

Introduction

Globalization of Minimally Guided Interventions

There is an alarming mismatch between the prevalence of mental disorders and the availability of services to meet mental health needs, particularly in low- and middle-income countries (LMICs) [1]. The Movement for Global Mental Health [2] emphasizes increasing the coverage of treatments for mental disorders worldwide, particularly in countries where the *treatment gap* is greatest (ie, in low- and middle-income countries) [3]. There is a growing interest in how to deliver psychological interventions to diverse populations, and various innovative solutions may expand their reach and accessibility in low- and high-income countries alike.

Evidence shows that minimally guided interventions (ie, self-help and guided self-help) may be as efficacious as face-to-face interventions for the treatment of a broad range of common mental disorders [4], including in routine care [5], with guided self-help being slightly superior to complete self-help [6]. Indeed, the World Health Organization (WHO) has updated recommendations on the treatment of depression in low-resource settings to include both face-to-face (eg, high therapist investment) and self-help interventions [7].

Bibliotherapy (ie, therapeutic books) and e-mental health are established means of providing minimally guided psychological interventions requiring one hour or less of face-to-face support time or up to 90 minutes total telephone or email support [8]. They may also appeal to people who are concerned about stigma associated with accessing mental health services. However, evidence on their efficacy is currently limited to high-income countries (HICs) and in culturally homogenous groups [9,10]. A recent systematic review found only three studies on e-mental health interventions in LMICs [11]. Nevertheless, these types of interventions may be viable solutions to narrow the mental health treatment gap in LMICs [12,13], where two-thirds of the 3.2 billion people using the Internet live [14], and where literacy rates are rapidly rising—currently estimated at 85% of the world population [15]. An important consideration is that in areas with restricted resources and as a means of increasing coverage of minimally guided interventions, the guidance may be given by a trained layperson, such as a family carer [16] or a community volunteer.

Cultural Adaptation

Intervention developers and care providers should ensure that treatments are suited to the culture of the intended users, both for moral reasons and for technical, efficacy-related reasons [16]. Cultural adaptation is defined as "the systematic modification of an evidence-based treatment or intervention protocol to consider language, culture, and context in such a way that it is compatible with the client's cultural patterns, meanings, and values" [17]. Cultural adaptation to the needs and expectations of intended users is likely very important for minimally guided interventions because there is little or no therapist interaction to carry the dimension of culture into the intervention.

The Bernal and Sáez-Santiago framework was proposed in 1995 as a framework for planning and conducting interventions with culturally and linguistically diverse (CALD) clients [18,19]. It has eight elements of adaptation: (1) language, (2) person (client) attributes, (3) metaphors, (4) content, (5) concepts, (6) goals, (7) methods, and (8) context of the intervention or services [19].

Evidence suggests that culturally adapted interventions may be more efficacious than interventions that have not been adapted [20], and that effectiveness increases with the number of implemented adaptation elements, according to the Bernal and Sáez-Santiago framework [21,22]. Evidence from systematic reviews show that the extent to which face-to-face interventions are culturally adapted varies considerably [23,24]. However, little is known about the methods and potential benefits of cultural adaptation of minimally guided interventions designed to improve the mental health and well-being of CALD populations.

The aim of this paper was to understand the extent and effects of cultural adaptation of minimally guided interventions for the treatment of common mental disorders. We conducted a systematic review and meta-analysis of experimental studies of minimally guided interventions for the treatment of common mental disorders—depression, anxiety, and adjustment disorders—conducted with culturally diverse populations. We also tested whether the characteristics and extent of cultural adaptation of the minimally guided interventions under study were associated with the combined effect estimates.

Methods

The methods and procedures used to conduct the systematic review and meta-analysis are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [25].

Systematic Search

We designed our search strategy by combining relevant acronyms and synonyms that captured the population, intervention, comparator, and outcomes (PICO) elements, and the study design consistent with our study aim. Professional librarians from the University of Geneva and the University of Zurich assisted in testing and refining the search strategy, which was written for PubMed and adapted to Embase, the Cochrane Library, and PsycINFO.

We conducted a database search of Embase, PubMed, Cochrane Library, and PsycINFO. Four search concepts were combined in order to capture relevant literature: mode of delivery (eg, mobile phone, multimedia, and Web based), intervention program (eg, self-help, minimally guided, and Internet cognitive behavioral therapy [iCBT]), common mental disorders (eg, depression, anxiety, stress, and trauma), and cultural diversity. In order to identify culturally diverse populations, we took a proxy of LMICs classified according to the World Bank [26], using their names and population adjectives with additional high-income country and population names that we considered to be culturally divergent from North America, Europe, and Australia (eg, Saudi Arabia).

Searches were limited to experimental reports found in journal articles published between January 1995 and July 2015. Limits for *humans* were flexibly applied in the electronic searches in PubMed and PsycINFO, though unindexed articles were captured by removing the *humans* filter from 2013 onwards. Details of the search strategy can be found in Multimedia Appendix 1.

In addition, we hand searched citations of eligible articles, and forward citation of protocol articles found in the search, in order to identify additional relevant published studies. Finally, at the third conference of the *European Society for Research on*

Internet Interventions in Poland in September 2015, where we presented preliminary review results, we asked the audience of experts in e-mental health interventions to inform us if they were aware of any articles that we may have missed. All citations were managed using EndNote X7 (Thomson Reuters) and references and abstracts were exported into Microsoft Excel for easy title and abstract screening.

Study Selection

The inclusion criteria applied to articles to be included in this study are shown in Textbox 1.

Textbox 1. Inclusion criteria for articles.

Population:

- More than 75% of participants above a clinical cutoff for symptoms of unipolar depression or anxiety including trauma-related disorders, irrespective of the clinical measure used

- People culturally and linguistically different to those for which the intervention was originally designed

Intervention:

- A minimally-guided or unguided self-help program; one hour or less of face-to-face health worker or trained layperson time or up to 90 minutes total telephone or email support [8], regardless of delivery mode

- Structured and active therapeutic modality (ie, the intervention has clear theoretical underpinnings or an evidence base)

- Must include methodology used (ie, an observational or controlled study, process report, or a protocol)

Comparator:

- Any control condition, including placebo, treatment/care as usual, waitlist control, or active treatment comparison

Outcome:

- Postintervention measures of symptoms of mental illness

Study design:

- Randomized or nonrandomized experimental studies

Textbox 2. Exclusion criteria for articles.

- Intervention(s) as an adjunct to traditional face-to-face therapy

- Delivered in an inpatient setting

- Intervention designed for the culturally and linguistically diverse (CALD) population, therefore not adapted

- Training materials for health workers

- Prevention programs for mental disorders

The exclusion criteria applied to articles to be excluded from this study are shown in Textbox 2.

Two researchers (EH and MHS) independently screened titles and abstracts according to the inclusion and exclusion criteria, which were then applied to the full texts of the eligible publications. All disagreements were discussed and resolved. Where it did not become clear from the full text, we wrote to investigators to verify the eligibility of the primary study, focusing in particular on whether the intervention was minimally guided and adapted for, not developed for, culturally and linguistically diverse populations.

Data Extraction and Additional Data Collection

Two researchers (EH and MHS) designed and piloted a data extraction tool by considering all study characteristics related to the research question considering the PICO elements.

Consistent with the Cochrane Collaboration approach and the methods used in a recent review of cultural adaptations of traditional psychological interventions [24], we developed a structured checklist to critically appraise the methodological quality of the included studies considering the following four criteria: method of randomization, allocation concealment, blinding of outcome assessment, and attrition bias [24]. Two researchers (EH and MHS) independently applied the checklist

to each of the included primary studies and a third researcher (EA) was called upon in cases of discordance of opinion.

In order to find out more about cultural adaptation methods used by researchers, we developed a short online questionnaire based on the framework by Bernal and Sáez-Santiago [19] (see Multimedia Appendix 2) and asked the authors of the included studies to complete it. Based on the information from the full-text articles and the questionnaires received, we assigned each study a score according to the number of Bernal and Sáez-Santiago framework adaptation elements that were applied.

Data Analysis

We retained only the outcome measure designed as the primary endpoint in each study. We entered the number of participants, postintervention means and standard deviations, and the number of adaptation points into Stata 13 (StataCorp LP) [27]. Then we stratified the analyses by the adaptation score and conducted a meta-analysis using a random-effect method to calculate the pooled effect size based on the combination of the standardized mean differences of primary studies, and formally assessed and quantified heterogeneity using Higgins' I^2 [28]. We then examined whether the extent of cultural adaptation explained the heterogeneity across studies using an unadjusted random-effects meta-regression model.

In a sensitivity analysis, we tested the robustness of using primary outcomes data only for our main analysis by rerunning the meta-analysis separating depression and anxiety data, irrespective of whether measures were used as primary or secondary endpoints. We then compared the I^2 values and 95% CIs between models to gain insight into the potential contribution of the primary versus secondary outcome to the heterogeneity observed in the stratified analyses.

Results

Systematic Search and Study Selection

We identified 4911 records, and excluded 1125 duplicates and 3585 citations on the basis of their titles and abstracts, which left 101 publications that were taken forward for full-text review. Of these, 11 were conference abstracts only, leaving 90 full texts to screen. Two articles were in Korean, so a Korean-speaking acquaintance of the research team was given guidance as to how to screen the articles, neither of which met inclusion criteria [29,30].

Reasons for exclusion are reported in Figure 1. Briefly, several articles did not meet various inclusion criteria, examples of which follow: they were not interventions designed in the West and adapted for a CALD population, but instead were designed specifically for the population [31-33]; the participants were not considered a CALD population [34-36]; the interventions were not self-help according to our standard definition above [37-39]; and/or no common mental disorder outcome measure was reported [40-42].

A total of 12 articles were retrieved (see PRISMA diagram in Figure 1); eight were randomized controlled trials (RCTs), two were protocols for included RCTs [43,44], and one was a protocol for an RCT whose results have not yet been published [45]. One additional article [46] utilized one of the datasets already included [47] (ie, urban sample). One of the included RCTs [47] had two different study sites—urban and rural—with different methodologies; therefore, we treated these as two different datasets. Four studies investigated the effect of bibliotherapy [47-50], and the remaining four were of e-mental health interventions [51-54].

One additional unpublished dataset was identified from key informants at the European Society for Research on Internet Interventions (ESRII) conference, but this was excluded. Upon contacting the author, there was insufficient information to determine whether the intervention was designed for the CALD population and, therefore, whether the study met our inclusion criteria. Characteristics of the studies are presented in Table 1.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram with systematic search and selection process. RCT: randomized controlled trial.
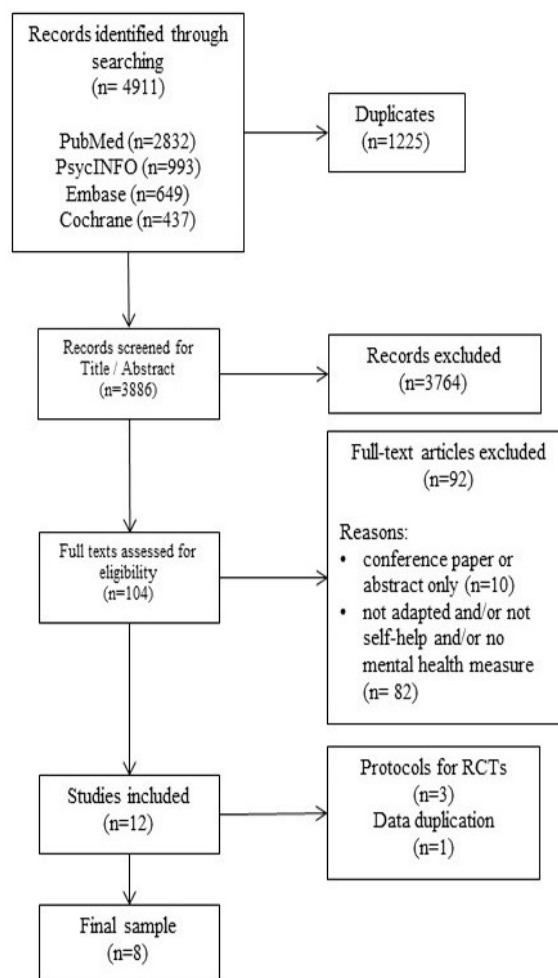
There were eight RCTs, including nine datasets for analysis. The cultural backgrounds of the participants included in the studies were Chinese, Romanian, Pakistani, Japanese, and Turkish. Most of the interventions had a cognitive behavioral approach [48,50-52]; however, one study used a problem solving approach [44], one study with two datasets used a social cognitive theory approach [47], and one study used acceptance and commitment therapy [53]. The duration of interventions ranged from 4 to 12 weeks and only two out of eight interventions were completely self-help (ie, no guidance from a health worker) [53]. The number of Bernal and Sáez-Santiago framework adaptation points carried out ranged from 0 to 7, out of a possible 8. Two interventions, across three datasets, focused primarily on anxiety symptoms, and six on depressive symptomatology, with a range of outcome measures to quantify effects.

Table 1. Characteristics of RCT[a] studies retrieved.

Study	Randomized, n (analyzed, n)	CALD[b] group	Delivery	Therapy approach	Length (weeks)	Guidance	Adapt.[c] points	Primary outcome measure
Choi et al 2012 [48]	63 (51)	Chinese	e-MH[d]	CBT[e]	8	MG[f]	7	(C)BDI II[g] depression
Liu et al 2009 [51]	52 (40)	Chinese	Biblio.[h]	CBT	4	MG	0	(C)BDI II depression
Moldovan et al 2013 [52]	96 (84)	Romanian	Biblio.	CBT	4.5	MG	0	BDI II[i] depression
Muto et al 2011 [53]	70 (42)	Japanese	Biblio.	ACT[j]	8	SH[k]	5	GHQ[l] depression
Naeem et al 2014 [54]	192 (183)	Pakistani	Biblio.	CBT	12	MG	5	HADS-D[m] depression
Tulbure et al 2015 [50]	76 (68)	Romanian	e-MH	CBT	9	MG	5	LSASSR[n] anxiety
Ünlü Ince et al 2013 [49]	96 (56)	Turkish	e-MH	PS[o]	5	MG	5	CES-D[p] depression
Wang et al 2013 [47] (urban)	103 (61)	Chinese	e-MH	SCT[q]	4.5	SH	3	PDS[r] anxiety
Wang et al 2013 [47] (rural)	94 (90)	Chinese	e-MH	SCT	4.5	SH	3	PDS anxiety

[a]RCT: randomized controlled trial.

[b]CALD: culturally and linguistically diverse.

[c]adapt: adaptation.

[d]e-MH: e-mental health.

[e]CBT: cognitive behavioral therapy.

[f]MG: minimally guided.

[g](C)BDI II: (Chinese) Beck Depression Inventory II.

[h]biblio.: bibliotherapy.

[i]BDI II: Beck Depression Inventory II.

[j]ACT: acceptance and commitment therapy.

[k]SH: self-help.

[l]GHQ: General Health Questionnaire.

[m]HADS-D: Hospital Anxiety and Depression Scale.

[n]LSASSR: Liebowitz Social Anxiety Scale Self Report.

[o]PS: problem solving.

[p]CES-D: Center for Epidemiological Studies Depression Scale.

[q]SCT: social cognitive theory.

[r]PDS: Patient Distress Scale.

Data Extraction and Additional Data Collection

We determined the overall risk of bias of the included studies to be moderate. The main issue that introduced potential bias into studies was the outcome measures being subjective self-report measures, coupled with the fact that participants could not be blinded. Details on risk of bias assessment are reported in Multimedia Appendix 3.

The cultural adaptation methods used were only minimally reported in the primary publications. Six researchers responded to the questionnaire that we sent. Using questionnaire responses, where provided, and the full texts of the RCTs plus any protocols or related previously published studies, we assigned each RCT an adaptation score according to the number of Bernal and Sáez-Santiago framework adaptation elements that we deemed were applied (see Figure 2). In some cases, researchers had considered an element of adaptation but chosen not to carry out that adaptation having not identified a need for it. These were coded as affirmative responses; examples of affirmative questionnaire responses can be found in Multimedia Appendix 4.

All but two researchers indicated that they had translated their interventions into the language of the target group. Seven researchers—five in e-mental health interventions—reported the use of adapted metaphors, using symbols, concepts, idioms, and sayings from the target culture. Local values and traditions in order to carry the content of the intervention were considered by five researchers—four in e-mental health interventions. Theoretical concepts and constructs were considered by four e-mental health researchers and one bibliotherapy researcher. No researcher reported having considered treatment goals in the adaptation of their intervention. The delivery method of the

intervention (eg, making particular allowances or breaking strategies into smaller tasks) was mentioned in the questionnaire response of three researchers—two e-mental health interventions. The socioeconomic and political context of the intervention was considered by five researchers—two e-mental health interventions—yet most researchers who responded to the qualitative element of this question mentioned that e-mental health or bibliotherapy in itself was used in response to the socioeconomic and cultural environment (eg, stigma and access to services).

Figure 2. Adaptation score assigned to the selected studies.
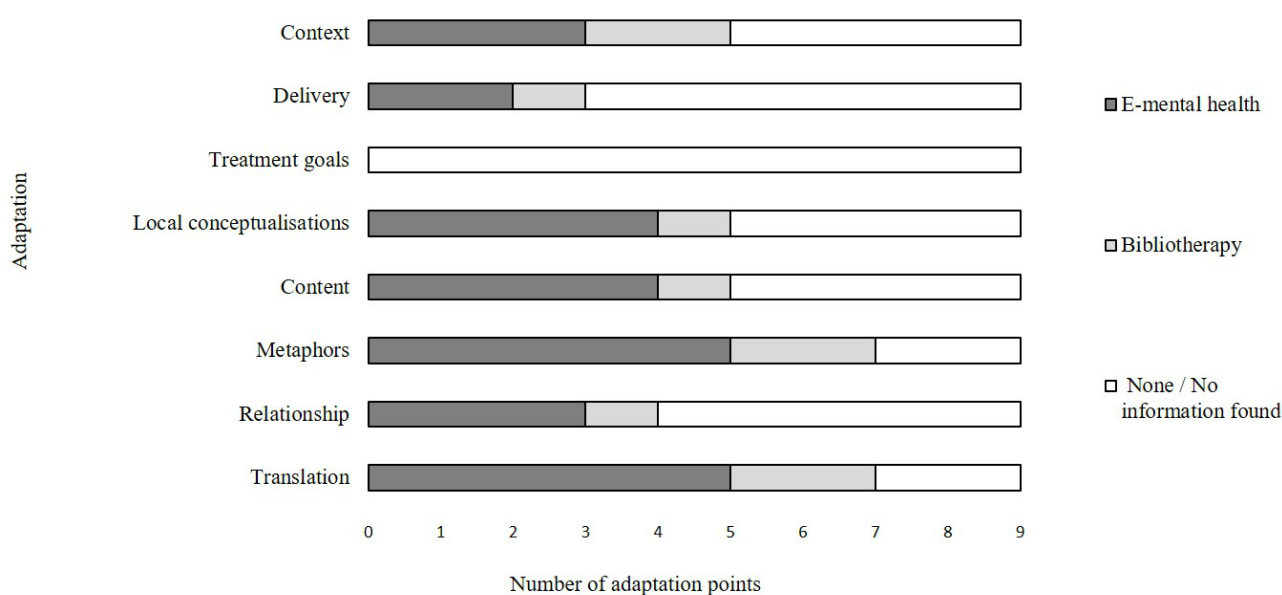

Data Analysis

The random-effects meta-analysis (see Figure 3) on the primary outcome measures included nine datasets with a total of 684 participants. We stratified the data by descending assigned cultural adaptation points.

Overall, the minimally guided and self-help interventions significantly improved depression and anxiety symptomatology; the pooled standardized mean difference (SMD) from primary outcome measures was -0.81 (95% CI -0.10 to -0.62), with low-to-moderate between-studies heterogeneity (I^2=28.9%).

The meta-regression (see Figure 4) showed that the adaptation scores significantly explained the pooled SMD. Specifically, a

1-point increase in the adaptation score was significantly associated with an increase in effect size of 0.117 (P=.04), or a 14% rise in pooled efficacy.

To test the robustness of our main model, which focused on the primary outcome measures, we carried out two separate meta-analyses for each outcome (ie, depressive or anxiety symptoms), irrespective of what the intervention was primarily designed for. Our results were largely unchanged, but the heterogeneity across the studies was greater (SMD=-0.65 [95% CI -0.92 to -0.38], I^2=62.2% for anxiety and SMD=-0.58 [95% CI -0.93 to -0.24], I^2=75.4% for depression), thus confirming our use of primary measures only in the analysis.

Figure 3. Random-effects meta-analysis of primary outcome measures in order of the study adaptation score. SMD: standardized mean difference.
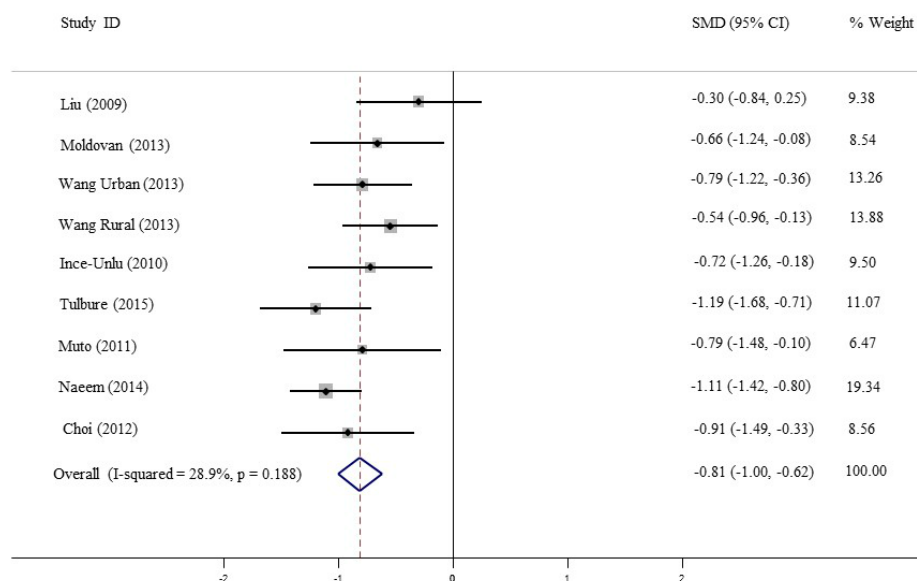
Figure 4. Meta-regression of the standardized mean difference and adaptation score.
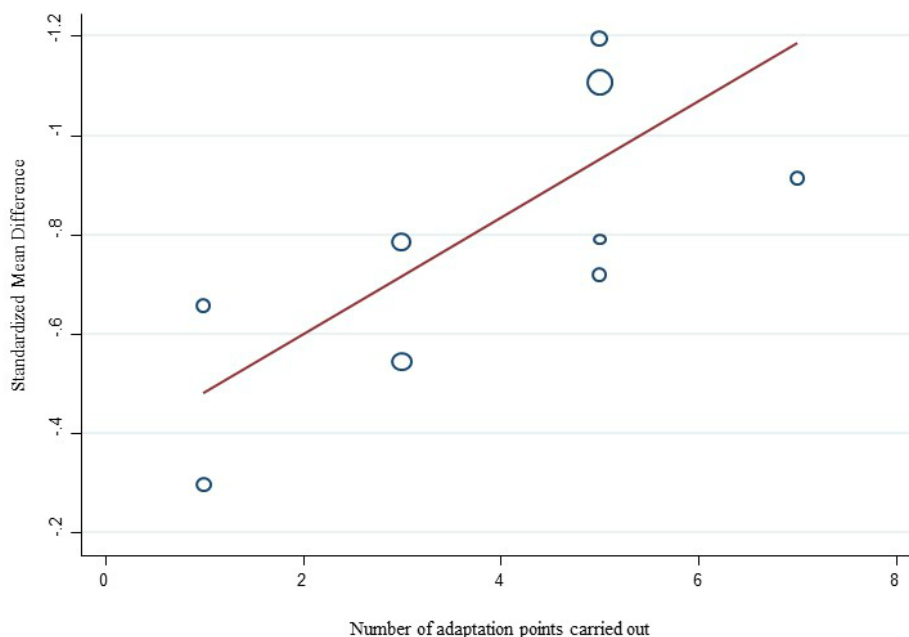
Discussion

Principal Findings

Culturally adapted self-help or minimally guided bibliotherapy and e-mental health interventions moderately, but significantly, reduced depressive and anxious symptomatology in populations culturally and linguistically distinct from those for which the interventions had been originally designed. More extensive cultural adaptation of the interventions under study was significantly associated with larger effect sizes; however, details of the cultural adaptation methodologies applied were largely underreported.

Researchers should be encouraged to report in detail their adaptation methods to enable readers to appraise both internal and external validity of the study findings, and to inform the implementation of minimally guided interventions and their scalability beyond the research context.

Our results have both public health and clinical relevance, particularly to program managers and health workers who aim to use minimally guided interventions among CALD clients. Decision makers should consider the implications of cultural adaptation on the expected efficacy of interventions before use and, if feasible, plan the required resources and time investments accordingly. A 14% rise in efficacy per adaptation point increase should be weighed against the costs of adapting intervention content, considering the anticipated coverage of the intervention. Adaptation could also positively affect attrition rates, which can be high in self-help interventions.

Our results suggest that the effect of minimally guided interventions used in CALD populations was significantly influenced by cultural adaptation. We were unable to review

the specifics of qualitative methodologies involved, but depending on resources, adaptation could resemble a single focus group of community members, or a costly and extensive multi-stakeholder consultation program. Precise information on the methods used is important to allow, on the one hand, a comprehensive adaptation to other settings and contexts and, on the other hand, the preservation of the original intervention's core therapeutic techniques and components to maximize the fidelity to the original intervention.

The Bernal and Sáez-Santiago framework was extremely useful but difficult to operationalize. Further research is needed to develop, pilot, and test an adaptation protocol for minimally guided interventions that would favor the utility and efficiency of the original framework's use in cross-cultural psychology and psychiatry. Such an adaptation protocol should strive to include the target community in qualitative research and discussions on adaptation of materials.

Limitations

Our study has limitations. First, we focused on selected countries that we arbitrarily considered to be culturally distinct. However, this choice was extensively discussed to include geographically diverse LMICs and high-income countries culturally diverse from North America, Australia, and Western Europe, where the majority of minimally guided interventions are developed and tested. We did not consider potential cultural differences between Western countries (eg, an intervention designed in the United States and used in Norway), and we did not focus on indigenous populations as culturally diverse, and underserved, groups.

Second, and briefly mentioned above, although the meta-analysis showed low heterogeneity across the studies, the meta-regression used to formally explore this further was based on only nine datasets for a total of 684 participants. The Cochrane handbook suggests a minimum of 10 studies to run a meta-regression [55], so these findings should be considered with caution. Further, because half of the studies (n=5) included completers only in their analyses, the reported effect sizes might have been inflated, and an overestimation of the true effect in our meta-analysis cannot be excluded [56]. In addition, the marked differences in intervention duration and in follow-up times between studies may further limit comparability. In the meta-regression, we focused only on the number of Bernal adaptation elements. This was coherent with our main scope and was statistically appropriate (see above). However, other study design characteristics could also explain the between-studies heterogeneity and, at least to some extent, they might even confound or modify the observed effect of cultural adaptation.

Third, using the Bernal and Sáez-Santiago framework carries its own limitations. It was developed over 20 years ago in North America in relation to transcultural issues of working with Latino communities. In addition, it was informed by a theory-driven and anecdotal approach, as opposed to being informed by community-based explorative and qualitative data. We used the Bernal and Sáez-Santiago framework because it had been used to categorize adaptations made in previous systematic reviews [22-24]. The number of elements of the Bernal and Sáez-Santiago framework carried out in each study

was based on a subjective assessment of the information from full texts and the qualitative information provided in the questionnaires. Though authors agreed that they had carried out most adaptation elements, the review researchers independently tended to assign lower completion rates. This coding remained subjective on both the authors' and the primary study researchers' part, mainly because Bernal concepts are rather abstract and can sometimes overlap. Also, if researchers stated that they had considered an element but chosen not to carry it out, we coded this as an affirmative answer. A further limitation of the adaptation coding stemmed from the fact that the Bernal and Sáez-Santiago framework was developed for face-to-face treatments. We chose to use the framework in its original state. Some of the categories (ie, treatment goals or therapeutic relationship) are likely less or modestly relevant for minimally guided interventions.

Comparison With Prior Work

Our results are consistent with evidence from previous systematic reviews on the cultural adaptation of face-to-face interventions for common mental disorders [21-24], particularly that completing more elements of adaptation is associated with a higher effect size [22]. Indeed, the effect size of the most comprehensively adapted, Chinese version of the *Sadness* intervention [48] was similar, if not slightly higher, compared to its original Australian version [57]—within-groups Cohen's d for reduction in Beck Depression Inventory score was 1.41 in the Chinese adapted intervention and 1.27 in the original Australian version.

Further comparisons with previous findings are less straightforward. Statistical power was limited by the total number of studies included (see below), which were not sufficient to conduct advanced, multivariable, meta-regression models to test which, if any, of the Bernal *adaptation elements* might have contributed the most to the observed between-studies heterogeneity. Similarly, we were not able to consider other plausibly relevant covariates in our models, such as therapeutic modality, level of health worker support, length of delivery, and level of engagement or medium. Evidence on the impact of cultural adaptation is scant, but previous studies found that therapeutic goals, metaphors and symbols [22], and conceptualizations (ie, explanatory models) [21] may significantly account for variance in effect sizes of the interventions under study. These previous findings seem plausible because, although little is known about specific components that determine the effectiveness of a self-help program [9], providing users with an explanatory model of their distress using meaningful terms and symbols may constitute a critical prerequisite of minimally guided interventions.

Conclusions

In conclusion, our results support the careful application of cultural adaptation of minimally guided and self-help interventions, whether provided via bibliotherapy or the Internet, before their use in diverse settings and populations. This largely applies to the *globalization* of mental health services and psychological interventions, for which cultural adaptation is key. Further, there is also a moral case to test and demonstrate the appropriateness, acceptability, and harmlessness of

interventions up front. Cultural adaptation is explicitly intended to render interventions meaningful and helpful to groups that are culturally diverse from those for which the intervention was designed. Therefore, these findings may be particularly relevant to program managers and treatment providers in non-Western settings.

Acknowledgments

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy.

[PDF File (Adobe PDF File), 36KB - mental_v3i3e44_app1.pdf]

Multimedia Appendix 2

Questionnaire for researchers.

[PDF File (Adobe PDF File), 49KB - mental_v3i3e44_app2.pdf]

Multimedia Appendix 3

Risk of bias analysis.

[PDF File (Adobe PDF File), 43KB - mental_v3i3e44_app3.pdf]

Multimedia Appendix 4

Example responses from researchers.

[PDF File (Adobe PDF File), 41KB - mental_v3i3e44_app4.pdf]

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Abbreviations

ACT: acceptance and commitment therapy
adapt.: adaptation
BDI II: Beck Depression Inventory II
biblio.: bibliotherapy
CALD: culturally and linguistically diverse
(C)BDI II: (Chinese) Beck Depression Inventory II
CBT: cognitive behavioral therapy
CES-D: Center for Epidemiological Studies Depression Scale
e-MH: e-mental health
ESRII: European Society for Research on Internet Interventions
GHQ: General Health Questionnaire
HADS-D: Hospital Anxiety and Depression Scale
HIC: high-income country
iCBT: Internet cognitive behavioral therapy
LMICs: low- and middle-income countries
LSASSR: Liebowitz Social Anxiety Scale Self Report
MG: minimally guided
PDS: Patient Distress Scale
PICO: population, intervention, comparator, and outcomes
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PS: problem solving
RCT: randomized controlled trial
SCT: social cognitive theory
SH: self-help
SMD: standardized mean difference
WHO: World Health Organization

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Original Paper

Barriers to Office-Based Mental Health Care and Interest in E-Communication With Providers: A Survey Study

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Abstract

Background: With rising availability and use of Internet and mobile technology in society, the demand and need for its integration into health care is growing. Despite great potential within mental health care and growing uptake, there is still little evidence to guide how these tools should be integrated into traditional care, and for whom.

Objective: To examine factors that might inform how e-communication should be implemented in our local outpatient mental health program, including barriers to traditional office-based care, patient preferences, and patient concerns.

Methods: We conducted a survey in the waiting room of our outpatient mental health program located in an urban, academic ambulatory hospital. The survey assessed (1) age, mobile phone ownership, and general e-communication usage, (2) barriers to attending office-based appointments, (3) preferences for, and interest in, e-communication for mental health care, and (4) concerns about e-communication use for mental health care. We analyzed the data descriptively and examined associations between the presence of barriers, identifying as a social media user, and interest level in e-communication.

Results: Respondents (N=68) were predominantly in the age range of 25-54 years. The rate of mobile phone ownership was 91% (62/68), and 59% (40/68) of respondents identified as social media users. There was very low existing use of e-communication between providers and patients, with high levels of interest endorsed by survey respondents. Respondents expressed an interest in using e-communication with their provider to share updates and get feedback, coordinate care, and get general information. In regression analysis, both a barrier to care and identifying as a social media user were significantly associated with e-communication interest (*P*=.03 and *P*=.003, respectively). E-communication interest was highest among people who both had a barrier to office-based care and were a social media user. Despite high interest, there were also many concerns including privacy and loss of in-person contact.

Conclusions: A high burden of barriers to attending office-based care paired with a high interest in e-communication supports the integration of e-communication within our outpatient services. There may be early adopters to target: those with identified barriers to office-based care and who are active on social media. There is also a need for caution and preservation of existing services for those who choose not to, or cannot, access e-services.

KEYWORDS

Introduction

As widespread usage and demand for Internet and mobile technologies grows, a parallel impetus to integrate and shift the traditional modes of health care delivery is emerging. Telemedicine, a long-standing and highly adopted form of remote e-communication in mental health care, has been rated by patients as highly convenient versus in-person consultations [1]. More recently, synchronous videoconferenced care has been extended to be available on personal devices through existing or custom platforms [2,3]. Similarly, software apps installed on mobile phones and other portable devices are being created to assist patients in assessing and monitoring their symptoms or are used as therapeutic tools allowing clinicians to communicate with their patients directly [2]. With a growing number of apps emerging, the use of such mobile technology for mental health care is on the rise. In 2011, of the 9000 consumer health apps that were available, 6% related to mental health, 11% to stress management, 4% to sleep, and 2% to smoking cessation [4]. It is estimated that by 2017, half of the 3.4 billion mobile phone or tablet users across the world will be using some type of mental health care app on their devices [4]. These and other eHealth interventions have the potential to overcome many of the attitudinal and structural barriers associated with accessing mental health care [5], and provide increased convenience for the patient, connect hard-to-reach individuals, reduce stigma, reduce health system costs, and bridge gaps in care provision [2]. The adoption of e-communication tools, which we are defining as online, Internet, or mobile phone-based tools that allow communication between patient and provider, in mental health care is contingent upon effectiveness and the comfort level of patients and providers.

Even among individuals with serious mental illness, mobile phone ownership is 80% or higher [6-9] and there is interest in using mobile apps and e-communication to receive mental health care and monitor symptoms [7,9,10]. The literature suggests that email communication [11,12] and mobile apps [13,14] can be used safely and effectively with a range of mental health patient groups. Of note, younger age groups express more desire and willingness to use technology and may respond to e-communication platforms differently [7]. Furthermore, there are a range of mental health-related services that people may be hoping to access, ranging from information on medication and side effects to reminders for appointments via short message service (SMS) text messaging [3]. The accessibility of e-communication tools for patients, such as having an Internet connection; having a computer, tablet, or mobile phone; having a safe and private place to work; and having adequate experience with using e-communication platforms, are all factors to consider when measuring the appropriateness of mental health therapy integration and technology [3].

Although the potential for e-communication in mental health services is undeniable, it is not entirely without risks, and there has been little formal evaluation of mental health e-communication [3,13]. As a result, it is still unclear exactly how e-communication should be implemented and incorporated into mental health care, and for whom. In this study, we sought to examine factors that might inform how e-communication should be implemented in our local outpatient mental health program. We conducted a survey to examine barriers to traditional office-based care, along with patient preferences and concerns about the use of e-communication tools in their mental health care.

Methods

Study Design and Setting

This study was conducted in the Women's College Hospital Mental Health Program (WMHP), located in downtown urban Toronto, Canada's largest city. The WMHP provides ambulatory psychiatric consultation and multi-disciplinary treatment in four areas: general psychiatry, mental health in medicine, reproductive life stages, and trauma therapy. The WMHP serves patients of all genders, however, due to the nature of its services, the gender distribution is biased toward women, who comprise about 70-80% of the patient population. The program does not have a catchment and patients are referred from primary care and specialist providers across a wide geographical radius.

A survey was available in hard copy and as a Web-based survey, hosted by the online survey development cloud-based company, SurveyMonkey. Postcards (see Figure 1) with the survey information and Web address were displayed throughout the waiting room of the WMHP. A free Wi-Fi network is available throughout the hospital. The receptionist also alerted patients to the survey and distributed a hard copy to willing individuals. Patients were free to take the postcards home to complete the survey at a later time. All hard-copy surveys were manually entered into the Web survey and cross-checked for accuracy. Survey participation was entirely voluntary and anonymous, and no personal information was collected. The Web and hard-copy surveys provided a description of the study and details of how data would be used prior to participants completing the questionnaire and, as such, consent was implied with survey completion. The survey was open for 3 months between August and December of 2015. Ethical approval for the study was obtained from Women's College Hospital Ethics Assessment Process for Quality Improvement Projects.

Figure 1. eHealth survey postcard. WCH: Women's College Hospital.
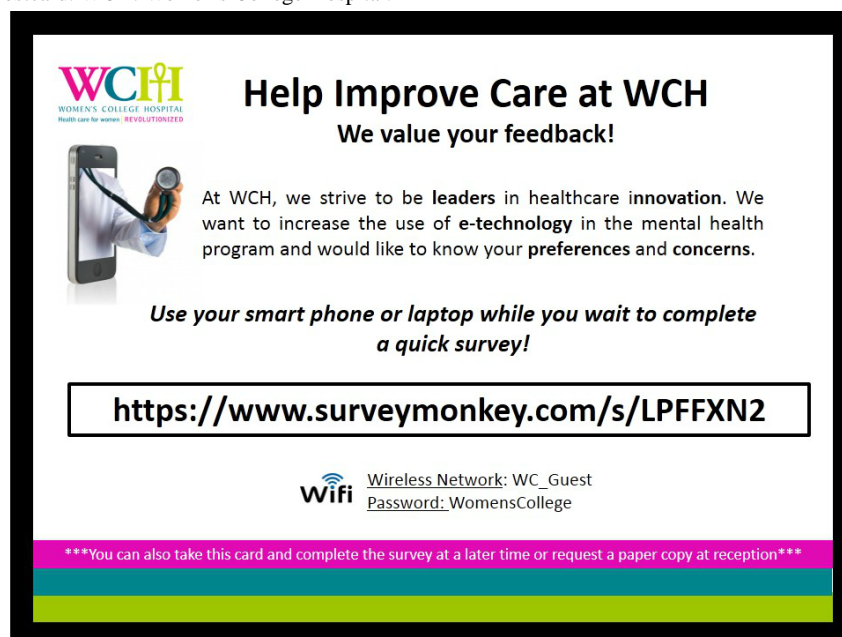
Survey Design

The survey was composed of eight items, including both quantitative and qualitative questions in the following topic areas: (1) age, mobile phone ownership, and general e-technology usage (3 items), (2) barriers to attending office-based appointments (1 item); (3) preferences for, and interest in, e-technology for mental health care (2 items), and (4) concerns about e-technology use for mental health care (2 items). We assessed interest and concerns surrounding email and SMS text or Internet messaging; online Web-based assessment tools; mobile phone symptom monitoring apps; health care social networks that may be open to other health care providers, such as family physicians; and personal computer videoconferencing. We asked, in an open-ended question, what respondents would use e-communication to communicate about. The Web survey had one question per page and participants were allowed to review and change their answers throughout the survey. All questions were optional and participation was restricted to one submission per IP address. Prior to the survey launch, a small number of representative individuals completed the survey to ensure usability testing.

Data Analysis

All survey responses were exported from SurveyMonkey as an Excel file, cleaned, and imported into SPSS version 23 (IBM Corp) for further analysis. We descriptively analyzed all quantitative survey items. We examined the data for associations between the presence of barriers to attending appointments and interest in e-communication, as well as use of social media and interest in e-communication using chi-square statistics. We created a summary *e-communication interest score*, calculated as the sum of responses to questions about the six e-communication tools included in the survey. For the calculation of this score, 2 survey respondents were eliminated because they did not provide a response for any of the e-communication tools questions. If a respondent answered in part, but had a missing response for any item, the score for that

item was set to 1 (*not interested*). We created a composite *motivation variable* to represent what we termed the level of motivation to use e-communication. This variable was the interaction between willingness to use based on existing use of social media, and need to use based on the presence of barriers to office-based care. For this variable, we categorized respondents into one of four groups: no barrier, not a social media user; no barrier, social media user; barrier, not a social media user; and barrier, social media user. We compared e-communication interest scores between these groups with the Kruskal-Wallis nonparametric mean rank test, adjusted for multiple comparisons. We also conducted a linear regression with e-communication interest score as the outcome, and age, barrier, and social media use as predictors. Open-ended qualitative survey questions were content analyzed and responses tabulated into thematic categories.

Results

Participants

A total of 68 patients completed the survey. Of the 68 respondents, 59 respondents (87%) completed the survey on paper in the waiting room, 3 respondents (4%) completed it in the waiting room on a portable electronic device (eg, tablet or mobile phone), and 5 respondents (7%) completed it at home on a portable device or desktop computer. Table 1 summarizes the demographics, general e-technology use, and barriers to care among respondents. The majority of respondents (51/68, 75%) were between the ages of 25 and 44 years; 91% (62/68) reported owning a mobile phone. A high percentage of respondents reported regularly using SMS text messaging and email, and 59% (40/68) identified as social media users. Just over half (36/68, 53%) identified at least one barrier to attending office-based services, most commonly related to pregnancy, caregiving, work, or distance lived from the hospital. Two or more barriers were reported by 19% (13/68) of respondents.

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Preferences Regarding E-Communication

Overall, there was very low existing use of any e-communication between survey respondents and their mental health care providers (see Figure 2). The majority of respondents (52/60, 87%) reported being interested or very interested in using email. Excluding nonresponders on the individual items, more than 60% were interested or very interested in each of SMS text or instant messaging (43/58, 74%), online assessment tools (45/54, 83%), symptom monitoring apps (35/56, 62%), and personal computer videoconferencing (38/58, 66%). Only 44% (25/56) of respondents were equally interested in health care social networks. Compared to respondents with no identified barrier to office-based care, those with at least one were significantly more likely to be interested in online assessment tools (28/30, 93% at least one barrier vs 17/24, 71% no barrier; P=.03), a health care social network (18/32, 56% at least one barrier vs 7/24, 29% no barrier; P=.04), and videoconferencing (26/34, 76% at least one barrier vs 12/24, 50% no barrier; P=.04). Similarly, compared to those who did not, those who identified as a social media user were more likely to be interested in online assessment tools (31/33, 94% social media user vs 14/21, 67% not a social media user; P=.01) and health care social networks (21/35, 60% social media user vs 4/21, 19% not a social media user; P=.003).

Table 1. Demographics, e-communication usage, and barriers to office-based care.

Variable	n (%)
Age in years (N=67)	
Under 25	4 (6)
25-34	32 (47)
35-44	19 (28)
45-54	7 (10)
55-64	5 (7)
65+	1 (1)
Owns a mobile phone (N=68)	
Yes	61 (91)
General e-communication use (N=68)	
Email	67 (99)
SMS[a] text or instant messaging	57 (85)
Social media user[b]	40 (59)
Barriers to care (N=68)[c]	
None	36 (53)
Pregnancy and/or child care	20 (29)
Work related[d]	11 (16)
Live too far from hospital	9 (13)
Medical problems	5 (7)
Travel related[e]	5 (7)

[a]SMS: short message service.

[b]Facebook, Twitter, LinkedIn, or *other social media site*.

[c]Respondents may have endorsed more than one barrier.

[d]Includes being unwilling/unable to take time off work to come into the office, or workplace being too far from the hospital to do so.

[e]Includes inability to get transportation and/or unwilling to pay for parking.

Analysis of open-ended responses to the question regarding what participants would use e-communication for yielded the following three categories: (1) sharing and feedback, (2) care coordination, and (3) general information. Sharing and feedback captured the desire to share updates on progress with the provider, receive resources such as therapy homework or educational materials, and seek advice, particularly as it related to symptom management and medications. Care coordination related primarily to appointment management, but also to lab requisition and referrals, and information about programming. Three respondents stated they would like to use e-communication for *general information* with no further clarification as to what that would involve.

Respondents who identified as a social media user and who had an identified barrier had the highest mean e-communication interest score (see Figure 3), with a significant difference in mean ranks between groups (P=.004). The *barrier, social media user* group had a mean rank significantly higher than the *no*

barrier, not a social media user group ($P=.002$, adjusted for multiple comparisons) with no significant differences between other groups. The regression model was significant ($F_{3,62}=5.54$, $P=.002$, $R^2=.21$). Both an identified barrier and being a social media user were significantly associated with higher e-communication interest scores (B=1.81, 95% CI 0.23-3.40, $P=.03$; and B=2.51, 95% CI 0.90-4.12, $P=.003$, respectively), each accounting for about half of the explained variance in the outcome.

Figure 2. Interest in e-communication for mental health care.
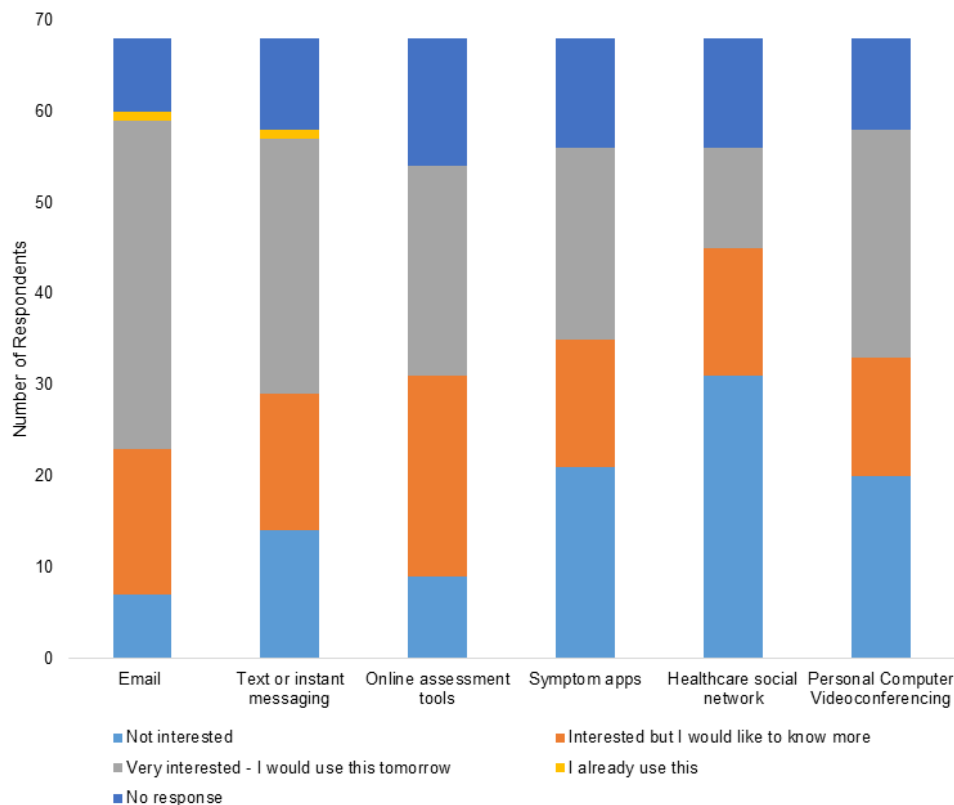
Figure 3. E-communication interest scores across motivation categories. ** $P=.002$ (adjusted for multiple comparisons).
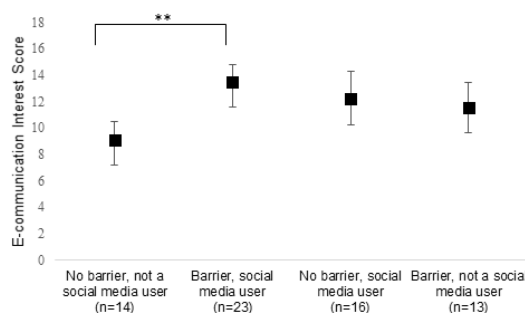
Concerns Regarding E-Communication

Regarding concerns about e-communication, 41 out of 68 respondents (60%) endorsed at least one (see Table 2). A concern about privacy was most commonly reported, followed by already being inundated with e-communication in their lives, and concerns over not having access to the services they prefer. Concerns over loss of face-to-face contact was expressed as an *other* concern by 4 out of 68 respondents (6%). Few respondents did not have access to the Internet or a mobile phone. Interestingly, social media users represented more of the concerns related to privacy (21/32, 66% of privacy concerns). The range of open-ended comments expressed by respondents at the end of the survey varied from a very eager stance to using e-communication tools as a way to connect with their mental health provider, while others reported major concerns about privacy or loss of in-person contact with their provider.

Table 2. Concerns surrounding e-communication use for mental health care (N=68).

Variable	n (%)[a]
Privacy	32 (47)
No access to the Internet	2 (3)
No mobile phone	3 (4)
Not interested in signing up for more e-services	4 (6)
I already get too many emails and/or SMS[b] text messages	8 (12)
If I don't use the e-communication, I won't get the same access to services	4 (6)
Other	5 (7)
None indicated	27 (40)

[a]Respondents may have endorsed multiple concerns.

[b]SMS: short message service.

Discussion

Principal Findings

Our study found a high level of interest in the use of e-communication for mental health care. The majority of survey respondents already owned and use a mobile phone equipped with downloadable apps, email access, SMS texting functionalities, and built-in cameras for videoconferencing capabilities. In our outpatient population, notable structural barriers to office-based care were present, most commonly being pregnant or having child care responsibilities. Respondents who identified as social media users and had a barrier to office-based care were the most interested in e-communication. While there was an enthusiastic response to the possibility of e-communication, significant concerns about privacy and loss of in-person contact, which for some mental health patients may be particularly meaningful and therapeutic, were reported. A small number of respondents indicated that they would choose not to, or could not engage in, the use of e-communication.

Comparison With Prior Work

Mobile phone ownership in our study was higher than in other studies. A recent study of adult mental health outpatients in the United States, the majority of whom were from low-income households, found that nearly 80% had a mobile phone [6]. Advanced-feature mobile phone ownership was lower (17%) in that study, however, and our rate was also higher than that found in a survey of an urban emergency department where 50% of patients had an Internet-enabled mobile phone [8]. Advanced-feature mobile phone ownership is rapidly increasing and if these studies were repeated, rates may be higher. Alternatively, our patient population may be of higher socioeconomic status, allowing for higher ownership of the costlier advanced-feature mobile phone compared to the basic-feature phone.

The barriers reported in our sample reflect what is known about the structural barriers to mental health care that are present [5]. Moreover, in a study of postpartum women with depression and pregnancy complications specifically [15], over 60% reported that time was a barrier to seeking treatment for depression. Child care and costs were a barrier for half of the sample. Of note,

over 90% of the participants in that study endorsed an interest in Internet-based treatments [15]. Similarly, in a study examining interest in mobile apps for mental health conditions in a more general sample, 67% of patients reported an interest and willingness to try mobile apps designed to monitor their mental health conditions [7]. Most of our sample fell into the age range shown to be most in favor of using e-communication, making the high rates of interest consistent with other age-based assessments [7].

Despite high rates of interest in our sample, rates of existing e-communication between provider and patient in our study were extremely low compared to other studies that have assessed this in other care areas [12]. This may reflect possibly outdated concerns about email use in mental health care [16], as well as practices within our program where emailing patients is discouraged. Beyond email, use of personal videoconferencing for mental health care alone or blended with traditional office-based care [3] is being rapidly adopted, clearly reflecting a patient interest in this type of care delivery as we found in our sample. Our study highlights a high number of patient concerns, despite high interest, that has not been as well represented in the literature on patient preferences. Musiat et al [2] did describe a perception among service recipients that expectations would not be met by computerized treatments versus face-to-face care. We have also described prevalent concerns about privacy and the potential impact on receipt of services for those who may choose not to use or do not have access to e-communication. In addition, our study ties together motivators for e-communication, including barriers to office-based care and use of social media with higher levels of interest for adoption.

Limitations

This study used a convenience sample of individuals from a mental health program in an urban academic ambulatory hospital that predominantly serves adult female patients, and employs psychiatrists and psychotherapists of varying training backgrounds. We feel that many of our results are generalizable to adult outpatient settings, but our population is unique and the types of barriers endorsed by respondents may not be the same in other programs. Barriers to office-based care, however, are likely to also be prevalent in outpatient clinics that serve a patient population consisting of young parents, and patients

engaged in vocational activities. Additionally, the predominant age range in our survey was young and middle-aged adults, so findings may not be generalizable to youth or older adults. We did not collect gender data in our survey, partly because our program is so gender biased toward women, but also because gender has not been shown to be associated with e-technology use or interest in mental health and general health care settings [9,12]. Although we did receive a range of responses, it is possible that some individuals may have been more willing to participate than others. Online survey completion was especially self-guided, whereas hard copies were distributed to some patients by our administrative staff. Although we actually designed this as a Web-based survey, a very small number of respondents completed it online. None of the survey questions were mandatory and, as a result, there were missing data in some questionnaire domains. Finally, the *e-communication score* and *motivation variable* were summary and composite variables, respectively, created by the authors based on the data available and should be interpreted as such.

Conclusions

E-technology for patient communication is becoming heavily integrated in health care [17,18]. The rapid rate at which mobile technologies are advancing with the potential to link patient and provider [4,13,18] requires some caution, alongside appropriate evaluation and implementation. We have shown that there may be early willing adopters with barriers to office-based care, already actively on social media, who would be good target groups for new e-communication tools to inform implementation more widely. The decision to use e-communication with an individual patient still needs to be part of the treatment assessment and plan. Where barriers to attending office-based care exist, e-communication has the potential to facilitate appropriate follow-up and treatment adherence. It is imperative to address patient concerns and ensure access to equitable services for patients who may not want to utilize e-communication. Assessing and responding to patient concerns about privacy or loss of in-person contact will be based on the type of e-communication being offered and the platform being used. In our institution, as elsewhere, privacy guidelines for the use of e-technology in health care are frequently being updated to align with local policies and legislation. A demonstration of the technology and assurance that traditional care is still available could increase likelihood of uptake among uncertain individuals. With more emerging research to inform recommendations regarding the use of e-communication tools in mental health [3,13], it will hopefully become more clear when, how, and for whom e-communication and mobile technology should be "prescribed."

Conflicts of Interest

None declared.

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Abbreviations

SMS: short message service
WCH: Women's College Hospital
WMHP: Women's College Hospital Mental Health Program

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<u>Original Paper</u>

Home-Based Psychiatric Outpatient Care Through Videoconferencing for Depression: A Randomized Controlled Follow-Up Trial

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Abstract

Background: There is a tremendous opportunity for innovative mental health care solutions such as psychiatric care through videoconferencing to increase the number of people who have access to quality care. However, studies are needed to generate empirical evidence on the use of psychiatric outpatient care via videoconferencing, particularly in low- and middle-income countries and clinically unsupervised settings.

Objective: The objective of this study was to evaluate the effectiveness and feasibility of home-based treatment for mild depression through psychiatric consultations via videoconferencing.

Methods: A randomized controlled trial with a 6- and 12-month follow-up including adults with mild depression treated in an ambulatory setting was conducted. In total, 107 participants were randomly allocated to the videoconferencing intervention group (n=53) or the face-to-face group (F2F; n=54). The groups did not differ with respect to demographic characteristics at baseline. The F2F group completed monthly follow-up consultations in person. The videoconferencing group received monthly follow-up consultations with a psychiatrist through videoconferencing at home. At baseline and after 6 and 12 months, in-person assessments were conducted with all participants. Clinical outcomes (severity of depression, mental health status, medication course, and relapses), satisfaction with treatment, therapeutic relationship, treatment adherence (appointment compliance and dropouts), and medication adherence were assessed.

Results: The severity of depression decreased significantly over the 12-month follow-up in both the groups. There was a significant difference between groups regarding treatment outcomes throughout the follow-up period, with better results in the videoconferencing group. There were 4 relapses in the F2F group and only 1 in the videoconferencing group. No significant differences between groups regarding mental health status, satisfaction with treatment, therapeutic relationship, treatment adherence, or medication compliance were found. However, after 6 months, the rate of dropouts was significantly higher in the F2F group (18.5% vs 5.7% in the videoconferencing group, P<.05).

Conclusions: Psychiatric treatment through videoconferencing in clinically unsupervised settings can be considered feasible and as effective as standard care (in-person treatment) for depressed outpatients with respect to clinical outcomes, patient satisfaction, therapeutic relationship, treatment adherence, and medication compliance. These results indicate the potential of telepsychiatry to extend access to psychiatric care to remote and underserved populations.

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Introduction

Depression affects approximately 350 million people worldwide and is the leading cause of disability, a major cause of morbidity, and thus a significant contributor to the global burden of disease at the social, economic, and clinical levels [1].

Antidepressant drugs and brief psychotherapy are effective, feasible and very cost-effective treatments for depression in primary health care settings [2]. However, less than half of those affected receive the care and support they need due to limited access to existing mental health care services [1]. The most common barriers include a lack of resources, the centralization of services in and near large cities and large institutions, low numbers of trained health care providers, inaccurate assessments, and social stigma [3]. The treatment gap is consistently worse in Low and Middle Income Countries (LMIC), where sometimes less than 10% of people in need receive treatment [1].

Information and communication technologies, such as mobile phones, apps and desktop software, and the Internet are able to overcome these barriers and reach a wide geographic area via remote delivery of care, thus expanding the reach of high-quality mental health care to patients who are otherwise unable to access it because of geographic location, transportation costs, or incapacitation due to serious physical or mental illness [4].

As verbal information and visual cues are the major and primary components of psychiatric treatment, the use of information and communication technologies such as live interactive videoconferencing is particularly well suited to psychiatric care. Unsurprisingly, the use of this technology in the field of psychiatry is over half a century old. In 1955, the first consultations via videoconferencing were conducted using a closed-circuit television system to transmit live therapy and education sessions via a macrowave link [5]. Due to technological advances in recent years and the tremendous global increase in Internet access and use of communication devices, including in remote and rural regions in LMIC—for example, with 108 million Internet users (53% of the population) in 2014, Brazil ranked fifth globally in the number of Internet users (behind China, the United States, India, and Japan) [6]—the provision of psychiatric treatment via videoconferencing, frequently called telepsychiatry, has become a viable method of delivering mental health care. Thus, telemental health services have been implemented around the world and are considered effective for the diagnosis and assessment of disorders in many populations (adult, child, geriatric, and different ethnicities) in many settings (emergency, home health), are comparable to in-person care, and complement other services in primary care [7].

According to the American Psychiatric Association, telepsychiatry is currently one of the most promising ways to increase access to psychiatric care for individuals living in underserved areas [8]. However, the number of randomized clinical trials is limited, and further studies are needed to generate empirical evidence for the large-scale use of psychiatric outpatient care via videoconferencing in high-, middle-, and low-income countries in clinically supervised and unsupervised (home-based) settings.

This study aims to verify the effectiveness and feasibility of a home-based treatment for mild depression through psychiatric consultations via videoconferencing.

Methods

Study Design and Setting

The study was designed as a parallel group, randomized controlled follow-up trial. With an allocation ratio of 1:1, outpatients were individually randomized to 2 different treatment conditions. Under the treatment as usual condition, participants underwent monthly face-to-face (F2F) consultations with their psychiatrists at the Institute of Psychiatry of the University of São Paulo Medical School. In the intervention condition, participants performed monthly home-based consultations with their psychiatrists using live interactive videoconferencing.

Participants

To provide 80% power (5% level of significance) and assuming a medium effect size of 0.25 and a loss to follow-up of 25% after 12 months, the target sample size was 104 participants [9].

Participants were recruited at the Institute of Psychiatry (IPq) of the University of São Paulo Medical School and through public and social media announcements between May 2012 and April 2014. Interested individuals were prescreened by email to verify their place of residence, age, Internet access, and preexisting diagnoses or past psychiatric history. The Patient Health Questionnaire (PHQ-9) was used to screen for depression and to assess the severity of depression [10].

Individuals who lived in São Paulo and the surrounding areas, were between the ages of 18 and 55 years, had broadband Internet access at home, and showed symptoms of depression (PHQ-9 ≥ 5) were assessed for eligibility. On the basis of at least 2 in-person screening consultations, a diagnosis of depression was established with the Mini International Neuropsychiatric Interview [11], medication treatment was initiated, and the degree of depression was established using the Hamilton Depression Rating Scale (HDRS) (Table 1) [12]. Those with a total score less than 17 on the HDRS were considered mildly depressed and thus able to be randomized [13]. Individuals were not randomized if they: (1) did not meet

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the aforementioned inclusion criteria, (2) missed the second screening consultation, (3) showed an increased risk of suicide, or (4) refused treatment (Table 1).

The allocation of participants to the treatment conditions (1:1) was conducted following a previously prepared randomization list in Excel. Fifty-three patients were randomized to the videoconferencing group and 54 to the F2F group. After 6 months, 3 patients in the videoconferencing group and 10

patients in the F2F group discontinued treatment. A total of 22 patients (8 in the videoconferencing group and 14 in the F2F group) were lost at second follow-up (Figure 1).

Discontinuation of treatment occurred if participants were fully remitted, missed 3 consultations in a row, had a relapse (HDRS > 17), needed additional care, or showed an elevated suicide risk. Even if they were excluded from the study, they continued receiving psychiatric treatment at the IPq.

Figure 1. Sample flow diagram.
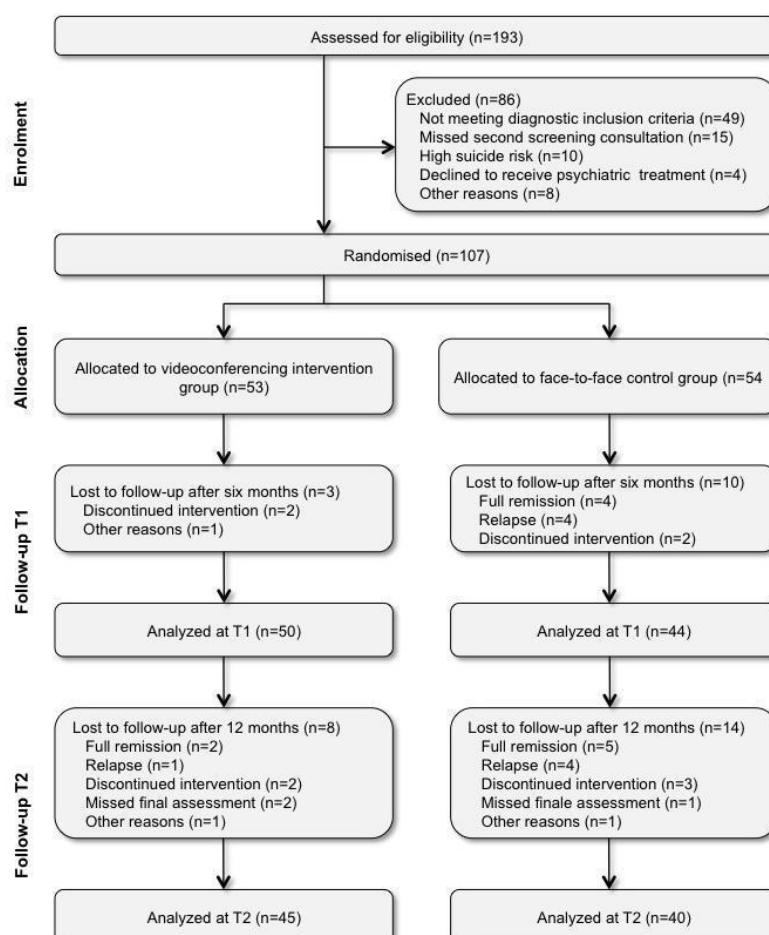
Intervention

All participants in both the groups concluded an in-person consultation at the beginning of the study (baseline), after 6 months (first follow-up) and after 12 months (second follow-up). In between those consultations, the control group received monthly psychiatric consultations in person at the psychiatric hospital, whereas the participants in the videoconferencing group underwent 5 home-based video consultations (once a month). Whereas patients in the F2F group received their medication right after each in-person consultation at the IPq, the medications for the patients treated via videoconferencing were delivered to the patient's home.

The consultations and medication treatment decisions were individualized and determined by 7 psychiatrists with an average of 13 years of professional experiences who were trained in implementing consultations via videoconferencing and willing to deliver treatment in both conditions. Thus, all involved

psychiatrists treated patients under both conditions. The consultations took approximately 20 minutes and included psychoeducation, medication monitoring, and counseling. During the entire study period, the participants were cared for by the same psychiatrist who conducted their initial screening consultation. Videoconferencing consultations were performed using the software Skype (Microsoft, Redmond, WA).

Data Collection and Outcome Measures

At baseline and after 6 and 12 months, an in-person follow-up consultation was conducted with all participants, during which the severity of depression was assessed by the psychiatrists using the HDRS-17. After the consultation, the participants completed an automatically generated Web-based questionnaire that measured mental health status, satisfaction with treatment, therapeutic relationship, and medication compliance. The Web-based questionnaire was provided by the Web-based survey platform SurveyMonkey [14]. The responses were sent over a

secure, Secure Sockets Layer–encrypted connection. The account was HIPAA-compliant and protected with a password. Only the study coordinator was allowed to access and export the collected data; the psychiatrists were blind to the ratings.

The clinical outcomes of this study were the severity of depression and self-reported mental health status, measured by the Mental Health Inventory (MHI-38) [15] and the number of relapses and medication history.

Additional outcome measures included treatment adherence, validated by the number of missed appointments and dropouts, medication compliance, satisfaction with treatment, and working alliance, measured by the following self-reported instruments: Morisky Medication Adherence Scale (MMAS-4) [16], Client Satisfaction Questionnaire (CSQ-8) [17], and the short version of the Working Alliance Inventory (WAI-S) [18].

Statistical Analyses

Descriptive results—mean (SD)—of the demographic characteristics and the total outcomes scores at baseline and first and second follow-up (with 95% CI) are presented for each treatment group and were compared between groups (treatment effect) using t-tests, Wilcoxon–Mann–Whitney tests or Fisher's exact tests.

To analyze changes over time in each group (time effect), one-way analysis of variance (ANOVA) was calculated for each outcome measure. To compare changes over time in the outcome measures between the F2F and videoconferencing group (treatment × time effect), repeated-measures ANOVA with a group–time interaction was performed. All statistical analyses were conducted using SPSS software, version 21.0 (IBM Corp.).

Ethical Considerations

The trial protocol was approved by the local ethics committee and registered at clinicalTrials.gov (identifier NCT01901315). The study was conducted at a single location at the Institute of Psychiatry of the University of São Paulo Medical School. Written consent was obtained from all participants before randomization.

Results

Baseline Participant Characteristics

The treatment groups did not significantly differ in demographic characteristics (Table 1). Most of the participants were taking antidepressants (98%) within the recommended dosages, sometimes combined with anxiolytics and sedatives (40%). The most prescribed antidepressant was sertraline (34%-45%), followed by fluoxetine (18%-27%) and venlafaxine (14%-24%). No group differences were found regarding the type and dosage of medication at baseline.

On average, participants spent 3 hours traveling from their residence to the psychiatric hospital and back. This did not include waiting time at the hospital and the consultation itself. The groups were balanced regarding time spent on traveling. To attend a consultation via videoconferencing, the participants spent, on average, 30 minutes.

The groups were not balanced with regard to the severity of depression (mean F2F group score: 6.19 (3.61); mean videoconferencing group score: 7.92 (3.59); P=.01) or mental health status (mean F2F group score: 132.89 (25.49); mean videoconferencing group score: 121.25 (26.19); P=.02) at baseline. That is to say, the videoconferencing group showed significantly higher levels of depression and lower levels regarding mental health status than the F2F group at baseline.

Table 1. Baseline characteristics of participants in each treatment arm.

Baseline Variables	Total (n=107)	VC[a](n=53)	F2F[b](n=54)
Age, mean (SD[c]), year	35.64 ± 8.33	35.42 ± 8.18	35.87 ± 8.53
Female (%)	76 (71.0%)	39 (73.6%)	37 (68.5%)
Brazilian (%)	103 (96.3%)	52 (98.1%)	51 (94.4%)
Marital Status (No., %)			
Single	58 (54.2%)	25 (47.2%)	33 (61.1%)
Married	34 (31.8%)	22 (41.5%)	12 (22.2%)
Divorced	13 (12.1%)	5 (9.4%)	8 (14.9%)
Widowed	2 (1.9%)	1 (1.9%)	1 (1.9%)
Education (No., %)			
Primary	2 (1.9%)	0 (0.0%)	2 (3.7%)
Secondary	30 (28.0%)	14 (26.4%)	16 (29.6%)
Higher	75 (70.1%)	39 (73.6%)	36 (66.7%)
Working situation (No., %)			
Student/Homemaker	13 (12.1%)	6 (11.3%)	3 (5.7%)
Employed	67 (62.6%)	32 (60.4%)	35 (66.0%)
Unemployed	24 (22.4%)	11 (20.8%)	12 (22.6%)
Retired	1 (0.9%)	0 (0.0%)	1 (1.9%)
Other	10 (9.3%)	4 (7.5%)	2 (3.8%)
Severity of depression, mean (SD)	7.05 ± 3.69	7.92 ± 3.59	6.19 ± 3.61
Mental health status, mean (SD)	127.12 ± 26.37	121.25 ± 26.19	132.89 ± 25.49
Medication – multiple choices; No. (%)			
Antidepressants	105 (98.1%)	52 (98.1%)	53 (98.1%)
Tranquilizers	29 (27.1%)	13 (24.5%)	16 (26.6%)
Mood stabilizers	2 (1.8%)	1 (1.9%)	1 (1.9%)
Antipsychotics	1 (0.9%)	1 (1.9%)	0 (0%)
Other	7 (6.5%)	2 (3.8%)	5 (9.4%)

[a] VC: Videoconferencing.

[b] F2F: Face-to-face.

[c] SD: standard deviation

Outcome Measures

Within the 35-month period of study, a total of 950 consultations were delivered (489 via videoconferencing and 461 F2F), and 286 assessments were conducted. The follow-up data are summarized in Table 2.

There were no differences in demographic variables, severity of depression, or mental health status at baseline between those who dropped out and those who did not.

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Table 2. Unadjusted mean scores and standard deviations of outcome measures.

Measure by Time Point	Score					
	VC[a]		F2F[b]		Total	
	Mean (SD)	No.	Mean (SD)	No.	Mean (SD)	No.
HDRS[c]						
Baseline	7.92 (3.59)	53	6.19 (3.60)	54	7.05 (3.69)	107
Follow-up: 6 months	4.65 (4.13)	49	3.90 (3.88)	42	4.31 (4.01)	91
Follow-up: 12 months	3.42 (3.58)	45	4.45 (4.13)	40	3.90 (3.86)	85
MHI[d]						
Baseline	121.25 (26.19)	53	132.89 (25.49)	54	127.12 (26.37)	107
Follow-up: 6 months	123.98 (27.56)	50	117.09 (25.54)	44	120.76 (26.72)	94
Follow-up: 12 months	137.71 (28.88)	45	143.32 (25.07)	40	140.35 (27.14)	85
CSQ[e]						
Baseline	27.66 (2.82)	53	28.43(2.61)	54	28.05 (2.73)	107
Follow-up: 6 months	28.24 (3.06)	50	29.45 (2.21)	44	28.81 (2.75)	94
Follow-up: 12 months	27.91 (3.76)	45	29.35 (2.48)	40	28.59 (3.28)	85
WAI[f]						
Baseline	68.90 (12.56)	52	72.11 (10.26)	54	70.54 (11.50)	106
Follow-up: 6 months	63.52 (8.86)	50	64.93 (8.95)	44	64.18 (8.88)	94
Follow-up: 12 months	70.78 (11.96)	45	73.41 (9.18)	39	72.00 (10.78)	84

[a] VC: videoconferencing.

[b] F2F: face-to-face.

[c] HDRS: Hamilton Depression Rating Scale.

[d] MHI: Mental Health Inventory.

[e] CSQ: Client Satisfaction Questionnaire.

[f] **WAI: Working** Alliance Inventory.

Clinical Outcomes

At 6 and 12 months, the initial group differences with respect to severity of depression and mental health status were no longer significant. Each group showed a significant decrease in the severity of depression (videoconferencing: $F_2 = 26.57$, $P<.001$; F2F: $F_2 = 29.99$, $P<.001$) and a significant increase in mental health status (videoconferencing: $F_{1.426} = 4.86$, $P=.02$; F2F: $F_{1.437} = 9.17$, $P=.001$) over the study period. The repeated-measures ANOVA showed a statistically significant interaction between treatment and time regarding the severity of depression ($F_2 = 6.12$, $P=.003$). The estimated partial-$\eta2$ for the interaction of time and treatment was 0.24.

Most of the participants continued taking antidepressants at 6 (95%) and 12 months (79%) within the recommended dosages, combined with sedatives (40%). No group differences were found with respect to the type and dosage of medication at the 6- and 12-month follow-up.

Five participants were excluded because they relapsed (scored higher than 17 on the HDRS); 4 in the F2F and 1 in the videoconferencing group.

Treatment Adherence and Medication Compliance

The dropouts did not differ significantly from the completers in demographic variables, degree of depression, or mental health status at baseline.

At 6 months, there were significantly more dropouts in the F2F group (n=10) than in the videoconferencing group (n=3; $X^2_1 = 4.143$, $P=.04$). At 12 months, there were still more dropouts in the F2F group (n=14) than in the videoconferencing group (n=8), but the difference was no longer significant.

Moreover, participants in the F2F group also tended to miss more appointments than participants in the videoconferencing group ($F_{105} = 0.753$, $P=.06$).

On average, 30% of the participants were adherent to their medication. There were no significant group differences regarding medication compliance at 6 and 12 months between the 2 groups. Participants in the F2F group tended to be more adherent than participants in the videoconferencing group at 12 months ($X^2_1 = 2.864$, $P=.07$).

Satisfaction With Treatment

There were no significant differences between treatment conditions with respect to satisfaction of the participant at 6 and 12 months. Overall, satisfaction significantly increased during the first 6 months among the whole sample (Z=−2.031, *P*=.04) and remained stable until the end of the study. There were no significant changes in satisfaction over the entire study period, and the repeated-measures ANOVA did not show a significant interaction between treatment condition and time.

Working Alliance

Similar to satisfaction, there were no group differences with respect to working alliance at either of the follow-ups. Both the groups showed a significant increase in working alliance during the 12 months of treatment (videoconferencing: $F_2 = 11.11$, *P*<.001; F2F: $F_2 = 29.23$, *P*<.001). There were no significant differences between groups regarding changes in the Working Alliance Inventory scores (repeated-measures ANOVA).

Discussion

Principal Findings

This study constitutes the first randomized clinical trial to evaluate the effectiveness and feasibility of home-based general psychiatric outpatient care via videoconferencing.

The implementation of the study was rigorously controlled, including sample size calculations, the use of standardized assessment instruments, monitoring of treatment and medication delivery, follow-up assessments up to 12 months, and a high participant adherence (79% completed 1 year of treatment).

The results are mostly in line with previous studies in clinically supervised settings, which compared F2F with videoconferencing treatment among patients with different psychiatric diagnoses. Most of those studies also did not find any significant differences regarding clinical outcomes between the 2 treatment conditions, measured by symptom severity, medication history, duration of inpatient treatment, mental health status, global functioning, or neuropsychological outcomes [19-27]. Self-reported satisfaction with treatment [21,23,27-29] and treatment adherence—assessed in terms of compliance, dropout rates, number of appointments kept, and pill counts [23,25]—were also comparable between F2F and videoconferencing psychiatric treatments.

Moreover, patients in the videoconferencing group were able to establish an equivalent therapeutic relationship as those treated in person in this study. This was also shown in a study with male inmates suffering from different psychiatric disorders [21].

However, in this study, the improvement in severity of depression was even greater among participants treated via videoconferencing. Two previous studies including depressed low-income Hispanic participants also found that psychiatric consultations via videoconferencing generated better clinical outcomes than usual (in person) care [25,30]. However, it has to be considered that in this study, the videoconferencing group started with a significantly higher score on the HDRS and thus had a greater potential to decrease. Moreover, the differences between groups, even at baseline, were only between 1 and 2 points; however, given the low HDRS total scores at 6 and 12 months (< 5), this difference has limited clinical relevance.

Another noteworthy result was the significantly lower dropout rate in the videoconferencing group after 6 months. Most of the participants travelled up to 3 hours to attend an in-person consultation at the psychiatric hospital. This typical long travel time is due to traffic and the limited public transportation system in São Paulo, and thus, the considerable time saved among patients treated by videoconferencing could be an explanation of the higher dropout rate in the F2F group.

Limitations

A major strength of this study was that it was conducted in a setting in which telepsychiatry is most likely to be used. However, the individualized treatment and thus the naturalistic nature of the service also produced limitations regarding the replicability and comparability of the results.

Another strength and, at the same time, limitation of the study was that all psychiatrists delivered F2F and videoconferencing consultations. The psychiatrists were instructed to provide the same type and level of service to patients seen in person and through videoconferencing. Nevertheless, a bias in terms of psychiatrist's favoring one method over another could have influenced the findings.

Moreover, there are advantages and disadvantages to using Skype in clinical settings. The advantages are its familiarity and ease of access; the disadvantages are security concerns. However, Skype uses a 256-bit encryption, which meets the Advanced Encryption Standard specified by the US National Institute of Standard Technology. Furthermore, no firm evidence either in favor of or against the use of Skype for clinical telehealth has been found thus far [31].

Most of the scales used in this study have been translated, adapted, and validated in the Brazilian population [32-35]. For the assessment of satisfaction, the official CSQ in (Brazilian) Portuguese was used [17], which has not been validated yet. Moreover, at the time the study was planned, no adequate scale measuring medication adherence was validated in a Brazilian Portuguese version. However, a translated version in Brazilian Portuguese of the MMAS-8 [16] scale was available, and thus, a short form was created based on this translation [36].

Another limitation of this study is that there was no intention-to-treat analysis. However, if a subject who actually did not receive the same or any treatment is included as a subject who received the whole treatment, then the results indicate very little about the efficacy of the treatment [37].

Conclusion

Based on the findings, psychiatric consultations via videoconferencing can be considered applicable for the home-based treatment of mildly depressed patients and as effective as F2F treatment with respect to clinical outcomes, treatment adherence, medication compliance, satisfaction, and working alliance.

Despite being largely successful elsewhere, telepsychiatry has yet to make its mark in LMIC of the developing world [38]. This study demonstrates the successful implementation and evaluation of treatment delivery for this population in a resource-limited setting. Moreover, it shows that home-based mental health care has the potential to provide effective treatment to many individuals who may not otherwise seek help, due to geographic or economic barriers or perceived stigma of receiving mental health treatment.

Further randomized clinical studies are needed to provide empirical evidence on the feasibility and treatment efficacy over time of large-scale, sustainable psychiatric outpatient care. The integration of videoconferencing as a routine component of psychiatric care would benefit patients through increased access to needed treatment and would thus help reduce the treatment gap in LMIC and in many industrialized countries.

Conflicts of Interest

None declared.

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Abbreviations

CSQ: Client Satisfaction Questionnaire
F2F: face-to-face
HDRS: Hamilton Depression Rating Scale
HIPAA: Health Insurance Portability and Accountability Act
IPq: Institute of Psychiatry

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MHI: Mental Health Inventory
PHQ-9: Patient Health Questionnaire
SD: standard deviation

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Original Paper

Who Are the Young People Choosing Web-based Mental Health Support? Findings From the Implementation of Australia's National Web-based Youth Mental Health Service, eheadspace

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Abstract

Background: The adolescent and early adult years are periods of peak prevalence and incidence for most mental disorders. Despite the rapid expansion of Web-based mental health care, and increasing evidence of its effectiveness, there is little research investigating the characteristics of young people who access Web-based mental health care. headspace, Australia's national youth mental health foundation, is ideally placed to explore differences between young people who seek Web-based mental health care and in-person mental health care as it offers both service modes for young people, and collects corresponding data from each service type.

Objective: The objective of this study was to provide a comprehensive profile of young people seeking Web-based mental health care through eheadspace (the headspace Web-based counseling platform), and to compare this with the profile of those accessing help in-person through a headspace center.

Methods: Demographic and clinical presentation data were collected from all eheadspace clients aged 12 to 25 years (the headspace target age range) who received their first counseling session between November 1, 2014 and April 30, 2015 via online chat or email (n=3414). These Web-based clients were compared with all headspace clients aged 12 to 25 who received their first center-based counseling service between October 1, 2014 and March 31, 2015 (n=20,015).

Results: More eheadspace than headspace center clients were female (78.1% compared with 59.1%), and they tended to be older. A higher percentage of eheadspace clients presented with high or very high levels of psychological distress (86.6% compared with 73.2%), but they were at an earlier stage of illness on other indicators of clinical presentation compared with center clients.

Conclusions: The findings of this study suggest that eheadspace is reaching a unique client group who may not otherwise seek help or who might wait longer before seeking help if in-person mental health support was their only option. Web-based support can lead young people to seek help at an earlier stage of illness and appears to be an important component in a stepped continuum of mental health care.

Introduction

The adolescent and early adult years are periods of peak prevalence and incidence for most mental disorders. One in 4 young people will experience a clinically relevant mental health problem within any 12-month period, with 75% of all mental disorders emerging before 25 years of age [1]. These disorders can have a wide range of major adverse effects on a young person's quality of life, impacting relationships with family and friends, educational attainment, and future economic stability [2].

The high prevalence of mental disorder in young people is not matched by a commensurate level of mental health service use. Rather, there is a marked mismatch between the prevalence of disorder and professional help-seeking [3]. In Australia, this mismatch is greatest for 16- to 24-year-old males. The 2007 National Survey of Mental Health and Wellbeing (NSMHW) found that only 13% of males in this age range who had experienced a mental disorder in the previous 12 months sought professional help [4]. Among females, the NSMHW found that 31.2% of the 16 to 24 age bracket who had experienced a mental disorder in the previous 12 months had sought help for a mental disorder [4].

Even for those young people who do seek help, there is often a considerable delay between onset of symptoms and accessing services. This varies according to factors such as type of disorder, gender, population group, and geographical location [5]. Seeking professional help in an appropriate and timely manner can reduce the long-term impact of many mental health difficulties [3], while delays in accessing help have been shown to have a significant impact on social, educational, and vocational outcomes for young people [6].

The monetary costs to the Australian economy associated with untreated mental disorders in young people aged 12 to 25 have been estimated at more than AUD$10.6 billion annually (equivalent to US$8.6 billion) [7], due to costs associated with unemployment, absenteeism, and welfare payments [8]. The World Economic Forum expects that costs of mental illness will double over the next 20 years worldwide [9], which highlights the need to develop and implement services and approaches that can effectively engage young people in appropriate and timely help-seeking [10].

The reasons young people do not access mental health services in accordance with their level of need are complex. They include: stigma (which includes embarrassment and concern about what others think); negative attitudes to and poor past experiences of treatment; problems recognizing symptoms; lack of awareness of available services; confidentiality concerns; and a preference for self-reliance or drawing on nonprofessional support through family or friends [11]. In addition to these personal factors, a number of structural barriers exist, including location, cost, and availability of services [12].

Given these substantial barriers to seeking help in-person, it is not surprising that many young people, including those with a probable serious mental illness, are turning to the Internet for information about mental health issues [13]. The Internet is an appealing alternative to traditional in-person services due to its accessibility, interactivity, and anonymity; it offers a wide variety of health information that is not impacted by structural constraints [14].

In response to demand for Web-based mental health information and support, and in order to address barriers associated with in-person help-seeking, Web-based options are rapidly being developed to enable young people to access information, support, and mental health interventions via communication technologies [15]. The effectiveness of Web-based counseling is a growing research area. A systematic review found that Web-based counseling was effective, despite the absence of face-to-face cues and often slow pace of sessions [16]. Young people report feeling safe and less emotionally exposed using Web-based counseling compared with in-person or telephone counseling [17]. There is also evidence to suggest that Web-based counseling can result in a similar level of impact [18], client satisfaction, and therapeutic alliance [19] compared with counseling conducted in-person.

There has been a concerted effort in Australia to make mental health counseling widely available and accessible to young people. In 2006, the Australian Federal Government established headspace, the National Youth Mental Health Foundation [20]–an enhanced primary care model for youth mental health care [21]. headspace centers have been progressively rolled out across Australia, and will soon reach 100 centers nation-wide. These centers are designed to break down common barriers to help-seeking and enable young people early access to in-person mental health counseling and support.

To extend the reach of headspace and further enable access for young people who do not live near a headspace center or do not want to visit one in person, eheadspace [22] was developed as a clinically supervised, youth-friendly, confidential, and free Web-based mental health support and information service. eheadspace commenced as a pilot in July 2010 and was rolled out nationally in July 2011. It offers synchronous online chat, asynchronous email, and telephone-based mental health counseling to young people aged 12 to 25 Australia-wide.

Despite the rapid expansion of Web-based mental health care options, supporting evidence is still emerging and there is little research investigating the characteristics of young people accessing Web-based counseling. The current study addresses this gap by presenting the first comprehensive profile of young people who access Web-based counseling (via eheadspace) and comparing them with those who access in-person counseling (via headspace centers). headspace is ideally placed to explore differences between Web-based and in-person clients as it offers both service modes and collects corresponding data from young people accessing each service type.

Methods

Participants and Procedure

Participants were all eheadspace clients aged 12 to 25 years (the headspace target age range) who received their first counseling session during the 6-month period November 1, 2014 to April 30, 2015 via online chat or email (n=3414). Clients who received

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their first counseling session via the phone were not included given the focus of this study is young people who choose to seek Web-based help.

These Web-based clients were compared with all headspace clients aged 12 to 25 who received their first center-based counseling session in a similar 6-month period (October 1, 2014 to March 31, 2015) (n=20,015 clients from across 81 centers). headspace center clients have previously been described in Rickwood et al [21].

headspace implements a minimum dataset across centers and eheadspace. Part of the minimum dataset is completed by the young person accessing counseling, while another section is completed by their service provider. While data items are completed at every occasion of service, this study examines first-time data recorded at initial presentation.

The data from both young people and service providers are collected via electronic forms. Data are de-identified via encryption and extracted to the headspace national office data warehouse. All headspace clients (eheadspace and center), agree to various terms and conditions including that the data they provide are used at an aggregate level to evaluate, report on, and improve headspace services.

Ethics approval was obtained through quality assurance processes, comprising initial consideration and approval by the headspace Clinical, Research, and Evaluation Committee, and subsequent consideration and approval by the headspace Board of Directors. The consent processes were reviewed and endorsed by an independent body, Australasian Human Research Ethics Consultancy Services.

Measures

Demographic measures reported comprise: age in years; gender; Aboriginal and Torres Strait Islander background; country of birth; living situation; location; and work and study situation. Client clinical presentation was measured by self-reported reason for presentation, level of psychological distress as measured by the 10-item Kessler Psychological Distress Scale (K10) [23], and days out of role [24]. Service provider–rated items include: stage of illness using the categories of no mental disorder, mild to moderate symptoms, subthreshold symptoms not reaching full diagnosis, diagnosed disorder, periods of remission, or serious and ongoing disorder without periods of remission [25]; and overall functioning using the Social and Occupational Functioning Assessment Scale [26].

Analyses

Descriptive statistics are presented, primarily percentages of young people according to presenting characteristics by mode of service (eheadspace vs centers). National population data comparisons are provided, where available. Pearson's chi-square tests of contingencies were undertaken to explore whether being an eheadspace compared with a headspace center client was associated with presenting characteristics. Effect sizes are reported as Phi or Cramer's *V*, with magnitude based on Cohen [27].

Results

Demographic Characteristics

Table 1 provides information about demographic characteristics of eheadspace and center clients, and where possible national data are provided as a comparison. More eheadspace than headspace center clients were female, and more eheadspace than headspace center clients were transgender, transsexual, intersex, or another gender. In contrast, more than one-third of center clients were male compared with less than one-fifth of eheadspace clients. The association between gender and type of service (eheadspace or headspace center) was significant (χ^2_1=598.7, $P<.001$), but quite small, Cramer's *V*=.17.

The peak age of presentation for eheadspace was the same as that for centers (15-17 years of age). Slightly more eheadspace clients than center clients were in the 15 to 17 and 18 to 20 age brackets. Much fewer eheadspace than center clients were aged 12 to 14, while more eheadspace than center clients were aged 21 to 25. The association between age and type of service was significant (χ^2_1=317.5, $P<.001$), but small, Cramer's *V*=.12.

A lower percentage of eheadspace than center clients identified as Aboriginal or Torres Strait Islander; the association was significant (χ^2_1=123.4, $P<.001$), but small, $\phi = .08$. A higher percentage of eheadspace than center clients reported that they were born outside Australia, and the association was significant (χ^2_1=24.2, $P<.001$), but very small, $\phi = .03$. In line with population trends, the most common places of birth outside Australia for both eheadspace and center clients were in the United Kingdom and New Zealand. There were 96% of eheadspace clients who reported that they did not speak a language other than English at home. This compares with 92.8% of center clients and 80.3% of the general population aged over 5 years [31]. The association between language spoken at home (English or not English) and type of service was significant (χ^2_1=56.5, $P<.001$), but very small, $\phi = .05$.

The location of eheadspace clients according to the 2011 edition of the Australian Statistical Geography Standard was largely in line with the location of the Australian population as estimated in 2014 [32]. More eheadspace than center clients were from major cities and outer regional areas and fewer were from inner regional and remote areas. The location of center clients is dependent on the location of centers as most clients live within 10 km of the center they attend [29]. The association between location and type of service was significant (χ^2_1=58.2, $P<.001$), but small, Cramer's *V*=.05.

More eheadspace than headspace center clients indicated that they had stable accommodation. A slightly lower percentage of eheadspace than center clients reported that accommodation was an issue, they were at risk of being homeless, or that they were currently homeless. This compares with 2011 Census estimates that 0.7% of the Australian population aged 12 to 24 years were homeless or in marginal housing [33]. The association between living situation (in stable accommodation or not in stable accommodation) and type of service was

significant (χ^2_1=2002.0, P<.001), and of medium strength, ϕ = .31.

A higher percentage of eheadspace than center clients indicated that they were currently at school (55.2% compared with 49.3%), while a similar percentage of eheadspace and center clients indicated they were currently engaged in higher education (18.3% compared with 18.8%). The association between education level (at school or in higher education) and type of service was significant (χ^2_1=7.4, P=.006), but very small, ϕ = .02. Among those aged 18 to 25 years, a lower percentage of eheadspace than center clients were not engaged in employment, education, or training. The association between not working or studying and type of service was significant (χ^2_1=105.9, P<.001), but small, ϕ = .10.

Table 1. Demographic characteristics of eheadspace and headspace center clients with national comparison data.

Demographic characteristics	eheadspace (%)	headspace centers (%)	National (%)
Gender			
Female	78.1	59.1	48.7[a]
Male	18.9	39.9	51.3[a]
Transgender, transsexual, intersex, or another gender	3.0	1.0	Not available
Age group			
12-14	10.2	23.6	31.2 (10-14)[a]
15-17	36.8	33.1	
18-20	28.8	22.9	32.4 (15-19)[a]
21-25	24.2	20.4	36.4 (20-24)[a]
Aboriginal/Torres Strait Islander	3.2	8.8	3.7[b]
Born outside Australia	10.3	7.8	17.0[c]
Only speak English at home	96.0	92.8	80.3[d]
Location			
Major city	70.2	65.1	70.9[e]
Inner regional	21.4	26.3	18.1[e]
Outer regional	7.5	6.7	8.8[e]
Remote or very remote	0.9	1.9	2.2[e]
Living situation			
Stable	90.4	89.1	Not available
An issue	8.4	8.8	Not available
At risk	1.1	1.6	Not available
Homeless	0.1	0.5	0.7[f]
Not engaged in education, employment, or training	15.6[g]	27.2[g]	27.3[h]

[a]10-24 years [28].

[b]12-25 years [29].

[c]10-24 years [30].

[d]5 years and older [31].

[e]All ages [32].

[f]12-24 years [33].

[g]18-25 years.

[h]17-24 years [34].

Table 2. Clinical presentation characteristics of eheadspace and headspace center clients.

Presenting characteristics	eheadspace (%)	headspace centers (%)
Reason for contact		
Problems with how they felt	79.3	75.9
Relationship problems	13.6	11.0
Physical health issues	1.6	2.1
School or work problems	3.6	7.8
Alcohol or other drug problems	1.6	2.4
Vocational concerns/assistance	0.3	0.8
High/very high psychological distress	86.6	73.2
Stage of illness		
No mental disorder	27.5	15.7
Mild/moderate symptoms	53.1	43.0
Subthreshold	13.8	19.1
Threshold diagnosis	4.9	16.3
Remission	0.5	1.4
Serious, ongoing	0.2	4.5
Not previously seen by a mental health professional	46.4	44.1
Days out of role		
None	34.7	41.2
1-3 days	30.0	26.3
4-6 days	15.3	13.1
7-9 days	14.9	5.6
10+ days	5.1	13.8
Serious or major impairment in functioning	5.0	11.7

Clinical Presentation Characteristics

Table 2 provides information about the clinical presentation characteristics of eheadspace and center clients. Approximately three-quarters of both eheadspace and center clients indicated that their primary reason for seeking help was regarding problems with how they felt. Specifically, 45.3% of eheadspace clients indicated that they were feeling sad or depressed, and 15.3% indicated that they were feeling anxious.

The second most reported reason for seeking help (for both eheadspace and center clients) was for relationship problems. Fewer eheadspace than center clients indicated that their primary reason for seeking help was physical health issues, school/work problems, alcohol or other drug problems, or vocational concerns. The association between reason for contact and type of service was significant (χ^2_1=2619.7, P<.001), and of medium strength, Cramer's V=.37.

Across both services the majority of clients presented with high or very high levels of psychological distress, although the percentage of eheadspace clients was higher than the percentage of center clients. Comparatively, the 2007 NSMHW data [4] indicated that 9% of those in the general community, and 21% of young people diagnosed with a mental disorder, aged 16 to

24 had high or very high levels of psychological distress. The association between psychological distress and type of service was significant (χ^2_1=3277.1, P<.001), and of medium strength, ϕ = .40.

Figure 1 displays the percentage of eheadspace clients that presented with high or very high levels of psychological distress broken down by age and gender while Figure 2 does the same for center clients. As shown, a higher percentage of eheadspace than center clients presented with very high distress–this was the case for both genders and all age groups, particularly 12- to 14-year-old males. For both eheadspace and centers, a higher percentage of females than males reported very high levels of psychological distress across all age brackets.

Stage of illness, as estimated by service providers, indicated that more eheadspace clients than center clients presented without a mental disorder or with mild to moderate symptoms. Fewer eheadspace than center clients presented with subthreshold diagnosis, full-threshold diagnosis, periods of remission, or serious and ongoing mental disorder. Importantly, for 46.1% of eheadspace clients and 16.1% of center clients, clinicians recorded that they did not have enough information available to make an assessment of stage of illness and these clients were excluded from these comparisons. The association

between stage of illness and type of service was significant (χ^2_1=431.7, P<.001), but quite small, Cramer's V=.15.

A higher percentage of eheadspace than center clients reported that they had never seen a mental health professional prior to their eheadspace/center visit. The association between prior help-seeking and type of service was significant (χ^2_1=5.9, P=.015), but small, ϕ = .02. Fewer eheadspace than center clients reported that they had been able to carry out their usual activities every day in the last 2 weeks. More eheadspace than center clients reported that they had 1 to 3, 4 to 6, or 7 to 9 days out of role, and fewer eheadspace than center clients reported they had 10 or more days out of role. The association between

days out of role and type of service was significant (χ^2_1=563.6, P<.001), but quite small, Cramer's V=.17.

Social and vocational functioning scores as assessed by service providers indicated that a lower percentage of eheadspace than center clients experienced serious or major impairment. The association between having a serious or major impairment and type of service was significant (χ^2_1=93.03, P<.001), but small, ϕ = .07. Importantly, for 33.5% of eheadspace clients and 8.3% of center clients, clinicians recorded that they did not have enough information available to make an assessment of social and occupational functioning and these clients were excluded from these comparisons.

Figure 1. Percentage of eheadspace clients at each level of psychological distress, by age group and gender (males and females only).
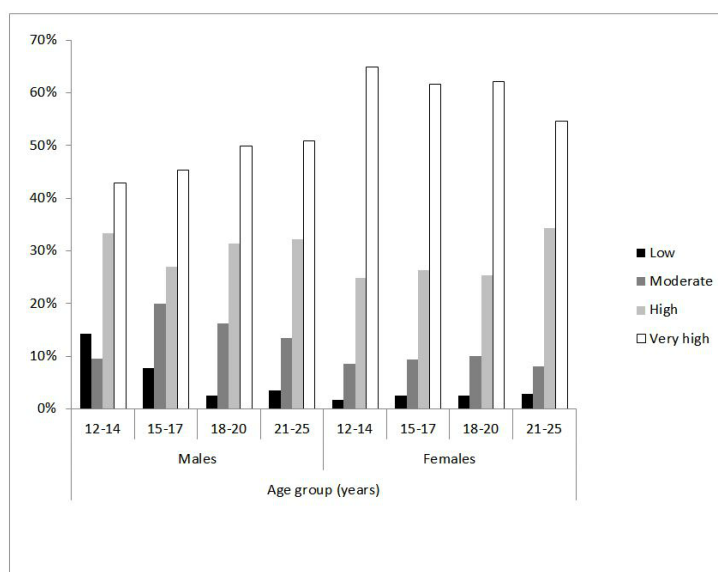
Figure 2. Percentage of headspace center clients at each level of psychological distress, by age group and gender (males and females only).
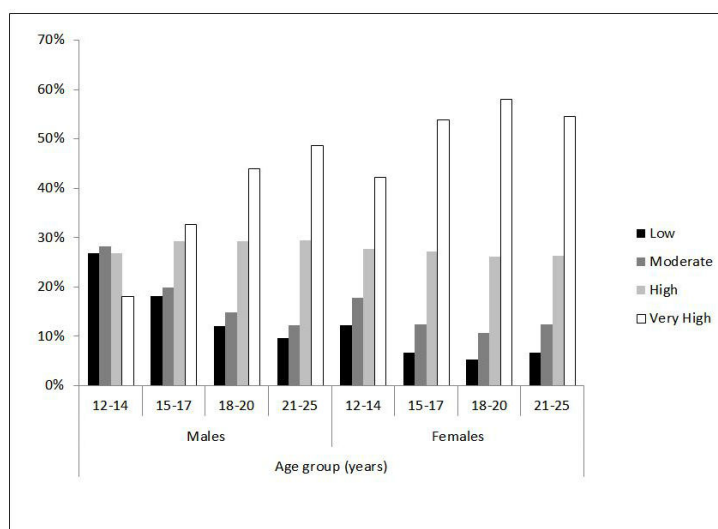
Discussion

Key Results

These are the first data to compare the characteristics of young people seeking Web-based mental health counseling and

in-person mental health counseling through the headspace service system. headspace is specifically designed to break down the barriers to young people accessing mental health support and the same branding and service promotion is applied to both the Web-based and in-person counseling services. While many

similarities were observed between the two groups of clients, important differences were identified.

The most striking finding was the extent of preference by females for Web-based counseling compared with males—close to 80% of the Web-based clients were female. Research from other Web-based services consistently reports a similar gender effect [17,35]. National surveys indicate slightly more females than males experience mental disorder (30% compared with 23%) and that the 16- to 24-year-old age bracket has the highest disparity between females and males in seeking professional help for mental health issues (with females more than twice as likely as males to use services). However, there is clearly something about the Web-based space that particularly appeals to females as opposed to males given the gender disparity for using the Web-based space is even greater. Males were comparatively more likely to access centers, particularly the adolescent males.

In general, males are more likely to be influenced by others, particularly family, to attend mental health services [36], and this personal encouragement may be more effective at getting young men to in-person services. It is also increasingly well established that the initial engagement of young men is challenging, and requires a concerted focus on rapport building, including greater flexibility and choice in how the service is accessed, and service promotion that assertively reaches out into the spaces that young men are likely to inhabit [37]. Such engagement may be easier face-to-face, as good interpersonal communication skills can be effectively applied, by both the family members encouraging young men to seek help and the service providers building rapport. Web-based service use is more dependent on self-motivation, and engagement and rapport take more effort to build via the Internet, which may act against young men's uptake.

For both service types there was the same peak age of presentation at 15 to 17 years, which coincides with the period when the common mental health problems of depression and anxiety develop [1]. The youngest adolescents were less than half as likely to use the Web-based service, however, possibly reflecting more restricted or closely monitored Internet access in the early teen years, as well as greater parental involvement in mental health care [34].

Young people from Aboriginal and Torres Strait Islander backgrounds were less likely to use the Web-based than the in-person service. The percentage of Aboriginal or Torres Strait Islander clients who accessed the in-person service was higher than the percentage of all Australians aged 12 to 25 years who identify as Aboriginal or Torres Strait Islander as indicated in the 2011 census [38]. Young people from culturally and linguistically diverse backgrounds were underrepresented in both service types. headspace has had a health promotion focus on young people who are Aboriginal and Torres Strait Islander through its Yarn Safe campaign [39]. This campaign commenced after the period during which the data for our study were collected. More recent data collected since this campaign indicate an increase in the number of Aboriginal and Torres Strait Islander young people to both centers and eheadspace,

suggesting that targeted promotion to this community is a worthwhile investment [40].

The geographical dispersion of center clients reflects the location of centers, which have been set up across Australia to meet community needs. The external evaluation of headspace centers noted a strong relationship between the use of headspace centers and the distance of the center from a client's home, with the majority of clients living within a 10-km radius [29]. The fact that the distribution of eheadspace clients reflects the general population distribution shows that the Web-based counseling option is equitably accessible throughout Australia, but indicates that greater targeted promotion may be required in regional and remote areas.

The psychological distress results reveal that young people who use Web-based services are highly distressed, more so than when they present to in-person counseling services, but that they are also earlier in the development of a mental health problem, being at an earlier stage of illness and less likely to have previously accessed mental health care. These results are an important validation of Web-based access as part of stepped-care approaches, revealing that this modality does enable earlier access. Nevertheless, even with earlier presentations, young people are still highly distressed by their symptoms and this distress needs to be a major focus of the initial Web-based counseling response [41].

Distress is likely to be greater for Web-based clients because service use is closer in time to the symptoms that are distressing. Clients of in-person headspace counseling services have to wait from when they make an appointment to when they receive their service [37]; so, in the Web-based environment service use is more proximal to distressing symptoms and events. Interpreted this way, the high psychological distress scores reported by Web-based clients can be taken as evidence that Web-based clients are able to access help at the time they most need it–that is, when they are most affected by their issues.

The issues that Web-based clients seek help for are also more strongly related to current feelings of depression and anxiety, as well as relationship problems. In contrast, clients of the in-person headspace centers are accessing a wider range of health care options, including for physical health issues. Again, this supports the value of Web-based counselling in addressing current emotional distress—there is clearly a need for this type of support, especially for teenage girls. The Young Minds Matter Australian national survey of young people's mental health and wellbeing reported high levels of major depressive disorder, psychological distress, self-harm, and suicidal behaviors among adolescents [42]. The results of this most recent survey revealed an alarming picture of distress, especially for teenage girls aged 16 and 17, with 19.6% experiencing major depressive disorder, 22.8% reporting self-harm, and 15.4% seriously considering attempting suicide. That eheadspace seems to be most effectively reaching this at-risk demographic group is a very positive response for Australia.

The Web-based clients were more likely to be living in stable accommodation, which may suggest that Web-based counseling access is easier for those at home with a computer and Internet connection, and it may be more difficult for young people to

go on the Internet in other living situations. While surveys show that almost all young people in Australia have Internet access, for young people who are homeless or couch surfing this can be through public facilities like libraries or drop in centers, or through use of a friend's computer [43], which may not be conducive to engaging in something as personal and time consuming as counseling [44].

Limitations and Further Research

This study has a number of limitations, including the diminishing sample size for eheadspace when broken down by age and gender categories, despite the overall very large sample sizes. The sample for eheadspace was particularly small for some variables, such as stage of illness and psychosocial functioning, with Web-based clinicians having more difficulty making these judgements during first presentation. Better guidance around these issues may be required in order to improve clinicians' ability to make these assessments.

It is important to acknowledge the possibility that some clients may use both health service types. Unique client codes are used in each service, however, a question in the center dataset asks young people if they have accessed eheadspace, and 5.6% indicated they had. It would be of interest to explore whether clients who access Web-based counseling or in-person counseling exclusively differ from those who access both types, and this is something that could be explored in future research.

Despite these limitations, the study represents an important step in understanding young people who access Web-based counseling. Future research and analysis should investigate the types of interventions that eheadspace clients are receiving and determine whether the approach is making a difference to their mental health and wellbeing. While Web-based counseling certainly has a role in the mental health care continuum, more research is needed to determine how it can best be used to improve access and engage hard to reach young people, as well as its role in stepped care and collaborative approaches between Web-based and in-person services.

Conclusions

During a period when mental health programs and services are being reviewed in Australia [45], it is timely to investigate the young people presenting to Web-based counseling and determine whether they differ substantively from those attending in-person services. The findings of this study suggest that the eheadspace Web-based service is reaching a unique client group who may not otherwise seek help or who might wait longer before seeking help if in-person support was their only option. In particular, Web-based support was shown to be highly accessed by young females with depressive symptoms, which is a demographic group that is growing and has been identified as particularly vulnerable and in need of greater focus. Web-based support can lead young people to seek help at an earlier stage of illness and is appealing to young people who have never sought mental health assistance before. This is important to enable young people to access support at the earliest opportunity with the aim of reducing the likelihood of more serious mental health problems developing.

Conflicts of Interest

All authors are employed by or directly involved with headspace National Youth Mental Health Foundation.

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Abbreviations

NSMHW: National Survey of Mental Health and Wellbeing

Original Paper

E-Mental Health Innovations for Aboriginal and Torres Strait Islander Australians: A Qualitative Study of Implementation Needs in Health Services

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Abstract

Background: Electronic mental health (e-mental health) interventions offer effective, easily accessible, and cost effective treatment and support for mental illness and well-being concerns. However, e-mental health approaches have not been well utilized by health services to date and little is known about their implementation in practice, particularly in diverse contexts and communities.

Objective: This study aims to understand stakeholder perspectives on the requirements for implementing e-mental health approaches in regional and remote health services for Indigenous Australians.

Methods: Qualitative interviews were conducted with 32 managers, directors, chief executive officers (CEOs), and senior practitioners of mental health, well-being, alcohol and other drug and chronic disease services.

Results: The implementation of e-mental health approaches in this context is likely to be influenced by characteristics related to the adopter (practitioner skill and knowledge, client characteristics, communication barriers), the innovation (engaging and supportive approach, culturally appropriate design, evidence base, data capture, professional development opportunities), and organizational systems (innovation-systems fit, implementation planning, investment).

Conclusions: There is potential for e-mental health approaches to address mental illness and poor social and emotional well-being amongst Indigenous people and to advance their quality of care. Health service stakeholders reported that e-mental health interventions are likely to be most effective when used to support or extend existing health services, including elements of client-driven and practitioner-supported use. Potential solutions to obstacles for integration of e-mental health approaches into practice were proposed including practitioner training, appropriate tool design using a consultative approach, internal organizational directives and support structures, adaptations to existing systems and policies, implementation planning and organizational and government investment.

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Introduction

E-Mental Health Services for Indigenous Australians

The role of digital technologies in addressing pervasive mental illness in the community has been explored over the past 15 years. The accessibility of new technologies to those with mental health concerns at any time or location, at low or no cost, and with a degree of anonymity has the potential to expand access to mental health services. Electronic mental health (e-mental health) interventions have emerged in response to this opportunity but their potential has not yet been fully realized.

E-mental health approaches provide treatment and support to people with mental health concerns through telephone, mobile phone, computer, and online applications, and range from the provision of health information, peer support services, virtual applications, and games through to real-time interaction with practitioners. They may be client-driven, practitioner-supported or involve a combination of support and self-driven use. There is growing evidence for the efficacy and cost effectiveness of e-mental health approaches [1,2].

E-mental health may provide a novel opportunity for improved health and well-being for Aboriginal and Torres Strait Islander (Indigenous) Australians. The potential adoption of e-mental health approaches amongst Indigenous people, however, has not yet been well explored [3]. Although diverse in life experiences, circumstances, and histories, Indigenous Australians display very high overall rates of psychological distress [4] and suicide [5], which may result from colonization, dislocation from country and loss of identity, previous government policies of assimilation and child removal, marginalization from mainstream society, institutionalized racism and poor education and employment outcomes, and intergenerational trauma [6,7]. Furthermore, Indigenous Australians do not access mental health services at rates commensurate with their burden of disease [4]. Often living in rural and remote areas, access to appropriate services for Indigenous people may be limited by lack of availability in addition to other factors such as the cultural inappropriateness of services and stigma associated with seeking treatment [8].

The Australian Government supports the use of e-mental health approaches by consumers and health services, including within Indigenous populations, through its National e-Mental Health Strategy. A key component is an e-mental health training and support service for practitioners working in primary health care known as e-Mental Health in Practice (eMHPrac). The present research was conducted within the Indigenous stream of eMHPrac in the Northern Territory.

Current Use of E-Mental Health

Despite the demonstrated potential, e-mental health approaches have not been well utilized in health services [9] and there is a general dearth of research into implementation and use within service settings [10,11]. While evidence-based treatments are proliferating [12], the number of evidence-based implementation strategies remains few [13]. Many theoretical frameworks seek to describe the dynamic process of the implementation of innovations. These various frameworks, strongly influenced by

Rogers, seek to describe the findings that health care innovations are implemented more successfully when certain conditions are favorable [14]. Greenhalgh et al sought to combine this diverse literature into a unifying model of the diffusion of innovations in health care organizations which included characteristics of the user system, the outer context, the innovation itself, and the adopters within the organization [15].

Over a decade ago, Whitfield and Williams found that the most significant impediments to use of e-mental health in health services were a lack of skills amongst practitioners, unclear guidelines for use, and negative perceptions about e-mental health (such as confidentiality concerns, lack of confidence in use, and perceptions of e-mental health as inferior to face-to-face therapy) [16]. However, in a more recent review of the implementation of electronic innovations in youth health services, Montague and colleagues found that a lack of time and resources, poor information technology (IT) skills amongst staff, and technical problems provided the greatest encumbrances, while negative perceptions of e-mental health amongst staff and clients did not significantly inhibit use. [11]

In a recent systematic review of e-mental health use by Australian consumers and practitioners, Meurk and colleagues described facilitators of e-mental health use that included therapist support for innovations, mental health literacy, convenience factors, integration into existing care, and cultural appropriateness [17]. Barriers included lack of awareness of e-mental health amongst clients and practitioners and lack of e-mental health training for practitioners. Several factors were reported to act as both facilitators and barriers across different studies (perceived anonymity of e-mental health, stigma associated with help-seeking, gender, rural residence, concerns about privacy, preferences for self-help), suggesting that contextual factors are likely to have a large influence on results. Meurk and colleagues also reported a need for further research exploring the appropriateness of e-mental health with different population groups. The current study aims to understand stakeholder perspectives on the requirements for implementation of e-mental health approaches in regional and remote health services for Indigenous Australians.

Methods

Data Collection

Semi-structured, qualitative interviews were conducted with 32 stakeholders to explore current and potential use of e-mental health approaches with Indigenous clients. Findings will be used within a broader formative evaluation framework [18] of training and support provided by the eMHPrac support service in the Northern Territory of Australia.

We acknowledge the subjectivity of our position as researchers within the eMHPrac collaboration and as developers of an e-mental health tool (the AIMhi Stay Strong App); however, throughout we have sought to render our position explicit and to reflect on how our experiences may have shaped our findings while considering other perspectives [19].

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Ethics approval was granted by all relevant ethics committees (ref #HREC 12-1881 and #CAHREC 12-100) including an Aboriginal sub-committee.

Recruitment

Interviews were conducted between December 2013 and March 2015 by SP, MS, and KD with managers, directors, chief executive officers (CEOs), and senior practitioners (eg, clinical supervisors including general practitioners, nurses and psychologists) of mental health, well-being, alcohol and other drug and other services (primarily chronic disease) working with Indigenous people in the Northern Territory of Australia. Participating organizations were either government health services or other non-profit, predominantly publicly-funded services: non-government organizations (NGOs) and Aboriginal community controlled health organizations (ACCHOs) offering a broad range of services and programs (eg, counseling, alcohol and drug rehabilitation, social support and primary care) (Table 1).

Table 1. Participant roles, organization types, and service types (N=32).

Participant	n (%)
Role	
Manager/CEO/director	21 (66)
Practitioner	11 (34)
Organization type	
Government health service	12 (37)
Aboriginal community controlled health organization	6 (19)
Non-government organization	14 (44)
Service type	
Alcohol and other drug service	9 (28)
Mental health service	13 (41)
Social and emotional well-being service	2 (6)
Other	8 (25)

A semi-structured interview guide was developed informed by literature, our previous research findings, and discussion among the research team. The guide covered knowledge of and attitude toward e-mental health resources (eg, Do you use or know of any e-mental health resources/strategies? If yes, which ones?) and a range of perceived implementation challenges and facilitators (eg, Can you identify any barriers to the e-mental health approaches in your practice and potential solutions to these barriers, for example, policy, staff availability, staff turnover, training?). The following description of e-mental health was provided to participants at the commencement of interviews:

> *e-Mental health services provide treatment and support to people with mental health disorders through telephone, mobile phone, computer and online applications and range from the provision of health information, peer support services, virtual applications and games through to real-time interaction with clinicians trained to assist people experiencing mental health issues.*

Participants were initially approached based on personal and professional networks and knowledge of the sector prior to participating in e-mental health training. Snowball and maximum variance sampling techniques were used to collect data from a broad range of organization and service types and to ensure inclusion of participants from outside our networks. Although interviews explored e-mental health in general, all participants had been provided with information about the AIMhi Stay Strong App prior to the interview and for many, this was the e-mental health tool that they were most familiar with. As a result many of the responses were focused on the use of e-mental health through mobile devices.

Some stakeholders (60%, 19/32) participated in group interviews with up to four colleagues while others (41%, 13/32) were interviewed individually. Decisions about interview format and setting were determined by participant preference and convenience. Interviews were recorded, transcribed verbatim and checked against audio recordings.

Analysis

An adapted grounded theory methodology was used to construct localized knowledge about the use of e-mental health in health services for Indigenous Australians from the data [20]. Our analysis oscillated between deductive and inductive approaches. Data were broken down into discrete parts and compared and contrasted with remaining data, and were put back together in new categories, making connections between categories involving conditions, context and consequences following Strauss and Corbin's method [20]. All authors immersed themselves in the data by reading and re-reading transcripts. Authors each developed codes and then arrived at a single set of axial codes (adopters, the innovation, and user system) and sub-codes within each through group consensus following reference to the model of the diffusion of innovations in healthcare organizations proposed by Greenhalgh et al [15]. The consensus codes were then applied to the data and as the key results in each code were initially summarized, codes were

refined to reduce duplication and more clearly present findings. NVIVO software was used to support storage and coding of transcripts.

Results

Adopters

Participants described the skills, experience, and personal attributes of practitioners and clients that would potentially influence the use of e-mental health in practice (Figure 1).

Figure 1. Adopter (practitioner and client) factors impacting use of e-mental health approaches.
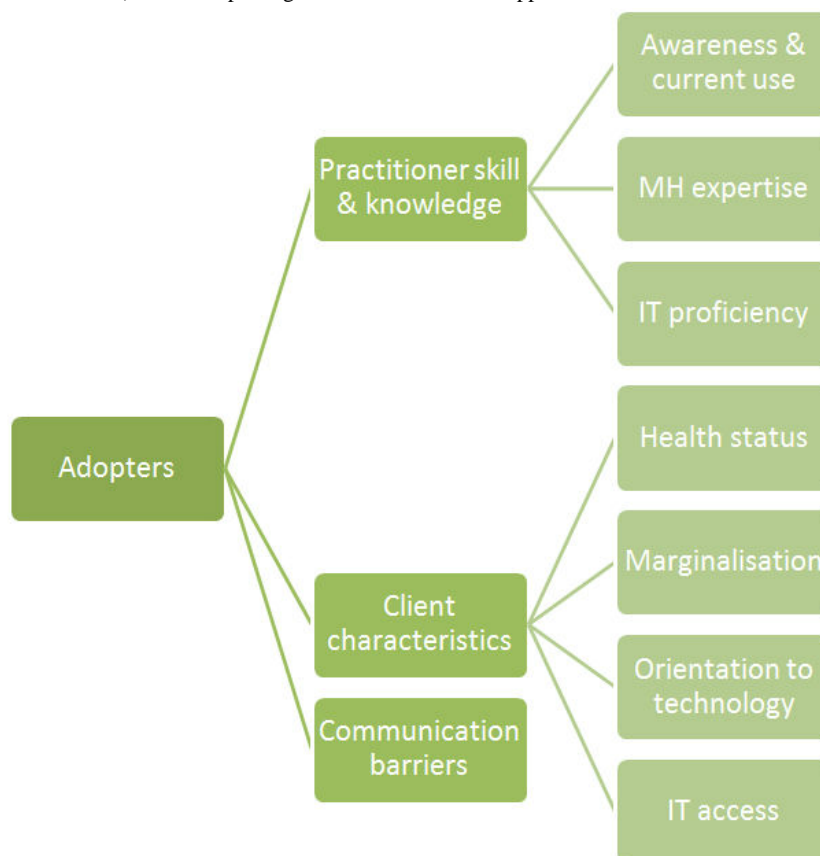
Practitioner Skill and Knowledge

Potential e-mental health adopters among health practitioners were defined as representing a diverse cross-section of the community. Participants perceived that different levels of mental health training and proficiency with IT and generally low levels of knowledge and awareness of e-mental health present challenges to implementation of e-mental health approaches in practice.

Awareness and Current Use of E-Mental Health

Lack of awareness was a key impediment to implementation. Very few participants had used e-mental health tools and some were not familiar with the concept of e-mental health. For example, one ACCHO manager commented: "I think this e-based, what do you call it, this e-mental health approach is a new concept, can I say for the Aboriginal health sector."

Of those who had some awareness of e-mental health, the most common tools mentioned were online cognitive behavioral therapy (CBT) programs and Internet- or phone-based counseling services in general, and the AIMhi Stay Strong App and beyondblue website specifically. Only one participant reported use of e-mental health services in practice through referral of clients to mindfulness apps. No participants reported previous exposure to e-mental health training.

Mental Health Expertise

Lack of mental health expertise amongst health practitioners was perceived to impact upon e-mental health uptake. Participants from a range of service types (mental health, alcohol and other drugs, community services) noted that some staff did not have formal qualifications in mental health.

> Some of them haven't done a basic Cert IV in mental health, so some of them have studied assessment but some of them haven't. They haven't got that sort of grounding. [Manager, NGO]

One participant expressed concern about risks in her staff using e-mental health tools which may induce them to make decisions about treatment which they were not qualified for.

Information Technology Proficiency

IT skills were identified as a key influence in e-mental health implementation. Participants described their colleagues as exhibiting varied levels of skill and comfort in using technology. The use of mobile devices such as tablets was new for many.

There's probably one or two [staff] that are proficient, can use a computer, the rest can't. They barely can send an email... They just freak out at the thought of having a tablet. [Manager, ACCHO]

We are increasingly becoming better at using new technologies. [Manager, ACCHO]

Age was reportedly an important determinant of familiarity and comfort with IT amongst health practitioners.

Client Characteristics

Health and socio-economic status emerged as client factors which may influence their ability or willingness to use e-mental health tools.

Poor Health Status and Well-Being Challenges

Poor health status and significant well-being challenges with high levels of comorbidity were thought to negatively impact on the suitability of e-mental health tools for some clients. One government health service manager said: "Often people with serious mental illness or with poor literacy, a lot of that stuff's still not suitable for them."

These factors were described as impacting upon clients' concentration and their ability to sit through a session with a practitioner to complete an e-mental health tool.

There's a lot of young people, whether they're diagnosed or not, are ADH or oppositional or any of that crap. To try to get them to sit in one place for more than two seconds is quite difficult and a lot of these issues have been compounded by fetal alcohol syndrome, compounded by other primary health issues, compounded by substance abuse. [Manager, NGO]

Poor concentration was particularly attributed to younger clients, however in the case of young clients receiving renal dialysis, using mobile devices was seen as an antidote to boredom.

Marginalization

Despite the need for mental health services, it was suggested that lack of engagement may impede clients from seeking treatment, including through e-mental health approaches. Poor health and well-being were described as being compounded by marginalization from society and the grief and trauma associated with events in some clients' communities such as suicide and conflict. A large number of participants described some of their clients as disengaged from the health care system, not well involved in decisions about their own health care or not fully participating in therapy, frequently missing appointments. A manager at a NGO said: "It's generational, it's the times, it's welfare dependency, it's the lack of an appropriate educational system, it's all that and what's work, why do you want me to work, you know that sort of despair that comes with addiction."

Orientation Towards Technology

Stakeholders described their clients as generally being positively oriented towards new technologies: "Young people are really

into iPads and electronic equipment" (Practitioner, government health service).

Electronic media were described generally as an important component of modern Indigenous youth culture and identity and most agreed that e-mental health tools would be particularly appropriate for this demographic. However, a small number of participants discussed the high level of client motivation needed for them to access some e-mental health tools independently.

A tool like that [AIMhi Stay Strong App] you need motivation to do it independently, so it will be a great tool to use with a worker or with someone you're sort of walking through things. Yeah, but if you just put it out there as an output, I don't know how many people would access it. [Coordinator, NGO]

Information Technology Access

Client access to IT was thought to be an important determinant of use. While most reported high rates of mobile phone ownership, including in remote communities, rates of smart phone or tablet ownership were thought to be lower and it was noted that some remote communities still did not have Internet connection.

mobile phone concentration's very high in the bush ... [Manager, government health service]

... in a lot of communities... there is mobile access, which still isn't all the communities in the western desert by any stretch.... [Manager, ACCHO]

Although financial constraints were not specifically raised, one participant suggested that health services could subsidize the cost of e-mental health tools for clients.

Communication Barriers

Potential communication barriers between staff and clients were discussed as factors influencing the effective use of e-mental health in health services. Practitioners and clients may not speak English as a first language or may have limited English literacy, presenting possible impediments to accessing mental health services, including e-mental health.

Our staff vary from people with uni degrees and used to working in hospitals and doing questionnaires and stuff to people who are very practically based and we have 35% Indigenous employees with a range of experience, tertiary and literacy and numeracy skills... [Manager, ACCHO]

English is not the first language for most of them [Indigenous clients]. [Senior practitioner, government health service]

The Innovation

Particular aspects or design features of e-mental health tools which may influence use were explored (Figure 2).

Figure 2. Innovation-related factors impacting use of e-mental health approaches.
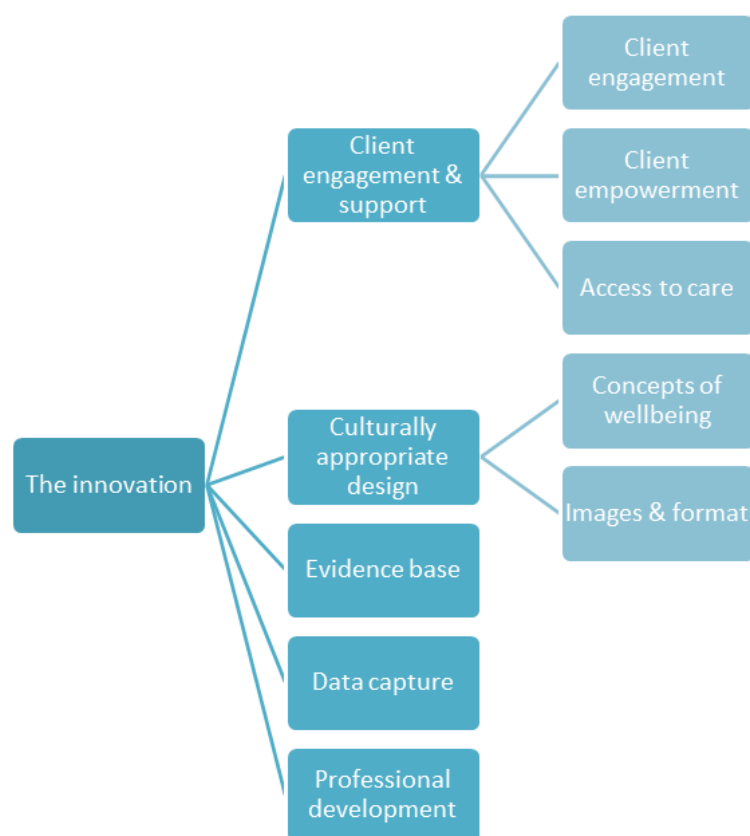
Client Engagement and Support

Client Engagement

E-mental health tools which support engagement between clients and practitioners in mental health services were viewed by most participants more favorably, especially those with the potential to lead to more open dialogue through a less direct approach to sensitive issues.

> it will make it easier to engage with some clients and again, I don't know whether I'm just a victim to stereotypes, but you think that young people who don't necessarily have the willingness or the language to kind of engage in those conversations in just a face to face chat… [Coordinator, ACCHO]

> …it allows people to focus on an indirect object, which would make that relationship building easier. So any elements of shame and embarrassment could be mediated to some level by the use of a tool that is introduced into that interaction. [Manager, NGO]

However, two participants saw potential for e-mental health tools used within a client session to intrude on the therapeutic relationship if tools were not understood by the client or if they interrupted a conversation, suggesting that introducing an electronic based tool to a client session would require some judgment and skill.

The optimism amongst participants in the potential for e-mental health tools to strengthen client engagement appeared to be limited to practitioner-supported tools. A small number of participants described client-driven tools as potentially disengaging and alienating clients. One participant commented: "It's around relationship stuff, so that's why, like that's awesome because you can sit there and be with the person and use it together and still have that relationship with the young person, whereas sometimes it's hard to establish that if they're working with a computer screen…" (Coordinator, NGO).

Client Empowerment

E-mental health tools which empower clients in the recording of their information were well received. Practitioner-supported e-mental health tools such as the AIMhi Stay Strong App were contrasted favorably with pen and paper approaches to collecting client information. Several participants described how pen and paper approaches could be disempowering experiences for clients due to low literacy and as reminders of intergenerational institutionalization.

> [The AIMhi Stay Strong App] has a collaborative approach that the information that is gathered is gathered with full awareness and permission of the participant. [Manager, ACCHO]

> it's certainly a whole lot less scary … than this pen and paper because there's things to push. [Manager, NGO]

One participant discussed preferences for tools that enable both staff and clients to enter information during and between sessions.

Access to Care

Participants saw a role for e-mental health in providing additional support during or between client sessions and acting as a "soft entry point into services " (Coordinator, NGO). The convenience of accessing e-mental health at any time of day and from any location was thought to supplement, but not replace face to face client sessions: "…giving your client like an extra dose of therapy like working with them and then sending them away with stuff that they love to access" (Coordinator, NGO).

However, one participant drew attention to the risk of creating new inequalities in the access to care: "...for people who are better educated they'll just take them to another level and the people who are less educated will get left further behind" (Manager, ACCHO).

Culturally Appropriate Design

Concepts of Well-Being

The small number of participants who offered comment appeared to favor e-mental health tools that adopted a cross-cultural approach by encompassing or acknowledging Indigenous concepts of mental health. Participants tended to favor a holistic and less medicalized approach to mental health concerns as represented by the broader term *social and emotional well-being*.

> *Aboriginal people don't see themselves in those sorts of stigmatized ways [diagnosed with bipolar disorder, schizophrenia etc]. They mainly refer to them as people with social emotional well-being type...you know they prefer to have a much softer approach to that.… It's more a subtle approach than a clinical approach.* [Manager, ACCHO]

Images and Format

Participants described the optimal overall design of e-mental health tools as being *easy to navigate* or *self-explanatory* to aid staff and clients who were not confident with technology. Translation into Indigenous languages or use of plain English was also thought to promote use. In addition, the use of audio prompts in Indigenous languages or plain English was recommended.

The use of *visual aids* to help explain complex mental health concepts and the inclusion of aesthetically engaging content was thought to be particularly important. The nature of desirable images and graphics were described as *friendly* and *non-threatening*, suggesting a need for sensitivity in graphic design. However, in reviewing the AIMhi Stay Strong App, one participant described the potential for some Indigenous clients to view the simple text and visual prompts as patronizing,

suggesting a need to ensure simplifying content does not result in omitting information or adopting a disrespectful stance.

Evidence Base

Participants confirmed that robust evidence of effectiveness would promote e-mental health implementation. Participants were generally unsure about the evidence base and effectiveness of e-mental health; however, there was optimism about its potential and consensus that more information and research was needed. Many called for more research, particularly within Indigenous populations: "We need to be aware of those apps, which ones are good, which ones are evidence based and which ones are crap" (Manager, ACCHO).

Data Capture

There was a general perception of both risks and benefits in the data capture functions of e-mental health tools. In particular, the capacity to measure outcomes in a clear, easy to interpret format, potentially using an automated function, was an attractive feature for health services. The ability to document a broad client history, including family mapping and other information specific to an individual client, was also appreciated by participants when discussing the AIMhi Stay Strong App: "We want to empower people in local communities to be able to access information and to record their own stories" (Manager, ACCHO).

However, there was a concurrent concern about the security of confidential client data collected by e-mental health tools. Several participants perceived e-mental health to afford a lower level of security than existing electronic information systems, particularly when information was stored in mobile devices and transmitted via email: "I've always been concerned about electronic forms of client recording, which is really around confidentiality and the ease with which things can be copied and transferred to people" (Manager, NGO).

Professional Development

Practitioner-supported e-mental health tools that adopt a structured approach or prompts for best practice care were perceived as providing professional development for practitioners. "The other beauty of the best e-health [tools], they can be quite a useful professional development tool for our staff, like you see some of these websites and then you think well they've got that right, my personal professional practice should at least match that" (Manager, ACCHO).

Prompts for health promotion messages, client engagement, identifying well-being markers and assessing client risk were appreciated.

User System

The factors supporting or inhibiting adoption of e-mental health approaches within stakeholders' service delivery settings were explored (Figure 3).

Figure 3. User system factors impacting use of e-mental health approaches.
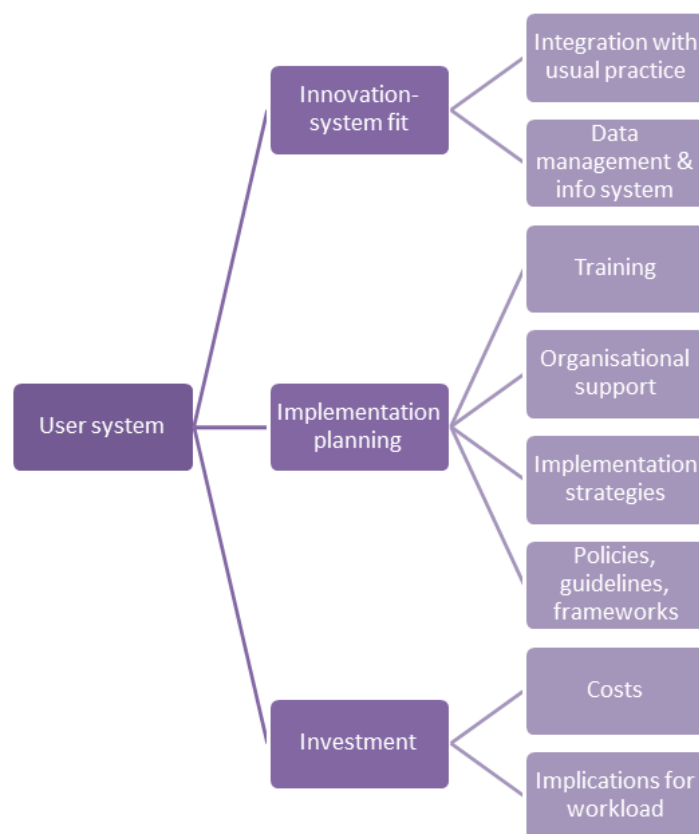
Innovation-System Fit

Integration With Usual Practice

The degree to which e-mental health tools captured or integrated with various aspects of usual practice in client care was described as an important factor mediating use. Most participants suggested e-mental health tools would integrate successfully. Many saw a role for e-mental health tools such as the AIMhi Stay Strong App in an initial session with a new client, as an engagement tool to help build a therapeutic relationship, as an additional component of client assessment, or both. Many saw a potential for e-mental health to replace current care planning processes, or to integrate with existing care plans. A number of participants also discussed the potential for e-mental health tools to improve case management within their organizations: "… probably fitting it somehow into their mental health care plan, their chronic disease care plan would be the best way" (Manager, government health service).

Some participants saw e-mental health tools as having the potential to support health services in remote community settings. The flexibility and portability of mobile devices were described as a favorable feature supporting such work.

Data Management and Alignment With Information Systems

Participants generally saw potential for e-mental health tools to support client data management within organizations but that challenges in integrating tools within existing information systems may detract from use. E-mental health tools were seen to offer support in client data management across organizations through immediate recording and availability of electronic data, measurement of client outcomes, reporting of client data, and improving client ownership of records. A number of participant perspectives on data management were expressed in the context of outdated or poorly managed existing information management systems, including continued reliance on paper-based record systems: " It will improve our capacity for making sure documents don't get lost…" (Manager, ACCHO).

While some participants saw e-mental health tools as providing a desirable addition to existing information management systems, others warned of the risks in failing to integrate e-mental health within existing systems, including the potential for information to be lost. Participants described a need for further technical work to ensure e-mental health tools were accessible within existing systems. They also described a need for data to be easily transferred between systems and clients to be easily identified across systems.

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Implementation Planning

Training

Participants differed in their views on the degree of change needed to implement e-mental health approaches into practice within health services and the steps required. However, almost all agreed that some staff training would be needed. Some participants added that staff in their organization would need other types of training in order to use e-mental health tools, including training in counseling skills, in using mobile devices, and in working in a cross-cultural context. A common theme amongst participants was the need to ensure sustainability of training programs and to address high staff turnover across the sector. Several participants recommended embedding e-mental health training in orientation processes for new staff.

Organizational Support

A number of participants described the importance of establishing supportive structures within organizations such as supervision, regular review, and helpdesk support in promoting implementation and treatment fidelity of e-mental health approaches: "You can have the training, but if you don't have the supervision and the support behind it, it never gets done" (Manager, NGO).

Support and commitment from senior managers were also thought to be an important aspect of the change process which would facilitate greater levels of adoption of e-mental health approaches.

Implementation Strategies

A small number of participants discussed development of specific organizational implementation planning strategies. Aspects of the planning process described included introducing e-mental health initially in a pilot process, using a staged approach, determining which aspects of usual practice e-mental health will replace, decisions on how the use of e-mental health tools will be documented in client records, and establishing and reviewing implementation milestones. Only one participant mentioned a need to consult with staff and clients.

Policies, Guidelines, and Frameworks

Participants suggested that effective and ethical e-mental health use should be governed by organizational policies, guidelines, and frameworks. Some thought that existing clinical governance frameworks could provide appropriate guidance for managing potential risks to clients, responding to incidents, and providing clinical supervision, and that existing client consent policies would equally apply to provision of e-mental health treatment.

There were mixed opinions as to whether existing policies on appropriate use of technology and the secure storage and transmission of electronic data would need to be adapted to take account of e-mental health use: "I think that there needs to be a lot of rigor around...controls around how this gets moved and transferred" (Manager, NGO).

A small number of participants described existing policies as preventing access to e-mental health tools (eg, restricted Internet use) and mobile devices. However, others described a need for policies to mediate appropriate use of and access to mobile devices, suggesting policies needed to achieve a balance between access and risk management.

Investment

Costs

The costs and expected benefits associated with e-mental health were a key consideration for participants in adopting e-mental health approaches within their organizations. Participants represented government departments or non-profit organizations and described financial constraints and uncertainty about future funding. The most common costs identified were in purchasing mobile devices and training staff. Although free training was offered within eMHPrac, there were associated costs in backfilling frontline staff and travel to be considered. The need to upgrade existing systems to enable utilization of e-mental health was also identified as a cost.

However, almost all participants planned to take advantage of the free training offered and to seek funding for mobile devices where not already available, suggesting that the costs involved were perceived as a worthwhile investment: "…I think that would be a cost benefit sort of situation equal…" (Manager, ACCHO).

Potential risks to the investment were discussed, such as the potential for mobile devices to be lost, damaged or stolen, and the possibility of hidden costs, for example in future upgrades to devices and e-mental health tools.

Implications for Workload

Some noted the potential for the initial investment in e-mental health to result in future savings for organizations through improved efficiency. Efficiency dividends were thought to arise from reducing the amount of staff time in writing client notes and the immediate transmission and availability of client data. However, others saw potential for e-mental health use to result in longer client sessions and thought the implementation process would increase staff workload initially.

Discussion

Principal Findings

There is strong potential for e-mental health approaches to complement existing mental health services for Indigenous people. However, several client, practitioner and system-level factors as well as the design of innovations will determine the level of perceived usefulness and ultimately the success of implementation efforts.

Adopters

Limited knowledge of e-mental health tools amongst health practitioners is a key obstacle to use. This finding accords with results from a recent eMHPrac training evaluation [21] and reports of poor implementation of e-mental health approaches across Australian health services, despite Australian developers playing a leading role in the development of e-mental health innovations internationally [22]. Similarly, a recent systematic review found that one of the key impediments to more widespread use included lack of awareness and knowledge about e-mental health amongst clients and practitioners [17]. Our

findings support the conclusions drawn on the need for greater promotion and awareness-raising amongst practitioners.

Mental health training and expertise amongst health practitioners is another factor driving use of e-mental health tools. These findings are in accord with those of a study which aimed to identify contextual influences on integration of innovations in mental health services in both UK National Health Service and community settings. Brooks et al (2011) found that service provider skills and knowledge were among the top enablers to implementation [23]. This theme of adopter confidence is also reflected in the findings of Panzano and Roth who found that the decision to adopt an innovative mental health practice involves consideration of risk [24]. Their data suggest that early adopters see the risks associated with adopting as lower and potentially more manageable.

The Northern Territory mental health and well-being workforce is varied and often limited in terms of formal training or qualifications [25]. Some have found that e-mental health approaches can be implemented successfully by practitioners with little mental health training [26]. An evaluation of a one-day e-mental health training course provided through eMHPrac has shown that participants with diverse roles and professional backgrounds improved their knowledge and skills in e-mental health significantly post-training [21]. The availability of appropriately-targeted training in e-mental health will be a crucial component of e-mental health implementation; however, workforce factors also indicate a need earlier in the development phase for production of new tools which are evidence-based, easily understood, appropriately targeted and require little training.

For Indigenous clients, stakeholders expressed preferences for tools that involve a level of practitioner support (Multimedia Appendix 1). This accords with the oral traditions of Indigenous Australians and the emphasis often placed on personal relationships [27]. Furthermore, studies of online treatments (particularly Internet-based CBT) have shown the largest effect sizes when combined with practitioner support [28,29]. Nevertheless, some level of client-driven use was also supported by stakeholders who saw an opportunity for e-mental health to complement traditional approaches to treatment and support self-management.

Reynolds et al [30] offer a framework of e-mental health use in primary care, describing a continuum of therapist involvement from promotion to case management, coaching, integration into symptom-focused therapy, and integration into comprehensive treatment. Our findings suggest that e-mental health tools which can be integrated into face to face therapy or treatment, or tools that can be used in a case management or coaching scenario, where service providers offer emotional and technical support to clients to use e-mental health tools either within a face to face session or externally, were preferred.

The Innovation

Specific design of e-mental health tools to address the needs of Indigenous Australians will facilitate use. As others exploring the use of e-mental health innovations with Indigenous Australians have found, very few tools have been developed to address the needs of Indigenous people [3,31]. Appropriate tool design has been identified as a key facilitator of acceptance of e-mental health tools [9]. E-mental health tools that adopt a social and emotional well-being framework acknowledging the broader social determinants of mental health may have more capacity for including Indigenous concepts of mental health than biomedical models. Christie and Verran have also called for the development of tools for Indigenous Australians that adopt a holistic perspective of health and the health system, and with interactive features than enable development of shared understandings rather than only transferring information [32].

However, there are challenges in developing a tool which reflects Indigenous worldviews and understandings of mental health, life experiences, and conversational style, particularly in the context of an extremely diverse population. Developers must seek to both avoid oversimplifying concepts or presenting Indigenous perspectives in a tokenistic manner and yet also avoid rendering tools and concepts too complex. While design features such as images, language style and tone, and audio prompts can impact on ease of use and successful uptake [33], developers may also encounter intellectual property issues and sensitivities to the use of certain images, words or concepts in certain contexts [34]. As others investigating the development of e-mental health innovations designed for Indigenous Australians have found, there continues to be a need to ensure that content is localized and adapted to different regions, communities and languages through consultative, collaborative approaches [3,35].

The security of personal data stored in e-mental health tools was a significant concern for participants and provides an imperative for developers to address prior to the integration of tools into routine care. The potential for e-mental health tools to record highly sensitive information while providing the means for rapid transmission of information online is a key risk. Historical and ongoing government intervention in the lives of Indigenous people [36] and difficulties in de-identifying client information in small inter-related communities may further heighten security concerns amongst this population group. Although Povey and colleagues did not find that data security concerns significantly detracted from the appeal of e-mental health amongst Indigenous community members [3], other studies have reported perceived risks to confidentiality amongst practitioners and consumers [11,17], and it may be the case that health service managers in their duty of care to clients and experience in managing client data are more attuned to potential risks.

Those e-mental health resources which can be used in a client session and potentially improve professional practice through the use of prompts and reminders, and through better recording of client data and are accompanied by further training, are most attractive to health services. This need is recognized by the National e-Mental Health Strategy which is currently offering e-mental health training and implementation support through the eMHPrac support service [30].

Robust research evidence will generate greater confidence in the use of e-mental health tools in health services. This finding is in accord with our earlier investigation of user perspectives

of a localized e-mental health tool [33]. Future research should consider the implementation context and practitioner fidelity to treatment to ensure that shifts in practice achieve the intended outcomes and are sustained over time.

User System

Health service organizational systems and processes with capacity to support e-mental health tools are needed. Current systems and supportive infrastructure such as Internet access and mobile devices were reported as often unavailable or outdated. Although Internet coverage in Australia is expanding, some remote communities remain without Internet connection while others continue to experience slow download speeds [37]. Poor Internet access has been reported as an impediment to e-mental health use in related studies [3,33]. A recently announced Digital Mental Health Gateway to support practitioner and client access e-mental health tools through a centralized portal as part of a new stepped-care system [38] may assist in connecting systems to e-mental health tools to some extent. Nevertheless, it is likely that service providers will need to adapt organizational systems and processes to some extent in order to integrate e-mental health approaches.

Other studies investigating implementation of mental health service innovations have similarly found the capacity and receptiveness of organizational systems to be pivotal in their success. Barnett et al identified a range of organizational factors either impeding or facilitating innovation: organizational receptiveness (including the fit between the innovation and the organizational ethos), available resources, as well as organizational capability to promote the innovation with other organizations [39]. Similarly Brooks et al found that resource limitations and lack of support from corporate departments such as HR and finance were key impediments to implementation [23].

Participants confirmed what is known from the diffusion of innovations literature: successful implementation of new innovations into service settings requires consultation, organizational support, support structures and lines of reporting established, planning, adaptation of current systems, supportive policies or guidelines and adequate resourcing [15]. As

Montague and colleagues have found, the availability of e-mental health innovations has often preceded the development of organizational policies and protocols governing their use [11].

Implementation of e-mental health approaches requires investment in supportive infrastructure and workforce capacity building for many organizations, as well as investment in tools and devices themselves. The need for e-mental health supports and technical upgrades is recognized by the e-Mental Health Alliance [9]. However, these were costs that some stakeholders described as posing a burden on already stretched budgets. Further government investment in health service systems and supportive infrastructure is needed.

Addressing staff training needs and embedding training in existing structures is also required. The current piecemeal approach to e-mental health implementation with an apparent lack of staff consultation appears to be leading to a small number of "early adopters" and a large proportion of "laggards" [14]. In the absence of a whole-of-organization approach, including formal guidance in which aspects of current practice e-mental health will replace or complement and technical work to adapt or upgrade existing information management systems, there are risks that e-mental health could lead to duplication in the delivery of care and recording of client data or that initial changes to practice are not sustained.

Recommendations

Practitioners, developers, service providers and governments all have important contributions to make in realizing the opportunities presented by e-mental health (Textbox 1).

Limitations

Participation in this study was restricted to service providers and we did not seek client, developer or community views directly. Nevertheless, the views expressed provide insight into current awareness of e-mental health and perceived potential for implementation in the health service settings in which the participants are expert. Indigenous community perspectives on the use of mobile applications for mental health have been explored elsewhere [3].

Textbox 1. Recommendations for practitioners, developers, and services to promote adoption of e-mental health approaches.

Recommendations

- Practitioners

  - Seek advice from local consumer or community groups on the appropriateness of particular tools for particular client groups.

  - Choose e-mental health tools to suit the individual, considering client language and literacy, cultural factors, engagement with technology, attitude, and type of mental health concern.

  - Research available e-mental health tools to increase awareness and familiarity.

- Developers

  - Collaborate with Indigenous communities and organizations to ensure sensitive adaptation to different regions, communities, and languages.

  - Develop tools that combine practitioner support with client-led use.

  - Develop tools that monitor client outcomes in a clear, easy to interpret format.

  - Develop tools that support best practice through a structured approach and are appropriate for use by practitioners with little mental health training.

  - Ensure that the security of client data collected in tools matches the level of security in existing electronic information systems.

  - Develop tools that can be used without ongoing Internet connection.

  - Conduct research to expand the evidence base for effectiveness of e-mental health approaches.

  - Evaluate implementation strategies and practitioner fidelity to treatment.

  - Develop training packages that address gaps in expertise including cross cultural skills and familiarity with technology.

  - Work with service providers to promote awareness of e-mental health.

- Health Services

  - Assess the alignment of individual tools with existing information management systems and any needs for technical adaptations to existing systems prior to implementation. Internal directives are needed on how client data from tools are to be saved in client records.

  - Consider what investment may be needed in systems and supportive infrastructure including Internet connection, mobile/tablet devices and information systems prior to implementation.

  - Consider the need to adapt existing policies, procedures, and frameworks including clinical governance frameworks and policies on electronic equipment and storage and transmission of client data to take account of e-mental health.

  - Provide internal directives to advise which aspects of existing practice e-mental health tools will complement or replace; and guide the use of tools within or as an adjunct to client sessions.

  - Establish support structures to guide the use of e-mental health, such as supervision, regular review and troubleshooting support in order to help staff adapt to e-mental health approaches and to promote treatment fidelity.

  - Consult with staff and demonstrate support and commitment from senior managers through a "whole of organization" approach.

  - Develop implementation plans, which may include a consultation phase, a pilot process, a staged approach to introduction, integration with treatment pathways/usual practice, and establishing and reviewing implementation milestones.

  - Undertake a needs analysis of staff training, considering staff skills and experience in IT, counseling, and working cross-culturally. Training should be included in orientation processes to ensure sustainability of implementation efforts.

- Government

  - Develop training packages for e-mental health which include training in IT skills, counseling skills, and working cross-culturally and which are flexible for use in diverse contexts.

  - Promote awareness of e-mental health including strategies that lead to positive attitudes and motivation to use.

  - Invest further in supportive infrastructure such as Internet connection and faster download speeds in remote communities.

  - Work with service providers to ensure integration of the Digital Mental Health Gateway with diverse information management systems.

  - Make grants available to service providers for staff training and appropriate hardware for e-mental health.

  - Consider incentives for use of e-mental health approaches through the Medicare Benefits Schedule.

Our established relationships within the sector and our role as the developers of an e-mental health innovation may have influenced participant responses. Although these relationships may have enabled us to gain a deeper understanding of contextual factors, they also create potential for bias. Nevertheless, participant responses represent a full spectrum of

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views. The AIMhi Stay Strong App may have dominated participant perceptions about e-mental health; however, participant views about various features of that app are also relevant to the development of other e-mental health resources for Indigenous Australians. We have indicated above where participants explicitly or implicitly referred to the AIMhi Stay Strong App.

The format of qualitative interviews may have influenced participant responses, particularly where participant contributions were made in the presence of a line manager or other colleagues. However, participants were given the choice of taking part in a group or individual interview. These factors were taken into consideration in our analysis where there was potential for social influence in order to avoid overstating the numbers of participants sharing a single perspective.

Conclusions

The present study contributes to understandings of the potential implementation of e-mental health approaches for Indigenous clients in health service settings. Results suggest e-mental health

interventions may be most effective when used to support or extend existing health services, involving elements of client-driven and practitioner-supported use. Used in this context, e-mental health approaches offer more than simply a new modality of treatment and, if adopted, are likely to change the very nature of health care, impacting on access to care, the therapeutic relationship and data recording, in addition to influencing the functioning of health services.

As practitioners and service providers consider the opportunity presented by e-mental health, several client, practitioner, and system-level factors and the design of innovations are likely to influence the level of effectiveness, the degree of change needed to current practice and organizational processes and ultimately, the level of use. Developers, service providers, practitioners and government all have contributions to make in designing tools and related training that meet client and stakeholder needs, embedding e-mental health approaches in practice frameworks and systems and supporting appropriate use while seeking solutions to obstacles such as poor supportive infrastructure, financial constraints and workforce capacity issues.

Conflicts of Interest

The authors are the developers of an e-mental health tool for Indigenous Australians, the AIMhi Stay Strong App; however, we did not incur any financial benefit as a result of this study.

Multimedia Appendix 1

Example of a practitioner-supported e-mental health tool.

[PDF File (Adobe PDF File), 229KB - mental_v3i3e43_app1.pdf]

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Abbreviations

ACCHO: Aboriginal community controlled health organization
CEO: chief executive officer
e-mental health: electronic mental health
eMHPrac: e-Mental Health in Practice
IT: information technology
NGO: non-government organization

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Original Paper

Achieving Consensus for the Design and Delivery of an Online Intervention to Support Midwives in Work-Related Psychological Distress: Results From a Delphi Study

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Abstract

Background: Some midwives are known to experience both professional and organizational sources of psychological distress, which can manifest as a result of the emotionally demanding midwifery work, and the traumatic work environments they endure. An online intervention may be one option midwives may engage with in pursuit of effective support. However, the priorities for the development of an online intervention to effectively support midwives in work-related psychological distress have yet to be explored.

Objective: The aim of this study was to explore priorities in the development of an online intervention to support midwives in work-related psychological distress.

Methods: A two-round online Delphi study was conducted. This study invited both qualitative and quantitative data from experts recruited via a scoping literature search and social media channels.

Results: In total, 185 experts were invited to participate in this Delphi study. Of all participants invited to contribute, 35.7% (66/185) completed Round 1 and of those who participated in this first round, 67% (44/66) continued to complete Round 2. Out of 39 questions posed over two rounds, 18 statements (46%) achieved consensus, 21 (54%) did not. Participants were given the opportunity to write any additional comments as free text. In total, 1604 free text responses were collected and categorized into 2446 separate statements of opinion, creating a total of 442 themes. Overall, participants agreed that in order to effectively support midwives in work-related psychological distress, online interventions should make confidentiality and anonymity a high priority, along with 24-hour mobile access, effective moderation, an online discussion forum, and additional legal, educational, and therapeutic components. It was also agreed that midwives should be offered a simple user assessment to identify those people deemed to be at risk of either causing harm to others or experiencing harm themselves, and direct them to appropriate support.

Conclusions: This study has identified priorities for the development of online interventions to effectively support midwives in work-related psychological distress. The impact of any future intervention of this type will be optimized by utilizing these findings in the development process.

Introduction

Midwives can experience both occupational and organizational sources of psychological distress [1]. The well-being of health care professionals can be directly correlated with the safety and quality of patient care [2]. Therefore, in order to ensure high quality maternity care, psychological distress experienced by the midwifery profession will need to be met with appropriate

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and effective support. Although there is record of some support available for midwives, there currently appears to be a lack of online support available for midwives [3,4].

A recent review on maternity services has highlighted that midwives are more likely to report episodes of work-related stress than other health care professionals [5]. Yet there has been a reluctance to report episodes of unsafe practice or "impairment" due to a fear of adverse consequences [6]. Midwives are exposed to a variety of events which they perceive to be traumatic, and demonstrate a reluctance to seek support for fear of stigma and punitive responses when engaging with face-to-face support [7-9]. In line with other support provisions offered to physicians, midwives may also benefit from customized support, away from other health service users, among other midwives [10,11]. As such, midwives may be more likely to engage with an online intervention, which can facilitate the provision of confidentiality and anonymity and so encourage positive help-seeking behaviors and disclosure.

Generally, online interventions offer unique benefits such as greater accessibility, anonymity, convenience, and cost-effectiveness [12]. These benefits may appeal to midwives who often work long shifts during unsociable hours in an area of high litigation, where speaking openly about their ability to cope may prove to be challenging [13-15]. In light of the stigma surrounding nondisclosure in midwives requiring further support, and for those needing to disclose episodes of psychological distress or impairment, the provisions of confidentiality and anonymity may be essential for midwives to speak openly. In providing both anonymity and confidentiality within an online intervention, users will become unidentifiable and therefore cannot be held to account. This situation would result in a subsequent and inevitable amnesty. We refer to the concept of amnesty in this case as a period of forgiveness, where an episode of misconduct is pardoned for the purpose of enabling those in need of help to take a unique window of opportunity to seek help, where they may not otherwise have done so. With this in effect, immediate accountability will not be possible, and the immediate protection of the public may be unattainable. As it may be unfeasible for midwives to engage with face-to-face support and make open disclosures otherwise, it is vital that we consult with both midwives and others to explore the priorities for online interventions that support midwives in work-related psychological distress.

It is not currently known what should be prioritized in any online intervention, designed to effectively support midwives in work-related psychological distress. This paper reports the results of an online Delphi study designed to achieve consensus in the development of an online intervention to support midwives in work-related psychological distress.

The Delphi method was chosen due to its ability to stimulate anonymous discussion and erase any geographical distances between participants [16]. This online technique also protects the collaborative discussion from any one person dominating the conversation or governing the group's thoughts and ideas [17].

Methods

Design

We conducted a two-round Delphi study between the 9th of September and the 30th of November 2015. Both rounds were completed online using Bristol Online Survey software and participants received feedback following both rounds electronically via blind carbon copied emails. Our study protocol has been published elsewhere [18]. The aim of this study was to achieve consensus in the design and delivery of an online intervention designed to support midwives in work-related psychological distress.

In total, 39 questions about what should be prioritized in the development of an online intervention for midwives were posed to eligible participants over two rounds. Questions were posed as statements for the expert panel to respond to, and were chosen in response to a scoping review of the academic and grey literature, and the lived experience of working within maternity services. This literature review was broad in scope, and included a combination of search terms relating to midwives, work-related psychological distress and online support interventions. A snowballing of the literature then led the research team to identify further themes of relevance [19]. Final themes were categorized within the online survey as; ethical inclusions, inclusions of therapeutic support and intervention design and practical inclusions.

Consensus was defined as a minimum of 60% of panelists responding within two adjacent points on the 7-point rating scale. This scale was anchored at "Not a priority" and "Essential priority". Any item could reach consensus at any point within the scale, whether at the higher or lower end of the scale. The presence of consensus in this study was specified in advance of data collection.

Ethical approval for this study has been granted by Coventry University Ethics Committee (project reference ID P35069).

Recruitment

Participant recruitment for panelists began in the September of 2015. Key papers which related to the subjects of midwifery work, psychological distress, online interventions and interventions designed to support mental well-being already known by the research team were screened for potential subject experts. A snowballing of the literature led the research team to scan reference lists and identify further key papers of relevance [19]. The authors of these papers were then invited to participate in the study.

Inclusion Criteria

Participants were eligible to participate if they possessed all or some of the following practical knowledge in either: midwifery, midwifery education, research, therapies, health care services, staff experience or patient experience. Participants were also eligible if they had been listed as an author in at least one academic paper relevant to midwifery, psychological trauma, psychology, psychiatry or health care services. No exclusion criterion was applied.

Online Recruitment Strategy

A social media recruitment drive was also conducted, in line with the study protocol [18]. Our strategy aimed to reach a range of midwifery professionals, those with a knowledge of psychology and psychological trauma, those with a background in psychiatry and/or practitioner health, patient and staff groups, those with a knowledge of risk, quality and safety in the health services and experts in the field of online interventions. In total, 185 people were invited to participate in the study. Some were contacted directly via email by the research team, and others contacted the research team expressing their interest in participation. All potential participants were invited to visit the research recruitment blog page, which detailed the study protocol and inclusion criteria [20].

During the study the research recruitment blog page was accessed 422 times. This blog page was also shared on Facebook 59 times, Linkedin 3 times, and Twitter 47 times. Additionally, the blog page was shared to a further 236 unidentified websites by its readership. The destination of a further 77 shares via social media remain unknown. An overview of social media engagement and the recruitment process are detailed within Multimedia Appendix 1.

Although participants remained anonymous throughout this study, some participants were keen to disclose their specific expert status to the research team. The team did not seek to verify the eligibility of each participant, and they simply consented to having the relevant expertise. The majority of participants who disclosed their expert status were either clinical and/or academic midwives. Other participants included psychiatrists, psychologists, health care, policy and midwifery leaders, and academic experts in the field of post-traumatic stress disorder (PTSD), secondary trauma and psychological distress. Some experts also disclosed their country of origin as the United Kingdom, the United States of America, Australia, Nigeria, Israel, and Oman. However, the locations of each individual participant are unknown.

Round 1

Round 1 comprised a list of 20 statements relevant to the design and delivery of an online intervention to support midwives in work-related psychological distress. Participants were asked to choose a number that best represented their response to each statement with a 7-point Likert response scale. Two questions were given for each statement: "Why did you choose this rating of priority?", followed by: "Do you have any additional comments you would like to share?" Space for free text responses was provided after each question.

Round 2

All panelists received feedback on the panels' responses to Round 1. The participant report delivered to participants following Round 1 can be found in Multimedia Appendix 2. Statements that did not achieve consensus in Round 1 were returned to participants in Round 2. In addition, 10 new statements were included in Round 2 on the basis of participant comments in Round 1 that were not reflected by the content of an existing statement. All statements are presented initially within Multimedia Appendix 2 and Multimedia Appendix 3.

All panelists who had participated in Round 2 were sent a summary of the outcome of Round 2, which can be found in Multimedia Appendix 3. Open text responses were coded by the primary researcher and then assigned to emergent themes in a succession of refinements. The themes and categorizations of statements were then revised and refined following an inspection and reflective discussion with the second researcher. The authorship of statements remained unknown to the researchers throughout.

Results

Consensus

Numerical data is reported in line with the outputs generated by the Bristol online survey software. Of people who were invited to participate in the study 35.7% (66/185) completed Round 1, and 67% (44/66) of those who contributed to Round 1 completed Round 2. Of the 20 statements posed during Round 1, 11 statements achieved consensus and 9 did not. Of the 19 questions posed within Round 2, 7 statements achieved consensus and 12 did not, giving a total of 18 consensus statements from the 30 statements posed to panelists. In total, 1604 free text responses were collected and categorized into 2446 separate statements. One free text response was removed in order to maintain confidentiality. An overview of results is presented in Figure 1. A detailed summary of the results for Rounds 1 and 2 are presented in Tables 1 and 2 respectively.

**Table 1.** Detailed summary of numeric results for Round 1.

Statement	Consensus achieved	% of consensus	Minimum score	Maximum score
Ethical inclusions				
Confidentiality for all platform users and service users in all matters of discussion	Yes (high/essential priority)	90.90%	Not a priority/low priority 0/66 (0%)	Essential priority 54/66 (82%)
Anonymity for all platform users and service users in all matters of discussion	Yes (high priority)	84.90%	Not a priority/low priority 0/66 (0%)	Essential priority 39/66 (59%)
Amnesty for all platform users in that they will not be referred to any law enforcement agencies, their employer or regulatory body for either disciplinary or investigative proceedings in any case	No	N/A	Low/somewhat a priority 3/66 (5%)	Essential priority 22/66 (33%)
Prompting platform users automatically to remind them of their responsibilities to their professional codes of conduct.	No	N/A	Somewhat a priority 0/66 (0%)	Essential priority 18/66 (27%)
Prompting platform users automatically to seek help, by signposting them to appropriate support	Yes (high/essential priority)	78.80%	Not a priority/low priority/somewhat a priority 0/66 (0%)	Essential priority 31/66 (47%)
Inclusions of Therapeutic Support				
The inclusion of Web-based videos, multimedia resources, and tutorials which explore topics around psychological distress	Yes (moderate/high priority)	68.20%	Not a priority/low priority/somewhat a priority 1/66 (2%)	High priority 27/66 (41%)
The inclusion of informative multimedia designed to assist midwives to recognize the signs and symptoms of psychological distress	Yes (high/essential priority)	71.30%	Somewhat a priority 0/66 (0%)	High priority 26/66 (39%)
The inclusion of multimedia resources which disseminate self-care techniques	Yes (high/essential priority)	74.20%	Low priority 0/66 (0%)	High Priority 29/66 (44%)
The inclusion of multimedia resources which disseminate relaxation techniques	Yes (moderate/high priority)	65.10%	Not a priority/low priority/somewhat a priority 1/66 (2%)	Moderate priority 23/66 (35%)
The inclusion of mindfulness tutorials and multimedia resources	Yes (moderate/high priority)	66.70%	Low priority 0/66 (0%)	High priority 27/66 (41%)
The inclusion of Cognitive Behavioral Therapy (CBT) tutorials and multimedia resources	Yes (moderate/high priority)	60.60%	Somewhat a priority 0/66 (0%)	Moderate Priority 22/66 (33%)
The inclusion of information designed to inform midwives where they can access alternative help and support	Yes (high/essential priority)	86.40%	Not a priority/low priority/somewhat a priority 0/66 (0%)	Essential priority 31/66 (47%)
The inclusion of information designed to inform midwives as to where they can access legal help and advice	No	N/A	Not a priority/low priority/somewhat a priority 1/66 (2%)	Essential Priority 24/66 (36%)
Giving platform users the ability to share extended personal experiences for other platform users to read	No	N/A	Not a priority 1/66 (2%)	Moderate priority 17/66 (26%)
The inclusion of a Web-based peer-to-peer discussion chat room	No	N/A	Somewhat a priority 2/66 (3%)	High Priority 20/66 (30%)

Statement	Consensus achieved	% of consensus	Minimum score	Maximum score
Giving platform users the ability to communicate any work or home-based subjects of distress	No	N/A	Somewhat a priority 1/66 (2%)	Moderate priority/high priority 16/66 (24%)
Intervention design and practical inclusions				
An interface which does not resemble NHS, employer or other generic health care platforms	No	N/A	Low priority/somewhat a priority 2/66 (3%)	Essential priority 18/66 (27%)
A simple, anonymized email log-in procedure which allows for continued contact and reminders which may prompt further platform usage	No	N/A	Low priority 1/66 (2%)	Moderate priority 20/66 (30%)
An automated moderating system where "key words" would automatically initiate a moderated response	No	N/A	Not a priority/low priority 3/66 (5%)	Neutral 21/66 (32%)
Mobile device compatibility for platform users	Yes (high/essential priority)	71.20%	Low priority/somewhat a priority 0 (0%)	Essential priority 27/66 (41%)

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Table 2. Detailed summary of numeric results for Round 2.

Statement	Consensus achieved	% of consensus	Minimum score	Maximum score
Ethical inclusions				
Amnesty for all platform users in that they will not be referred to any law enforcement agencies, their employer or regulatory body for either disciplinary or investigative proceedings in any case	No	N/A	Not a priority 2/44 (5%)	High priority 9/44 (21%)
Prompting platform users automatically to remind them of their responsibilities to their professional codes of conduct	No	N/A	Somewhat a priority 2/44 (5%)	High priority 9/44 (21%)
Inclusions of therapeutic support				
The inclusion of information designed to inform midwives as to where they can access legal help and advice	Yes (high/essential Priority)	65.90%	Not a priority 0/44 (0%)	High priority 17/44 (39%)
Giving platform users the ability to share extended personal experiences for other platform users to read	No	N/A	Not a priority 0/44 (0%)	High priority 11/44 (25%)
The inclusion of a Web-based peer-to-peer discussion chat room	Yes (moderate/high priority)	63.60%	Not a priority 1/44 (2%)	Moderate priority 15/44 (34%)
Giving platform users the ability to communicate any work or home-based subjects of distress	No	N/A	Not a priority 1/44 (2%)	Moderate/essential priority 11/44 (25%)
Intervention design and practical inclusions				
An interface which does not resemble NHS, employer or other generic health care platforms	No	N/A	Not a priority 1/44 (2%)	Essential priority 13/44 (30%)
A simple, anonymized email log-in procedure which allows for continued contact and reminders which may prompt further platform usage	No	N/A	Not a priority/low Priority 0/44 (0%)	High priority 14/44 (32%)
An automated moderating system where "key words" would automatically initiate a moderated response	No	N/A	Low priority 2/44 (5%)	Neutral 13/44 (30%)
New items for consideration				
An interface which resembles and works in a similar way to current popular and fast pace social media channels (eg, Facebook)	No	N/A	Not a priority 0/44 (0%)	Neutral 12/44 (27%)
The inclusion of midwives from around the world	No	N/A	Not a priority 3/44 (7%)	Moderate priority 11/44 (25%)
Proactive moderation (ie, users are able to block unwanted content and online postings are "pre-approved")	Yes (high/essential priority)	61.40%	Not a priority 1/44 (2%)	High priority 15/44 (34%)
Reactive moderation (ie, users are able to report inappropriate content to a system moderator for removal)	Yes (high/essential priority)	70.50%	Not a priority 1/44 (2%)	High priority 16/44 (36%)
24/7 availability of the platform	Yes (high/essential priority)	84.10%	Not a priority/low priority 0/44 (0%)	Essential priority 25/44 (57%)
The implementation of an initial simple user assessment using a psychological distress scale to prompt the user to access the most suitable support available	Yes (moderate/high priority)	70.40%	Not a priority/somewhat priority 1/44 (2%)	High priority 25/44 (39%)

Statement	Consensus achieved	% of consensus	Minimum score	Maximum score
The gathering of anonymized data and concerns from users, only with explicit permission, so that trends and concerns may be highlighted at a national level.	No	N/A	Not/low/somewhat a priority 2/44 (5%)	Essential priority 15/44 (34%)
Access for a midwife's friends and family members	No	N/A	Essential priority 0/44 (0%)	Not a priority 17/44 (39%)
The follow up and identification of those at risk	Yes (high/essential priority)	63.70%	Low/somewhat a priority 1/44 (2%)	Essential priority 16/44 (36%)
The provision of a general statement about professional codes of conduct and the need for users to keep in mind their responsibilities in relation to them	No	N/A	Not a priority 1/44 (2%)	Essential priority 12/44 (27%)

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Figure 1. Number of Round 1 and 2 opinions, themes and statements achieving consensus.
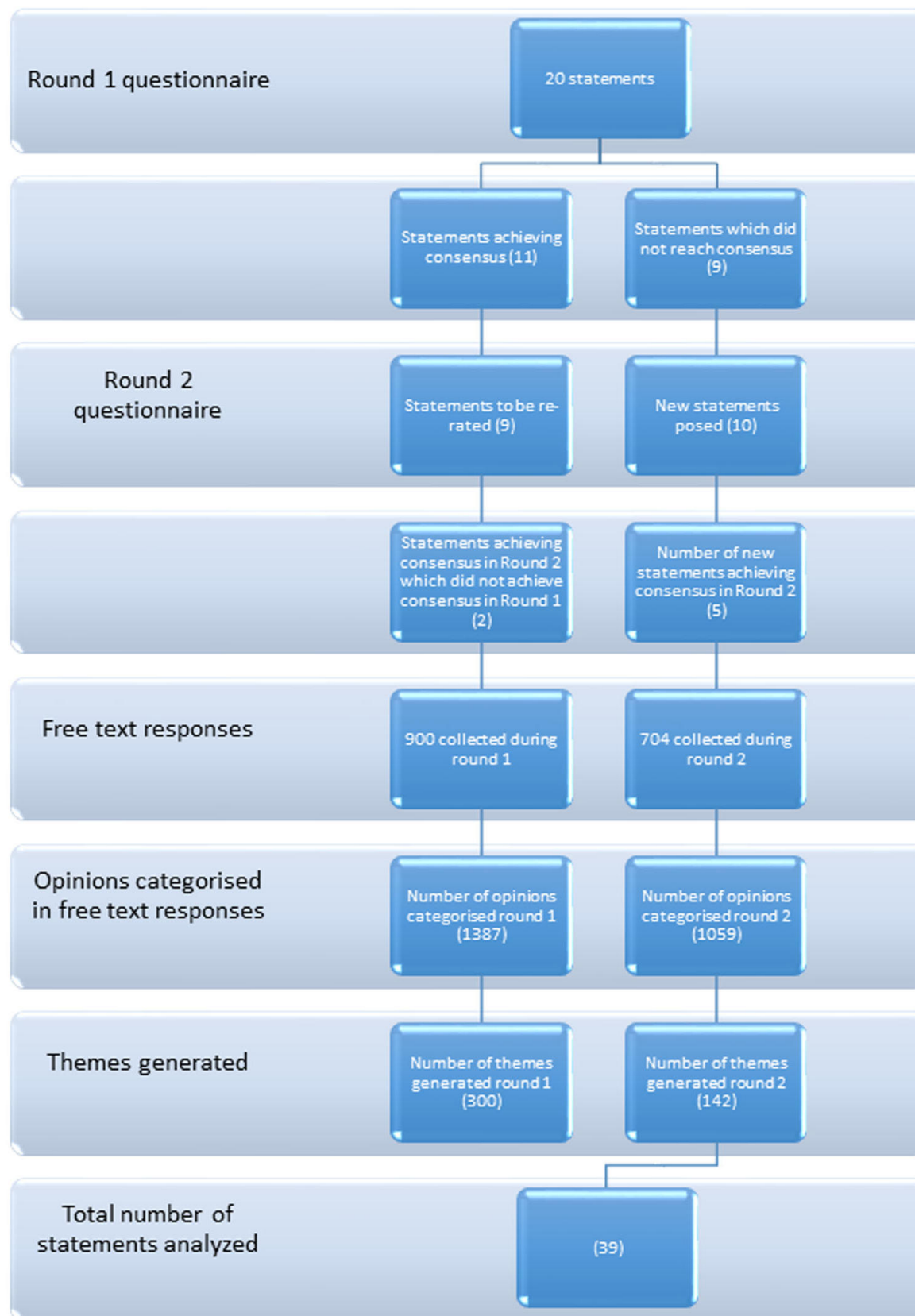
Thematic Analysis

Themes

Full details of the number of statements recorded in each theme are given in Multimedia Appendix 4. Below we describe the thematic analysis, presented by statement type. More detailed reports of the thematic analysis of Round 1 and 2 can be found in Multimedia Appendix 5 and Multimedia Appendix 6, respectively.

Ethical Inclusions

Confidentiality and anonymity were both considered to be an essential priority, with one participant describing how "some midwives would be fearful of people finding out they were finding it difficult to cope and would therefore seek anonymity to feel safe to access support" and another revealing how "anonymity would enable honesty and a true space to unburden" as "a confidential forum allows discussion to take place without feeling judged". However, the corollary to confidentiality and anonymity, amnesty, is a source of tension, both within some participants who are ambivalent about amnesty and between participants with different perspectives.

Panelists remained largely conflicted in opinion about the provision of amnesty. Consequently, consensus was not achieved for the statement regarding amnesty in either Round 1 or Round 2. One comment illustrates this conflict well: "amnesty is an ethical issue, particularly relating to criminal matters; however, without it midwives may not feel able to disclose their concerns causing distress". Polarized views were also apparent, as one comment suggests that "people are not going to be fully revealing if they believe they will suffer as a result!" and another participant expressed concern that this statement "almost suggests that there may be grounds for this route to be considered". Finally, one participant commented that "unless amnesty is assured confidentiality/anonymity won't be maintained".

Opinion remained divided throughout both rounds of questioning about whether an online intervention designed to support midwives should remind users of their professional codes of conduct. Similarly, experts did not agree about whether the provision of a general statement about professional codes of conduct and the need for users to keep in mind their responsibilities in relation to them should be prioritized or not. Although participants expressed a loyalty to their professional codes of conduct, they also conveyed concerns about whether this may deter midwives from speaking openly and/or seeking help. There was also some concern that reminders about codes of conduct may be seen as condescending. Experts were unable to agree upon whether this would inhibit the functionality of effective support or should be provided to reinforce the professional responsibilities of the midwife.

In terms of opening the online intervention up to global midwifery populations, many experts highlighted the challenges in relating to the various cultural and contextual differences across the globe. However, many acknowledged the need for midwifery support all over the world. Equally, when panelists were asked to consider whether an online intervention designed to support midwives in work-related psychological distress should prioritize access for a midwife's friends and family members, a consensus of opinion could not be reached. In this case, experts highlighted that midwives may lose their anonymity if friends and family members were permitted access to the intervention. Many open text responses expressed the need to prioritize access to the intervention for midwives only. One in particular summarizes that "while family and friends provide important support, the needs of the midwife should remain paramount."

Experts expressed a need to prioritize the implementation of an initial simple user assessment using a psychological distress scale to prompt the user to access the most suitable support available. This was largely "as individuals may not realize that they are in psychological distress "or "don't recognize the signs and symptoms of stress, PTSD, depression or anxiety". However, many remained unsure about what may trigger a response, how the user may be prompted, and what support may then be offered. Additionally, experts stated that midwives may feel uncomfortable with this level of screening. This point was also one of the reasons given by panelists reluctant to prioritize the gathering of anonymized data and concerns from users, even with explicit permission. Where many experts saw the benefits of capturing national trends, with one comment summarizing that it may be "critical that trends are identified and strategies developed to address those trends at a national level", others were wary that if this was the case, midwives may be reluctant to engage.

Experts agreed that the intervention should prioritize the follow-up and identification of those at risk. However, there were requests to clarify the definition of what may classify someone as being "at risk". Some panel members suggested that "if suicidal behavior is conveyed through the postings" or if there is "talk of harming someone", those individuals may be identified as being "at risk". Yet many open text responses illuminated the difficulties in following up anonymous users. Some experts were also unsure about how this particular component may be facilitated. Additionally, others purported that this should not be the responsibility or purpose of this particular online platform.

The expert panel concurred that midwives using the platform should be automatically prompted to seek help, by signposting them to appropriate support. However, some panelists questioned how this may be organized, what types of support may be on offer, and whether or not this provision may encourage users to pathologize normal reactions to certain types of events.

Therapeutic Support

In terms of the nature of the support within an online intervention to support midwives, the expert panel agreed that priorities include Web-based videos, multimedia resources and tutorials which explore psychological distress and assist midwives to recognize the signs and symptoms of psychological distress. One comment which illustrates a widely held belief was that "midwives often feel guilty for catching up on sleep, having time out watching TV, gently exercising with friends etc." As such, it was also agreed that an online intervention should prioritize resources which disseminate self-care techniques and Cognitive Behavioral Therapy (CBT) tutorials through a range of online media sources. Largely, it was inferred that this online intervention should establish itself as a "one stop shop".

Expert participants also agreed that midwives in distress should be offered information designed to inform them where they can access alternative help and support. The most frequent reason given for this was the need for provision of choice. Equally, there was consensus that an online intervention should prioritize

the inclusion of information to inform midwives about where they can access legal help and advice. During Round 1, participants noted that midwives could already find this information from trade unions such as the Royal College of Midwives (RCM), and may be further distressed by the thought of needing legal assistance. Yet one comment in particular highlighted the notion that "we live in a litigious and unforgiving world". However, during Round 2, experts noted that midwives may need a wider range of legal information available to them in order to be prepared should a need arise. One comment illustrated this by reiterating that "any help and advice is welcome".

When expert panelists were asked whether an online intervention to support midwives should prioritize giving users the ability to share extended personal experiences for other platform users to read, no consensus of opinion was reached. Open text responses gravitated towards concerns relating to breaches in confidentiality, risk of misuse, and the need for active moderation. However, a number of responses highlighted the potential cathartic and therapeutic benefits of both reading and writing personal experiences, providing opportunities for reflection, sharing, learning, and fellow feeling with others.

Although experts did not agree to prioritize the inclusion of a Web-based peer-to-peer discussion chat room during Round 1, within Round 2 this item became a moderate to high priority inclusion. While many experts expressed a need for the appropriate moderation of an online chat room, the benefits of peer-based discussion were highlighted as a key component of support. One comment summarizes these thoughts by stating that "sharing experiences and getting feedback from peers who have experienced similar situations is very helpful". More significantly, it was also highlighted that this chat room "would require high volume site traffic to be viable and sustainable". When asked about topics of discussion within the chat room, experts did not reach a consensus as to whether the chat room should give users the ability to communicate any work or home-based subjects of distress. However, these two subjects were seen as being intertwined.

Intervention Design and Practical Inclusions

Regarding the aesthetics of the online intervention, opinions remained divided about whether the intervention should resemble any National Health Service (NHS), employer or other generic health care platforms. Although the panel acknowledged that the intervention should look trusted, professional and official, they were also wary that should the intervention resemble an official health care organization, midwives may feel unable to speak openly. One particular comment defines opinion in that "any resemblance to NHS etc.… could deter people from using the platform", however, this same panelist also felt that the intervention "needs to resemble a clean professional image". Additionally, panelists remained divided in opinion and wary of an anonymized email log-in procedure which allows for continued contact and reminders which may prompt further platform usage. Although experts favored the use of anonymity in log-in procedures, some felt that prompting use may cause further distress.

In terms of accessibility and ease of use, experts agreed that making the intervention available to midwives in work-related psychological distress 24 hours a day and via mobile access should be made high to essential priorities. However, experts did not agree upon whether an online intervention to support midwives in work-related psychological distress should prioritize an interface which resembles and works in a similar way to current popular and fast-paced social media channels (eg, Facebook). In this case, many free text responses alluded to the fact that Facebook and other social media channels are perceived as risky to use by midwives. Nevertheless, many other comments suggested that emulating the familiarity of a known platform may promote an inherent ability for midwives to engage with the intervention more sinuously. Ultimately, one particular comment summarizes that "ease of use and familiarity for most users will encourage engagement".

The importance of effective moderation remained a recurrent theme throughout this study. Experts agreed that both proactive moderation (ie, users are able to block unwanted content and online postings are "pre-approved") and reactive moderation (ie, users are able to report inappropriate content to a system moderator for removal) should be made high to essential priorities. One comment in particular highlights one recurring theme in that "the platform needs to be regulated to avoid inappropriate posts and language".

Other interventions of this nature have employed an automated moderating system where "key words" would automatically initiate a moderated response. However, this group of experts remained divided about whether this should be prioritized in an online intervention to support midwives. Many panelists cited the importance of regulation; however, some were unsure about how this particular provision may work in the real world. Additionally, fears were raised that this provision may make the intervention seem impersonal. Overall, it was the principal judgment of this group that, easy 24-hour mobile access and "an easy log-in and easy to use interface couldn't be more essential".

Summary of Results

Out of 39 questions posed over two rounds, 18 statements (46%) achieved consensus, 21 (54%) did not. Provisions that were endorsed tended to favor those which enabled knowledge acquisition, ease of use, ongoing support, skill development, and human interaction. The highest priority scores were given to the provisions of anonymity (84.9%) and confidentiality (90.9%). For those items which achieved consensus, the lowest priority scores were given to the provisions of CBT resources (60.6%) and proactive moderation (61.4%). Overall, the expert panel agreed that each statement should be made at least a moderate priority.

Overall, open text responses demonstrated both interest and enthusiasm for the development of an online intervention to support midwives in work-related psychological distress. However, some provisions were favored over others, and in some cases, when invited to engage in moral decision making participants were polarized and conflicted in opinion.

Discussion

Principal Findings

This Delphi study has extracted the priorities, associated underlying beliefs and opinions of a panel of experts regarding the delivery of an online intervention to support midwives in work-related psychological distress. The expert panel in this case identified 18 statements to be prioritized by those seeking to design and deliver an online intervention to support midwives. This is the first study of this type to identify these matters of salience. Additionally, the thematic analysis of free text responses offered by the panel illuminates the ethical, moral, and practical challenges involved in the design and delivery of an effective online intervention to support midwives.

Overall, the recurring themes explored by this study were the reluctance of midwives to speak openly and/or seek help for the fear of retribution, the need for both anonymity and confidentiality at all times, ease of use, effective moderation and the necessity to help and support midwives in work-related psychological distress. Challenges remain in complex ethical, legal, and moral decision making in facilitating effective online support provision for midwives in distress.

Interpretation of Findings

Interestingly, based on quantitative and qualitative responses, participants in this study do not readily differentiate between confidentiality and anonymity in this particular context. Their reasons or justifications for the requirement to have both confidentiality and anonymity are generally very similar. Ethicists and intervention developers may differentiate between these two concepts but this group does not. There is no meaningful difference between confidentiality and anonymity for this stakeholder group, which largely comprises the potential end users of the online resource.

When both confidentiality and anonymity are in place, their corollary, amnesty becomes apparent. Many of the expert panel members cited that midwives would not speak openly for the fear of stigma and retribution. Indeed, these findings have been verified within other studies where midwives reported stigma, and a perceived punitive response to face-to-face discussions concerning work-related traumas [6,7,9,21]. As such, many of the expert panel members saw amnesty as an essential provision in supporting midwives to seek help. Other panel members were opposed to the provision of amnesty, either because they feared that this would be in direct conflict with moral or professional duties and obligations, or because they favored immediate accountability for the direct protection of the public and patients. A number of panel members recognized both sides of this argument, and were therefore unable to decide their position in this case. This moral conflict is reflected in the many confidential health practitioner services that exist for doctors in distress [22-24]. In these cases, the public recognize the value in offering impaired physicians' identity protection for the purpose of remediation, yet they also call for open reporting where risks to patients and the public are identified within the public sphere.

The primary concern for those who are ambivalent or who are opposed to amnesty was the risk of harm to third parties by midwives; both preventing future harm and accountability for harm that has already occurred. Satisfying this concern will be essential for the acceptance of an online resource for midwives experiencing psychological distress. One element of negotiation may be to encourage those in distress to self-disclose episodes of impairment with the support of the online community. This idea is supported by one free text response which purports that "ideally an online platform should encourage the professional themselves to take action if appropriate". This outcome could result in more midwives coming forward in help-seeking, for the benefit of maternity services as a whole.

It is clear that this expert group feels that a range of multimedia resources in relation to help-seeking, diagnostic criteria, therapeutic, and practical inclusions should be prioritized in the development of an online intervention to support midwives. Future developments should consider becoming a "one stop shop" for midwives in relation to this finding. Going further, it may be prudent to develop online interventions with the functionality to incorporate a range of midwifery populations, global health care workforces, and other groups of clinical professionals as a prospective future growth model evolves. This concept is also supported by an expert response, suggesting that "in developing this platform for a specific group of midwives, a future goal may be to adapt it for other specific groups once this project is functioning and any difficulties have been eliminated".

In developing an effective online intervention to support midwives in work-related psychological distress, the practicalities of galvanizing a large user base, evolving a robust system of moderation and rousing the support of professional and regulatory bodies will be vital in securing its sustainability. Gaining the trust of midwives in distress and engaging them in using a safe online intervention may enable this one solution to flourish and improve the health of midwives, which crucially may increase protection for the public, secure the long term health of midwives, and increase safety for maternity services. This study will be integral to the development process of any online intervention designed to support midwives, as the application of this data to the development process optimizes the likelihood of accomplishing an efficacious intervention overall.

Strengths and Limitations

The research team invited experts in the subject areas of both e-mental health and m-health via the academic emails provided in recently published research papers to participate within this study. We also invited midwives, psychologists, psychiatrists, other physicians, and academic experts to take part. While this Delphi study has harnessed the opinions of a diverse group of experts on a practice-related problem, we are unable to verify the expert status of all participants due to the provision of participant anonymity. Therefore, some fields of expertise may not have been reflected in the data.

Although we acknowledge that the decision to allow respondents to be completely anonymous in a Delphi study is an unusual one, we feared that participants would feel unable to be

completely open and honest without the provision of anonymity in place. As such, this course of action has undoubtedly impacted upon the confirmation of the participants' expertise, especially as the expertise of participants was not confirmed by the research team, leaving participants merely to consent to having the relevant expertise.

Additionally, and unlike many Delphi studies, the feedback provided after each round did not include each participant's own previous response. This was again due to the provision of anonymity afforded to participants. Therefore, Participants were unable to compare their own response to the groups' response. We also note that there has been a significant participant dropout rate between the two rounds. Therefore, the change in item endorsement may have been influenced by the different participants that remained in the study. This is a limitation of this study, but one that is not possible to explore.

Though our response rates may be deemed relatively low (35.7% and 67% respectively), these response rates are similar to those found in other Delphi studies [25,26]. Additionally, the Delphi technique relies on the opinions of those recruited, yet its methodology requires empirical measures to determine consensus. Therefore, the presence of consensus in this study has been determined empirically and was specified in advance of data collection.

Our literature searches to both identify salient themes and recruit expert panel members were broad. As such, our searches may have failed to identify some key papers of relevance and potential expert panel members. Our search terms were led by a process of snowballing, where the research team responded to emerging themes and findings [19]. We recognize that these searches may not have captured all of the key literature relating to the characteristics which may be salient in supporting midwives online.

Conclusions

This paper has reported the results of a two-round Delphi study to achieve consensus about the key features of online interventions to support midwives in work-related psychological distress. This study provides an account of some key priorities for the development of such interventions; although some practical, ethical, and moral challenges remain unresolved.

In pursuit of excellence in maternity services, future research has the opportunity to explore the provision that might best support midwives in psychological distress. Future studies could use this information to turn the vision of online support for midwives in distress into practice.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Social media engagement and recruitment summary.

[JPG File, 135KB - mental_v3i3e32_app1.jpg]

Multimedia Appendix 2

Participant report – Round 1.

[PDF File (Adobe PDF File), 211KB - mental_v3i3e32_app2.pdf]

Multimedia Appendix 3

Participant report – Round 2.

[PDF File (Adobe PDF File), 155KB - mental_v3i3e32_app3.pdf]

Multimedia Appendix 4

Results of thematic analysis.

[PDF File (Adobe PDF File), 152KB - mental_v3i3e32_app4.pdf]

Multimedia Appendix 5

Analysis report – Round 1.

[[PDF File (Adobe PDF File), 1MB](#) - [mental_v3i3e32_app5.pdf](#)]

Multimedia Appendix 6

Analysis report – Round 2.

[[PDF File (Adobe PDF File), 1MB](#) - [mental_v3i3e32_app6.pdf](#)]

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Abbreviations

CBT: Cognitive Behavioral Therapy
NHS: National Health Service
PTSD: Post-Traumatic Stress Disorder
RCM: Royal College of Midwives

Original Paper

Can We Foster a Culture of Peer Support and Promote Mental Health in Adolescence Using a Web-Based App? A Control Group Study

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Abstract

Background: Adolescence with its many transitions is a vulnerable period for the development of mental illnesses. Establishing effective mental health promotion programs for this age group is a challenge crucial to societal health. Programs must account for the specific developmental tasks that adolescents face. Considering peer influence and fostering adolescent autonomy strivings is essential. Participation in a program should be compelling to young people, and their affinity to new technologies offers unprecedented opportunities in this respect.

Objective: The Companion App was developed as a Web-based app giving adolescents access to a peer mentoring system and interactive, health-relevant content to foster a positive peer culture among adolescents and thereby strengthen social support and reduce stress.

Methods: In a control group study design, a group of employed (n=546) and unemployed (n=73) adolescents had access to the Companion App during a 10-month period. The intervention was evaluated using a combination of quantitative and qualitative approaches. Linear mixed effects models were used to analyze changes in chronic stress levels and perception of social support. Monthly feedback on the app and qualitative interviews at the end of the study allowed for an in-depth exploration of the adolescents' perception of the intervention.

Results: Adolescents in the intervention group did not use the Companion App consistently. The intervention had no significant effect on chronic stress levels or the perception of social support. Adolescents reported endorsing the concept of the app and the implementation of a peer mentoring system in particular. However, technical difficulties and insufficiently obvious benefits of using the app impeded more frequent usage.

Conclusions: The Companion Project implemented a theory-driven and innovative approach to mental health promotion in adolescence, taking into account the specifics of this developmental phase. Particularities of the implementation context, technical aspects of the app, and insufficient incentives may have played considerable roles concerning the difficulties of the Companion Project to establish commitment. However, adopting peer mentoring as a strategy and using an app still seems to us a promising approach in mental health promotion in adolescents. Future projects should be careful to invest enough resources into the technical development of an app and consider a large use of incentives to establish commitment. When targeting risk groups, such as unemployed adolescents, it may be expedient to use more structured approaches including face-to-face support.

Introduction

Fostering Adolescent Health

There is now substantial evidence that thoughtfully designed health promotion programs for adolescents can be efficient and cost effective [1-3]. However, such programs must account for the specific developmental challenges adolescents face and carefully consider their expectations and needs [4]. We advocate that this implies accounting for the importance of peer influence and the adolescent drive for autonomy. Moreover, program participation needs to be compelling to young people.

Including Peers and Fostering Empowerment

Adolescents must navigate many biological, cognitive, and psychosocial transitions. Most of all, they have to confront themselves with who they are and who they want to be [5,6]. Distancing themselves from parental ties, adolescents find new identifications and role models within their peer group [7,8]. Given the crucial importance of peer influence in adolescence [9-11], prevention programs should consider targeting peer groups as a whole. It is with their peers that adolescents negotiate health-related behaviors and attitudes. While research on peer groups has long focused on their role in reinforcing maladaptive behavior (eg, substance use), the peer group is also a place where self-enhancing and healthy behavior can be reinforced. In the 1980s, Vorrath and Brendtro [12] developed the concept of a positive peer culture by assuming that young people need to identify with positive values, such as caring for their peers and helping them thereby improving their self-worth, feeling significance, and enhancing responsibility. Similarly, the positive youth development perspective has gained importance in adolescent research, stressing the resources and potentials of young people [13,14]. There are a number of preventive intervention programs that built on these ideas with considerable success [15-18]. Most programs aimed at promoting emotional and social core competencies such as self-determination, confidence in oneself and the future, engagement for others, and prosocial bonding. Many encouraging findings of these studies expand upon insights gained during decades of research on the protective role of social support for mental (and physical) health [19-23].

Health promotion programs for young people need to provide for their desire to act and feel autonomously. Adolescents strive for a sense of self-governance, self-reliance, and individuation [8]. Adopting participatory approaches such as those advocated in youth empowerment approaches are promising in this respect [24,25]. Young people do not want to be addressed as passive recipients in health promotion programs; they want to be respected as active agents with sophisticated knowledge on health relevant issues and the socioeconomic environment in which they live [26]. Programs must account for the adolescents' perspective on their health and how they construct their world [4,27]. Ideally, this should be the foundation of the development and implementation of a mental health promotion program.

Peer approaches account for both the essential influence of peers on the adolescent individual behavior and the adolescent drive for autonomy. They build upon existing expertise among adolescents and their specific view on health-related issues. There is a growing body of research on peer education in health promotion; examples exist in the field of HIV prevention [28] and substance use [29]. Peer mentoring has played a less prominent role in health promotion to this point, although we can refer to many insights from research on other forms of mentoring [30,31]. In fact, peer mentoring appears particularly attractive for health promotion efforts that embrace a holistic approach and do not target prevention of a specific pathology [32]. Karcher [33] demonstrated the usefulness of cross-age peer mentoring in a program with high school and elementary school students in a randomized trial. He showed the program enhanced feelings of connectedness to school and parents and that mentor attendance had a positive impact on several psychosocial outcomes in mentees. Results such as these are promising and may also be transferable to other contexts such as adolescents in transition to work life.

Choosing an Attractive Medium to Reach Young People

The means of program delivery is an important aspect of health promotion efforts in adolescence. Research suggests that the use of new media provides powerful tools for health promotion programs. Adolescents in Switzerland and other high-income economies show a great affinity for smartphones and social media; 97% of Swiss 12- to 19-year-olds and 83.7% of American 13- to 17-year-olds own a smartphone [34,35]. Mobile's share of Internet use is steadily growing [36], and apps are becoming more dominant: 86% of the time on American mobile devices is spent on apps [37]. New technologies supply novel forms of participatory communication that may render health promotion programs more attractive to young people. During the last decade, a growing number of studies have implemented new technologies in mental health promotion and prevention programs in adolescents [38]. Modalities such as cognitive behavioral therapy (CBT)–based Internet programs, Internet-based education programs, psychoeducational websites, online professional support and self-help groups and forums, counseling chats, Internet group therapy in chat rooms, and Internet-based games have been used to promote health and prevent mental disorders. Interventions are aimed at healthy adolescents, adolescents at risk, and adolescents with psychiatric symptoms, mostly in the context of mood disorders or disturbed social functioning. It remains difficult to judge the overall effectiveness of such interventions. Study designs are heterogeneous, and their quality varies to a great extent. There is growing evidence for the effectiveness of CBT-based programs for mood disorders [39]. Other approaches still need to strengthen their evidence base. Specifically, we know little about the effectiveness of peer approaches using new media. Two recent interventions integrated such an approach but could not show any effects of their intervention [40,41]. Few interventions have explored the advantages of implementing a

project via an app [42], although there has recently been an effort to clarify the premises of using smartphone apps in mental health care and prevention [43].

The Companion Project took on this challenge and developed an app (the Companion App) aiming at fostering peer support and reducing stress in adolescents.

The Context and Aims of the Companion Project

Being an Adolescent in Switzerland

After lower secondary education, two-thirds of Swiss adolescents start work life with an apprenticeship. On average, they are 15.5 years old when leaving lower secondary education [44]. This requires choosing a profession and beginning an adult-life work rhythm at a young age. In a recent study on stress levels in the Swiss working population, Grebner et al [45] found not only that chronic stress is a widespread issue but also that young workers (aged 15 to 24 years) experience higher stress levels than their older colleagues. Many Swiss apprentices report being markedly exposed to the experience of stress [46] and desire support in this respect [47]. Furthermore, adolescents who do not manage the transition from school to a profession are a particularly vulnerable group suffering from psychological distress [48,49]. Given the major mental health impairments that may result from unemployment at this age [50], these young people should be given special attention. So far, no specific stress reduction or mental health promotion strategies have been implemented for adolescents taking their first paths into work life in Switzerland nor for those failing to do so. The Companion Project fills in this gap.

Aims and Hypotheses

The Companion Project pursued a global approach to promote mental health in adolescents taking their first paths into work life as well as for those failing to do so. We proposed that the peer mentoring system, increased communication via the Companion App, and informational elements of the app would contribute to a positive peer culture among users. We supposed that enhanced social support through peers would globally promote the well-being of the adolescents and specifically impact experienced stress levels. Correspondingly, we hypothesized that the intervention via the Companion App would influence stress levels (reduce chronic stress) and perceived social support (augment perceived social support) in the adolescents of the intervention group compared to controls.

Methods

Overall Study Design

The Companion App was developed based on the theoretical premises described above and as part of a mental health promotion effort initiated by Health Promotion Switzerland [51]. Health Promotion Switzerland aimed at developing a specific intervention targeting employed (in an apprenticeship) and unemployed youth. The conception and features of the Companion App were developed by the study team and discussed with the target group. Our information technology specialist team ran the technical implementation. The Companion App was then tested in a 10-month study using a control group design (Figure 1). The Companion App was introduced to the adolescents in a group presentation at the beginning of the study. Special attention was drawn to the peer mentoring system during that presentation. Throughout the study, the frequency of use of the Companion App was monitored: access to the app was tracked using Google Analytics. Importantly, the research team did not access the content users put on the app (eg, messages) because anonymity was guaranteed. Several incentives were employed to stimulate use of the app, such as monthly emails reminding the adolescents of the app and the peer mentoring systems and the distribution of flyers and posters. Users were invited to answer a monthly survey on the app concerning their use and suggestions for improvement. Doing so, they could participate in a lottery. Stress levels and perception of social support were evaluated before and after the intervention. Qualitative interviews at the end of the project explored the adolescent perceptions of the intervention and the Companion App.

Figure 1. Control group study design.
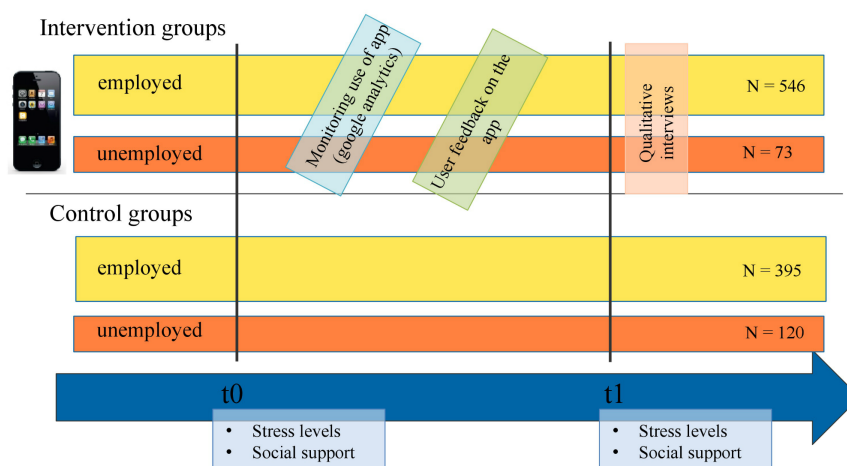
Recruitment

For the employed group, workers in their first and second year of apprenticeship at a large Swiss company were recruited for the intervention and control groups. In the intervention group, all apprentices across professions and sites of the company had access to the Companion App (n=546). The control group received no intervention and was recruited from different regional sections of the same company (n=395). For the unemployed adolescents, the intervention group was recruited from a publically financed transitional program for unemployed youth (n=73). The control group was, again, recruited from a different regional section of the same type of transitional program (n=120). We based our recruitment on an estimation of the necessary sample size to detect a small-to-medium effect size at a 95% confidence level according to Cohen [52]. Approximating the statistical models we used in order to explore changes in chronic stress and the perception of social support, we assumed a regression model with 6 predictors. Given such a model, a sample size of 200 is sufficient to detect an effect of R^2=.07 with a power of .83.

Instruments

Stress was measured using the Trier Inventory of Chronic Stress (TICS) [53], a 57-item scale tapping different stress dimensions including work overload, social overload, pressure to perform, work discontent, excessive demands from work, lack of social recognition, social tensions, social isolation, and chronic worrying. All items are rated on a 5-point Likert scale (0 = never, 1 = rarely, 2 = sometimes, 3 = often, 4 = very often). Answers refer to how often participants had an experience during the last 3 months. The Trier Inventory of Chronic Stress screening scale (TICS-SCSS) uses 12 of the most salient items of the other dimensions and provides a global index for chronic stress. In our sample, all scales of the TICS showed good to excellent internal consistency (Cronbach alpha range .80-.92).

Satisfaction with social support and reciprocity in social support were captured using two scales of the social support questionnaire (Fragebogen zur sozialen Unterstützung, F-Soz-U) [54]. Whereas satisfaction with social support using four items showed good internal consistency (Cronbach alpha=.83), the internal consistency of reciprocity in social support using four items was questionable (Cronbach alpha=.63). All items are rated on a 5-point Likert scale (0 = strongly disagree to 4 = strongly agree).

Procedures

We evaluated stress and perception of social support before and after the intervention. In the employed group, questionnaires were administered in paper-and-pencil form at the beginning of the year of apprenticeship (t0) and at the end (t1). For apprentices in their second year of apprenticeship, the t1 evaluation was done using an online survey. In the unemployed

group, evaluations took place when the young people first joined the transitional program (t0) and when they left (t1). They filled out paper-and-pencil questionnaires. In general, adolescents leave the transitional program once they find an apprenticeship, an internship, or another form of employment.

At the end of the study, we also conducted semistructured interviews with 6 employed adolescents and 8 unemployed adolescents for an in-depth exploration of their perceptions of the Companion Project.

The Companion App

The concept of the Companion App was discussed with adolescents taking their first paths into their working life. Five school classes with 10 to 15 apprentices aged 15 to 17 years participated in focus groups and discussed their expectations and needs concerning a mental health promotion intervention.

Core features of the Companion App:

- Peer mentoring system: every Companion App user had a mentor who was in a similar professional situation. The peer mentoring system was presented to all of the app users in the beginning of the intervention. Emails explaining the mentoring system and reminding the Companion App users of it were sent once a month during the intervention. In the employed group, mentees and mentors were associated by the research team based on their apprenticeship and location. In the unemployed group, the mentoring system was looser. App users could ask other users on the app to become their mentor.
- Individual profile for each user with the possibility to upload pictures and mention specific interests
- Messaging and discussion groups
- Links to interactive and informative websites on mental health-related issues (eg, psychological tests, sexuality, drug use)
- Links to websites concerning leisure activities (eg, tips for going out on the weekend)
- An anonymous professional counseling service (run by a psychologist or social worker) including a blog run by the professional with posts on diverse topics

The Companion App (see Figure 2) was programmed as a Web-based app so users could access it from either a smartphone or a computer.

During the Companion Project, all users had the option to give monthly feedback on their use of the Companion App and to communicate suggestions for improvements or new features. Frequently mentioned suggestions consistent with the app's concept were then implemented in the app. For instance, some users asked for the option to have a status on their profile, where they could describe current activities. A corresponding feature was added during the study.

Figure 2. Design of the companion app.
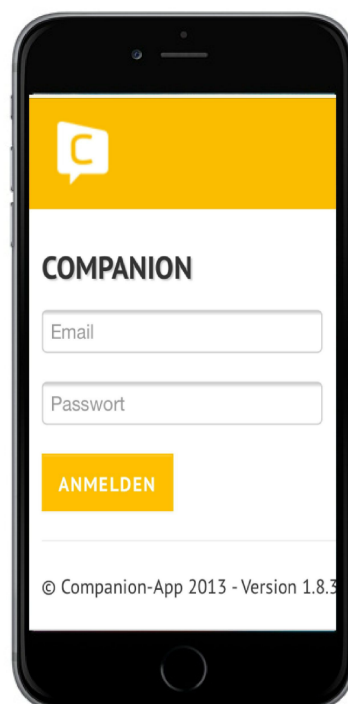
Analyses

Descriptive statistics were used to describe the sample, and all statistical analyses were conducted using SPSS 22 (IBM Corp). Monthly surveys on the frequency of use, perception of the app, and suggestions for improvement were analyzed regrouping answers into thematic categories. Access to the app was recorded using Google Analytics. Qualitative interviews were conducted using a semistructured interview outline. Interviews were coded and answers categorically regrouped using the qualitative data analysis software MAXQDA (Verbi GmbH).

Multiple linear regression was used to analyze stress levels and perception of social support. Status of employment (employed vs unemployed), gender, nationality (Swiss vs non-Swiss), and age were used as predictors while stress and the perception of social support were dependent variables in separate regression models.

Linear mixed models were then employed to investigate changes in stress levels and the perception of social support during the Companion Project. These models allow analyses of data with repeated measures estimating changes at the individual as well as at the group level. To estimate differences between control and intervention groups and changes over time (group-time interaction), sets of predictors were used in different models and compared with likelihood-ratio tests. The sequence of predictor sets is described in the results section.

Results

Participants

In the employed group, 477 apprentices in their first year participated in the t0 (return rate of 477/492, 97.0%) and 443 in t1 evaluation (return rate of 443/492, 90.0%). Evaluations

were anonymized. Apprentices filled out a personalized but anonymous code on their questionnaires (first letter of the first name of mother and father and the sum of their date of birth). Due to many errors in these codes, only 65.9% (292/443) of the questionnaires could be matched (matching code from t0 to the one of t1). A total of 464 apprentices in their second year participated in the t0 (return rate of 464/472, 98.3%) and 226 in the t1 online evaluation (return rate of 226/472, 47.8%). More than two-thirds (156/226) of the t1 questionnaires could be matched to the corresponding t0 questionnaires.

In the unemployed group, 193 adolescents participated in the t0 and 43 in the t1 evaluation. We estimated that return rates were 43% for t0 and 10% for t1. Because of the small number of t1 evaluations, the data of this group was not analyzed longitudinally.

In the employed group, age was on average 16.9 (standard deviation [SD] 1.73) years in the first year of apprenticeship and 17.6 (SD 1.46) years in the second. A total of 50.2% and 56.7% of the participants were female in the first and second years, respectively.

In the unemployed group, participant average age was 18.4 (SD 1.96) years, and 40.4% of the participants were female.

Use of the Companion App

Google Analytics revealed that in the first two weeks of the study, the app had 61 daily visits on average with a peak of 189 visits the day after we sent out the log-in details to the adolescents. Six months later, halfway through the project, daily visits over two weeks averaged 8. A significant augmentation in use was not achieved until the end of the study.

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Companion App User Feedback

In the employed intervention group, adolescents were invited to evaluate their use and satisfaction with the app 8 times. On average, 34.4 adolescents participated in these evaluations. Evaluation 1 had the most participants, with a total of 60.

In evaluation 1, the most frequently identified reasons for using the app were curiosity and interest in a new app (13 answers, regrouped into this thematic category) and getting to know other apprentices (14 answers). Participants also mentioned that they used the app because of the peer mentoring system (6 answers) and for the psychological tests that they could take on the app (4 answers).

The most frequently mentioned reasons for not using the app more often were that participants could not see the benefits of using the app (14 answers) and lack of time (12 answers). Moreover, participants mentioned that they did not use the app more frequently because there was not enough activity by other users (5 answers) and there had been technical difficulties (3 answers).

Participants suggested making the design of the app more attractive (eg, improve the layout, create a more intuitive structure; 8 answers) and rectifying technical issues (7 answers). Some participants suggested rendering the app more interesting by creating supplementary contents such as games or by connecting the Companion App to other social media or existing Web platforms of the company (5 answers).

Qualitative Interviews

Qualitative interviews were conducted with both employed (n=6) and unemployed adolescents (n=8) in the intervention group for an in-depth analysis of their perceptions of the Companion App project (Table 1).

The majority of the interviewees in both groups regarded the concept of the app as well conceived. For instance, participant 4 said, "I like the basic idea, the idea of helping one another and getting feedback from a friend instead of an authority." Equally, almost all of the interviewees judged that a peer mentoring system would be helpful to them. Whereas the majority of employed adolescents reported that they would ask a mentor questions about organizational aspects of their apprenticeship, the unemployed adolescents said that they would turn to a mentor for advice on how to best find an apprenticeship

and how to perform best during a working trial. For example, participant 5 said, "I would ask [my mentor]: How did you do it [find an apprenticeship], what was your approach? How did you pull through, where did you find the energy for that?"

Concerning the design of the app, the most common feedback from the employed adolescents was that they thought it was well structured and visually attractive. The content was judged informative and interesting. Most interviewees said that the Companion App would offer them something specific that existing commercial apps could not provide. However, all interviewees judged that the app was not competitive compared to existing apps on the market.

Both employed and unemployed adolescents named technical problems as the main reason for not using the app more frequently. Some of them had forgotten their log-in details and did not put any effort into getting a new log-in, as illustrated by participant 10's statement: "The only reason I didn't use it was that I forgot my password." Additionally, interviewees reported lacking interest and not knowing the purpose of the app as further reasons for not using it. In the employed group, three adolescents also said that they communicated on other social media platforms. Moreover, two interviewees named a missing user base as a reason for not using the app more frequently.

The two groups differed substantially in their suggestions on how to improve the app. Whereas the majority of employed adolescents recommended easier and more intuitive handling of the app, the majority of unemployed adolescents suggested that the app should be promoted more intensively. In line with that, unemployed interviewees also mentioned that it would have been a great help to them to be reminded more frequently to use the app.

In sum, all of the interviewed adolescents who used the Companion App rated the content and design as attractive and well conceived. All interviewees appreciated the idea of having a peer mentor and being able to ask him or her for advice on aspects of their professional situation. They mentioned that the handling of the app should be improved and technical problems resolved. Unemployed interviewees reported that it would have been a help to be reminded more frequently and that the app should have been promoted more intensively.

Table 1. Selected quotes from interviews regrouped into thematic categories.

Category	Subcategory	Example
Perception of the app		
	Design	I think the app is professionally designed. [Participant 11]
	Content	Lots of information and diverse topics. [Participant 1]
	Handling	The handling is inconvenient [...]. [Participant 12]
Obstacles to frequency of use		
	Technical issues	My password wasn't valid, and I didn't try again. [Participant 6]
	No interest	I didn't want to download the app. [Participant 7]
	Purpose uncertain	The app was briefly explained, but I didn't entirely get it. [Participant 3]
	Missing user base	[I did not use the app more often]...because my friends didn't use it. [Participant 13]
	Other networks used	Since there are Facebook and other platforms, those are used more frequently. [Participant 10]
Areas of improvement		
	Easier handling	Faster access. [Participant 12]
	Extended promotion	Promotion should be extended, more precise and more attractive information. [Participant 2]

Stress and Social Support

Stress levels and the perception of social support were explored before and after the intervention in a control group design. Here, we first report our findings at baseline and then those on changes in stress levels and the perception of social support throughout the study.

At baseline, employed adolescents of the intervention group (539/964) showed a mean score of 1.25 (SD 0.64) on the TICS-SCSS assessing chronic stress. This means that on average these adolescents had rarely experienced chronic stress during the last 3 months. The mean of perceived social support (measured with the F-Soz-U) was 2.74 (SD 0.85) implying that employed adolescents were often satisfied with the social support they received.

Unemployed adolescents of the intervention group (73/193) showed a mean score of 1.37 (SD 0.66) on the TICS-SCSS at baseline, implying that on average they also had rarely experienced chronic stress during the last three months. On the F-Soz-U, they showed a mean of 2.63 (SD 0.92) indicating that they were often satisfied with the social support they experienced.

We used multiple linear regression to explore differences in chronic stress and the perception of social support considering the status of employment, gender, nationality (Swiss vs non-Swiss) and age. Regarding chronic stress, employment and age did not significantly predict this dimension, while gender and nationality did (see Table 2). However, the variance explained by the model was small, with R^2=.04, $F_{4,549}$=5.73, P<.001. Visual inspection of residual plots revealed no obvious deviations from homoscedasticity or normality.

An equivalent model was applied regarding perceived social support. Age and gender but not employment or nationality predicted perceived social support (see Table 3). The variance explained by the model was, again, small with R^2=.025, $F_{4,528}$=3.36, P=.01. Also, visual inspection of residual plots revealed slight deviations from homoscedasticity and normality.

Table 2. Multiple linear regression by chronic stress (employment reference category—employed, gender reference category—female, Swiss reference category—Swiss).

Predictor	B	SE B	β	T	P value
Constant	1.311	.040	—	33.063	.000
Employment	.081	.092	.038	.876	.381
Gender	−.223	.054	−.177	−4.158	.000
Swiss	.138	.062	.094	2.234	.026
Age	.016	.015	.046	1.070	.285

Table 3. Multiple linear regression by perceived social support (employment reference category—employed, gender reference category—female, Swiss reference category—Swiss).

Predictor	B	SE B	β	T	P value
Constant	2.653	.055	—	48.325	.000
Employment	.089	.128	.031	.696	.487
Gender	.191	.075	.112	2.556	.011
Swiss	−.076	.087	−.037	−.866	.387
Age	−.061	.021	−.131	−2.943	.003

For the group of employed adolescents, linear mixed effects analyses were performed to explore changes in stress levels and perception of social support before and after the intervention.

We used the TICS-SCSS to track changes in chronic stress levels. In a first step, we entered general predictors (time, gender, year of apprenticeship, and age) as fixed effects in a linear mixed model (see model A in Multimedia Appendix 1). Age was mean centered. We took intercepts for participants as random effects. In subsequent steps, we added group (intervention vs control, see model B in Multimedia Appendix 1) and the interaction between group and time (see model C in Multimedia Appendix 1) as fixed effects. Likelihood ratio tests were carried out to compare the deviances (D) of these models. Comparing model B (D=1575.98) to A (D=1572.46) indicated that adding group as predictor did not significantly improve model fit (P=.06). Comparing model C (D=1579.24) to B (D=1575.98) revealed that adding the group and time interaction did not significantly improve model fit (P=.07). Thus, no significant effect was found for group and the group and time interaction.

We inspected changes in perception of social support with equivalent models to those used for the analyses of stress levels (see Multimedia Appendix 2). The comparison of model E (D=2006.83) and D (D=2004.57) revealed no significant improvement in model fit (P=.13) when adding group as a predictor. Comparing model F (D=2007.32) and E indicated that adding the group and time interaction did not contribute to any better model fit (P=.49). Thus, there was again no significant effect of group and the group and time interaction on perception of social support.

For all models, visual inspection of residual plots revealed no obvious deviations from homoscedasticity or normality.

In summary, the intervention via the Companion App did not have any measurable effects on chronic stress levels or the perception of social support among adolescents in the intervention group.

Discussion

Principal Findings

Our Companion Project implemented a mental health promotion program with adolescents in Switzerland using an app. At the core of the project was a peer mentoring system. For 10 months a group of employed (n=546) and unemployed (n=73) adolescents had access to the Companion App. Effects of the intervention on stress levels and perception of social support were assessed in a control group study design. Monitoring of the use of the app showed that the adolescents did not use the Companion App frequently. We found no effects of the intervention on stress levels and perception of social support.

Here, we discuss our findings of the qualitative evaluations as well as the quantitative findings on stress levels and perception of social support. Most importantly, we consider reasons why the Companion App struggled to achieve solid utilization. Finally, we review what we can learn from the Companion Project and formulate recommendations for future intervention projects using apps in adolescent health promotion.

Findings From Qualitative Interviews With the Adolescents: Interest But Insufficient Incentives and Unsatisfactory Technical Development

The Companion App failed to achieve solid participation. While in the first 2 weeks of the study daily visits averaged around 60, these numbers decreased markedly in later weeks. Qualitative interviews and feedback on the app by users gave us some hints on reasons for this.

Adolescents reported being interested in discovering a new app and that the content and design of the Companion App was attractive and well conceived. Moreover, the peer mentoring system was judged helpful. This suggests that the concept of the Companion App was essentially well received.

However, some adolescents reported that the benefits and purpose of the Companion App had not been evident to them. Some unemployed adolescents said they would have appreciated a more intense promotion of the app. It may be that the communication around the app and the incentives for use provided during the study were insufficient. We know that developing and maintaining engagement with an app is challenging [55]. We presented the app to the adolescents at the beginning of the study and sent emails throughout the study to the users informing about the app and the mentoring system. We also distributed flyers and posters in common spaces used by the adolescents of the intervention group. However, it seems that these efforts were insufficient.

According to the feedback of the adolescents, technical problems also hindered more frequent use of the app. This surely is a key factor. The Companion App was developed within the frame of a research project. Therefore, available resources for the technical implementation were limited. Time constraints limited some steps of the development process required for launching an app [56]. The app was technically improved during the study, but it may be that adolescents stopped attempting to use the app

after the first experience of technical difficulties. We know that only a few users will try an app again once they have experienced technical failure [57,58].

Findings on Social Support and Chronic Stress: No Wish for More and No Need for Less?

We will now discuss findings of the evaluation of chronic stress and the perception of social support. Because the Companion App struggled to achieve solid utilization and our analyses did not reveal significant changes in stress levels or perception of social support before and after intervention, we focus on discussion of the baseline results.

At baseline, we found that the adolescents in our intervention group were often satisfied with the social support they received and that they had rarely experienced chronic stress during the previous three months. Does this imply insufficient interest in an intervention of the type implemented by the companion project?

It may be that the overall satisfaction with social support in our sample led to a weaker interest in the peer mentoring system. This would, however, contradict some of our findings in the qualitative evaluations in which adolescents reported endorsing the implementation of a peer mentoring system. Also, from a health promotion perspective, one can argue that social support still can be enhanced or sustained respectively.

Concerning the experience of stress in our sample, can it be that stress was not a relevant matter for these adolescents? This would diverge from what we know from other studies. Jeannin and colleagues [47] asked apprentices and students in Switzerland in a representative sample (ages 16-20 years, n=7428) in which health domains they would like to receive support. More than one-quarter of the male and almost half of the female participants reported desiring support concerning the experience of stress. Padlina et al [46] found in their study that 64.3% of Swiss apprentices (n=211) reported they felt generally overburdened and stressed. We also compared the stress levels of the employed group of our sample to the German TICS norm sample for a similar age group (16-30 years, n=146) [53]. In the employed group, a mean of 1.25 (SD 0.64) and sum score of 14.97 (SD 07.65) on the TICS-SCSS corresponded to a t value of 52. This implies that mean scores of chronic stress of the employed adolescents in our sample are comparable to those of other adolescents and young adults. We do not have data collected using the same instrument (TICS-SCSS), so we cannot do a direct comparison to other Swiss apprentices.

We can, however, reflect several aspects of why stress levels in our sample may have been low. We should give consideration to the choice of our stress measurement instrument and the environment of our sample. The TICS-SCSS scale specifically measures chronic stress, thereby capturing severe and enduring experiences of stress. It is possible that by focusing on this screening scale, we left aside experiences of more mild forms of stress that may still be of importance to the adolescents. Additionally, lower stress levels in our sample may be linked to certain aspects of the organization (eg, preexisting structures such as an informal buddy system). We discuss these specifics in more detail in the subsequent part of the discussion.

Still, it is important to point out that despite the possibility that stress levels were lower in our sample compared to other apprentices, the Companion Project is a health promotion project. Therefore, in a preventive perspective, participation should also appeal to those adolescents who do not necessarily suffer from elevated stress levels.

Taking a closer look at the stress levels in the unemployed group of our study, we were surprised that they did not experience significantly higher stress levels than the employed adolescents. Also, their mean of 1.38 (SD 0.66) and a sum of 16.51 (SD 7.81) on the TICS-SCSS corresponded to a t value of 54 compared to the aforementioned German TICS norm sample. This was surprising to us, as we know that mental health of unemployed youth is often eroded and that the experience of stress is common [59]. For example, in a representative sample of 100 unemployed 16- to 24-year-olds, Reissner and colleagues [48] found that 43% presented a mental illness often associated with high stress levels. In Switzerland, Sabatella and von Wyl [49] found that 74% percent of the 151 unemployed adolescents they interviewed in state-funded transitional programs showed signs of psychological distress. The way we recruited the unemployed adolescents may explain why we found relatively low stress levels in our sample and why these did not differ from the employed group. The participants of our study were recruited from a state-funded transitional program, and our evaluation took place when they entered the program. Thus, the situation of being unemployed was still new to most of them. Also, participating in the transitional program likely provided a perspective of having a structure in daily life and of receiving support to find an apprenticeship or a job. Finally, the same considerations regarding our measurement scale of chronic stress not capturing milder forms of stress mentioned before apply to this group. Regardless of these findings, we should keep in mind that early prevention in this group of youth is of major importance, because unemployment seems to affect mental health and vice versa [60,61].

Difficulties in Establishing Commitment to the Companion Project

We have already presented a few reasons provided by the adolescents in the qualitative evaluation for the infrequent use of the Companion App. We discuss additional considerations here.

First, specifics of the implementation context may have played a meaningful role for the nonadoption of the app by the users. Employed participants were recruited from a large Swiss company and unemployed participants from a state-funded transitional program. In the large Swiss company, the project was not directly adopted as a part of the company's own health promotion strategy. This likely had an influence on the adherence to the project. For example, the information flow concerning the Companion App within the company environment may not have been sufficient. Also, the company had sophisticated preexisting structures to promote mental health amongst their employees. Although these were not specifically conceived to target their apprentices, it was not obvious how the Companion Project would integrate with these structures. Moreover, for apprentices, a sort of a natural buddy system

already existed within the company. Apprenticeship positions were manned each year. The apprentice having occupied the position the year before was in charge of introducing the new apprentice. These preexisting structures may have contributed to the Companion App not signifying much additional benefit to the apprentices.

In the state-funded transitional program for unemployed youth, organizational structures were very flexible. Adolescents started and left the program throughout the duration of the study. The lynchpin to reach the adolescents in these programs was the social worker population. Each adolescent had one social worker responsible for him and accompanying him throughout the program. These social workers introduced the adolescents to the Companion App upon entering the program and also followed up on the adolescent's participation. Time resources of the social workers were, however, limited. Unemployed adolescents mentioned in the qualitative interviews that they would have needed more reminders and promotion to use the app. We assume that a more intense follow-up and a sort of personal assistance in using the app would have been required. For example, some adolescents said that they had forgotten their log-in details and did not put any effort into getting a new log-in. As the social workers were not able to provide assistance of this type, implementing another form of personal follow-up may have been necessary. Obviously, such additional assistance would have augmented the costs of the Companion Project significantly. Generally, we presume that promoting health with unemployed adolescents needs to be more structured and that an intervention, including some face-to-face follow-up, may enhance their program adherence.

Second, we consider if the choice of implementing the Companion Project using an app was appropriate. Given the widespread use of mobile phones, the Internet, and specifically mobile phone apps [34-36], the choice to use an app seemed opportune. Also, this choice made the intervention less costly and likely increased our reach to more adolescents compared to face-to-face intervention. This is the great advantage of mental health interventions using new technologies [39,62]. However, initiating commitment and maintaining engagement are preeminent challenges for online interventions, and dropout rates have been mentioned as a central issue in previous studies [38]. Especially with regard to the peer mentoring system, we must consider if implementation of a face-to-face mentoring system would have fostered participation in the Companion Project. In its implementation for this study, personal contact remained mediated by a technical device. Chatting with a mentor on a device is much different than meeting a mentor in person and likely creates a different level of commitment to the mentoring relationship.

Third, we examine our use of incentives. Incentives probably play a major role in prevention programs for adolescents [63]. Throughout the program we created different kinds of incentives to use the app (advertisement via posters and flyers, emails informing about the app, lotteries in which adolescents could participate when taking part in evaluation of the app), but apparently these were insufficient. Further, adolescents received little to no personalized monitoring concerning their use of the Companion App. They were introduced to the Companion App

at the beginning of the program and received reminder emails throughout its course. However, there was no personal follow-up on their use of the app. Such follow-up may have enhanced their engagement with the app.

Insights for Future Mental Health Promotion Programs in Adolescence Using an App

In summary, we can draw several insights from the Companion Project that may be useful to future mental health promotion projects with adolescents using an app.

First, we think that a theory-driven approach acknowledging the specific developmental challenges that adolescents face is recommended. Given the importance of peer influence at this age and the adolescent drive for autonomy, peer mentoring seems to offer a great opportunity to do so. The qualitative interviews we conducted with the adolescents revealed that adolescents supported this concept. However, future projects should carefully consider if a peer mentoring system can be implemented with an app only and if face-to-face contact between mentors and mentees enhances adherence to the mentorship.

Second, we would like to emphasize the advantages of adopting a holistic approach to health promotion (versus focusing on the prevention of a specific pathology). There is evidence concerning the protective effects of social support regarding many domains of mental (and physical) health [19-23]. This evidence also takes into account that adolescents tend to engage in combinations of health-risking behaviors [64]. Peer mentoring offers a natural opportunity of implementing an holistic approach.

Third, using an app in a health promotion effort is promising. Given the frequent use of apps by wide parts of the population, and by adolescents in particular, apps have the potential to reach many people. However, we experienced first-hand the difficulties of establishing user commitment. We found that adolescent app users tend to be unforgiving if there are technical difficulties. Moreover, we realized that any app launched today enters a difficult competitive battle with many commercially developed apps. Therefore, establishing usability, feasibility, and accessibility and ensuring enough time for the technical refinement of the app is essential. Recently, efforts have been put into clarifying the requirements for apps in the mental health field [43]. We also propose that adopting a participatory approach by involving adolescents in the development of such an app is encouraging. This can enhance the adoption of the app in the respective target group.

Fourth, using well-chosen and sufficient incentives to strengthen commitment to the program seems essential. The form and use of incentives surely depends on the specific project. In the case of the Companion Project, more intensive promotion of the app and a personalized follow-up of the use of the app may have been necessary.

Finally, we think that certain groups of adolescents, especially a high-risk group as our intervention group of unemployed adolescents, likely benefit from more structured interventions. In the case of our project, providing these groups with additional

face-to-face support to aid in discovering the Companion App and peer mentoring system may have been advantageous.

Conclusion

The companion project implemented a theory-driven and innovative approach to mental health promotion in adolescence, taking into account the specifics of the adolescent developmental phase. The Companion App struggled to achieve solid utilization, and the intervention did not have any effects on chronic stress and the perception of social support. Nevertheless, the project generated insights on opportunities and pitfalls when using an app in a mental health promotion effort in adolescence and can inform future projects in the field.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Mixed models for the prediction of change in chronic stress levels from pre to post evaluation: Model A, B, and C.

[PDF File (Adobe PDF File), 31KB - mental_v3i3e45_app1.pdf]

Multimedia Appendix 2

Mixed models for the prediction of change in perception of social support from pre- to postevaluation: Model D, E, and F.

[PDF File (Adobe PDF File), 31KB - mental_v3i3e45_app2.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
F-Soz-U: Fragebogen zur Sozialen Unterstützung
TICS: Trier Inventory of Chronic Stress
TICS-SCSS: Trier Inventory of Chronic Stress screening scale

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<u>Original Paper</u>

Online Obsessive-Compulsive Disorder Treatment: Preliminary Results of the "OCD? Not Me!" Self-Guided Internet-Based Cognitive Behavioral Therapy Program for Young People

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Abstract

Background: The development and evaluation of Internet-delivered cognitive behavioral therapy (iCBT) interventions provides a potential solution for current limitations in the acceptability, availability, and accessibility of mental health care for young people with obsessive-compulsive disorder (OCD). Preliminary results support the effectiveness of therapist-assisted iCBT for young people with OCD; however, no previous studies have examined the effectiveness of completely self-guided iCBT for OCD in young people.

Objective: We aimed to conduct a preliminary evaluation of the effectiveness of the OCD? Not Me! program for reducing OCD-related psychopathology in young people (12-18 years). This program is an eight-stage, completely self-guided iCBT treatment for OCD, which is based on exposure and response prevention.

Methods: These data were early and preliminary results of a longer study in which an open trial design is being used to evaluate the effectiveness of the OCD? Not Me! program. Participants were required to have at least subclinical levels of OCD to be offered the online program. Participants with moderate-high suicide/self-harm risk or symptoms of eating disorder or psychosis were not offered the program. OCD symptoms and severity were measured at pre- and posttest, and at the beginning of each stage of the program. Data was analyzed using generalized linear mixed models.

Results: A total of 334 people were screened for inclusion in the study, with 132 participants aged 12 to 18 years providing data for the final analysis. Participants showed significant reductions in OCD symptoms ($P<.001$) and severity ($P<.001$) between pre- and posttest.

Conclusions: These preliminary results suggest that fully automated iCBT holds promise as a way of increasing access to treatment for young people with OCD; however, further research needs to be conducted to replicate the results and to determine the feasibility of the program.

Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12613000152729; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=363654 (Archived by WebCite at http://www.webcitation.org/6iD7EDFqH)

KEYWORDS

Introduction

Obsessive-compulsive disorder (OCD) is a potentially disabling psychological condition affecting 0.5% to 3% of children and adolescents [1-4]. The disorder is associated with high levels of comorbidity [1,5] and significant psychosocial impairment [6,7], such as difficulties concentrating at school and completing homework, disruption in household routines, and impairments in social functioning [6]. When young people with OCD do not receive adequate treatment, they are at risk of experiencing continued symptoms and additional psychopathology in adulthood [8-10]. As a result, early intervention is imperative.

The development of Internet-based cognitive behavioral therapy (iCBT) for OCD provides a promising pathway toward increasing the accessibility and availability of evidence-based treatment for young people with OCD. Substantial evidence supports the effectiveness of face-to-face cognitive behavioral therapy (CBT) with exposure and response prevention (ERP) as the gold-standard psychotherapeutic intervention for OCD [11,12]. However, there are significant limitations to the availability and accessibility of this treatment in the community [13-16]. In addition, young people may be unlikely to seek treatment for anxiety disorders, thereby increasing the likelihood of long-term impairment [17,18]. Online treatments help to overcome these obstacles by providing immediate, cost-effective, and remote access to treatment [19], and emerging evidence supports the use of iCBT and computerized CBT (cCBT) in young people with depression and anxiety. For example, one meta-analysis of 13 randomized controlled trials found moderate-to-large effect sizes across studies of iCBT and cCBT in the treatment of depression and anxiety in children and adolescents [20]. Another meta-analysis found that the effectiveness of iCBT for childhood anxiety is comparable to that of face-to-face CBT [21], whereas in a systematic review, Richardson et al [22] found that young people and their parents report moderate-to-high levels of satisfaction with cCBT for depression and anxiety, although attrition and noncompletion rates are often high.

Although research on the development and evaluation of Internet-based treatment for children and adolescents with OCD is relatively limited, these results suggest that iCBT may be a viable intervention for young people with this disorder. To our knowledge, only one study has examined the efficacy of iCBT for OCD in young people [23]. Using an open trial, Lenhard et al [23] delivered a 12-week therapist-assisted iCBT program to 21 young people aged 12 to 17 years who had a primary diagnosis of OCD. Participants reported significant pre-post reductions in OCD severity and related impairment, as well as significant improvements on measures of anxiety and global functioning. Although limited by the small sample size, these results are encouraging and raise the question of whether similar outcomes might be achieved without the inclusion of therapist support.

The minimal costs and consistent availability and accessibility associated with self-guided online programs supports the proposition that iCBT without therapist assistance has the potential to confer important public health benefits, if deemed safe and effective [19]. Moreover, such programs may be preferable for individuals who are concerned about stigma, confidentiality, or talking to a therapist about personal issues [24,25]. Preliminary results from studies with adults support the efficacy of self-guided iCBT for OCD [26], with initial evidence suggesting long-term (12-month) impact [24]. However, a recent meta-analysis suggests that completely self-guided interventions for adults with OCD suffer from high attrition rates, and that therapist-assisted iCBT produces superior treatment outcomes [27]. Across studies of iCBT for other anxiety and mood disorders, it has been found that when dropout and compliance is taken into account, therapist-assisted iCBT is more effective than self-guided iCBT [28]. An important question that remains to be answered is whether purely self-guided iCBT is effective for young people with OCD.

Aims and Hypotheses

To our knowledge, there is no prior research evaluating the impact of fully self-guided iCBT for young people with OCD. Therefore, we aimed to conduct a preliminary evaluation to determine whether self-guided iCBT using the "OCD? Not Me!" program was effective in reducing OCD psychopathology in young people. We formed two main hypotheses: (1) that mean number of OCD symptoms would significantly decrease between pre- and posttest and (2) that mean OCD severity would significantly decrease between pre- and posttest. We also aimed to investigate the pattern of change in OCD psychopathology over time in the program.

Methods

Study Design and Procedures

The data for this study were early and preliminary data collected as part of a longer study currently being conducted to investigate the effectiveness and feasibility of the OCD? Not Me! program for reducing OCD symptoms and related distress among young people with OCD [29]. This study is a 4-year open trial utilizing a within-groups design to examine pre-post changes in young people's OCD symptoms and severity, associated functional impairment, quality of life, family accommodation, and self-esteem, as well as parent/caregiver distress. The study was approved by the Curtin University Human Research Ethics Committee, Bentley, Western Australia, Australia (HR 45/2013).

Intervention

As described in Rees et al [29], OCD? Not Me! is a fully automated, eight-stage online program that is designed to treat symptoms of OCD in young people aged 12 to 18 years (for an overview of the eight stages of the program, see Figure 1). The treatment protocol is structured around the metaphor of "climbing OCD Mountain" to conquer OCD symptoms; in undertaking this journey, young people are provided with psychoeducation regarding OCD and a rationale for treatment using CBT with ERP. They are taught how to identify the functional link between their obsessions and compulsions (Figure 2), how to construct exposure exercises to target their OCD symptoms, and how to construct an exposure hierarchy that will support them to reduce their compulsions in a gradual way. In this process, participants in the program learn strategies

for habituating to anxiety, dealing with problematic cognitions, and managing stress and setbacks. The strategies provided in the program are illustrated using the metaphor of "mountaineering equipment" that supports the participant to ascend OCD Mountain, and include an interactive log book for participants to record their OCD Mountain Challenges (ERP exercises) as they complete them (see Figure 3). At each stage

of the program, parents and caregivers are also emailed with a link to online resources. These online resources outline information about what the young person is learning in the program, provide tips for supporting the young person in the program, and help parents and caregivers to manage family/caregiver stress.

Figure 1. Screenshot from the OCD? Not Me! program: overview of the eight stages of the program.
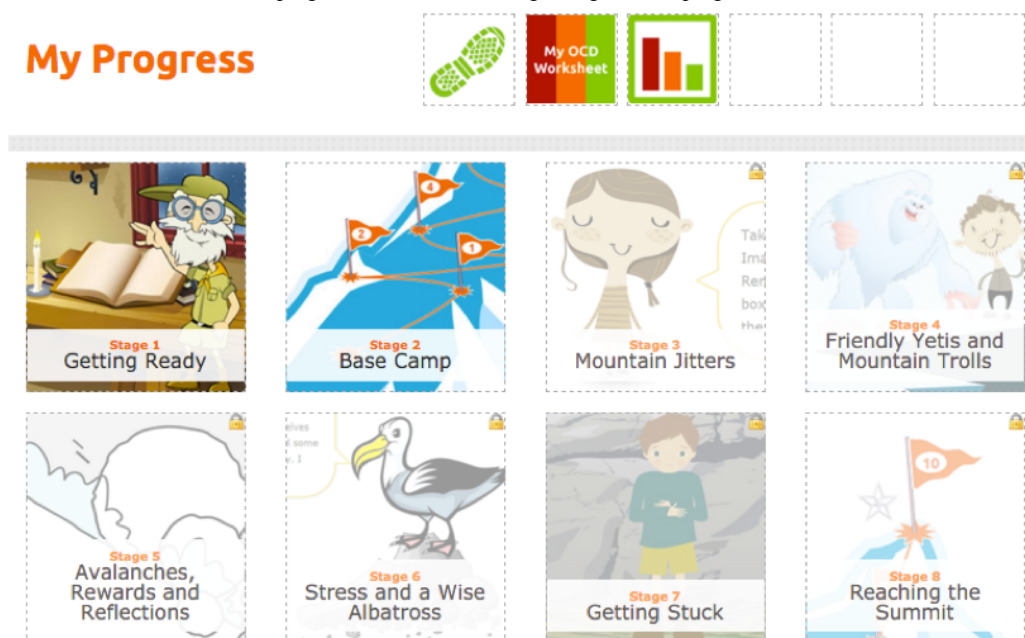

Figure 2. Screenshot from the OCD? Not Me! program: illustration of the OCD cycle explaining the functional link between obsessions and compulsions.

Figure 3. Screenshot from the OCD? Not Me! program: the log book used to record OCD Mountain Challenges (ERP exercises).

Participant Eligibility and Recruitment

The OCD? Not Me! program is designed for youth aged 12 to 18 years; although individuals outside this age bracket are allowed to access the program, their data were not used in this study. Because the OCD? Not Me! program is designed to treat OCD, to be eligible for inclusion in the program, potential participants were required to have at least subclinical symptoms of OCD. The Short OCD Screener (SOCS) [30] was used to screen for OCD symptoms, with participants required to have a SOCS score of two or more to be included in the study. We expected that young people with eating disorders might be drawn to the program, given that rapid weight loss and starvation can cause obsessional thinking [31]. Our online measures were not able to differentially diagnose eating disorders from OCD to the degree that a clinician was able and, given the potential need for more intensive and specialized treatment for individuals with eating disorder symptoms, participants were excluded from the study if they reported symptoms of an eating disorder. The SCOFF questionnaire was used to screen for these criteria [32], with participants excluded if they reported a score of two or more on this measure. Similarly, due to the overlap between psychosis symptoms and psychotic-like symptoms in OCD [33], participants were excluded from the program if they reported moderate-to-high symptoms of psychosis. The Adolescent Psychotic-Like Symptom Screener (APSS) [34] was used to screen for this outcome, and participants were excluded from the program if they reported a score of four or more on this measure. Finally, participants who reported moderate-to-high suicide risk were excluded from the study and encouraged to seek more specialized services. To assess suicide and self-harm risk, a measure was adapted from the suicide risk assessment module of the Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-KID) [35].

Participants were self-referred or recommended the program by a friend, family member, or health care provider. Written consent to participate in the study was obtained from all participants and their parents/caregivers online. All screening measures were completed online, and individuals who were not eligible for participation in the program were referred to the treatment provider database on the OCD? Not Me! website. Using this website, individuals can search for face-to-face mental health services in their local area, as well as access phone numbers for crisis counseling hotlines. Participants who were deemed eligible for participation in the program went on to complete the online assessment measures detailed subsequently.

Measures

Demographic Measures

Participants were asked to complete a series of demographic questions regarding their gender, age, country and state of residence, and education. Participants were also asked whether they were currently receiving psychological treatment for OCD and whether they were currently prescribed medication for OCD.

Obsessive-Compulsive Disorder Diagnosis and Comorbid Diagnoses

There were no freely available, online, self-report comprehensive psychiatric assessments for young people; therefore, we developed the Youth Online Diagnostic Assessment (YODA) to evaluate whether participants met diagnostic criteria for OCD as outlined in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-V*) [36]. The YODA covers the majority of disorders outlined in the *DSM-V*, although only the OCD diagnostic section was used in this study.

Obsessive-Compulsive Disorder Symptoms and Severity

The self-report version of the Children's Florida Obsessive-Compulsive Inventory (C-FOCI) [37] was used to assess OCD symptoms and severity. The C-FOCI is a brief measure of OCD psychopathology in children and adolescents

that consists of a 17-item symptom checklist, and a five-item severity scale. The C-FOCI has been validated for Internet administration and has adequate psychometric properties [37]. In this sample, the internal consistency for the symptoms scale was α=.79, whereas the internal consistency for the severity scale was α=.82.

Procedure

Following screening, participants completed pretest measures online and were given access to the program once pretest measures were complete. Although the recommended time frame for the program is 8 weeks, participants completed the program at their own pace. At the beginning of each stage of the program, participants were asked to complete a brief online assessment consisting of the C-FOCI and a risk assessment for suicide and self-harm. Therefore, C-FOCI data were collected at nine time points throughout the study: pretest, posttest, and at the beginning of stages 2 to 8 of the program.

Analysis

Data were analyzed with generalized linear mixed models (GLMM) using the GENLINMIXED procedure of SPSS (version 22.0), with "participant" treated as a random effect and "stage" (pretest, per stage 2-8, and posttest) treated as a fixed effect. To accommodate violations of sphericity, the covariance matrix was changed from the default of compound symmetry to autoregressive (ARMA11). To maximize the likelihood of convergence, separate GLMM analyses were conducted for both of the outcome variables, and alpha levels were corrected to control for inflation of the family-wise error rate. The Bonferroni-corrected alpha level for all statistical tests was .025.

The GLMM maximum likelihood procedure is a full information estimation procedure that uses all the data available at each assessment point, rather than requiring data from all participants at each point. This optimizes statistical power and reduces sampling bias associated with subject attrition [38,39], making it suitable for research on Internet-based interventions, which often demonstrate high dropout rates [40]. Additionally, this analysis is robust to unevenly distributed assessment points [39,41]. Two GLMMs were used to evaluate the relationship between the fixed effect of time and each of the subscales of the C-FOCI (symptoms and severity). Post hoc least significant difference (LSD) tests were conducted to test for significant differences between time points. The *t* test values for the T1-T9 effects were computed using maximum likelihood (ML) to compensate for missing data. Cohen's *d* [42] calculations were conducted to determine the size of pre-posttest change. Effect size magnitude was interpreted using Cohen's [42] conventions (0.2=small, 0.5=moderate; and ≥0.8=large).

Results

Of the 334 potential participants who completed screening measures, 21 were younger than 12 years and 59 were older than 18 years. Their data were not included in these analyses. Of the 254 participants were within the target age range, 93 participants were screened out because they met the exclusion criteria. A further 29 participants failed to complete pretest assessments. The screening and pretest procedure and number of participants meeting each exclusion criteria are detailed in Figure 4.

A total of 132 participants who were in the target age range completed pretest measures. This sample was 43.2% (57/132) male and 56.8% (75/132) female, with a mean age of 14.58 years (SD 1.94). In this sample, 73.5% (97/132) of participants met the *DSM-V* criteria for OCD as determined using the YODA.

Participant Flow

The number of participants that commenced each stage of the program at the time the data were collected were: stage 1 (n=116), stage 2 (n=67), stage 3 (n=27), stage 4 (n=16), stage 5 (n=14), stage 6 (n=12), stage 7 (n=11), and stage 8 (n=11).

Estimated Means

Estimated means were used to describe the average pretest scores on the C-FOCI for the target sample. The pretest (T1) mean score for OCD symptoms was 7.82 (SE 0.34) and 11.56 (SE 0.31) for OCD severity. At posttest (T9), the means for these outcomes were 3.87 (SE 0.83) and 5.77 (SE 0.97), respectively. Per-stage means for each outcome are shown in Table 1.

Main Effects of Time and Pairwise Contrasts

Our first hypothesis predicted a significant main effect of time on mean number of OCD symptoms, using a Bonferroni-adjusted alpha level of .025. This hypothesis was supported ($F_{8,285}$=7.38, *P*<.001), with significant decrease in OCD symptoms observed between pre- and posttest (*P*<.001). Per-stage LSD tests with pairwise contrasts indicated that significant decreases in OCD symptoms occurred between stages 1 and 2, stages 2 and 3, stages 3 and 4, and stages 6 and 7 (Table 2). A slight, nonsignificant increase in OCD symptoms was reported between stage 8 and posttest. Effect size calculations indicated a moderate effect for the changes in OCD symptoms between pre- and posttest (*d*=.64).

Figure 4. Flowchart of assessment and clinical characteristics of screened participants.
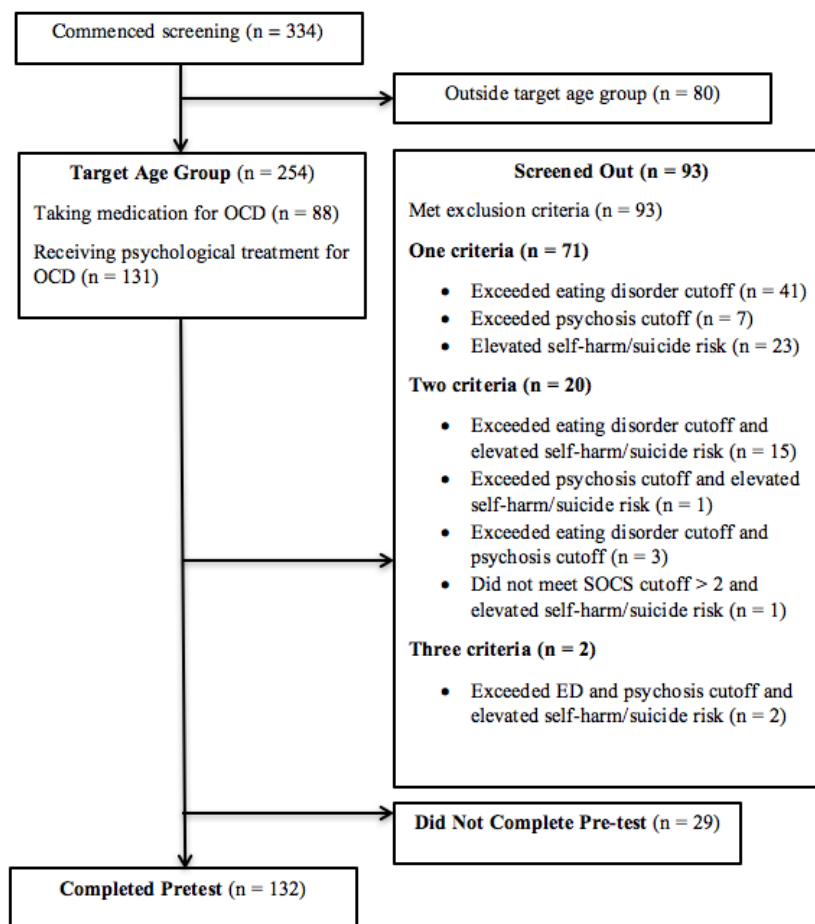
Table 1. Estimated means and standard errors for OCD symptom and severity scores.

Outcome	Test time, mean (SE)								
	T1	T2	T3	T4	T5	T6	T7	T8	T9
Symptoms	7.82 (0.34)	7.34 (0.35)	6.76 (0.44)	5.93 (0.52)	5.72 (0.60)	5.33 (0.62)	4.30 (0.69)	3.76 (0.82)	3.87 (0.83)
Severity	11.56 (0.31)	10.61 (0.43)	10.40 (0.54)	9.52 (0.88)	8.60 (0.88)	8.10 (0.96)	6.92 (0.95)	5.99 (1.18)	5.77 (0.97)

Table 2. Least significant difference (LSD) tests of the simple main effects of time with pairwise contrasts (contrast estimate; CE) of OCD symptoms and severity (T1-T9).

Outcome and time interval	CE (SE)	t_{285}	95% CI	P (adjusted)
Symptoms				
T1-T9	3.96 (0.84)	4.70	2.30, 5.61	<.001
T1-T2	0.49 (0.15)	3.26	0.19, 0.78	.001
T2-T3	0.58 (0.27)	2.15	0.05, 1.11	.003
T3-T4	0.82 (0.25)	3.24	0.32, 1.33	.001
T4-T5	0.21 (0.27)	0.79	–0.32, 0.74	.43
T5-T6	0.39 (0.34)	1.15	–0.27, 1.05	.25
T6-T7	1.03 (0.38)	2.75	0.29, 1.77	.006
T7-T8	0.54 (0.35)	1.53	–0.15, 1.22	.13
T8-T9	–0.10 (0.37)	–0.28	–0.83, 0.62	.78
Severity				
T1-T9	5.79 (0.99)	5.87	3.85, 7.73	<.001
T1-T2	0.96 (0.34)	2.79	0.28, 1.63	.006
T2-T3	0.21 (0.52)	0.41	–0.81, 1.24	.68
T3-T4	0.88 (0.63)	1.38	–0.37, 2.12	.17
T4-T5	0.91 (0.58)	1.57	–0.23, 2.05	.12
T5-T6	0.50 (0.34)	1.45	–0.18, 1.18	.15
T6-T7	1.18 (0.35)	3.37	–0.49, 1.86	.001
T7-T8	0.94 (0.41)	2.28	0.13, 1.74	.02
T8-T9	0.22 (0.65)	0.34	–1.05, 1.49	.73

Our second hypothesis predicted a significant main effect of time on mean OCD severity, using a Bonferroni-adjusted alpha level of .025. This hypothesis was also supported ($F_{8,285}$=15.21, P<.001), with significant decreases in OCD symptom severity observed between pre- and posttest (P<.001). Per-stage LSD tests with pairwise contrasts indicated that significant decreases in OCD severity occurred between stages 1 and 2, stages 6 and 7, and stages 7 and 8. Although OCD severity continued to decrease steadily over the course of the program, other per-stage reductions did not reach significance (Table 2). Effect size calculations indicated a large effect for the changes in OCD severity between pre- and posttest (d=.89).

Discussion

This study aimed to evaluate early and preliminary results from a longer trial examining the impact of the OCD? Not Me! program on OCD symptoms and severity in young people aged 12 to 18 years. This is the first study to examine the effectiveness of a fully automated iCBT program for reducing OCD symptomology in young people.

Results from this study are encouraging. Participants in this study reported average pretest OCD symptoms and severity that were higher than those reported by a sample of young people with a primary diagnosis of OCD (mean 6.22, SD 3.54 for OCD symptoms and mean 11.22, SD 4.07 for OCD severity) in Storch et al's [37] study. Although assessment of OCD symptoms in this study was based on self-report rather than diagnostic interview, it appears that, on average, participants were experiencing levels of OCD pathology comparable with clinical samples. Significant decreases in OCD symptoms and severity were observed between pre- and posttest. Per-stage analyses of OCD symptoms and severity indicated that mean scores on these outcomes decreased gradually over time in the program. In addition, effect size calculations demonstrated a moderate effect for reduction in OCD symptoms and a large effect for reduction in OCD severity. These effect sizes may be contrasted with Lenhard et al [23], who reported large effect sizes for reduction in OCD symptoms and severity (d= 1.09 and d= 1.43, respectively) in their trial of therapist-assisted iCBT for adolescents with OCD, although it should be noted that they used a different measure to evaluate OCD symptoms and severity. A recent meta-analysis reported standardized effect sizes of 0.70 across five studies of iCBT with varying levels of therapist assistance for childhood anxiety [21]. Importantly, it should be emphasized that our results were observed in the absence of any therapist involvement. This is an exciting finding given the notable limitations in the accessibility and availability of evidence-based psychotherapeutic treatment for young people with OCD. As Klein et al [43] have pointed out, the availability of fully automated, effective e-mental health interventions means that people can access treatment immediately and remotely, at a time and location that suits them.

It should be highlighted that these results are preliminary, and the final results of the trial might be quite different. Additionally, although entirely self-help programs make an important contribution to stepped care approaches to mental health, the value of some level of therapist contact should not be dismissed. A recent meta-analysis of self-help interventions for adults with OCD found that across studies, attrition rates declined and clinical outcomes improved with increasing therapist contact [27]. It would be beneficial for future research to consider how the inclusion of therapist assistance might impact outcomes and completion rates in the OCD? Not Me program. Future research is also required to determine those young people fully self-guided programs are appropriate for, and those from whom therapist contact is necessary.

Because the OCD? Not Me! program (including assessment) is designed to be entirely self-guided, this study did not use therapist-administered clinical interviews and, therefore, it cannot be determined whether participation in the program made an impact on OCD as a diagnosis. As assessment must be conducted without therapist involvement in order for self-guided programs to be truly self-help and anonymous, a key direction for future research is the development and evaluation of online, self-administered diagnostic interviews. We recommend further research to determine the validity, sensitivity, and specificity of the YODA relative to face-to-face diagnostic assessment.

A further limitation of this study was because it was an open trial with no control group, it cannot be reliably concluded that changes in the outcome measures were due to participation in the intervention. However, it should be noted that OCD in childhood and adolescence is characterized as a chronic disorder with high persistence rates [8,44]; therefore, it is unlikely that the observed outcomes are linked to spontaneous remission. It is recommended that future research compare the efficacy of the OCD? Not Me! program to a waitlist control group in order to more reliably link outcomes to the effects of the intervention. It is also recommended that future research on this intervention include some follow-up assessment to investigate whether changes in symptomology are durable over time.

Attrition analyses were not conducted in the current study because the study is ongoing and some participants were still undergoing treatment at the time of collecting this data. Although the GLMM procedure is particularly useful for conducting intention-to-treat analyses in studies where moderate-high rates of attrition are anticipated [39], attrition analyses are recommended in future studies. Understanding the factors that predict attrition (including attrition at pretest) is essential to understanding who fully automated iCBT is most suitable for and how the program might be adjusted to optimize participant retention.

It should be noted that almost 25% of the sample who completed screening measures in this study were outside of the intended age range for the iCBT program, indicating that there is a need for online OCD treatment services that target children younger than 12 years, as well as adults older than 18 years. In addition, almost a third of potential participants in the target age range were screened out of the study for meeting one or more of the exclusion criteria (elevated eating disorder or psychosis symptoms, and/or elevated suicide/self-harm risk). There is a clear need for services that are targeted to this group, and for better understanding of how best to manage risk within the context of self-guided treatment. Although most efficacy studies exclude individuals with suicide or self-harm risk, it is recommended that future developments in iCBT consider including strategies and protocols for managing suicide and self-harm risk, to support translation into effective intervention.

One of the benefits of the OCD? Not Me! program is that it includes a searchable database of mental health providers that participants can use to seek more intensive or specialized services, such as face-to-face treatment or telephone support services. Our data indicate that such services are relevant for those who seek treatment via the online program (who are screened out or who require more intensive services due to the severity of their symptoms). In addition, the findings support the potential for online assessments and services to be more comprehensively integrated into stepped care models, with treatment-seekers offered the most appropriate level of care for their needs following assessment. Increasing communication between online platforms and frontline health services supports continuity of care and also reduces the need for repeated assessments by different health care professionals. On this point, we found that approximately half the participants in our sample were already receiving psychotherapeutic treatment for OCD, and a third were currently taking prescribed medication for the disorder. This finding suggests that it may be of benefit to support health practitioners to use the iCBT programs with their clients through the provision of manuals and training.

In conclusion, the results of this study provide preliminary evidence that fully automated iCBT offers promise as a way of increasing access to effective treatment for young people with OCD. Future research is needed to replicate these results and to investigate predictors of treatment retention and outcome.

Acknowledgments

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
CE: contrast estimate
ERP: exposure and response prevention
GLMM: generalized linear mixed models
LSD: least significant difference
ML: maximum likelihood
OCD: obsessive-compulsive disorder
SOCS: Short OCD Screener
YODA: Youth Online Diagnostic Assessment

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Review

Gamification and Adherence to Web-Based Mental Health Interventions: A Systematic Review

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Abstract

Background: Adherence to effective Web-based interventions for common mental disorders (CMDs) and well-being remains a critical issue, with clear potential to increase effectiveness. Continued identification and examination of "active" technological components within Web-based interventions has been called for. Gamification is the use of game design elements and features in nongame contexts. Health and lifestyle interventions have implemented a variety of game features in their design in an effort to encourage engagement and increase program adherence. The potential influence of gamification on program adherence has not been examined in the context of Web-based interventions designed to manage CMDs and well-being.

Objective: This study seeks to review the literature to examine whether gaming features predict or influence reported rates of program adherence in Web-based interventions designed to manage CMDs and well-being.

Methods: A systematic review was conducted of peer-reviewed randomized controlled trials (RCTs) designed to manage CMDs or well-being and incorporated gamification features. Seven electronic databases were searched.

Results: A total of 61 RCTs met the inclusion criteria and 47 different intervention programs were identified. The majority were designed to manage depression using cognitive behavioral therapy. Eight of 10 popular gamification features reviewed were in use. The majority of studies utilized only one gamification feature (n=58) with a maximum of three features. The most commonly used feature was story/theme. Levels and game leaders were not used in this context. No studies explicitly examined the role of gamification features on program adherence. Usage data were not commonly reported. Interventions intended to be 10 weeks in duration had higher mean adherence than those intended to be 6 or 8 weeks in duration.

Conclusions: Gamification features have been incorporated into the design of interventions designed to treat CMD and well-being. Further research is needed to improve understanding of gamification features on adherence and engagement in order to inform the design of future Web-based health interventions in which adherence to treatment is of concern. Conclusions were limited by varied reporting of adherence and usage data.

KEYWORDS

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Introduction

Common mental health disorders and poor well-being have significant economic, social, and individual costs [1-3]. The issue of promoting well-being while improving and managing mental health conditions remains a worldwide priority [4].

Web-based apps have been widely accepted and recognized as a cost-effective means by which to deliver proven and effective evidence-based therapies that were traditionally face-to-face, such as cognitive behavioral therapy (CBT), to improve mental health and well-being outcomes [5-9]. Web-based interventions provide an advantage over traditional face-to-face delivery due to their potential to reach wider populations through the removal of many access barriers, such as limited numbers of trained and available therapists, long waiting lists, high delivery costs, transportation, geographical issues, and social stigma attached to treatments [10-12].

An increasing number of Web-based platforms have been developed that provide treatment and resources for a wide range of conditions, common mental disorders (CMDs), serious mental health disorders, well-being, and lifestyle improvement. However, dropout and nonadherence are often high and vary widely. Reported rates of attrition range between 35% and 99% [13-18]. Context effects and health conditions influence adherence [19,20]. This is of critical importance because greater adherence to Web-based interventions is associated with improved mental health outcomes [21,22], whereas low adherence is reported to limit effectiveness of treatments [23].

A growing body of research has identified a range of technology-driven features that contribute to program adherence, quality, design, and usability of Web-based interventions [24,25]: persuasive technology [26], including "push factors" and short message service (SMS) text message notifications, alerts or personalized reminders [27,28], weekly tracking [29], incentives [30,31], interactive features [32], and social networks [33]. However, variation in reporting and measuring adherence has complicated understanding of the role of technological features [21].

Findings from the gaming literature have suggested that the inclusion and use of gamified features in Web-based health interventions may increase interest and enjoyment, improving user experience. This, in turn, may positively influence engagement and program adherence and encourage desired health behavior changes [34-38]. *Gamification* has been defined as "the use of game design elements in nongame contexts" [39]. It differs from *serious games*, which refers to the use of games in their entirety within nongaming contexts (as opposed to selected elements or individual features of a game). Thus, gamification is the use of individual features of game design applied in a context not usually associated with video gaming or game play. However, agreement of conceptual understanding remains debated [40] and academic opinion is varied. Gamification has enjoyed a recent explosion of success and increasing interest in a wide array of contexts beyond entertainment, health, education, news, and sustainability [41-43]. However, interest in game design has been researched in the fields of human-computer interaction and motivational psychology for much longer.

Recent research has called for the continued identification of features and "active" components that are most effective in improving program adherence while ensuring treatment remains effective [8,34,43]. A number of important adherence review studies have been published. For example, Kelders et al [19] identified predictors of high adherence such as randomized controlled trial (RCT) study design, frequency of counselor interaction (frequency of peer interaction was not found to predict adherence), more frequent updates and reminders, more extensive use of dialog support, and more frequent intended usage. In addition, van Ballegooijen et al [44] reported adherence to guided Internet CBT (iCBT) interventions for depression were equal to that of face-to-face delivery. Before that, Brouwer et al [45] reported that elements of interventions associated with human support (guided) were associated with higher adherence in physical health interventions. Schubart et al [46] identified that tailored advice, feedback, and guided programs increased user engagement in chronic health interventions. Earlier reviews focused on reporting the extent of the problem in the context of mental health interventions [18,47]. However, no prior reviews were identified that explicitly examined the role of gamification on adherence in the context of Web-based health interventions designed to treat CMD and improve well-being.

This review seeks to (1) explore, through systematic review of published peer-reviewed studies, the role of gaming features in Web-based interventions for the treatment of common mental health disorders or well-being and (2) to identify the "active ingredients" that influence treatment adherence.

Objectives

The specific objectives of this study were to:

1. Identify studies that have incorporated gaming features into the design of their intervention to improve outcomes for CMDs and well-being;

2. Identify gamification features that influence adherence;

3. Report current rates of adherence;

4. Determine whether effects of the gamification feature on adherence varies across subgroup populations; and

5. Identify all terms commonly used to report adherence and maintenance with Web-based CMD and well-being and report the extent to which these are commonly reported in studies.

Methods

Protocol

This review was registered with PROSPERO on April 16, 2015 (CRD42015017689).

Procedure

A comprehensive search of seven electronic databases was conducted: Medline (Ovid interface), PsychINFO (Ovid interface), Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINHAL; EBESCO interface),

Business Source Complete (EBSCO interface), Inspec (Ovid interface), and the ACM Digital Library. Search dates were between database inception and April 2015. Search strategies were customized for each database.

A combination of search terms were used to identify all relevant articles under the following categories: "Web-based," "intervention," "CMD/well-being," and "adherence" (Multimedia Appendix 1).

Inclusion Criteria

The inclusion criteria included:

1. The study must have included one or more gamification feature in the intervention;

2. The study was designed to manage any CMD or improve well-being (including physical conditions that report CMD/well-being outcome);

3. The intervention was delivered via the Web (Internet);

4. The intervention was designed to be accessed on more than one occasion;

5. RCT study design; and

6. The study must have reported at least one measure of attrition, adherence, engagement, dropout, or other term referring to such.

Exclusion Criteria

The exclusion criteria were (1) the intervention was delivered via paper, face-to-face, CD-ROM, or other non-Web-based method and (2) participants were younger than age 18 years.

Gamification

The definition of *gamification* used in this review was "the use of game design elements in nongame contexts" [39]. Ten gamification features were reviewed. The features reviewed were those identified by Cugelman [36]. These were informed by Hamari et al [48] and are described in Multimedia Appendix 2. Two authors (MB, AJ) discussed the selection of this list.

Review Process

Two reviewers (MB, NoN) independently reviewed the title for relevance, then the abstract against inclusion/exclusion criteria. A third reviewer (HvW) resolved any disagreements. Measures of agreement were calculated (kappa statistic). Full-text articles of those included were retrieved at this stage. Two reviewers (MB, NoN) independently reviewed each article. Each was assessed against the inclusion/exclusion criteria outlined previously. The first instance where it did not meet eligibility was recorded as the reason for exclusion and the study was not assessed against additional inclusion criteria [49]. Reviewers discussed all articles that were not unanimous (see the PRISMA flowchart in Multimedia Appendix 3).

Data Extraction

A data extraction form was developed and piloted with five studies meeting the inclusion criteria. The following data were extracted for review (MB):

1. Participant characteristics: including recruitment setting, use of diagnostic interview, total number of participants randomized to intervention, sample size, gender, and age.

2. Intervention characteristics: including intervention name, number of trial arms, primary condition, therapeutic approach, intended duration (weeks), modules to be completed, automated or guided delivery, format of delivery, and outcome measures used.

3. Interactive elements of intervention: including automated email reminders, interactive quizzes, social networking (community forum), homework, or diary tasks.

4. Gamification features: a record of the feature(s) used in the intervention design.

5. Adherence: including adherence to study protocol, completion rate, and term used to refer to adherence.

Assessment of Risk of Bias in Included Studies

The quality of each included study from a risk of bias perspective was assessed (NoN) using the Cochrane Collaboration Risk of Bias tool as described in the *Cochrane Handbook for Systematic Reviews of Interventions* [50]. Each included study was assessed against the six bias domains and source of bias subdomains outlined in order to produce a summary risk of bias assessment score (low, high, or unclear). The majority risk level in each subdomain was utilized and summarized across all domains. If there were four or more subdomains with a low risk of bias, then it would be judged that the study showed an overall low risk of bias.

Data Analysis

Descriptive and exploratory analyses were conducted in SPSS 22 (IBM Corp, Armonk, NY, USA) and Review Manager 5.3 (RevMan 5.3; The Cochrane Collaboration, Copenhagen, Denmark).

An adherence rate to study protocol was calculated as the principal summary measure. A percentage score for adherence to each intervention was calculated to allow comparison across interventions. This was the percentage of those completing postassessment by the number of participants initially randomized (to an intervention trial arm) because limited data were available on total completion rate of interventions.

A series of procedures were carried out. First, the adherence rates of interventions using only one gamification feature were visually presented in a series of forest plots, shown in comparison to adherence rates for inactive controls (where available). The mean adherence rate of interventions using only one gamification feature was calculated by adding the adherence rate for each study that used this feature and dividing it by the number of these studies. A one-way ANOVA was conducted to identify statistical differences between adherence rates for studies using different, single gamification features. Second, adherence rates for interventions using one, two, or three (total number of) gamification features were similarly calculated and presented visually in a bar chart. Forest plots showing adherence compared to inactive control (where available) are also presented. A one-way ANOVA explored statistical differences

in adherence. Third, the mean adherence rate was calculated per condition and displayed in a bar chart. A one-way ANOVA explored statistical differences in adherence per condition. Finally, following these comparisons, an independent *t* test was conducted to examine statistical differences in adherence as a result of additional interactive features (in dichotomous features; ie, sequential or free navigation and automated or guided delivery). A one-way ANOVA was conducted to explore differences in features which included three or more categories (intended duration and modules, total number of interactive intervention characteristics). Values within each were recategorized to form three distinct categories.

A standard multiple regression analysis was performed to explore the role of interactive intervention characteristics in explaining adherence. Independent variables were entered into the model as a block using the enter method (total number of gamification features, guided or automated, sequential or free navigation, intended duration, modules, and total number of interactive intervention features). Adherence was entered as the dependent variable. It is recommended that 15 cases be included per predictor variable in social sciences [49].

Results

Summary Data

After duplicates were removed, 2170 titles and 774 abstracts were reviewed. Following full-text review, 61 RCTs remained (Multimedia Appendix 3). The kappa statistic showed good agreement between reviewers at the title and abstract stage (κ=.933 and κ=.694, respectively).

In all, 47 RCTs were two-armed trials, 12 were three-armed trials, one was a four-armed trial, and one was a six-armed trial. Of the two-armed trials, 21 compared to a wait-list control group, three to treatment as usual, one to placebo, one reported no treatment, and 20 used an active comparator. These included 11 interventions and nine attention controls. Of the 12 three-armed trials, two compared to two inactive controls, nine compared to an active intervention plus wait-list control or treatment as usual, and one included two interventions using different therapeutic approaches. The four-armed trial compared to a Web-based intervention plus tracking and two inactive conditions. The six-armed trial consisted of six active interventions. Multimedia Appendix 4 provides a full reference list of all 61 included articles and a summary of intervention characteristics of all 82 included arms (where no arm is recorded this is to indicate it was the additional trial arm in an RCT).

Cochrane Risk of Bias Score

Of the 61 RCTs included in this systematic review, 37 (61%) were judged to be of high risk of bias, eight (13%) were judged to be of low risk of bias, and an unclear risk of bias was assigned to 16 (26%) of the included studies (Figure 1). The quality of the evidence provided within the included studies was variable. Sources of bias included inconsistent implementation of interventions, follow-up methods, completion rates, and studies being underpowered to statistically detect intervention effects, and self-selected study populations (Figure 1).

Figure 1. Risk of bias assessment of included articles (N=61).
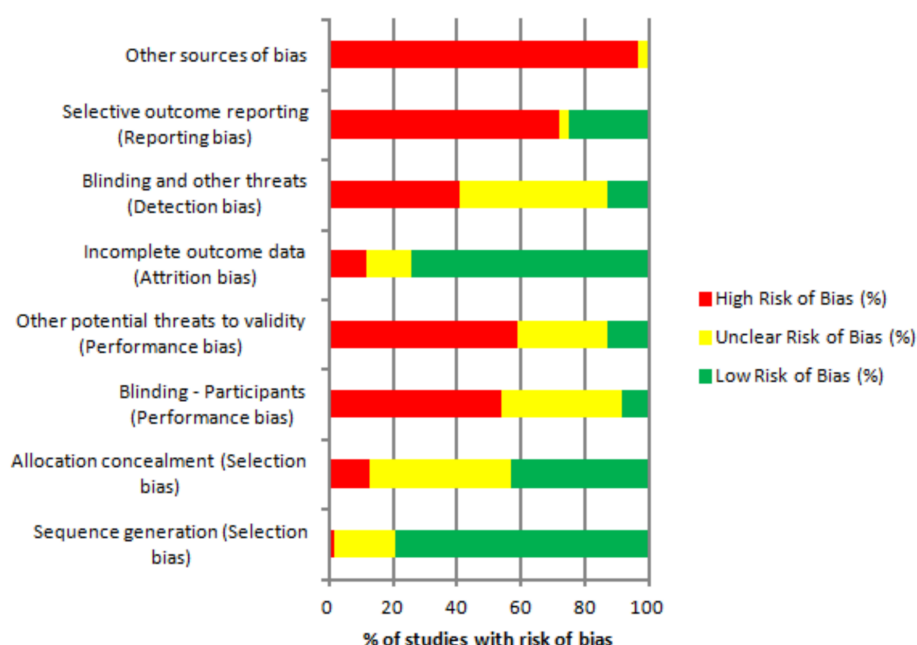
Descriptive Statistics

The main results table presented in Multimedia Appendix 4 reports a summary of key characteristics for all included intervention arms (n=82).

Participant Characteristics

Across the 61 RCTs, 14,726 participants were randomized to either an intervention or control condition. The RCTs varied widely in size from a total of 24 to 23,213 randomized participants. Overall, 41 RCTs had sample sizes less than 200, 15 had sample sizes between 200 and 999, and five had sample

sizes more than 1000. Four RCTs included females only. Four RCTs restricted inclusion to those older than 45 years and one included a sample of those between the ages of 18 and 24 years; the remainder (n=56) recruited from age 18 years and older. Participants were recruited from the general population (n=39), clinical populations (n=11), students (n=4), military (n=2), and organizational workplaces (n=5). The majority of RCTs were conducted in Australia (n=20) and the United States (n=18). The majority of participants self-referred into a trial (87%).

Intervention Arms

From the 61 RCTs, a total of 82 active intervention arms were identified. As such, the following section presents the adherence and gamification results from 82 interventions.

Condition

Interventions were designed to treat a range of symptomology: depression (n=30), depression with comorbid anxiety (n=5), anxiety including social anxiety disorder and generalized anxiety disorder (n=9), well-being (n=7), social phobia (n=7), posttraumatic stress disorder (n=4), obsessive compulsive disorder (n=1), panic disorder (n=1), stress (n=3), binge eating disorder (n=1), and physical conditions (n=14). A total of 37 interventions reported use of clinical diagnostic interview.

The 14 interventions designed to manage physical conditions were physical activity (n=3), smoking cessation (n=1), sexual dysfunction in female cancer patients (2), headache (n=2), insomnia (n=4), and weight loss (n=2). Pre- and postoutcome measures for a CMD or well-being were reported in each of these trials.

Intervention Characteristics

All interventions were Web-based and available via personal computers, laptops, and Internet-enabled devices. In total, 47 different therapeutic interventions were identified and a number of these were utilized in successive RCTs: MoodGYM (n=6), Beating the Blues (n=3), MoodGYM and BluePages combined (n=2), deprexis (n=2), SHUTi (n=2), and The Shyness Program (n=5). In this review, "intervention" refers to the Web-delivered therapeutic treatment program.

Automated/Guided

Of the 82 interventions, 50 were automated. Automated delivery of an intervention refers to the use of an intervention treatment program without any human support. The remainder (n=32) were guided. Guided delivery refers to support of a human guide during the course of the treatment. Guided interventions included a range of guided interactions: therapeutic telephone contact (n=13), face-to-face therapy (n=5), and therapeutic emails (n=21).

Therapeutic Approach

In total, 59 interventions were based primarily on CBT, one of which used CBT in combination with psychoeducation and interpersonal psychotherapy, two used cognitive restructuring without behavioral activation, two used mindfulness, two used positive psychology, one was based on a stress and coping model, two used Internet psychotherapy, five employed health behavior change techniques, and nine did not specify a

therapeutic approach. Some studies noted additional elements used in the intervention. These included cognitive bias modification online (n=1), Internet-delivered supportive counseling (n=1), psychoeducation (n=2), interpersonal therapy (n=2), problem solving (n=2), motivational interviewing or motivational principles (n=2), and physical activity (n=1).

Format of Delivery

In all, 63 intervention arms were released sequentially in a predetermined order over time, 16 could be freely navigated, two [51,52] presented modules in sequence but allowed participants free navigation, and one [53] included free navigation once a specific module had been completed.

Duration

The duration of the interventions ranged between 3 and 20 weeks (mean 7.8, SD 2.4). One did not specify the intended duration [54], although it clearly stated that the intervention was to be used more than once. Many were eight (n=25), six (n=22), or 10 (n=8) weeks in duration.

Modules

The number of modules within each intervention ranged between zero and 13 (mean 6.4, SD 2.6). Three did not use a modular format. Most interventions included six (n=30), eight (n=11), or five (n=9) modules.

Interactive Intervention Elements

Information available regarding interactive elements employed in each intervention varied. Text was presented in all, accompanied by a range of additional elements, automated email reminders (n=36), SMS text message reminders (n=13), telephone reminders (n=12), interactive quizzes (n=37), social media (n=11), and homework (n=47).

Gamification

Eight of 10 gamification features reviewed were identified in use: story/theme, progress, feedback, goal setting, rewards, challenge, badges/trophies, and points. No study incorporated levels or game leaders. The majority of interventions used only one gamification feature (n=58); the maximum number used in any one intervention was three. Of the interventions employing only one gamification feature, story/theme was most commonly used (n=33), followed by progress (n=10), goal setting (n=6), rewards (n=6), and feedback (n=3). Of those using more than one feature (n=24), 19 used two features and five incorporated three features.

Adherence

A wide variety of terms were used to report a measure of adherence: adherence, attrition, dropout, noncompleters, lost to follow-up, participant withdrawal, nonresponse, completion rate, did not complete, retention rate, loss, and compliance.

Overall adherence to study protocol ranged between 3.37% and 100% (n=82, mean 71.7%, SD 20.3%). Adherence to control groups ranged from 5.98% to 100% (n=58, mean 78.2%, SD 19.1%). The mean adherence rate of studies excluded for not including a gamification feature was 75.2% (SD 19.6%) with a range of 5.3% to 100%. There were differences between the ways in which studies classified adherence and reported their

data, making meaningful comparison complicated. The limitations of such are addressed in the Discussion.

Reasons for nonadherence were provided in 33 RCTs. The following reasons were provided: lack of time, disinterest, no need for treatment, hardware or technical issues, program perceived as noneffective, life events, felt better after a few modules, disappointed by group assignment, holiday, work commitments, poor health, and no longer wish to participate. One RCT [55] reported removal of 19 participants due to fraudulent participation. One RCT only reported data for those participants who completed the entire intervention (due to a programming error).

Usage Data

Limited usage data were reported, mean number of modules completed (n=39 reported this data), program completion (n=45), with a mean completion rate of 54.0% (SD 24.6%), and log data. The way in which log data was reported varied further; mean time spent per visit in minutes (n=4), mean log-on rate (n=5), total time duration (n=2), total page views (n=1), and activities opened (n=1).

Statistical Analysis of Intervention Characteristics and Adherence

Gamification

Adherence was examined per gamification feature for those interventions that employed only one gamification feature (n=58). Forest plots present the adherence per intervention arm in comparison to its control condition (where a control condition was used as opposed to an active intervention). The following forest plots show two columns: the intervention arm and the control group. The term "events" refers to the number of randomized participants remaining at postassessment, whereas "total" refers to the total number randomized to that intervention

at the start of the trial. If a score of zero is recorded, either the data was unavailable or there was no control group to compare against. For example, in some RCTs the comparator group was another (treatment) intervention or a modified version of the same intervention. The weight is automatically calculated by RevMan based on the total number of participants in the trial. A mean adherence is also reported; this does not include the control arm data (unlike the forest plots).

Goal Setting

Goal setting was defined as users informed of a goal or are required to establish their own goals to achieve over the duration of the program (intervention). Six interventions incorporated goal-setting activities. Adherence compared to control is shown in Figure 2. Mean adherence for the six interventions was 72.3% (SD 22.8%).

Progress

Progress was defined as progression through the program or game. Participants could monitor progress with self or others. Ten interventions incorporated progress. Adherence compared to control is shown in Figure 3. Mean adherence was 53.5% (SD 31.2%).

Feedback

Feedback was defined as automated feedback provided on progress. Three interventions incorporated automated feedback. Adherence compared to control is shown in Figure 4. Mean adherence was 75.9% (SD 24.0%).

Rewards

Rewards for achievement included in-game goods or artifacts (functional or nonfunctional to the program). Six interventions utilized rewards. Adherence compared to control is shown in Figure 5. Mean adherence was 72.1% (SD 13.3%).

Figure 2. Forest plot showing the adherence rate of interventions using goal setting as a gamification feature.
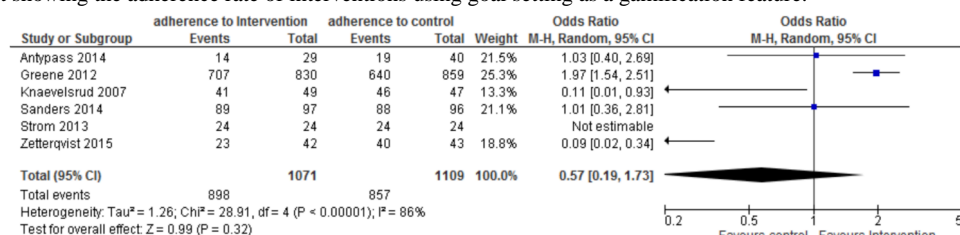

Figure 3. Forest plot showing the adherence rate of interventions using progress as a gamification feature.
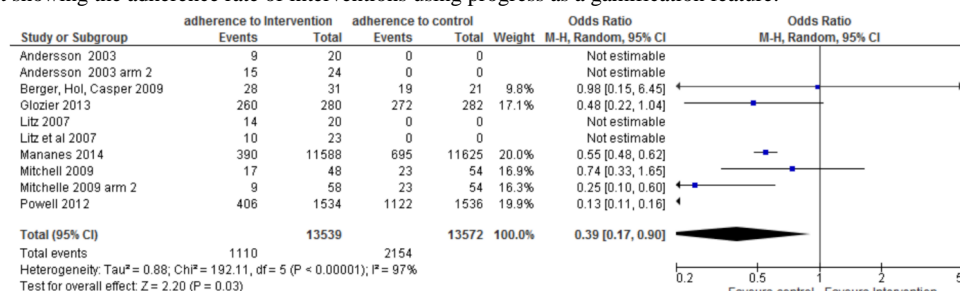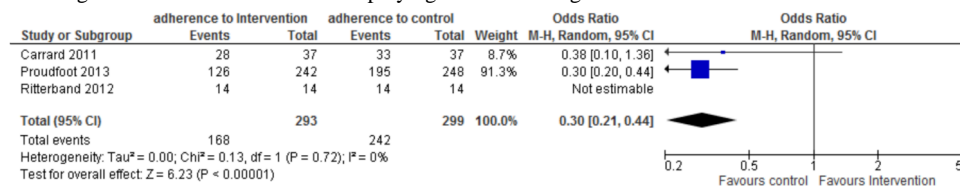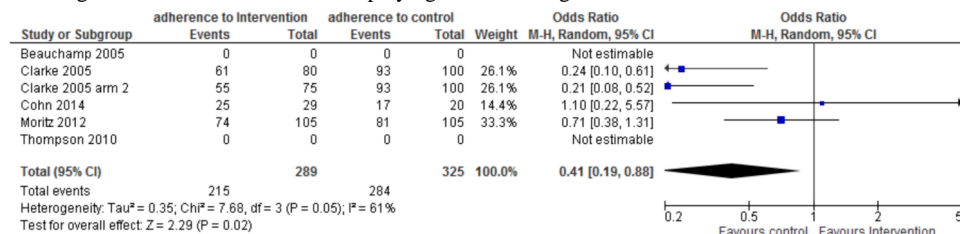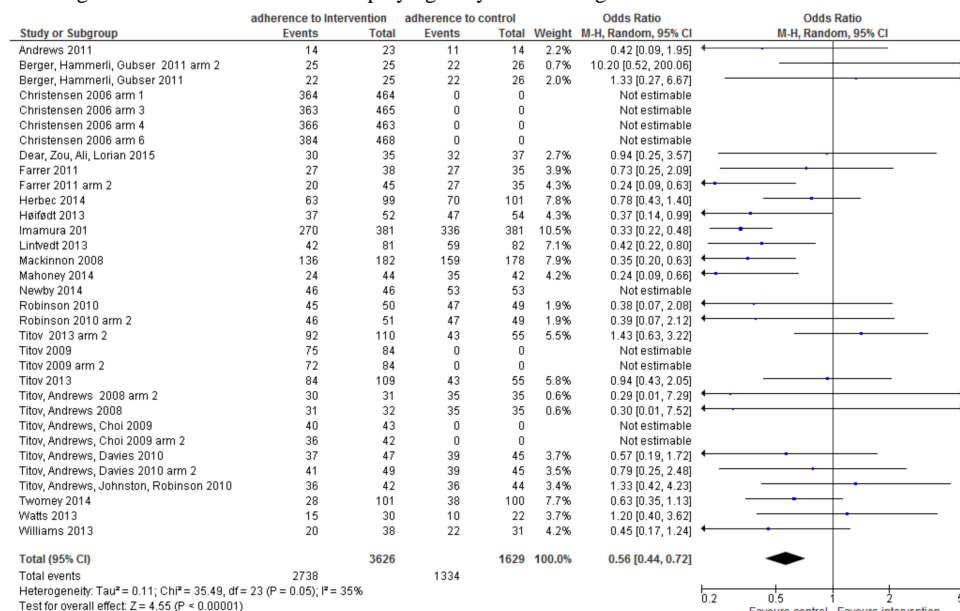
Figure 4. Forest plot showing adherence of interventions employing feedback as a gamification feature.

Figure 5. Forest plot showing adherence of interventions employing rewards as a gamification feature.

Figure 6. Forest plot showing adherence of interventions employing story/theme as a gamification feature.

Story/Theme

A story/theme included fun and playfulness, playing out an alternate reality, an avatar, or an illustrated story. In all, 33 interventions used a story/theme feature . Adherence compared to control is shown in Figure 6. Mean adherence was 76.3% (SD 17.0%).

A one-way ANOVA did not reveal any statistical differences between interventions using the preceding gamification features (n=58, *P*=.19).

Comparison of Adherence Rates per Use of Total Number of Gamification Features

The mean adherence rates for interventions incorporating one, two, and three gamification feature were 71.5% (SD 21.6%), 70.5% (SD 17.9%), and 78.2% (SD 12.3%), respectively. A one-way ANOVA did not reveal any statistically significant differences (*P*=.74). Adherence compared to control are displayed in three forest plots to visualize differences in studies employing one, two, and three gamification features (Multimedia Appendix 5).

Gamification Use by Condition

Multimedia Appendix 6 shows the frequency each individual gamification feature was employed in an intervention per condition. The total number is more than 82 because some interventions used two or more features. The mean adherence rate per condition is presented in Multimedia Appendix 7. One-way ANOVA did not reveal any statistical differences (*P*=.18).

Examination of Additional Intervention Characteristics

Delivery format, such as sequential (n=65, mean 72.1%, SD 21.3%) and free navigation (n=17, mean 70.2%, SD 16.2%), did not influence adherence to intervention (*P*=.20). Automated interventions had a mean adherence of 67.9% (n=50, SD 21.8%) compared to guided interventions (n=32, mean 77.5%, SD 16.2%). An independent *t* test did not reveal this to be statistically significant (*P*=.05).

One-way ANOVA did not reveal any statistical difference for intended duration (6 weeks: mean 65.1%, SD 24.3%; 8 weeks: mean 74.0%, SD 17.3%; 10 weeks: mean 76.4%, SD 17.1; P=.15), number of modules (<6 modules: mean 70.5%, SD 24.3%, 7-9 modules: mean 73.5%, SD 17.3%; ≥10 modules: mean 73.6%, SD 17.1%; P=.80), or total number of interactive features (0-2 features: mean 67.5%, SD 22.3%, 3-4 features: mean 77.5%, SD 15.3%; 5-6 features: mean 77.8%, SD 19.0%; P=.08).

Standard multiple regression indicated that the independent variables only explained 10.3% (P=.22) of the variance in adherence rate.

Discussion

This review sought to identify RCTs that incorporated gaming features into the design of Web-based health interventions to treat CMDs or well-being. Physical health interventions that included an outcome measure for CMD or well-being were included when identified. This is the first review that has examined the use and role of gamification features on adherence in this context. Ten key gamification features were examined [36].

A total of 61 RCTs comprising 82 intervention arms were analyzed and 47 separate interventions were identified. Interventions designed to treat depression, which were intended to be 8 or 6 weeks in duration, incorporating six modules, and utilizing CBT were most common. This is shorter than the typical 10-week duration identified previously [19]. The most common format of delivery was a weekly sequential release of modules. Interventions allowing free navigation were less common. Interventions were more likely to be automated rather than guided. The majority of RCTs were found to have a high risk of bias.

One aim was to explore whether gamification features have been incorporated into the design of interventions developed to manage CMD or improve well-being. This review identified eight gaming features in use. The majority of studies used only one feature (goal setting, progress, feedback, reward, or story/theme). No studies specifically compared the impact of different gamification features on program adherence in the same RCT; however, one trial compared six versions of the same intervention (MoodGYM). Two of these trial arms were found to incorporate two gamification features, whereas the remaining four arms only included one [56]. However, the purpose of the trial was not to compare use of these features. Overall, the most common feature utilized was story/theme . Interventions using this did not commonly incorporate additional features; only six were found which did [56-61]. Progress and feedback were used together in six interventions [27,56,62-65]. Points and challenge were not frequently implemented and levels and game leaders were not incorporated at all.

The main aim of this review was to explore whether incorporating gamification features into the design of these interventions influenced adherence to treatment. In order to examine this, adherence was examined first. Adherence to intervention was lower overall than adherence to control when control was inactive (means 71.7% and 78.2%, respectively). Previous reviews reported higher adherence to guided interventions compared to automated interventions [45]. This review supported this (77.5% and 67.9%, respectively) lending further support for the role of guides in self-help treatments. However, this difference was not statistically significant.

Looking at the role of gamification features, adherence rates were compared across those using different features when only one feature was incorporated. No statistical difference was observed, which supported use of one single feature over another, despite the mean adherence rates ranging from 53.5% to 75.9% for progress and feedback, respectively. Nor was there any significant difference found between studies using different total numbers of gamification features (one, two, or three features). However, the forest plots suggest that as additional features are added, adherence moved closer to favoring the intervention over control.

An additional aim of this review was to determine whether adherence to interventions using gamification differed across health conditions. Interventions designed to treat social phobia had higher adherence than those designed to treat well-being (P=.048). However, no other statistical difference was observed. Findings reported here are in line with established published findings. Kelders et al [26] reviewed the impact of persuasive features and system design. They characterized typical studies and identified that RCT design, more frequent usage, updates, and dialog support predicted higher adherence. Interventions covered lifestyle, physical health, and mental health programs. Health care context did not predict adherence.

As a result, additional intervention features were also examined in an effort to shed light on active ingredients influencing adherence. Again no statistically significant differences were observed and none of the variables were found to explain any significant proportion of the variance in adherence rate (total variance explained was only 9.4%). However, mean adherence increased as intended duration increased from 6 or 8 weeks to 10 weeks' duration.

Criticisms of gamification have been levied and discussed in the literature [66]. For example, a Gartner report [67] stated "gamification is currently driven by novelty and hype," whereas Bogost [68] considered it a quick fix adopted by businesses to increase and promote engagement. Underpinning these criticisms is the concern that implementation of individual features such as points and leader boards actually miss the real essence and power of games as motivational techniques, which have the potential to positively encourage behavior change [69] or positively encourage adherence to treatment programs that reduce individual suffering through reductions in clinical symptoms. Although many studies were found to have incorporated one game feature into their treatment program, it is possible that such negative opinions may have reduced wider application in this health context due to concerns of appropriateness. However, Cugleman [36] highlighted that gamification, like other persuasive architectures, has merit if implemented in the right way.

It is important to consider the way in which gamification features identified in use were incorporated into intervention

designs. There were only three examples in which the use of game mechanics was clearly acknowledged and the intention of use identified as a means to address and increase user engagement and enhance enjoyment. Cobb and Porier [70] used in-game rewards, badges, and challenges to engage participants in a daily challenge to improve well-being. In this example, adherence was high and usage data well reported. More than half the participants continued to engage with the program at 60 days and 92.4% were reported to have completed one challenge. Authors reported a positive dose-response relationship for well-being in which higher program engagement predicted better well-being at postassessment and follow-up. Similarly, a guided physical activity intervention that assessed well-being outcomes applied motivational principles and game elements, including visualization of progress and automated goal setting activities, specifically to enhance engagement and participation [55]. Imamura et al [51] incorporated comic strip stories in an effort to "foster learner's interest in the program" (p 3). However, the remaining interventions did not commonly acknowledge or describe their use of gamification features. For example, Titov et al [61] implemented story/theme, goal setting, and challenge in The Shyness Program, without acknowledgement that game mechanics were incorporated in the intervention. Indeed incorporation of such features may not have been considered (by those who developed the intervention) to represent implementation of game mechanics. Further examples include Sheeber et al [71] who incorporated three features, without recognition of such, in a guided intervention to manage maternal depression. In this example, intervention design and development was focused on principles that promoted self-regulated learning. Adherence and completion rate was high (97% and 63%, respectively). Intervention descriptions focused on the theoretical basis rather than the technological aspects of development. The intentional use of game design elements has recently been suggested as a defining feature of the operationalization of gamification [40]; as such, this highlights the potential importance of intended use in operationalization of features. Doherty et al [32] outlined the importance of encouraging engagement with, or adherence to, treatment rather than technology and that it is important to bear this in mind during discussion on use of gamification features in this context in which the ultimate intention is to alleviate suffering and improve well-being.

Strengths and Limitations

This review was based on an extensive search of a large number of health and computer science databases. Hand searching was not conducted, but the expertise of the multidisciplinary team means that although publication bias cannot be excluded, this comprehensive review did identify a large number of relevant studies.

This review aimed to explore the potential role of gamification to increase program adherence and engagement, adherence being an issue that has plagued Web-based health interventions for some time [47,72]. In order to examine the role of gamification on adherence, adherence to study protocol was used. This was considered an objective, comparable measure calculated as a percentage of those (randomized) who completed postassessment outcome measures. Although this is useful, it

offers less insight than module completion rates would. However, limited reporting of data, such as log-on rates, module completion, and mean access time, meant this was not possible. Only 34 studies reported a percentage for program completion and only 10 provided data for log-on rates, with one exception [73]. These studies were all reported after 2009. A more comprehensive and standardized usage report across trials would assist and inform further analyses of adherence and program engagement. This finding is in line with previous discussion on adherence reporting [19,62,74]. Morrison and Doherty [74] provided a useful analysis of log data that could be replicated in future studies.

Interventions evaluated via RCT methodology was a specific inclusion criteria of this review; as such, it is possible that a body of literature pertaining to management of CMD or well-being that incorporate gamification features may have been excluded. However, RCTs follow robust methodological procedures and are considered to provide the highest quality evidence, so the approach adopted is of value [75].

Varied reporting complicated initial identification of studies for inclusion. Not all studies provided a detailed description of the intervention programs. However, seven provided clear, detailed descriptions of intervention features, including screenshots and illustrations [27,51,70,76-78].

Interventions using gamification features in conditions other than depression were small in number, which limited opportunity to explore the influence of gamification features on adherence across health conditions.

Furthermore, the way in which specific gamified features were incorporated warrants discussion. In this study, rewards were commonly seen to be financial in nature, whereas progress was often controlled progression through the system. Goal setting and feedback were aligned with established strategies used in therapeutic treatment of CMD and their role is well defined in terms of supporting and encouraging behavior change. In reviewing intervention designs, it was not always possible to identify the intention behind each feature and they are also commonly used features in Web-based programs. However, they were not employed in all interventions and so remain of interest in this context.

It is important to acknowledge that adherence also may be influenced by additional factors that could not be assessed in this review. This is highlighted in the small variance rate (10.3%). Furthermore, attrition to mental health treatments is also experienced in face-to-face delivery formats.

Implications for Practice

Future research should look to examine whether application of specific gamification features influences adherence to protocol and completion rate. No RCT was identified that specifically considered the role of gamified features on promotion of adherence to mental health programs. This could be achieved through comparisons of the same intervention (in the same clinical population) adjusted to include either different gamification features, different combinations of gamification features, increasing numbers of gamification features, or use of one specific gamification feature compared to none. Studies

looking to explicitly make these comparisons may shed further light on the role of individual features extracted from game design on adherence to Web-based health interventions. These effects should also be explored across different health and well-being contexts to identify whether inclusion of gamification features are more or less effective at increasing engagement and adherence across different patient populations and subgroups, such as different levels of clinical symptomology.

It would also be beneficial to explore the use of gamification in interventions based on alternative therapies to that of CBT (which comprised the majority of those reviewed here); for example, whether they have a role to play in encouraging engagement to interventions based on acceptance and commitment therapy. In addition to this, future research might benefit from exploration of gamification in interventions, allowing free navigation as opposed to a linear, weekly format as identified here. This may shed further light on the potential role of game mechanics on program engagement and adherence to treatment.

Assessment of participant's motivation to complete the full intervention on entering the program might also offer an alternative way to explore the role of gamification. Use of extrinsic motivation features may influence some people more than others. Exploration of people's reasons for participating at the onset of a RCT might shed light on the role of gamification features. Gamification promotes motivation through external means, which means those who are internally motivated may not be influenced to the same extent.

Research findings have indicated that higher adherence is associated with increased treatment effectiveness (dose-response relationship). Some have discussed a beneficial level of engagement that facilitates a positive health outcome [32] and this is certainly an area for future interest. This was not examined in this review, but could be further explored in relation to the inclusion of gamification features.

Conclusion

Gaming features have explicitly been implemented into the design of interventions to treat CMDs and well-being. However, this was not common. This review did not find any evidence that use of specific gamification features was associated with higher adherence to the intervention program as measured by adherence to protocol. Furthermore, no evidence was found to suggest that interventions incorporating additional gamification features had any statistically significant influence on adherence. However, no studies explicitly examined the role of gamification on program adherence or engagement.

What the review did show was that guided interventions and interventions intended to last 10 weeks, as opposed to 6 or 8 weeks duration, and those incorporating three gamification features had a higher mean adherence rate. This may provide initial insight into the design of future interventions wishing to utilize gamification features in an attempt to address adherence and contribute to the ongoing discussions surrounding the use of game design elements in nongame contexts.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Keyword search table.

[PNG File, 998KB - mental_v3i3e39_app1.png]

Multimedia Appendix 2

Gamification features.

[PNG File, 299KB - mental_v3i3e39_app2.png]

Multimedia Appendix 3

PRISMA Flow diagram of included and excluded studies.

[PNG File, 2MB - mental_v3i3e39_app3.png]

Multimedia Appendix 4

Main results table and references of included studies.

[PDF File (Adobe PDF File), 78KB - mental_v3i3e39_app4.pdf]

Multimedia Appendix 5

Forest plots showing mean adherence in studies using one, two and three gamification features.

[PNG File, 6MB - mental_v3i3e39_app5.png]

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Multimedia Appendix 6

Gamification features used per condition.

[PNG File, 727KB - mental_v3i3e39_app6.png]

Multimedia Appendix 7

Mean adherence rate per condition.

[PNG File, 1MB - mental_v3i3e39_app7.png]

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Abbreviations

CBT: cognitive behavioral therapy
CMDs: common mental disorders
iCBT: Internet cognitive behavioral therapy
RCT: randomized controlled trial
SMS: short message service

Original Paper

Feasibility and Outcomes of an Internet-Based Mindfulness Training Program: A Pilot Randomized Controlled Trial

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Abstract

Background: Interventions based on meditation and mindfulness techniques have been shown to reduce stress and increase psychological well-being in a wide variety of populations. Self-administrated Internet-based mindfulness training programs have the potential to be a convenient, cost-effective, easily disseminated, and accessible alternative to group-based programs.

Objective: This randomized controlled pilot trial with 90 university students in Stockholm, Sweden, explored the feasibility, usability, acceptability, and outcomes of an 8-week Internet-based mindfulness training program.

Methods: Participants were randomly assigned to either an intervention (n=46) or an active control condition (n=44). Intervention participants were invited to an Internet-based 8-week mindfulness program, and control participants were invited to an Internet-based 4-week expressive writing program. The programs were automated apart from weekly reminders via email. Main outcomes in pre- and postassessments were psychological well-being and depression symptoms. To assess the participant's experiences, those completing the full programs were asked to fill out an assessment questionnaire and 8 of the participants were interviewed using a semistructured interview guide. Descriptive and inferential statistics, as well as content analysis, were performed.

Results: In the mindfulness program, 28 out of 46 students (60%) completed the first week and 18 out of 46 (39%) completed the full program. In the expressive writing program, 35 out of 44 students (80%) completed the first week and 31 out of 44 (70%) completed the full program. There was no statistically significantly stronger intervention effect for the mindfulness intervention compared to the active control intervention. Those completing the mindfulness group reported high satisfaction with the program. Most of those interviewed were satisfied with the layout and technique and with the support provided by the study coordinators. More frequent contact with study coordinators was suggested as a way to improve program adherence and completion. Most participants considered the program to be meaningful and helpful but also challenging. The flexibility in performing the exercises at a suitable time and place was appreciated. A major difficulty was, however, finding enough time to practice.

Conclusions: The program was usable, acceptable, and showed potential for increasing psychological well-being for those completing it. However, additional modification of the program might be needed to increase retention and compliance.

ClinicalTrial: ClinicalTrials.gov NCT02062762; https://clinicaltrials.gov/ct2/show/NCT0206276 (Archived by WebCite at http://www.webcitation.org/6j9I5SGJ4)

KEYWORDS

mindfulness; Internet-based intervention; Internet; usability; acceptability; feasibility; randomized controlled trial

Introduction

Structured group-based meditation interventions, such as the Mindfulness-Based Stress Reduction (MBSR) program [1], have increasingly been used to alleviate stress in individuals over the last several decades. The concept of mindfulness has been defined as "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment" [2]. In mindfulness-based programs, a number of specific meditation and yoga exercises are used to develop and increase the ability to be mindful in the present moment. The MBSR program was originally developed for individuals with somatic disorders [3], but over the years the effects of mindfulness-based programs have been evaluated in a large number of studies for various population groups and for different symptoms and conditions. A meta-analysis examining the effects of mindfulness training in nonclinical settings on a wide variety of outcomes showed small to medium effect sizes for anxiety, stress reduction, and psychological well-being [4].

The Internet provides an opportunity to deliver evidence-based psychosocial programs to a broader range of individuals and a possibility to disseminate interventions targeting stress and stress-related problems to large groups [5-8]. An increasing proportion of the global population has access to the Internet—more than 70% of people in Europe, nearly 90% in North America, and 95% in Sweden are Internet users [9]. Internet-based programs can be cost efficient [10], and the stigma that might be associated with some face-to-face consultations regarding mental disorders can be avoided [6]. A growing number of treatment programs are Internet-based, targeting many stress-related and mental conditions and behaviors such as smoking, insomnia, and depression [11-13]. An increasing number of studies of patients with various mental disorders have shown the positive effects of Internet-based programs [14-18]. Several of these programs have been based on or included mindfulness techniques. The effects of specific mindfulness-based programs delivered through the Internet have been promising regarding the improvement of mental states such as stress, anxiety, and depression [19-23], and results apply to persons with psychological symptoms of stress or distress [19], as well as to persons without previously known mental health problems [21,24], including students [23].

Several studies have explored the experiences of Internet-based interventions among users, although few of them have investigated participant perceptions of specific mindfulness-based programs. In one randomized controlled trial (RCT) assessing the feasibility of an Internet-based mindfulness program for stress management in the Unites States, participants were asked to complete a questionnaire about overall feedback on the intervention and reasons for early study or program termination [22]. About 25% of those who completed the baseline questionnaire responded to the feedback questionnaire. Of those who gave feedback, 45% found the overall program to be very or extremely helpful, 35% somewhat helpful, and 19% little or not at all helpful. The most common reason for leaving the program was that the participant was too busy. The second most common reason for termination was technical or

access problems. In an American interview study assessing participant experiences of a mindfulness-based intervention delivered through the Internet for reducing residual depression symptoms and preventing relapse, participants reported on a perceived lack of support during the program but appreciated the flexibility of completing weekly sessions according to their own schedule [25].

This randomized controlled pilot trial examined the feasibility, usability, acceptability, and outcomes of a newly developed 8-week Internet-based mindfulness training program among Swedish students. Feasibility was examined by determining the degree to which participants were engaged in and completed the program. Usability and acceptability were assessed using postintervention questionnaires and semistructured interviews of experiences at completion of the program. Outcomes were examined by comparing pre- and postassessments of psychological well-being and depression symptoms both within the intervention group and between those participating in the mindfulness training program and those randomized to an active control condition. This broad approach of evaluation aims to expand the knowledge about the potential of Internet-based self-administered mindfulness-based programs to improve mental health status.

Methods

Participants and Procedures

Study participants were recruited between December 2013 and March 2014 by advertising at different university campuses in Stockholm, Sweden. The study was open to students aged 18 years and older with access to a computer and an email address. Students interested in participation phoned or sent an email to the study coordinators to receive additional information about the study design. Participants were randomized to either the intervention group (Internet-based mindfulness training program) or an active control group (Internet-based expressive writing program) on a rolling basis using a random sequence of numbers. One of the authors generated the sequence of numbers using SPSS statistical analysis software (IBM Corp) and another author enrolled and assigned participants in the order they were recruited. All participants in both groups were asked to fill out a questionnaire before and after the program and complete weekly assessments. Participants who did not respond to the weekly assessments were reminded by email. The completion of a week's training was not time-limited, but the next set of program material was only made available after the participant completed the previous training and assessment. Those who did not respond to the reminder or did not fill out the weekly assessments marking continued participation were not asked to give a reason for discontinuation or noncompliance. All participants completing the Internet-based programs were compensated in an amount of SEK 500 (about $54).

The Internet-Based Mindfulness-Based Intervention

The mindfulness training program developed for this study was a modified version of the group-based mindfulness program developed by Jon Kabat-Zinn [3,26]. The adaptation of the program to an Internet environment was based on experiences gained from other Internet-based programs [27-32]. Participants

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were given access to the course platform by logging in and using an individual password. The program consisted of 8 weekly modules including information about the theoretical foundations of mindfulness regarding relaxation, meditation, and the body-mind connection. Each weekly module consisted of a few pages of text (ie, the lecture) and a set of exercises. All formal exercises described in the standards of practice of MBSR from the University of Massachusetts Medical School Center for Mindfulness in Medicine [26] (body scan meditation, hatha yoga, sitting meditation, and walking meditation) as well as the informal exercises awareness of pleasant and unpleasant events, awareness of breathing, and deliberate awareness of routine activities and events were included in the program (see Table 1).

Table 1. Program content.

	Topic of lecture	Formal exercises	Informal exercises
Week 1	Mindfulness: benefits to quality of life and health	Introduction of: – Mindful breathing – Body scan meditation	Introduction of: – Deliberate awareness of routine activities and events such as waking up, eating, taking a shower, driving, awareness of interpersonal communications
Week 2	Cultivation of mindful attitudes	Continued practice of introduced exercises	Continued practice of introduced exercises

Week 3	The desire to keep or avoid	Introduction of:
		–Lying yoga
		Continued practice of introduced exercises
			Introduction of:
			– 3-minutes meditation:
			  ○Step 1: Becoming aware
			  ○Step 2: Gathering and focusing attention
			  ○Step 3: Expanding attention
			Continued practice of introduced exercises

Week 4	Mindfulness and stress	Continued practice of introduced exercises	Continued practice of introduced exercises
Week 5	Relations and social context	Introduction of: – Standing yoga – Sitting meditation – Walking meditation Continued practice of introduced exercises	Continued practice of introduced exercises
Week 6	Automatic thoughts	Continued practice of introduced exercises	Introduction of: – STOP: A Short Mindfulness Practice enabling distancing from instant feelings Continued practice of introduced exercises
Week 7	Sleep and Mindfulness	Encouragement to train without audio files and experiment with different combinations of exercises	Introduction of: – Short exercise to facilitate falling asleep Continued practice of introduced exercises
Week 8	No lecture	Encouragement to again use audio files and choose preferred exercises	Continued practice of introduced exercises

The main departures in the content of our self-administrated program from MBSR as described in the standards of practice from the University of Massachusetts Medical School [26] were (1) no face-to-face sessions, (2) no group dialogue or contact between participants, (3) no all-day silent retreat during the sixth week, and (4) no introduction of self-evaluation instruments at the end of the course. Participants could navigate within each module in the texts by clicking on navigational icons. Audio files, 15 or 30 minutes in length, were provided to facilitate daily practice of formal exercises. The participants were encouraged to practice 30 to 45 minutes a day, continuously or throughout the day, 6 to 7 days per week. The program also included short-duration meditation and exercises aimed to promote the integration of mindful awareness into everyday activities. New exercises were introduced gradually during the first 5 weeks, including mindful breathing and body-scan meditation in the first and second weeks, lying yoga in the third and fourth weeks, and standing yoga, sitting meditation, and walking meditation in the fifth week. In weeks 6 to 8, participants could choose which exercises to perform. None of the exercises required a high degree of physical strength or agility. Participants were presented with alternative ways of doing the exercises if needed, like choosing other positions, to ensure their safety. The study coordinator supported participants by sending weekly messages informing them that a new week's text and exercises were available. The study coordinator could monitor each participant's log-in history and send extra reminders to participants who did not visit the platform for 14 days or longer. The participants could contact the study coordinators through the program platform or by sending an email or making a phone call.

The Internet-Based Expressive Writing Intervention

Participants in the Internet-based expressive writing program were asked to write about stressor-related emotions and thoughts for 20 minutes on 4 occasions spread out over approximately 4 weeks. This procedure is drawn from work by Pennebaker and colleagues and has been tested across dozens of RCTs [33]. In this study, the standardized procedure by Pennebaker was complemented with an additional writing instruction. In addition to writing about stressor-related emotions, participants were asked to write for 10 minutes using a positive prompt following the first writing assignment. Examples of positive prompts are: "What has become better since . . .," "What personal strengths helped you deal with . . .," and "What makes you feel hopeful about the future?" The exercises were made available on an Internet-based platform participants could access by logging in using an individual password. Participants could make contact with the study coordinators through the program platform or by sending an email or making a phone call.

Internet-Based Measurements at Baseline and Postintervention

Participant Characteristics

Participants were asked to complete a baseline questionnaire which included questions on age, gender, level of education, and living situation. This was done in connection to the obtaining of baseline measures of the outcome variables.

Outcome Variables

Psychological Well-Being is a questionnaire measuring 6 dimensions: environmental mastery, self-acceptance, positive relations with others, purpose in life, personal growth, and autonomy. It has been extensively used and has shown acceptable factor structure and validity [34]. In this study, an overall total measure of psychological well-being was used. The alpha coefficient of the scale was .82 in our sample.

The Center for Epidemiologic Studies Depression Scale is a 20-item scale measuring depression symptoms in nonpsychiatric populations [35]. The alpha coefficient of the scale was .90 in our sample.

Weekly Follow-Up Assessments

After each week, the participants in the mindfulness intervention group were asked to answer questions about how much time they had spent on exercises during the previous week. Participants in both groups were also asked to respond to a number of questions assessing potential mediators of intervention effect: mindfulness skills after weeks 2, 4, 6, and 8 and positive/negative affect after weeks 1, 3, 5, and 7. For the analyses in this paper, the time and frequency of practice is reported, but no analyses of the mediation was performed.

Evaluations of the Program

At the postassessment follow-up, respondents were asked to answer 7 questions on a scale of 1 to 9, where 1 indicates "not at all" and 9 indicates "very," to evaluate their overall experiences of the programs. The questions were based on research into factors considered to be important for participation in Internet-based programs (ie, how well the intervention is received and perceived by users) [22,29,31] and included: How meaningful do you think the program was? How successful do you think the program was in improving your way of being? How likely is it that you would recommend the program to someone in the same situation as you? How emotionally demanding do you think the program was? On the whole, how challenging do you think the program was? If you had known as much about the program before starting as you know today, how likely would it have been that you would still have participated? Do you feel that your ability to reach mindful awareness has changed during the program? Items rated 1 to 3 points were considered to have a low value to participants; items rated 4 to 5, middle value; and items rated 7 to 9, high value.

Statistical Analysis

Baseline characteristics of the sample, stratified by experimental group, were examined to ensure that key variables were evenly distributed by randomization using Student t tests. The most specific test of the hypothesis as a whole was the difference between groups on the contrast between baseline and follow-up. This was tested using multivariate repeated-measures analyses of variance (MANOVA) with baseline and follow-up scores as dependent variables. Time and group (mindfulness vs expressive writing) were entered as factors in the analyses. In addition to the MANOVA, inferential analyses were conducted to examine pre- and postintervention change for each dependent variable, stratified by randomization condition, using independent sample t tests. Cohen's d effect size for within and between group differences was calculated based on the difference between group means on baseline and follow-up change scores. The denominator was based on the pooled standard deviation (SD) at baseline and follow-up adjusted for different sample sizes [36]. All tests of intervention effects were done with intention-to-treat analyses with missing data at follow-up imputed according to last-observation-carried-forward strategy, meaning that some baseline values were used as postintervention values. All tests of significance were two-tailed. Analyses were performed in SPSS.

Semistructured Telephone Interviews Postintervention

To get information about participant perceptions of the mindfulness training program, telephone interviews were conducted with a small number of participants shortly after program completion. The focus of the interviews was the participant experience of the techniques, information, instructions, and exercises, as well as the perceived support received from the study coordinators. The first students who completed the mindfulness program were asked to participate in an interview. One of the study coordinators (PK) conducted all interviews using a semistructured guide with open-ended questions along with probing statements. The interview guide reflected issues that have previously been shown to influence participant perceptions of Internet-based programs (eg, if the program was easy to use [32], how it was perceived in terms of reliable information and professional appearance, and challenges in carrying out the exercises [22,27-30]). The interviews were 15 minutes long on average and recorded with the permission of the interviewees. After 6 to 7 interviews, no new information seemed to appear, and the interview process was discontinued

when 8 participants had been interviewed. The interview questions were as follows: Do you want to say something in general about the program and your experiences of it? How did you experience the Internet technique by which the program was delivered? How did you experience the information in the program? How did you experience the interaction with the study coordinators? How did you experience the training? What is your view on the items in the questionnaires? Do you have any suggestions on how the program could be improved? The audio records were transcribed verbatim after the interview process was completed.

Content Analysis of Semistructured Interviews

Qualitative content analysis was used to analyze the interview data [37]. The analysis was to a large extent deductive, since the interview questions initially directed the analysis. Unexpected content was also taken into account in order to refine and extend the understanding of the material. The approach most closely resembling ours has been described as directed content analysis [38]. A team-based approach was used for developing codes and coding the narratives [39]. All interviews were initially coded by researcher PK, who developed a coding scheme by identifying meaningful units that could be grouped into categories, as exemplified in Table 2. To assess the reliability of the coding [40], an independent recoding was undertaken by researcher YB using the original coding scheme. A high degree of agreement between coders was obtained with disagreements resolved through discussion.

Table 2. Example of analysis.

Meaning unit	Condensed meaning unit	Code	Subcategory	Category
I think that the layout was very good. The way you clicked and came forward. You click on one side and then you move on in a logical sequence. And then all the exercises, and after that the questions before starting the next week.	The user perceived the platform as easy to navigate.	The platform was perceived as easy to navigate.	Program-related facilitators	Usability

Ethical Considerations

All procedures were performed in accordance with the ethical standards of the institutional and/or national research committees, the 1964 Helsinki Declaration and its later amendments, or comparable ethical standards. Informed consent was obtained from all the individual participants included in the study. The study was approved by the Ethics Committee of the Karolinska Institutet (No. 2010/1407-31).

Results

Enrollment, Follow-Up, and Demographics

A total of 104 students contacted the study coordinators requesting more information about the study or expressing an interest in participating with 90 students deciding to participate. Some students left the trial before completing the baseline questionnaire and initiating the program (6 were randomized to the mindfulness training program and 8 to the control condition). A flowchart showing enrollment and number of participants completing each week of the programs is presented in Figure 1.

Of those randomized to the mindfulness training program (n=46), 40 individuals (30 women and 10 men) began the program and 39% (18/40, 16 women and 2 men) completed it.

A total of 22 participants (14 women and 8 men) did not complete the postintervention questionnaire. The median age of the completers was 25 years (range 18-45), and the mean age was 29 years. Corresponding figures for the 22 participants who did not complete all 8 weeks of the mindfulness program was 22 years (range 19-37) and 24 years, respectively. On average, participants practiced 3.6 days per week. Even though the reason for participants to leave the program was not systematically assessed, half of those who terminated the program before completion stated an explanation for leaving by email to the study coordinator. Of these, 9 mentioned lack of time, one had technical problems with the computer at home, and one participant referred to changed circumstances. Of the 18 who completed the mindfulness program, 8 (7 women and 1 man) were interviewed.

Of the 44 students randomized to the expressive writing intervention, 36 (26 women and 10 men) began the program and 31 (70%, 23 women and 8 men) completed it. A total of 5 who started the program (3 women and 2 men,) did not complete the postintervention questionnaire.

Those who completed the programs were significantly older than those who did not (t=2.22, P=.03). There was, however, no significant difference in gender, level of education, or income.

Figure 1. Flowchart showing enrollment and number of participants at each phase of the study.
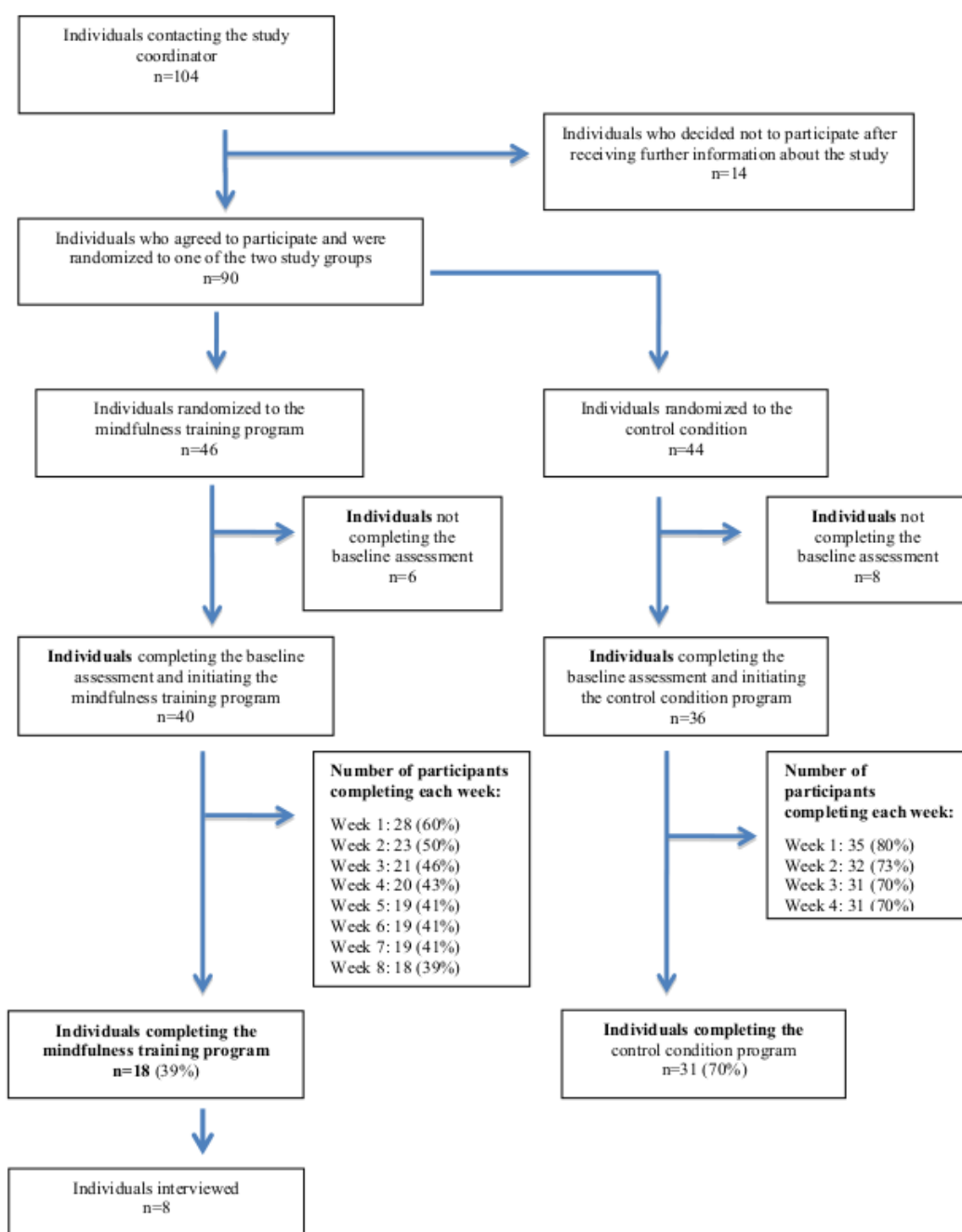
Effects of the Mindfulness Training Program

There were no statistically significant differences between the intervention and control groups concerning baseline scores on psychological well-being ($t=-1.07$, $P=.29$) and depression symptoms ($t=0.69$, $P=.49$).

The MANOVA analyses with baseline and follow-up on psychological well-being and depression symptoms showed no significant time × group (intervention vs active comparison) interaction ($F_{2,73}=0.18$, $P=.83$, partial $\eta^2=0.005$), indicating that there was no significantly stronger intervention effect for the

mindfulness intervention compared to the expressive writing intervention. No significant intervention effect was found in the overall test, but separate within-group comparisons are presented in Table 3. In these within-group comparisons, participants in the Internet-based mindfulness training program had a statistically significant increase in psychological well-being over time with a small effect size ($d=0.2$). No statistically significant change over time appeared for depression symptoms. Participants in the control condition did not report any statistically significant pre- and postassessment changes on the two outcomes.

Table 3. Results of within-group *t* test of change on outcome variables.

	Intervention condition (n=40) Internet-based mindfulness program mean (SD)	*P* value	Active control condition (n=36) Internet-based expressive writing program mean (SD)	*P* value
Psychological well-being				
Baseline	60.0 (8.7)		62.7 (13.0)	
Postintervention follow-up	62.0 (10.1)	.04	64.1 (11.8)	.11
Depression symptoms				
Baseline	20.3 (10.4)		18.7 (9.9)	
Postintervention follow-up	18.2 (9.6)	.08	17.5 (9.8)	.30

Participant View of the Program in the Postintervention Evaluation

The results from the postintervention questionnaire are presented in Table 4. Overall, the participants in the intervention group were satisfied with the program, and all of them thought it was meaningful to some degree. All but one participant found the program to some extent successful in improving their way of being but most of them also found it challenging. Participants in the control group seemed to find their program less challenging as compared to the participants in the intervention group.

Table 4. Participant responses to the postintervention questionnaire.

	Not at all n (%)	Some n (%)	A lot n (%)	*P* value
How meaningful do you think the program was?				.11
Mindful	0 (0)	7 (39)	11 (61)	
Control	4 (13)	16 (52)	11 (36)	
How successful do you think the program was in improving your way of being?				.21
Mindful	1 (6)	13 (72)	4 (22)	
Control	8 (26)	18 (58)	5 (16)	
How likely is it that you would recommend the program for someone in the same situation as you?				.35
Mindful	1 (6)	8 (44)	9 (50)	
Control	6 (19)	14 (45)	11 (36)	
How emotionally demanding do you think the program was?				.93
Mindful	8 (44)	7 (39)	3 (17)	
Control	14 (45)	13 (42)	4 (13)	
On the whole, how challenging do you think the program was?				<.001
Mindful	1 (6)	5 (28)	12 (67)	
Control	16 (52)	15 (48)	0 (0)	
If you had known as much about the program before starting as you know today, how likely would it have been that you would have still participated?				.28
Mindful	0 (0)	9 (50)	9 (50)	
Control	4 (13)	13 (42)	14 (45)	
Do you feel that your ability to reach mindful awareness has changed during the program?				
Mindful	0 (0)	6 (33)	12 (67)	
Control	—	—	—	

Results From Content Analyses of the Telephone Interviews

Two main categories and seven subcategories were identified in the interview material. In the category *usability* —defined in terms of the extent to which applications were easy to learn, error-tolerant, efficient, effective, and engaging [32]—the subcategories were program-related facilitators, program-related deficiencies, and proposals for improvement. We define *acceptability* in terms of how well the intervention was received by users, met their needs, and how challenging it was perceived [31]; its subcategories were personal facilitators, personal barriers, positive experiences, and negative experiences. The reason for including proposals for improvement in the first category was that the proposals concerned factors closely related to the way the program was designed and organized and thus relating to how easy it was to use. In what follows, the results of the content analyses are presented under headings that accord to the names of the subcategories.

Program-Related Facilitators

The salient topics in this subcategory are positive or satisfactory experiences of technique, web layout, information, questionnaires, and support from study coordinators. Most of the participants were satisfied with the technique and web layout and reported no problems navigating and downloading files.

> *I think that the layout was very good, the way you clicked and came forward. You click on one side and then you move on in a logical sequence. And then all the exercises. And after that, the questions before starting the next week.* [Woman, 26 years]

> *I had no problems with the technology and stuff, with audio files and so on.* [Woman, 32 years]

Most of the participants perceived the content of the information texts and audio files as informative and enjoyable. The amount of information was also regarded as suitable. The differing lengths of the guiding audio files were appreciated.

> *I thought it was a very good way to get some background information every week. I thought the texts were just the right length. The material was interesting to read.* [Woman, 23 years]

Opinions regarding the weekly questionnaires varied among those interviewed. Some participants made both positive and negative statements about them. Positive statements concerned, for example, clarity and suitable scales. The communication with study coordinators and the weekly reminders were perceived as positive and supportive by several of the participants.

> *Yes, it has been great. The weeks go so damn fast, so without the emails, I probably would have forgotten about it altogether.* [Woman, 25 years]

Participants felt that they got answers quickly when they emailed questions to the study coordinators. The weekly reminders made it easier for them to remember to practice.

Program-Related Deficiencies

The salient topics in this subcategory are negative or unsatisfactory experiences of web layout, information, and questionnaires. Although most of the participants expressed satisfaction with the information content of the program, some highlighted deficiencies in the texts, focusing on spelling, grammar, and lengthy sentences.

> *Yes, there was a typo here and there and, yes, maybe there was a sentence structure or two, which I couldn't understand. But there were some typos, I reacted to them [. . .] there were unfinished sentences that were difficult to understand.* [Woman, 26 years]

The organization of audio files in the weekly modules was perceived as confusing by one of the respondents. In addition, some participants had complaints about the questionnaires. Most of these were about repetitive questions and difficulties in finding a suitable answer.

Proposals for Improvement

This category comprises explicit proposals for improvements of the program mentioned by the interviewees. Some participants suggested improvements regarding the interaction with study coordinators and technical and layout issues. One of the respondents said that more emails reminding participants to exercise might facilitate completion of the program. Another suggestion was to arrange a meeting with the study coordinators and other participants at the beginning of the program in order to facilitate participation in and completion of the program. It was also suggested that a phone call from the study coordinators at the beginning of the program would increase the completion rate. Other suggestions were related to technical improvements, such as providing access to a special smartphone app where the participants could log their training. A reorganization of the audio files was proposed as was the provision of some kind of bank with questions from other participants, with related answers from the study coordinators.

Personal Facilitators

The topics included in this subcategory are about circumstances connected to the participants' personal situations that contributed to facilitating implementation of the program. Some of them were related to attitudes or motivation, like curiosity and personal interest, and others to more practical or technical conditions, like having the opportunity to download files onto a phone and listen to them on the way to work.

> *Well, I have a positive attitude towards it because I have practiced mindfulness before, privately on my own, in different ways [. . .] I am very curious and interested.* [Woman, 32 years]

Personal Barriers

The topics in this subcategory are about circumstances connected to the participants' personal situations that impeded implementation of the program. The absolutely dominant topic was that participants had difficulties in getting the training to fit into their daily lives and in finding the time to practice.

During that time, I was preparing for an exam and it was a bit hard and challenging to find the time to perform these exercises, and it was a little more stressful than I thought. I needed time, and more time, and everything. [Woman, 28 years]

At the beginning I was more careful to ensure that it was 45 minutes every day, but then sometimes it became only 30 minutes. Then there were some days when my schedule didn't work out, and I didn't have time for anything at all. [Woman, 25 years]

A couple of other issues were also mentioned as impeding the training. One of the participants had technical problems with the computer at home, and another lived together with a partner in a small flat and therefore had difficulties finding an undisturbed environment to practice.

Positive Experiences

Statements reflecting satisfaction that are not closely related to the technical and pedagogic functioning of the program were categorized as positive experiences. A prominent topic in this subcategory is appreciation of the opportunity to choose between exercises and time to practice.

The advantage is that it has been great to be able to do it just when you feel like it, that you don't need to fit in with a time. [Woman, 23 years]

A number of participants also mentioned positive experiences from the training itself, like getting help to relax and calm down. The facts that participation was anonymous and that the exercises were performed at home were also mentioned as positive, as well as the experience of being in a permissive condition.

Negative Experiences

Statements reflecting dissatisfaction not closely related to the technical and pedagogic functioning of the program were categorized as negative experiences. The negative experiences reported were to a large extent the stress the participants felt when they tried to find time to practice with the intended duration and frequency.

What I do think is that I have felt a little stress that there have been so many times when we've had, so to speak, . . . when it has been expected that you should do these exercises. It's been something that I thought, what can I say, was a bit stressful. [Woman, 26 years]

Some participants found it stressful to plan for the training on their own. Somewhat related to the issue of planning was a statement regarding difficulties in choosing between different exercises in the program. Lack of contact with other participants was also brought up as a dissatisfying, in contrast to the expressed view that anonymity was a good thing.

Discussion

Principal Findings

This study gave support for the usability and acceptability of our self-administered Internet-based mindfulness training program among those who completed it. Although less than two-fifth of the participants completed the full program and participants practiced less than recommended, a significant increase in psychological well-being was observed. There were, however, no statistically significant differences between the intervention and control group. Most of those completing the program expressed that the program was meaningful and helpful in improving their way of being. The flexibility to perform exercises where and when it was convenient for them was appreciated and overall the program layout was perceived as satisfactory. More frequent contact with the study coordinators and reminders were suggested as ways to help participants to complete the daily exercises and to increase the likelihood of successful completion of the program. A major difficulty for several of the participants was to find enough time to practice. In addition, the majority of the participants perceived the program as challenging.

Comparison With Prior Work

The fact that no statistically significant differences in outcomes between the mindfulness and expressive writing group was detected could be due to the active condition in the control group and the large drop-out rate in the mindfulness group. A large drop-out rate is often associated with an underestimation of the intervention effect in intention-to-treat analysis using last-observation-carried-forward approach [41-43]. The rate of participants completing the full program in this study corresponds to previous experiences from studies of Internet-based programs [22,23,29,44]. In an RCT assessing the effects of a brief 14-day Internet-based mindfulness-based intervention among British students, 43% completed a postintervention measure [23]. In another study of an Internet-based mindfulness program for stress management, the 8-week completion rate was 41% [22]. Interestingly, in this study the proportion of men who did not complete the full program was much larger than the proportion of women. Previous studies have indicated that women are more interested in participating in mindfulness training programs than men [23,45]. In a study among British students, only 12 out of 104 participants who signed up for an Internet-based mindfulness-based intervention were men [23]. However, no gender differences between the British students who completed the mindfulness-based program and those who dropped out were found. In our study, the students were not aware of which program they would be randomly assigned to when they signed up. Students might therefore have realized that they were expected to practice mindfulness after having consented to participate, increasing the risk for early termination among those who had a less positive attitude to mindfulness. The reasons for early termination of the program were not systematically explored in this study, but several of the participants stated spontaneously that lack of time was the main reason, which is in line with earlier research [22,29]. The fact that 70% of the participants in the less time-consuming and shorter expressive writing program completed their program supports that hypothesis. About a quarter of the students left the program early (before initiating week 2). Reasons for this could be that they did not like the program or realized that they did not have enough time to spend on the program. In a similar study of a brief 14-day program instructing British students to listen daily

to a 10-minute guided mindfulness meditation exercise, more than half of the students dropped out before completing a postassessment questionnaire, indicating that there are other reasons than lack of time that influence termination shortly after initiation [23]. In the interviews after the program in our study, lack of contact with other participants was brought up as a negative feature of the program, similar to what has been reported in earlier research [30]. In a US study of an Internet-based mindfulness program, however, the completion rate among participants who received an Internet-based program without a message board was only slightly lower (41%) compared to participants who had access to an Internet-based message board where they could make contact with other participants (44%) [22], suggesting that contact with other participants does not contribute very much to an increased completion rate. Interviewees also mentioned the importance of contact with the study coordinators for successful completion of the program. Results from another study using computer-based mindfulness meditation training indicated that virtual coach-based training of mindfulness is both feasible and potentially more effective than a self-administered program [46]. One suggestion from the completers in this study regarding facilitation of completion of the mindfulness program was to arrange a meeting between participants and study coordinators at the beginning of the program or at least having a phone call. In an expert review on Internet-based psychological treatments for depression [47] examining different levels of contact between therapists and client in relation to outcomes, the authors stated that contact before and/or after the treatment may potentially enhance both guided and unguided Internet-based psychological treatments. Whether this is the case for self-administrated mindfulness-based and Internet-based programs among students is still unknown.

The flexibility regarding location and time for training was perceived as positive by participants, in line with earlier research [5,7,8,25]. Anonymity was also mentioned as beneficial, which has been previously observed as advantageous for participants in Internet-based interventions [6]. Furthermore, the participants reported that it was easy to navigate the program content using the Internet-based platform and that they had few or no problems with technical issues, important conditions when distributing an Internet-based program [27].

Choosing between different exercises and having to plan one's own training were considered demanding by some of those interviewed. Perhaps some participants might have felt the need for clearer guidance and support in the latter part of the program. Earlier research has shown that participants need support, for example in managing time challenges, when taking part in Internet-based programs [25,30].

The participants did not spend the intended amount of time practicing mindfulness in this training program. It is possible that greater improvements in well-being and depression symptoms could have been reached with a higher level of compliance. However, a previous 14-day Internet-based mindfulness-based program encouraging students to practice mindfulness meditation 10 minutes each day resulted in a significant group × time interaction for anxiety/depression symptoms, suggesting that it is possible to achieve improvements in mental states with a rather limited effort. In summary, results from this study suggest that students can benefit from an Internet-based mindfulness training program.

Our study highlights the challenge of developing health-related Internet-based interventions, including mindfulness-based programs, that are sufficiently easy to complete for an intended target group. A way to enhance completion of Internet-based programs might be to use more reminders and make personal contact by phone before program start. Less time-consuming exercises and a shorter program period might also be considered in order to raise the completion rates in these interventions. Acquiring further knowledge about how to develop and deliver such programs is warranted in order to make use of the potential of the Internet in health care and other relevant settings.

Limitations

Although this study is of great interest because it is one of the first to explore the feasibility and effect of an Internet-based mindfulness intervention, it has several limitations. First, the participants were not required to have a certain level of stress or other psychological symptoms to be included in the study, which may have reduced the ability to detect changes in the outcome measures. A possible absence of stress or distress may also have influenced participant perceptions of the program and their motivation to practice. Perhaps they would had given the program a higher priority in their daily lives if they had felt that they really needed the training. Second, our study did not systematically investigate if the students experienced some negative effects from the mindfulness training. A literature review from 2008 concluded that no negative effects from mindfulness-based interventions have been documented [48]. However, research of face-to-face treatment suggests that 5% to 10% of patients experience negative effects in terms of deterioration, and other types of negative effects have been proposed to exist as well [49]. Third, there is a risk that the method for selecting students for interviews brought bias to the results. However, some of the first students who were asked to participate in an interview did not have time for it immediately and others who finished the program later volunteered for an interview, which led to a more mixed group of interviewees. Another concern regarding bias was that one of the study coordinators interviewed the participants, potentially influencing their responses. We consider the risk of socially desirable replies to be highest concerning the issue of support from study coordinators but to be smaller regarding topics related to technique, information, instructions, and exercises, as these issues are not closely connected to the personality and skills of the coordinator. Fourth, the study was carried out among students, which limits the generalizability of the findings to other groups. Students are perhaps relatively accustomed to Web technology and may have found the program easier to navigate than for older people, for example. In addition, women were largely overrepresented in the study, especially in the investigation of usability and acceptability, which limits the generalizability of our findings to men. Another issue that limits the generalizability of the results lies in the fact that the participants received reimbursement for their participation. It is possible that the expectations regarding the program and

perceived improvements of well-being would have been different without a reimbursement.

Conclusions

Our findings support the usability and acceptability of a self-administered Internet-based mindfulness training program for several participants. The program showed potential for increasing psychological well-being. However, additional modification to the target group might be needed to increase retention and compliance.

Authors' Contributions

Two of the authors (PK and RB) developed the programs.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshot 1.

[PNG File, 427KB - mental_v3i3e33_app1.png]

Multimedia Appendix 2

Screenshot 2.

[PNG File, 406KB - mental_v3i3e33_app2.png]

Multimedia Appendix 3

Screenshot 3.

[PNG File, 407KB - mental_v3i3e33_app3.png]

Multimedia Appendix 4

CONSORT-eHealth Checklist V1.6.

[PDF File (Adobe PDF File), 1MB - mental_v3i3e33_app4.pdf]

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Abbreviations

MANOVA: multivariate analysis of variance
MBSR: mindfulness-based stress reduction
RCT: randomized controlled trial
SD: standard deviation

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Original Paper

Internet Mindfulness Meditation Intervention for the General Public: Pilot Randomized Controlled Trial

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Abstract

Background: Mindfulness meditation interventions improve a variety of health conditions and quality of life, are inexpensive, easy to implement, have minimal if any side effects, and engage patients to take an active role in their treatment. However, the group format can be an obstacle for many to take structured meditation programs. Internet Mindfulness Meditation Intervention (IMMI) is a program that could make mindfulness meditation accessible to all people who want and need to receive it. However, the feasibility, acceptability, and ability of IMMI to increase meditation practice have yet to be evaluated.

Objectives: The primary objectives of this pilot randomized controlled study were to (1) evaluate the feasibility and acceptability of IMMIs in the general population and (2) to evaluate IMMI's ability to change meditation practice behavior. The secondary objective was to collect preliminary data on health outcomes.

Methods: Potential participants were recruited from online and offline sources. In a randomized controlled trial, participants were allocated to IMMI or Access to Guided Meditation arm. IMMI included a 1-hour Web-based training session weekly for 6 weeks along with daily home practice guided meditations between sessions. The Access to Guided Meditation arm included a handout on mindfulness meditation and access to the same guided meditation practices that the IMMI participants received, but not the 1-hour Web-based training sessions. The study activities occurred through the participants' own computer and Internet connection and with research-assistant telephone and email contact. Feasibility and acceptability were measured with enrollment and completion rates and participant satisfaction. The ability of IMMI to modify behavior and increase meditation practice was measured by objective adherence of daily meditation practice via Web-based forms. Self-report questionnaires of quality of life, self-efficacy, depression symptoms, sleep disturbance, perceived stress, and mindfulness were completed before and after the intervention period via Web-based surveys.

Results: We enrolled 44 adults were enrolled and 31 adults completed all study activities. There were no group differences on demographics or important variables at baseline. Participants rated the IMMI arm higher than the Access to Guided Meditation arm on Client Satisfaction Questionnaire. IMMI was able to increase home practice behavior significantly compared to the Access to Guided Meditation arm: days practiced ($P=.05$), total minutes ($P=.01$), and average minutes ($P=.05$). As expected, there were no significant differences on health outcomes.

Conclusions: In conclusion, IMMI was found to be feasible and acceptable. The IMMI arm had increased daily meditation practice compared with the Access to Guided Meditation control group. More interaction through staff and/or through built-in email or text reminders may increase daily practice even more. Future studies will examine IMMI's efficacy at improving health outcomes in the general population and also compare it directly to the well-studied mindfulness-based group interventions to evaluate relative efficacy.

Trial Registration: Clinicaltrials.gov NCT02655835; http://clinicaltrials.gov/ct2/show/NCT02655835 (Archived by WebCite at http://www.webcitation/ 6jUDuQsG2)

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KEYWORDS

Internet; mindfulness; meditation; behavior modification; controlled trial

Introduction

Group mindfulness meditation interventions like Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) improve a variety of health conditions and quality of life, are inexpensive, easy to implement, have minimal if any side effects, and engage patients to take an active role in their treatment [1-4]. Despite the growing evidence for positive benefits from well-studied mindfulness-based programs like MBSR and MBCT, many people who could benefit from them face obstacles blocking their enrollment in and successful completion of the programs such as aversion to sharing, scheduling constraints, and travel and accessibility issues. First, the group classes require people to share in public (aversion to sharing). A certain percentage of people are fearful of social situations such as group or employee wellness programs. Statistics from the National Institute of Mental Health show that 18.1% US adults have an anxiety disorder annually (includes generalized, obsessive compulsive, panic, post-traumatic stress, social and agoraphobia) . Social phobias account for 6.8% of US adults over a lifetime [5]. These patients are likely averse to attending group sessions. The group classes also require attending at a specific time and day (scheduling constraints). Working adults may not have time to attend 2.5-hour sessions once a week for 8 weeks. In addition, the extensive home practice (45-60 minutes per day) was also a barrier to receiving group programs because many participants can not commit to home practice times or feel discouraged by their inability to maintain these practices times and thus, do not practice at all. Travel to a specific location requires time and transportation (travel and accessibility constraints). The travel time to get to the location where the class is being held is a burden, and it is not feasible for many, such as for those living in rural areas. This aversion to sharing, scheduling, and travel and accessibility factors are barriers for people who want and would benefit from the mindfulness interventions for reducing anxiety, depression, and pain.

An alternative delivery format may offer more options for people who want and need meditation therapy. In a cross-sectional Web-based survey, we asked 510 participants (mean age, 42 ± 15 years, 70% female) what format they would prefer to receive a mindfulness meditation intervention. The Internet received more positive responses than the group format, and 11% of participants said they would refuse a group format. The Internet was rated as the first choice format (Internet, 44%; individual, 37%; group, 19%), and group was the last choice for most participants (Internet, 29%; individual, 14%; group, 57%) [6]. The survey was administered on the Web, which could bias preference ratings toward the Internet version, but not explain the individual format being preferred to the group format. Regardless, these cross-sectional data lend support to the evaluation of different mindfulness meditation delivery formats.

Based on our laboratory experience with clinical mindfulness research studies and results from the cross-sectional survey, we transitioned from administering the standard group MBCT program to developing and then administering a one-on-one intervention. The intervention was adapted from MBCT and MBSR to include shorter weekly sessions (1 hour vs 2.5 hours), less weekly sessions (6 vs 8), shorter meditations (30 minutes vs 45 minutes) and still included all the core mindfulness concepts (see Wahbeh, 2014 for the full curriculum [4]). After using this program, we found that some participants, especially those with increased stress and life demands still had obstacles to receiving the one-on-one intervention. We then developed an Internet version of the one-on-one program that could be delivered on the Web at any time or place the participant could access the Internet [7]. Although the Internet version is not the full "dose" that a participant or patient might receive from MBSR or MBCT, it allows those who have obstacles to receiving the full programs to have some access to mindfulness meditation training that they would otherwise not have available to them or be willing to receive.

Internet formats of mindfulness meditation are promising because they address a number of barriers to care. They allow people to receive the therapy in the privacy of their homes, so there are no travel or accessibility constraints. Participants or patients complete the programs by themselves so there is no need to share sensitive or personal information in a group setting. Finally, people can take the program at any time, on any day so there are no scheduling constraints.

Internet meditation interventions have small but growing evidence for their use in a variety of settings. Studies have been conducted for a variety of populations: generally healthy adults [8], stressed older adults [7], smokers [9], and distressed cancer survivors [10]. They have also been examined for a variety of symptoms: anxiety [11], stress, anxiety and depression [12], stress [13], trauma [14], and residual depressive symptoms and relapse prophylaxis [15]. Most studies are small but show preliminary evidence for some benefit and no adverse events.

This study builds on this previous research of Web-based mindfulness meditation interventions and applies it to the general population, asking whether Web-based delivery programs can actually change behavior by increasing meditation practice compared with just having access to the guided meditations (GMs) themselves. The primary objectives of this pilot randomized controlled study were to (1) evaluate feasibility and acceptability of Internet Mindfulness Meditation Intervention or IMMI in the general population and (2) to evaluate IMMI's ability to change meditation practice behavior. The secondary objective was to collect preliminary data on health outcomes.

Methods

Participants

Potential participants were screened by self-report to ensure appropriate enrollment according to the inclusion/exclusion criteria (Textbox 1). Broad inclusion criteria aided in recruitment and determine usage information from a wide variety of adults.

To maximize the generalizability and public health relevance of the study, exclusion criteria were minimized and based primarily on screening out participants with an underlying illness that might limit the benefit of the intervention, confound outcomes, or increase the likelihood of dropout. Participants were recruited from the public through flyers, Web-based advertisements and listservs, the Oregon Health & Science University study board, and ResearchMatch [16]. The timeline for the project was as follows: funding – September 2014; recruitment – April 2015 to August 2015; closed to enrollment – September 2015; final data collection – December 2015.

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Age 18-80 years

- Access to computer and Internet

- Can hear and understand instructions

- Willing to accept randomization scheme and agrees to follow the study protocol

Exclusion criteria

- Significant acute medical illness that would decrease likelihood of study completion (self-report).

- Significant, untreated depression, as assessed by Center for Epidemiologic Studies Depression Scale-5 >20 during screening.

- Current daily meditation practice (≥5 min/day daily for at least 30 days in the last 6 months. Past practice not exclusionary but will be recorded)

Study Procedures

This study was the first phase in a two-phase research program. Phase 1 is reported here. (For details of phase 2 see clinicaltrials.gov NCT02655835) The study was a pilot randomized controlled trial of English-speaking adults. The goal was to enroll at least 40 participants. All participants underwent a telephone screening, baseline measure collection, an intervention period, and end point measure collection. After the baseline measure collection, participants were randomized to 1 of 2 arms: IMMI or access to GM. The study was approved by the Oregon Health & Science University Institutional Review Board.

Following volunteer inquiries, the research assistant (RA) described the study, inclusion/exclusion criteria, risks and benefits of participation, and answered any questions by telephone. If the volunteer was still interested, the telephone screening was conducted by the RA, who was appropriately trained on study procedures, with an institutional review board–approved telephone screening script to confirm eligibility. The telephone screening script included the Center for Epidemiologic Studies Depression Scale-5 (CESD-5) [17] to rule out untreated depression (greater than 20). If the participant was not eligible based on these scores, the RA gave the volunteer resources for mental health care. If the participant was eligible, the RA continued with the assessment. Eligible and interested participants were sent a unique link to a Health Insurance Portability and Accountability Act–compliant SurveyMonkey website where they completed their baseline questionnaires. Due to the minimal risk of the study, a Waiver of Documentation of Consent was used. The first page of the SurveyMonkey [18] baseline questionnaire had language describing the nature of the study, risks and benefits of participation, voluntary participation, and the understanding that if the participant continues with the survey they are giving consent to have the information used for research purposes.

The baseline questionnaires were completed through the SurveyMonkey on the participants computer or an accessible computer to them before randomization. Self-report questions included demographics, quality of life (SF-36), self-efficacy (General Perceived Self-Efficacy Scale), depression symptoms (Center for Epidemiological Studies Depression Scale-20), sleep disturbance (Pittsburgh Sleep Quality Inventory), perceived stress (Perceived Stress Scale), and mindfulness (Five-Factor Mindfulness Questionnaire). All measures are widely used, validated, and sensitive to stress and/or mindfulness meditation and described in more detail in the Measures section.

Once participants completed their baseline surveys, they were randomized to the IMMI or the GM arm. Participants and study staff communicated via email and telephone. Participants received study staff emails and phone numbers in case they needed any assistance with technology or had questions about the content. The RA reminded all IMMI participants weekly to complete their sessions by email. Guided meditation participants were contacted weekly by email to report their adherence. Although in a group MBSR or MBCT program there would be intensive face-to-face support available for the participant in terms of problem-solving for their practice techniques and to answer questions about content, the goal for this study was to have very limited study staff interactions with the participants. This allowed us to evaluate IMMI independent from any teacher interaction or extensive study staff support.

IMMI is an interactive Web-based platform with one 60-minute session per week for 6 weeks with daily home practice between sessions. The IMMI program was accessed through the Internet. IMMI participants were emailed a link to the program and a unique username and password to enter the program and a digital workbook. IMMI is a standardized and structured program modeled after MBCT [19] and MBSR [20], 2 standardized, well-studied 8-week group programs that have strong evidence for their effectiveness [2]. The IMMI program was piloted in our laboratory with stressed older adults [7]. Content of the

program was frozen for this trial. IMMI's objectives are to (1) help participants understand their personal reactions to stress, (2) teach them skills to modify their stress reactions, and (3) promote their desire for self-care and feelings of competence and mastery. Each IMMI session included: (1) didactic instruction and discussion on stress, relaxation, meditation, and mind-body interaction; (2) instruction and practice in formal and informal mindfulness meditation; and (3) enquiry about problem-solving techniques regarding success and difficulty in practicing mindfulness (see Wahbeh, 2014 for full curriculum) [4]. The Mindful Body Scan and Sitting Meditation (awareness of breathing, body sensations, and cognitive and emotional processes) are some of the formal meditations. Observing and being mindful during daily activities like washing the dishes or making a cup of coffee are informal practices that are also taught

to generalize mindfulness to daily life. Each week's session had multiple lessons (6-10). Each session had multiple videos providing course instructions, content about a theme, and describing the home practice instructions. After each video, participants answered questions about the video content via the Web-based platform. The themes/lessons, in-session meditations, and home practice meditation recommendations are listed in Table 1. All meditations were guided and presented as an audio file accessed from within the IMMI program. Participants needed to complete each session and lesson to proceed to the next. Each week's session began with a review of the previous week's content and home-practice and ended with a summary of the current session and home practice recommendations for the following week.

Table 1. IMMI curriculum.

Week	Themes/Lessons	Meditations
1	Starting Where You are and Looking to the Future; What is Mindfulness?; Awareness Exercise; The Body Scan.	Awareness Exercise (I^a – 4 min); Body Scan (I – 30 min; H^b – daily)
2	The Body Scan; Dealing with Barriers; Responding versus Reacting; Staying Present: Different Objects of Focus; Breath is Life.	Body Scan (I – 30 min; H – daily); Sitting (I – 5 min; H – 10-15 min daily)
3	Sitting Meditation; Layers of Mindfulness and the Breathing Space; Caring for Ourselves.	Sitting (I – 30 min; H – daily); 3-step Breathing Space (I – 4 min; H – 3x/day)
4	Thoughts are Not Facts; Coping Space; Attitude of Acceptance; Mindfulness of Thoughts Meditation; Ways You Can See Your Thoughts Differently.	Sitting with Difficulty (I – 30 min; H – daily); Breathing Space (4 min; H – 3x/day); Mindfulness of Thoughts (I – 10 min)
5	Compassion Meditation; Practicing Compassion; Applying Compassion and 4-Step Breathing Space; 4-Step Coping Space; Giving Back; Taking Care of Ourselves.	Compassion (30 min; H – daily); 4-step Breathing Space; 4-step Coping Space (4 min; H – as needed)
6	Body Scan; Recap of Mindfulness Meditation; Life; The Future; Motivations; Everyday Usage of Mindfulness; Sitting Meditation.	Body Scan (I – 30 min); Sitting (I – 5 min); Home practice – Participant's choice

[a]I: In-session meditations

[b]H: Home practice meditations

GM participants were emailed a link to access the same GMs used as home practice for IMMI (see Table 1). Participants accessed them as audio files on Dropbox.com. They were also emailed a brief handout about mindfulness meditation one time after learning about their randomization. The instructions for listening to the GMs were as follows, "Below you will find the links to the GMs. Feel free to listen to these directly from the link or download them to your device. You can listen to them as often as you would like." Institutional affiliation was not displayed on either of the intervention platforms. Participants completed their end point questionnaires through the SurveyMonkey in the same manner as the baseline collection. In addition to the baseline measures, participants completed a Client Satisfaction Questionnaire (CSQ) to evaluate acceptability [21].

Measures: Self-Rated Questionnaires Listed in Alphabetical Order

Center for Epidemiologic Studies Depression Scale

Depression was assessed during the screening procedure with a 5-item subset of the original 20-item scale (CESD-5). The CESD-5 raw score was multiplied by 4 for cutoff score criteria

determination. The CESD-5 has demonstrated very good sensitivity (>0.84), specificity (≥0.80), and high validity (>0.90) for identifying people classified as depressed by the full 20-item scale [22]. The full version was used to evaluate depression symptoms at the baseline and end point visits. The CESD is a commonly used subjective measure of depressive symptoms. It asks participants about how they felt or behaved in the past week, yielding global scores ranging from 0-60, with higher scores indicating greater depression [23].

Client Satisfaction Questionnaire (CSQ-8)

The eight-item CSQ [21] was administered at the end point visit. It is an 8-item questionnaire used to assess satisfaction with the intervention. The questionnaire has demonstrated high internal consistency (α=.93) and strong construct validity, evidenced by correlation with service utilization and clinical outcomes [21]. The eight questions are presented in Table 2. Higher scores reflect greater satisfaction.

Credibility/Expectancy Questionnaire

The Credibility/Expectancy Questionnaire is a standardized instrument that assesses participant intervention expectancy and rationale credibility in clinical outcome studies [24]. The

wording was minimally modified to assess attitudes toward the mindfulness interventions. The scale has a high internal consistency (α=.84) and good test-retest reliability (.75 credibility; .82 expectancy). Expectancy assessment is essential in controlled intervention studies [25].

Five-Factor Mindfulness Questionnaire (FFMQ)

Mindfulness was measured with the FFMQ, which assess 5 elements of a general tendency to be mindful in daily living: observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience [26]. The questionnaire presents a series of 39 statements and asks participants to respond according to "what is generally true for you" using a Likert scale ranging from 1 (*never or very rarely true*) to 5 (*very often or always true*). The 5 facets can be combined to yield a composite score that reflects a global measure of mindfulness.

Pittsburgh Sleep Quality Index

Sleep quality and disturbances across a 1-month time span were measured with this 19-item instrument that yields 7 component scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction [27]. Only the sleep disturbance scores are reported in this paper missing data leading to the inability to calculate many of the subscales. Sleep quality suffers with chronic stress and is known to affect health and also be improved by mind-body interventions such as mindfulness meditation [28].

Perceived Stress Scale

Perceived stress was measured using the Perceived Stress Scale, a commonly used 10-item subjective instrument that measures respondents' perceived stress in the past week [29]. It has good internal reliability (α=.76) and strong construct validity. The global score ranges from 0 to 36, with higher scores indicating greater perceived stress.

SF36v2

The SF36, version 2 is a 36-item self-report questionnaire of quality of life that measures eight health domains and results in a physical component score and mental component score. The SF Health Surveys are the most widely used tools in the world for measuring patient-reported outcomes, with more than 41,000,000 surveys taken and over 32,000 licenses issued to date [30].

Participant adherence for all participants was measured by subjective report of home practice. Participants were emailed a fillable form weekly to recall their daily practice for the previous week in minutes. Adherence was defined as the number of home-practice days, total number of minutes practiced over the six weeks, and average number of minutes practiced per practice day. For IMMI participants, the total number of sessions completed on the Web was also recorded.

Statistical Analysis

Sample size was determined with power calculations using data from 40 participants who completed the same 6-week mindfulness meditation program as IMMI but in a one-on-one

format. Daily meditation means and standard deviations during the 6-week program were used for the treatment values (mean, 28.3; standard deviation, 9.6) compared with the 6-week period after the intervention where they had access to the meditations but were not receiving any instruction (mean, 16.0; standard deviation, 13.1). Using a 2-tailed t-test model with an alpha of .05, 20 people in each group would result in power of 0.91. Dropouts were considered and with 15 completers in each group, power would be 0.81 [31].

Randomization was conducted by an unblinded RA with a covariate adaptive randomization approach [32] to help ensure arms are matched on age, gender, and depression score and to reduce selection bias after the baseline collection. The same RA enrolled and assigned participants to the interventions. Covariate adaptive randomization is recommended for small trials to balance important factors between groups [33]. Missing data were addressed at the participant level to minimize attrition and incomplete data. This was supported through mandatory fields in SurveyMonkey. Participants were considered "dropouts" if they completed fewer than half of the sessions (<3 of 6) and did not complete the end point collection [34]. Compliance enhancement measures included weekly check-ins by email. Statistical analysis was conducted in a blinded fashion with a blinded code for the intervention.

The primary and secondary aims were assessed as follows. The aim to evaluate feasibility and acceptability for IMMI was first analyzed in a descriptive fashion. Recruitment rates and drop-outs were described and noted for future studies and demographic data in relation to these numbers were qualitatively examined. The CSQ total and individual answers were then evaluated with 2-sample t-tests to evaluate differences between the arms. The aim to evaluate IMMI's ability to change meditation practice behavior was analyzed as follows. Before inferential analysis, measure distribution was evaluated with Shapiro-Wilk test of normality. Expectancy for IMMI and GM, Physical Quality of Life scores, and Total Minutes practiced were not normally distributed. Nonparametric Kruskal-Wallis tests were conducted on these variables. Participant characteristics at baseline were evaluated for unbiased randomization with the χ^2 test for discrete variables or the 2-sample Kruskal-Wallis test for non-normally distributed data. There were no unbalanced variables noted. A Wilcoxon paired test was conducted on expectancy for IMMI and GM for all participants. Differences between the IMMI and GM arms on all measures were evaluated with a simple 2-sample t-test (or nonparametric Kruskal-Wallis) for completers only.

The secondary aim to collect preliminary data on health outcome changes from IMMI was conducted in an exploratory fashion since the study was not powered to assess differences between the arms on these outcomes. Differences between the IMMI and GM arms on all measures were evaluated with a simple 2-sample t-test (or nonparametric Kruskal-Wallis) for completers only as described previously. Cohen's d and 95% CIs on the change score from preintervention to postintervention was also calculated. Results from support power analyses and sample size estimation for future clinical trials examining these outcomes.

Statistical analyses were conducted in SPSS 20.0 (IBM, USA) and STATA 12.0 (Statacorp, LP, USA). This manuscript is reported according to the CONSORT statement for the reporting of randomized controlled trials [35] as well as the CONSORT-EHEALTH extension (see Multimedia Appendix 1). The study is registered at ClinicalTrials.gov (NCT02655835).

Results

Recruitment

An email invitation with information about the study was sent to 228 potential volunteers who responded to flyers or Web-based advertisements. Of those, 46 volunteers enrolled in the study. Most participants were from the Pacific Northwest (31, Oregon; 3, Washington). Other states represented were California (3), New York (3), Maryland (2), Massachusetts (1), Minnesota (1), and Virginia (1). Two withdrew before randomization. Thirteen withdrew or were lost-to-follow after randomization (5 were randomized to IMMI and 8 to GM). There were no demographic differences between participants who dropped out of the study and those who remained in the study (Figure 1). Participants reported no adverse events or side effects from either intervention.

Thirty-one participants were randomized and completed the study—16 in the IMMI arm and 15 in the GM arm. This reflects

a 14% completion rate for those contacted and a 71% completion rate for those who were randomized. There was no difference in age, gender, education, annual household income, relationship status, health coverage, or experience with complementary and alternative medicine between the IMMI and GM arms (Table 2). Participants' mean age was 42 ± 14 years, and they had an average of 18 ± 3 years of education. Participants were mostly Caucasian, employed, well-educated, females in a relationship, and with income level greater than $50,000. Of those unemployed, 17% from the GM arm were retired (0% from IMMI arm). Most people (except 9% in each arm) had some experience with complementary and alternative medicine.

At baseline, there were no differences between arms on physical or mental quality of life, depression symptoms, perceived stress, sleep disturbance, or mindfulness. Taking all participants together, there was a difference in expectancy (IMMI 7.24 ± 0.26; GM 6.78 ± 0.27; $Z=2.06$, $P=.04$) and credibility (IMMI 6.27 ± 0.30; GM 5.33 ± 0.35; $t(28)=2.88$, $P=.008$) ($Z=2.86$, $P=.004$ for the 2 arms with the IMMI intervention having higher perceived expectancy and credibility scores. These differences in perceived expectancy and credibility of the interventions were not evident between arms, namely all participants thought IMMI was a more credible intervention that would be more effective but these perceptions were the same across the 2 arms (Table 2).
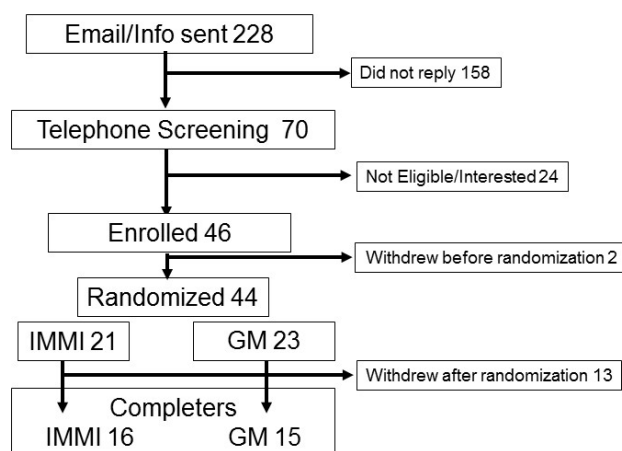
Figure 1. Recruitment.

Table 2. Demographics.

Demographics	GM[a] (n=16)	IMMI[b] (n=15)	Stats
Age (years)	45 (15)	38 (11)	t=91; P=.37
Gender			
% Female	94	80	X^{2c}=1.3; P=.25
Race			
% Caucasian	88	86	X^2=2.01; P=.57
% Asian	0	7	
% Hispanic	6	7	
% Unknown	6	0	
Education			
% Bachelor's or higher	81	87	X^2=2.37; P=.67
Income			
% 0-25K	19	13	X^2=6.42; P=.49
% 26-50K	25	34	
% 50-100K	25	20	
% >100K	31	33	
Employment status			
% Employed	74	87	X^2=3.40; P=.49
Relationship status			
% In relationship	63	60	X^2=5.79; P=.22
Health coverage			
% With coverage	94	93	X^2=.002; P=.96
Experience with CAM (%)			X^2=7.03; P=.22
None	6	7	
Once in the past	0	7	
Few times in the past	56	66	
I go every few months	19	0	
I go every month	6	20	
I go every few weeks	13	0	
I go more than once a week	0	0	
Expectancy[d]			
IMMI	6.94 (.42)	7.62 (.26)	X^2=.40, P=.52
GM	6.61 (.37)	7.00 (.41)	X^2=.66, P=.42
Credibility			
IMMI	5.88 (.41)	6.76 (.43)	t=−1.48, P=.15
GM	5.22 (.47)	5.47 (.53)	t=−.35, P=.73

[a]GM: access to guided meditation

[b]IMMI: Internet Mindfulness Meditation Intervention

[c]X^2: Chi-square test for categorical variables

[d]Expectancy did not have normal distribution so a nonparametric Kruskal-Wallis chi-square test was used.

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Table 3. Client Satisfaction Questionnaire.[a]

Items	GM[b] (n=16)	IMMI[c] (n=15)	Stats
1. How would you rate the quality of service you have received?	2.29 (0.91)	3.13 (0.83)	$t=-2.61$, $P=.02$
2. Did you get the kind of service you wanted?	2.36 (0.63)	2.93 (0.88)	$t=-2.01$, $P=.05$
3. To what extent has our program met your needs?	2.07 (0.83)	2.67 (0.90)	$t=1.85$, $P=.08$
4. If a friend were in need of similar help, would you recommend our program to him or her?	2.31 (0.95)	3.07 (0.88)	$t=-2.20$, $P=.04$
5. How satisfied are you with the amount of help you have received?	2.00 (0.78)	2.87 (0.74)	$t=-3.06$, $P=.005$
6. Have the services you received helped you to deal more effectively with your problems?	2.36 (0.50)	2.67 (0.62)	$t=1.48$, $P=.15$
7. In an overall, general sense, how satisfied are you with the service you have received?	2.29 (0.73)	3.00 (0.93)	$t=2.30$, $P=.03$
8. If you were to seek help again, would you come back to our program?	2.29 (0.73)	2.80 (0.77)	$t=-1.84$, $P=.08$
Client satisfaction total	17.79 (1.31)	23.13 (1.25)	$t=-2.95$, $P=.007$

[a]Values are means (standard deviation).

[b]GM: access to guided meditation

[c]IMMI: Internet Mindfulness Meditation Intervention

Table 4. Change in meditation practice behavior.

Item	GM[a] (n=16)	IMMI[b] (n=15)	Statistics
Days practiced over 6 weeks (total)	14.38 (2.67)	22.20 (2.92)	$t^{c}=-1.98$, $P=.05$
Minutes practiced over 6 weeks (total)	176.25 (157.42)	507.00 (424.94)	$X^{2d}=6.4$, $P=.01$
Average minutes per practice day	13.35 (1.45)	19.77 (2.97)	$t=-1.98$, $P=.05$
Weekly logs completed	3.44 (0.40)	4.30 (0.49)	$t=-1.32$, $P=.20$

[a]IMMI: Internet Mindfulness Meditation Intervention

[b]GM: Access to guided meditation

[c]t: Student's t test

[d]X^2: Kruskal-Wallis test

Feasibility and Acceptability

On average and also by individual questions, participants in the IMMI arm rated the intervention higher than participants in the GM arm on the CSQ (Table 3).

Change in Meditation Practice Behavior

The primary aim of the study was to evaluate IMMI's ability to change meditation home practice behavior. The IMMI participants completed 4.27 ± 2.3 Web-based lessons (range 0-6). Eight participants completed all 6 Web-based lessons. IMMI had significantly more home practice days, total minutes practiced, and average minutes per day (Table 4). There was no difference between arms on weekly reporting of home practice.

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Table 5. Preliminary data on health outcomes.

Variable	GM[a] (n=16)			IMMI[b] (n=15)			Statistic	Cohen's D on Δ 95% CI
	Pre	Post	Δ	Pre	Post	Δ		
SF36-Physical	55.18	55.82	0.64	53.83	53.15	−0.68	X^{2c}=0.83 P=.36	0.30
	(7.67)	(9.78)	(3.53)	(6.57)	(7.06)	(5.42)		(−.42 to .99)
SF36-Mental	43.58	46.02	2.44	44.65	47.93	3.27	t^d=−0.31 P=.76	−0.12
	(11.18)	(10.92)	(8.95)	(9.17)	(9.44)	(5.43)		(−.82 to .59)
Depression	15.63	14.00	−1.36	15.73	14.27	−1.47	t=0.05 P=.96	0.02
(CESD[e])	(7.29)	(6.76)	(4.88)	(7.21)	(5.52)	(6.39)		(−.71 to .75)
Self-Efficacy	31.00	32.86	1.29	32.07	32.93	0.87	t=0.33 P=.74	0.13
(GPSE[f])	(5.10)	(5.11)	(3.81)	(3.9)	(4.35)	(2.95)		(−.61 to .85)
Perceived Stress	17.94	13.79	−3.36	16.53	14.67	−1.87	t=−.91 P=.37	0.22
(PSS[g])	(7.58)	(6.61)	(3.41)	(5.29)	(5.95)	(5.19)		(−1.1 to .40)
Sleep Disturbance	1.06	0.88	−0.19	1.27	1.27	0	t=−.80 p=.43	−0.30
(PSQI[h])	(0.68)	(0.5)	(0.75)	(0.59)	(0.46)	(0.53)		(−.99 to .42)
Mindfulness	124.13	132.5	7.21	128.47	131.8	3.33	t=0.62 P=.54	0.24
(FFMQ[i])	(24.26)	(22.02)	(15.33)	(14.27)	(13.96)	(18.23)		(−.50 to .96)

[a]GM: Access to guided meditation

[b]IMMI: Internet Mindfulness Meditation Intervention

[c]X^2: Kruskal-Wallis test

[d]t: Student's t test

[e]CESD: Center for Epidemiologic Studies Depression Scale

[f]GPSE: general perceived self-efficacy

[g]PSS: Perceived Stress Scale

[h]PSQI: Pittsburgh Sleep Quality Index

[i]FFMQ: Five-Factor Mindfulness Questionnaire

Health Outcomes

Because this was a pilot study and not powered to evaluate superiority of the 2 arms, we did not expect to see significant findings in between-arm analysis. As expected, we did not see any differences (Table 5).

Discussion

Overview

This study was a pilot study examining the feasibility and acceptability of an Internet mindfulness meditation intervention for the general public, whether it could cause behavior change (ie, increase in daily meditation), and secondarily, collecting preliminary data on health outcomes. We found that an Internet mindfulness meditation intervention for the general public was feasible and acceptable and increased daily meditation compared with the control arm. Health outcome data were collected for future study preparation.

Demographics

The covariate adaptive randomization was effective resulting in similar characteristics for both arms. The participants were mostly women, which is common for complementary and alternative medicine modalities [36]. Interestingly, most

participants had only tried CAM a few times in the past. The racial distribution reflected the Portland, Oregon metropolitan area where most (74%) participants were from. Income distribution matched the United States where the mean household income, according to the US Census Bureau 2014 Annual Social and Economic Supplement, was $72,641 (median $51,939). Most participants were employed, and many of those not employed were retired. We had anticipated more unemployed participants since the intervention does require a time commitment, but this was not the case.

Feasibility and Acceptability

Recruitment was feasible, with a 20% enrollment rate from those contacted and a 71% completion rate from enrollees. The participants found IMMI acceptable and more acceptable compared with the GM participants on the CSQ. Although the average scores for the total and individual questions were not excellent (ie, as high as the maximum value of 4), they were all above median of 2.5 reflecting average-to-good satisfaction. The interaction with study staff for this study was minimal. The RA contacted the participants by email once a week; to remind IMMI participants to complete sessions and collect adherence for the GM participants. The goal of this study was to have very limited interactions with the participants, and thus evaluate the program on its own without study staff support. Increased

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interaction with study staff may have improved the client satisfaction scores.

There was also a difference in the expectancy participants had toward the 2 interventions introducing an inherent bias into the study. Looking at expectancy and credibility scores of all participants before randomization, IMMI scored significantly higher than GM. The skewed bias toward IMMI was present in all participants before randomization and was not different between arms (ie, both arms felt IMMI was more credible and would be more effective). Recruitment materials attempted to be as unbiased as possible with language in regard to which arm would improve meditation practice. Regardless, the differences between the content of the arms were clear and reflected in the skewed expectancy and credibility.

Change in Meditation Practice Behavior

Adherence was lower than we would have hoped. Participants completed about half of the weekly logs for home practice. Future studies will incorporate objective adherence built into the program so that we can track actual practice time more accurately as we have done in other studies [7,37,38]. The practice days were lower than we have seen in previous studies and only 8 IMMI participants completed all 6 Web-based sessions [7].

Regardless of this low compliance, IMMI did demonstrate the ability change behavior through increased meditation practice. IMMI participants had twice as many total meditation practice minutes over the 6 weeks. Most Americans have access to GMs through buying CDs, downloading from the Internet, or watching on YouTube. Considering the increasing positive evidence for meditation practice, encouraging daily meditation practice is a beneficial behavioral goal. Adding a Web-based meditation program can help encourage the daily meditation practice behavior. Although interactions with study staff and participants were purposefully kept to a minimum, programs that had more interaction and/or built in reminders through email or text to practice daily may result in an even greater level of daily practice.

Health Outcomes

As expected, we found no differences between arms on health outcomes. The health outcome data will support planning for future clinical trials to evaluate the efficacy of IMMI in the general population.

Limitations

This study addressed whether IMMI was feasible and acceptable to adults in the public, whether it increased meditation practice compared with access to GMs, and collected preliminary data on general health outcomes. The study was not powered to assess differences between the IMMI and the GM arm. From the effect sizes and large confidence intervals seen for the health outcomes, we are uncertain of any clinical effect. More research is needed to ascertain this. It may be that the intervention is more useful for participants with significant mental health symptoms rather than healthy adults in the public. Future studies would include or perhaps target those participants to evaluate IMMI with that population. In addition, this study found that IMMI was acceptable and feasible compared with a very low-dose mindfulness meditation. However, our results do not imply anything about how IMMI would compare with the well-studied group mindfulness-based meditation programs like MBSR and MBCT. One could consider IMMI an entry-level experience to mindfulness meditation, with a greater dose than simply having GMs but a lesser dose compared with MBSR and MBCT. Future studies could compare multiple delivery formats with different doses to each other to evaluate the effect of mindfulness dose on adherence and effects. In addition, the study was designed to assess shorter-term effects of mindfulness meditation (6 weeks). Ideally, a study would assess sustained effects over a longer period. The study used novel technology that may be difficult for some people to use and participants must have access to computers and Internet to be able to participate. The IMMI program is in an early pilot phase and has not been developed in languages for non–English-speaking individuals. Due to language and cultural differences, the tool cannot yet be developed for non–English-speaking individuals. Plans to develop such tools are contingent on showing efficacy in the general population.

Conclusion

In conclusion, IMMI was found to be feasible and acceptable. IMMI was also able to change behavior and increase daily meditation practice compared with the GM arm control. More interaction through staff and/or through built-in email or text reminders may increase daily practice even more. Future studies will examine IMMI's efficacy at improving health outcomes in the general population.

Conflicts of Interest

None declared.

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Multimedia Appendix 1

CONSORT eHealth Checklist.

[PDF File (Adobe PDF File), 10MB - mental_v3i3e37_app1.pdf]

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Abbreviations

CESD: Center for Epidemiologic Studies Depression Scale
CSQ: Client Satisfaction Questionnaire
FFMQ: Five Factor Mindfulness Questionnaire
GM: access to guided meditations
HIPAA: Health Insurance Portability and Accountability Act
IMMI: Internet Mindfulness Meditation Intervention
IRB: institutional review board
MBCT: Mindfulness-Based Cognitive Therapy
MBSR: Mindfulness-Based Stress Reduction
RA: research assistant
SF-36: 36-Item Short Form Health Survey

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Corrigenda and Addenda

Metadata (ORCID) Correction: Effectiveness of Internet-Based Interventions for the Prevention of Mental Disorders: A Systematic Review and Meta-Analysis

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Related Article:

Correction of: http://mental.jmir.org/2016/3/e38/

The authors of "Effectiveness of Internet-Based Interventions for the Prevention of Mental Disorders: A Systematic Review and Meta-Analysis" (JMIR Mental Health 3(3):e38) inadvertently provided an incorrect ORCID for author Lasse Sander.

The ORCID originally published for Lasse Sander belonged to another author with the same name. The correct ORCID is: 0000-0002-4222-9837. This error has been corrected in the online version of the paper on the JMIR website on August 25, 2016, together with publishing this correction notice. The correction was made before submission to PubMed Central.

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