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Contents

Editorial

Theme Issue on E-Mental Health: A Growing Field in Internet Research

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Abstract

This theme issue on e-mental health presents 16 articles from leading researchers working on systems and theories related to supporting and improving mental health conditions and mental health care using information and communication technologies. In this editorial, we present the background of this theme issue, and highlight the content of this issue.

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KEYWORDS

editorial; e-health; e-mental health; randomized controlled trials; collborative care; feasibility study

What is E-Mental Health?

We are pleased to introduce this JMIR Theme Issue on E-Mental Health. “E-mental health” can be understood as a generic term to describe the use of information and communication technology (ICT) –in particular the many technologies related to the Internet –when these technologies are used to support and improve mental health conditions and mental health care, including care for people with substance use and comorbid disorders. E-mental health encompasses the use of digital technologies and new media for the delivery of screening, health promotion, prevention, early intervention, treatment, or relapse prevention as well as for improvement of health care delivery (eg, electronic patient files), professional education (e-learning), and online research in the field of mental health. In a broader sense, all Internet interventions are, in one way or another, targeting the “mind” and human behavior. For the purpose of this theme issue, we focus on mental health conditions, while interventions that facilitate behavior change for general health problems (such as obesity) or systems that provide general emotional or social support for nonmental health conditions (eg diabetes) lie somewhat outside of the core scope of “e-mental health” (and this theme issue), although developers working in these areas can clearly learn from principles and findings presented in this issue.

Looking through the “e-mental health” articles published in JMIR in the past 3 years, it becomes evident that depression remains a major public health issue and a primary target for Internet interventions [1-9]. In addition, the question of whether Internet use itself has an impact on depression – a question fuelled by earlier studies on the apparent “Internet paradox” – has been studied [10]. Other conditions often targeted by e-mental health interventions are alcohol [11,12] and tobacco dependencies (a previous JMIR theme issue was devoted to

Web-based tobacco interventions [13]) or conditions such as panic disorder [14] or pediatric encopresis [15]. Other recent e-mental health articles in JMIR have validated Web-based screening questionnaires for mental disorders [16] or explored the use of emerging technologies such as virtual reality [17] or mobile technologies [18].

The First International E-Mental Health Summit

The current theme issue brings together a group of papers presented at the First International E-Mental Health Summit in Amsterdam in 2009 organized by the Trimbos Institute in collaboration with the International Society for Research on Internet Interventions (ISRII) [19], VU University Amsterdam, and the University of Amsterdam (UvA). The summit welcomed more than 500 people from over 40 countries.

The summit was preceded by the fourth ISRII meeting, which was opened by Professor Pim Cuijpers (VU University Amsterdam, Netherlands). He highlighted the need for international collaboration – a need illustrated by the growing numbers of ISRII participants. He symbolically transferred the ISRII chair to Professor Helen Christensen, who will lead ISRII up to its fifth meeting in Sydney, Australia, in April 2011.

Many young researchers presented their latest results during the ISRII meeting. Some of them moved beyond traditional cognitive-behavioral effectiveness studies. Björn Paxling (Linköping University, Sweden, and VU University Amsterdam, Netherlands), for example, ventured to compare Web-based cognitive-behavioral therapy (CBT) with Internet-delivered psychoanalytic therapy for general anxiety disorder (GAD). He found that the two interventions had comparable impacts in terms of clinical improvement. The ISRII 2009 Best Paper Award was won by Sylvia Gerhards (Maastricht University, Netherlands), who reported on one of the first economic evaluations of unguided online CBT for depression in primary care [20]. It favored online CBT alone in comparison with treatment as usual as well as treatment as usual supplemented by online CBT.

At the summit itself, 195 presentations were given by academics, health professionals, and policymakers, including some of the world's most respected experts on eHealth intervention evaluation and dissemination research (see www.ementalhealthsummit.org). Presentations highlighted the effectiveness of Web-based treatment, new treatment developments, novel research methodologies, and the need for international collaboration. The summit was opened by Dr. Annemiek van Bolhuis, a deputy of the Dutch Minister of Health, who spoke of the importance of e-mental health as a response to growing demand and rising costs in mental health care. Dr. Jan Walburg, chair of the board of the Trimbos Institute, stressed the importance of mental well-being in the life cycle and the potential role of information and communication technologies in fostering it.

At the close of the summit, Professor Isaac Marks (University College London, London, United Kingdom) and Professor Alfred Lange (University of Amsterdam, Netherlands) were honored by the ISRII board as founding fathers of e-mental health in research and practice. It was also in Amsterdam that Professor Lange introduced in 1999 the first Web-based treatment program for people with posttraumatic stress disorders, known as Interapy.

This theme issue illuminates the evolving fields of eHealth and e-mental health, including topics such as the need for international collaboration, ethical considerations, cost-effectiveness, treatment attrition, and self-management.

Figure 1. Professor Ricardo Muñoz at the E-Mental Health Summit

Articles in This Theme Issue

International Collaboration and Ethical Issues

Professor Ricardo Muñoz won the best presentation award, and we open this theme issue with his paper [21]. Echoing the enthusiasm of this international summit, he calls for smart international collaboration to disseminate Web-based interventions (eg, through portals like Beacon, www.beacon.anu.edu.au). Given the wide-scale, low-cost implementation potential of Internet interventions, the international dissemination of evidence-based interventions could help to reduce health disparities worldwide. Muñoz offers a framework for such an endeavor under the inspiring slogan, “Think globally, act locally, and share globally.”

In the study by Lange and Ruwaard [22], the authors demonstrate that sexually abused adolescents can be treated effectively in online treatment, but pretreatment withdrawal is frequent. These authors focus on several still unresolved ethical dilemmas in eHealth research. While adolescents are overwhelmingly present in the digital world, recruiting vulnerable adolescents to take part in outcome studies is hindered by a lack of perceived anonymity and the need to obtain permission and informed consent from their parents. Lange and Ruwaard also demonstrate that altering study designs may decrease the withdrawal rate. Full anonymity, however, is not a viable solution, either legally or professionally. The authors end their paper with a list of smart strategies to bolster youth participation in evaluation trials.

Another important ethical imperative, dealing with privacy and security, is discussed by Bennett and colleagues [23]. According to the authors, many interventions do not yet satisfy the necessary technical or other security requirements. One possible way to bring these security issues center stage is to apply an “ongoing risk assessment” design principle and to develop multidimensional security standards. The achievement of such aims could be greatly furthered by international collaboration.

Cost-effectiveness

Cost-effectiveness trials are long overdue. In this issue, Warmerdam and colleagues [24] present evidence from one of the first such studies on Web-based, low-intensity guided self-help for depression. They assess the cost-utility and cost-effectiveness of problem-solving and cognitive-behavioral interventions for depression as compared with a wait-listed control group. Both interventions prove cost-effective, with no clear advantage for either the problem-solving or the cognitive-behavioral approach.

Online self-administered questionnaires for screening and for routine outcome assessment by patients themselves could also boost cost-effectiveness, but these questionnaires need to be validated when applying them in an online environment, as shown by Holländare and colleagues [25]. In a clinical sample, these authors compared the psychometric properties of online versions of Beck Depression Inventory (BDI-II) and the Montgomery-Åsberg Depression Rating Scale—Self-rated (MADRS-S) with the respective pen-and-paper versions. They conclude that both of these tests can be effectively delivered online, with the advantages of easy administration,

dissemination, and data analysis. This, in turn, could both strengthen patient self-management and enhance clinicians' knowledge, with a potential for improved clinical outcomes and cost savings.

White and colleagues [26] conducted a systematic review to assess the effectiveness of Web-based interventions for problem drinking by college students and adults. They found small to moderate effect sizes and conclude that Web-based interventions may be of particular interest to groups less likely to access traditional services, such as young people and women.

Of the contributors in this issue, two [27, 28] conducted randomized controlled trials of problem drinking among European young people, thereby widening the geographic scope of Web-based evaluation research of problem drinking beyond the United States. Contrasting with the review findings of White et al are those presented by Spijkerman and her coauthors concerning a younger group (ages 15 through 20) than those normally included in college trials [27]. Although the authors did not find a main effect on drinking outcomes associated with the Web-based intervention, it did appear to benefit males as compared with females in the short-term. Bewick and colleagues [28] evaluated the effectiveness of a personalized normative feedback intervention for alcohol use among university students at four institutions, finding positive results consistent with those obtained by White [26]. An interesting additional finding was the favorable influence on drinking outcomes in the assessment-only condition.

Parental skills were assessed in a pretest-posttest study by Van der Zanden and colleagues of a Web-based intervention aimed at parents with psychological problems [29]. These authors found improvement in parental competencies but no impact on child well-being. They conclude that the latter outcome may be attributable to the nonclinical baseline status of two thirds of the children, leaving little space for clinical improvement.

Treatment Outcomes and Attrition

The high levels of study and treatment attrition (dropout) are hot and debated issues in eHealth and e-mental health intervention research, as exemplified by four papers in this issue. Applying theoretical considerations and empirical data, the authors build further on what Eysenbach has labeled the "law of attrition" [30].

Study dropout from eHealth interventions may not be random, and, if not adequately addressed, dropout may lead to biased estimations. Blankers and colleagues [31] provide an overview of imputation techniques for handling missing data—highly readable for nonexperts in statistics. They make use of data from a prospective cohort study of 124 participants in a self-help course for problem drinking. They conclude that multiple imputation techniques are best to avoid biased interpretations.

Nicholas and colleagues [32] studied predictors of treatment adherence using data from a randomized clinical trial of an online psycho-education program for people diagnosed with a bipolar disorder, supplemented by subsequent qualitative interviews with noncompleters about their reasons for nonadherence. The authors first contextualize online treatment attrition arguing that, although high, it does not differ significantly from that in face-to-face psychotherapy. Predictors of attrition identified by these authors, such as young age and male gender, as well as better insights into participants' needs may aid in devising strategies to improve treatment adherence.

Mohr and colleagues [33] undertook a feasibility study in the community to investigate how adherence rates for online depression treatment, as well as the treatment outcome itself, could be improved by using multimodal functionalities. They used protocol-driven telephone coaching and Internet support based on persuasive technology. Their results, though tentative because of their single-arm design and small sample, revealed a low attrition rate in this online intervention, decreased depression scores, and high patient acceptability. In an interesting observation from a self-management point of view, they argue that the poorer moods associated with more intense use of the intervention may reflect patients' titration of treatment in accordance with their own needs.

Meglič and colleagues [34] conducted a feasibility trial of primary-care depression treatment, investigating how collaborative care and online self-management support could improve medication adherence and lead to better clinical outcomes. As in the Mohr study [33], Meglič and colleagues found improved adherence rates, reduced depressive symptoms, and greater patient satisfaction. Notwithstanding these positive results, about one third of the sample reported drawbacks due to issues that included practicability. The results of both studies have prompted randomized controlled trials to investigate the robustness of these pilot results.

Patient Self-management, Preferences, and Acceptability

The importance of self-management is addressed directly or indirectly in all papers in this issue. Nonetheless, empirical knowledge about patients' preferences for and usage of Web-based interventions is still in its infancy. A study by Proudfoot and colleagues sheds light on the acceptability to patients of using mobile phones for the self-assessment and self-monitoring of clinical progress [35]. Applying a triangulation method, they conclude that those experiencing mental health problems such as depression were particularly interested in such an approach; those not interested mainly disliked using mobile phones or feared a lack of privacy.

Klein and colleagues assessed the preferences of 1214 people aged 16 or older who used information websites on alcohol and other drugs [36]. Easy search facilities, open access, and validated content were highly valued by the users. Differences in preference were associated mainly with age and educational level.

Schrank and colleagues conducted semistructured interviews to investigate Internet use among 26 people with schizophrenia, which may be the first such study conducted with mental health patients [37]. The respondents used the Internet to obtain information about their illness. Their Internet behavior resembled that of people without mental health disorders, though some were liable to specific problems such as stimulus overflow. Respondents believed the Internet had the potential to favorably

change patients' attitudes toward medication and their relationships with doctors.

The guest editors would like to thank all of the authors, who contributed their high-quality papers to this issue. We are also grateful to the reviewers for their helpful and pertinent comments on the submitted papers. Last but not least, we hope the readers will enjoy this theme issue of JMIR. It shows that Internet intervention research is clearly coming of age, though it still faces many challenges. And we hope to welcome you all to the fifth ISRII meeting in Sydney in 2011.

Theme Issue Guest Editors: Heleen Riper, Gerhard Andersson, Helen Christensen, Pim Cuijpers, Alfred Lange

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Conflicts of Interest

None Declared

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Abbreviations

BDI-II: Beck Depression Inventory
CBT: cognitive behavioral therapy
GAD: general anxiety disorder

ISRII: International Society for Research on Internet Interventions
ICT: information and communication technology
JMIR: Journal of Medical Internet Research
MADRS-S: Montgomery-Åsberg Depression Rating Scale—Self-rated
UvA: University of Amsterdam

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Review

Online Alcohol Interventions: A Systematic Review

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Abstract

Background: There has been a significant increase in the availability of online programs for alcohol problems. A systematic review of the research evidence underpinning these programs is timely.

Objectives: Our objective was to review the efficacy of online interventions for alcohol misuse. Systematic searches of Medline, PsycINFO, Web of Science, and Scopus were conducted for English abstracts (excluding dissertations) published from 1998 onward. Search terms were: (1) Internet, Web*; (2) online, computer*; (3) alcohol*; and (4) E\effect*, trial*, random* (where * denotes a wildcard). Forward and backward searches from identified papers were also conducted. Articles were included if (1) the primary intervention was delivered and accessed via the Internet, (2) the intervention focused on moderating or stopping alcohol consumption, and (3) the study was a randomized controlled trial of an alcohol-related screen, assessment, or intervention.

Results: The literature search initially yielded 31 randomized controlled trials (RCTs), 17 of which met inclusion criteria. Of these 17 studies, 12 (70.6%) were conducted with university students, and 11 (64.7%) specifically focused on at-risk, heavy, or binge drinkers. Sample sizes ranged from 40 to 3216 (median 261), with 12 (70.6%) studies predominantly involving brief personalized feedback interventions. Using published data, effect sizes could be extracted from 8 of the 17 studies. In relation to alcohol units per week or month and based on 5 RCTs where a measure of alcohol units per week or month could be extracted, differential effect sizes to posttreatment ranged from 0.02 to 0.81 (mean 0.42, median 0.54). Pre-post effect sizes for brief personalized feedback interventions ranged from 0.02 to 0.81, and in 2 multi-session modularized interventions, a pre-post effect size of 0.56 was obtained in both. Pre-post differential effect sizes for peak blood alcohol concentrations (BAC) ranged from 0.22 to 0.88, with a mean effect size of 0.66.

Conclusions: The available evidence suggests that users can benefit from online alcohol interventions and that this approach could be particularly useful for groups less likely to access traditional alcohol-related services, such as women, young people, and at-risk users. However, caution should be exercised given the limited number of studies allowing extraction of effect sizes, the heterogeneity of outcome measures and follow-up periods, and the large proportion of student-based studies. More extensive RCTs in community samples are required to better understand the efficacy of specific online alcohol approaches, program dosage, the additive effect of telephone or face-to-face interventions, and effective strategies for their dissemination and marketing.

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KEYWORDS

Alcohol; drugs; Internet; physical health; website interactivity; online treatment; online information

Introduction

The World Health Organization (WHO) has estimated that there are about 2 billion people worldwide who consume alcoholic beverages and 76.3 million with diagnosable alcohol use disorders [1]. Alcohol use is related to a wide range of physical, mental, and social harms [1], with harmful use ranked as the fifth leading risk factor for premature death and disability in the world [2]. Alcohol is estimated to be responsible for 3.8% of deaths and 4.6% of disability-adjusted life years lost worldwide, costing more than 1% of the gross national product of middle-income countries [3]. These disorders can negatively impact on social functioning [4] and contribute to fatalities and injuries related to drinking and driving, reduced job performance and absenteeism, aggressive behavior, and family and other relationship conflicts [5]. Tragically, young people are significantly affected, with 18 to 35 year olds having the highest peak consumption and the greatest risk of short-term harm [6,7].

The size of the community-wide challenges posed by alcohol consumption has triggered a substantial body of research into brief, low-cost interventions. These interventions have demonstrated efficacy [8] and informed the way in which services are delivered at primary care and specialist levels. However, there remains a need to engage people with risky levels of drinking or low-level problems who are unwilling to or simply do not seek assistance through traditional health services or self-help groups [8]. Compounding this issue is a lack of health care professionals who routinely deliver effective interventions for alcohol misuse, especially in rural and remote areas [9,10]. Previous research on alcohol interventions by mail or other bibliotherapy approaches have shown these delivery methods to be effective [11,12], but there are delays in providing timely support and feedback by mail unless these are used in conjunction with telephone support.

In 2009 it was estimated that over a quarter of the world's population used the Internet [13], with 18 to 32 year olds representing 30% of all adult Internet users [14]. Given that the peak age for binge drinking is 20 to 29 years [7] and that young people are underrepresented in users of standard face-to-face alcohol and other drug (AOD) specialist services, the Internet could be an effective medium to engage this population. In fact, 14% of young adult Internet users in the United States (18 to 29 year olds) have searched the Internet for information concerning alcohol or drug problems [15].

Several interactive computer-based alcohol screening and intervention programs have been developed to be delivered either through stand-alone computers [16] or via the Internet. Current Internet programs range from user-generated content applications such as Web logs/blogs, Web-based instant messaging technologies, or discussion boards (eg, AlcoholHelpCenter.net [17]), to interactive software applications. Even within interactive applications there is substantial variability, from brief normative feedback interventions [18] to multi-session modularized programs (eg, AlcoholEdu [19]) and psychotherapy substance mediation services involving a therapist [20,21]. Many of these program applications include brief intervention strategies and educational content based on a harm-reduction philosophy [22] and motivational interviewing techniques that are presented in a self-help workbook style [23].

Much of the published literature concerning online alcohol interventions has been descriptive [24], providing general information on program evolution, application, acceptability, and usage [17,25]. Several studies of problematic drinkers confirm the acceptability of online alcohol screening and intervention [26,27], and usage data confirm that these types of websites are accessed by numbers of users that would overwhelm traditional face-to-face services. Linke et al [28] reported that the alcohol-specific intervention website for heavy drinkers, Down Your Drink, had an average of 1039 visits per month (range 706 to 1541) or 34 visits per day (range 25 to 49), with 1319 people from 41 countries registering with the online program over a 6-month period.

Internet available AOD information and services have considerable reach and are often accessed by populations who do not necessarily access standard AOD services. For example, over half of the users of the 6-week Down Your Drink Internet intervention were women [29] as were 61% of individuals who accessed the online self-assessment tool, Drinking Habit Test [30]. One of the most commonly cited reasons for using online AOD health resources has been their 24-hour accessibility [29] unconstrained by geographic locale. Other reasons include ease of access to a computer, the anonymity and privacy afforded by the medium, and not having to attend face-to-face meetings [31,32].

The Internet is a medium that is increasingly being used to deliver alcohol resources and services. In parallel with this has been burgeoning research on the Internet's impact, with an increasing number of studies now being published in this area. It is, therefore, timely to assess the current status of the efficacy of online alcohol intervention programs to inform both the clinical application of such interventions, as well as identify directions for future research.

Method

Literature Search and Selection of Studies

Relevant articles published in English from 1998 up to and including December 2009 were identified through electronic searches of Medline, PsycINFO, Web of Science and Scopus databases. The following terms were used in the search: (1) Internet, Web*; (2) online, computer*; (3) alcohol*; and (4) E\effect*, trial*, random* (where * denotes the relevant wildcard for the database). Titles and abstracts of all potentially relevant articles were independently reviewed for possible inclusion by

3 of the authors (AW, HS, DK). Articles were included if (1) the primary intervention was delivered and accessed via the Internet (including password-protected sites), (2) the intervention focused on moderating or stopping alcohol consumption, and (3) the study was a randomized controlled trial of an alcohol-related screen, assessment, or intervention. Unpublished dissertations were not included.

Data Extraction and Analysis

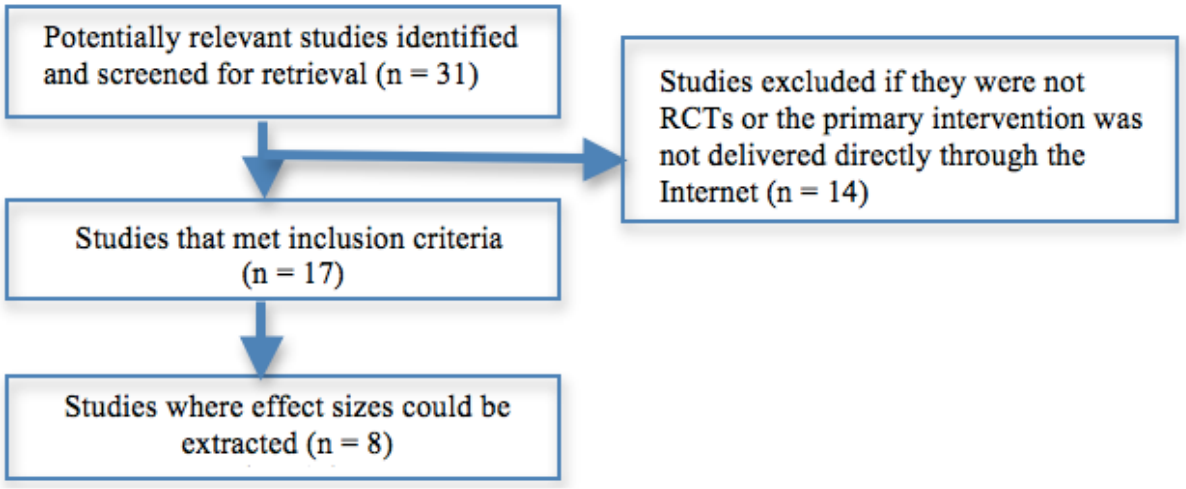
Data extraction was carried out independently by 3 authors (AW, HS, DK). The primary outcome measure employed in this review was the number of 10-gram units of alcohol; wherever possible, reported outcomes were converted into this metric. Effect sizes were estimated using the pooled baseline standard deviation [33]. Differences between posttreatment or follow-up means of each group and their baseline mean were obtained. The change score for the control group was subtracted from the change score of the experimental group, and the result was divided by the pooled standard deviation. Where a full set of data was not provided, the calculation of the pre-post effect sizes between conditions employed the mean changes from baseline to posttreatment and their associated standard deviations. Where data was insufficient or not available in the published paper or by contacting authors, studies were excluded from the relevant analysis.

Results

Description of Studies

The literature search identified 31 studies, 17 of which were of online Internet alcohol intervention programs that met inclusion criteria (see Figure 1). After seeking clarification from the lead authors of the respective papers, 2 studies [8,34] were excluded from the analyses of effect sizes since the computer intervention was delivered on an intranet platform rather than via the Internet. A third study by the same research group was included [35] because the intervention was developed to be Web-based and was delivered online albeit accessed in the course of this specific study on student health clinic computers. Studies by Newton et al [36] and Turrisi et al [37] were also excluded from the primary outcome analyses because they included significant face-to-face components. Differential effect sizes were calculated for 8 of the 17 identified randomized controlled trials (RCTs).

Figure 1. Study identification and analysis flow diagram



Participants

Most studies that met inclusion criteria targeted university students (12/17 or 70.6%), although some recruited general company employees [38,39] or community members [40-42]. While the university-based studies generally involved participants aged 18 to 25, in other studies, the median reported age was 43.1 years. The size of recruitment pools and participation rates varied substantially. This appeared to be mediated in part by the study's target population, the presence of incentives, the marketing and recruitment strategy, and whether participation was mandated (Table 1). In fact, Matano et al [38] distributed 8567 invitations to achieve 316 preintervention surveys.

Study sample sizes ranged from 40 to 3216 (median 196) with 64.7% (11/17) of the RCTs targeting at-risk, heavy, or binge drinkers. The percentage of females ranged from 27.6% to 77.9% (mean 54.5%, median 52%), which is substantially greater than in most AOD clinics (Table 1).

Interventions

Of the studies that met criteria, 70.6% (12/17) evaluated the impact of brief personalized feedback, and 41.2% (7/17) examined an online multi-module information/education treatment (often incorporating personalized feedback). Control groups typically received psychoeducational resources (10/17 or 58.8%) or completed an online assessment.

Duration of Trials

Posttreatment assessments were conducted anywhere from 1 week to 12 months posttreatment, with several studies conducting assessments at multiple time points. Across the 17 studies, 7 (47.1%) had a maximum follow up period of a month, 4 (23.5%) had a maximum 3-month follow up, and 3 (17.6%) followed participants to 6-months post intervention. Only Kypri et al [35] employed a 12-month follow up.

Reported retention rates in the intervention groups ranged from 38.9% to 100%, and in controls, from 33.4% to 100%. Median

reported retention in the treatment condition was 83.4% at 1 month, 74.5% 3 months, and 74.5% at 6 months. In control groups, the median retention rates at the same time points were 80%, 70.4%, and 74.9%. The Kypri et al study [35] reported 12-month retention rates of 83.5% for the intervention group and 86.3% for the control condition.

Several studies reported only combined retention data. The studies by Doumas and Hannah [39] and Doumas et al [43] reported 1-month whole sample retention rates of 63.3% and 88.2% respectively, with the Walters et al [23] study reporting retention rates of 71.7% at 2 months and 77.4% at 4 months. The Motano et al [38] study reported whole sample retention rates of 83.8% at 3 months.

Outcomes

A wide variety of outcome assessments were employed across the studies with all studies including some measure of alcohol consumption (eg, unit grams of alcohol, number of standard drinks, or blood alcohol concentrations) in relation to either a typical drinking occasion or when the greatest amount was consumed on a single occasion. In many cases, the measure of frequency of alcohol consumption used was either 4 or more or 6 or more drinks per occasion or drinking to intoxication. Quantity and frequency measures related to a designated assessment period (a typical week, the previous week, 2 or 6 weeks, or up to the last 12 months). Several studies assessed alcohol use in relation to specific events (eg, 21st birthdays [44], homecomings, holidays, or pub nights [45]). A number of studies included measures of personal, social, sexual, or legal consequences of drinking [34,36,46,47], protective factors [45], alcohol-related knowledge [19,36], readiness to change [40,45,48], intention to seek help [48], drinking related self–efficacy [46], or outcome expectancies [36,46].

Table 1. Characteristics of online alcohol-related randomized controlled trials

Author	Recruitment Pool	Description and Size of Intervention Group	Description and Size of Control Group	Age Reported Mean (SD) and/or Range (Years)	Percent Female Gender
Bewick et al [49][a]	University students recruited through a student experience survey	Personalized normative feedback n = 234	Assessment only n = 272	Mean 21.3 (SD 3.7)	69
Chiauzzi et al [45][b]	2nd and 4th year university students from 5 colleges who responded to local advertisement and subsequently screened as binge drinkers	MyStudentBody, a website that provides motivational feedback and alcohol-related resources n = 131	Alcohol and You, a website that provides educational material only n = 134	Mean 19.9 (SD 1.6)	54
Croom et al [19]	All incoming 1st year university students	Participant survey, knowledge test, and online course n = 1608	Survey and knowledge test n = 1608	18 to 24	49.1
Cunningham et al [41][b]	Problem drinkers identified through a general population telephone survey	Web-based personalized feedback (approximately 10 minutes) n = 92	List of alcohol education resources n = 93	Mean 40.1 (SD 13.4)	47
Doumas and Hannah [39][c]	Workplace employees of 5 local companies	(1) Web-based feedback (approximately 15 minutes) n = 60 (2) Web-based feedback and motivational interviewing n = 63	Assessment only n = 73	18 to 24	73
Doumas et al [43]	University students mandated for alcohol counselling	Web-based personalized normative feedback (15 minutes) n = 46	Web-based education (approximately 45 minutes) n = 31	Mean 19.2 (SD 1.33) 18 to 24	27.6
Hester et al [40]	Newspaper advertisement recruiting heavy drinkers	Online alcohol education resource and Web-based alcohol moderation program n = 40	Access to online alcohol education resources n = 44	Intervention group mean 48.7; control group mean 52.1	56
Hustad et al [47][b,d]	1st year university students	(1) AlcoholEdu, 3-hour modularized program n = 26 (2) Alcohol eCHECKUP TO GO (eCHUG), 20-minute personalized normative feedback program n = 31	Assessment only n = 25	Mean 18.1 (SD 0.3)	51
Kypri et al [50][b]	Heavy drinking university students majoring in psychology and attending university health care	Web-based motivational assessment and personalized feedback (10 to 15 minutes) n = 1251	Screening only n = 1184	Mean 19.7 (SD 1.8), 17 to 24	45.3

Author	Recruitment Pool	Description and Size of Intervention Group	Description and Size of Control Group	Age Reported Mean (SD) and/or Range (Years)	Percent Female Gender
Kypri et al [35][b]	Undergraduate university students, who scored ≥ 8 on Alcohol Use Disorders Identification Test (AUDIT)	(1) Multidose motivational intervention n = 145 (2) Single dose motivational intervention n = 138	Information pamphlet n = 146	Mean 20.1 (SD 2.2), 17 to 29	52
Matano et al [38]	Workplace employee website	Full individualized feedback regarding alcohol risk, information regarding alcohol use, and feedback regarding stress and coping n not specified	General information regarding alcohol and limited individualized feedback regarding stress and coping n not specified	Mean 39.9 (SD 11.3)	77.9
Moore et al [51]	Convenience sample of 1st year university students enrolled in 3 college courses	Web-based binge-drinking intervention n = 59	Correspondence-based binge-drinking intervention n = 57	Mean 21.7 (SD 0.2), 18 to 25	57.8
Neighbors et al [44][b]	University students turning 21 during 2 academic quarters who intended drinking 2 or more drinks on their birthday	Web-based personalized feedback n = 150	Assessment only n = 145	20 year olds	51.1
Riper et al [42][b]	Advertisements in national newspapers and health-related websites recruiting adult problem drinkers	Web-based multicomponent Cognitive Behaviour Therapy self-help intervention n = 130	Online psycho-educational alcohol use brochure n = 131	18 to 65, intervention group mean 45.9 (SD 8.9), control group mean 46.2 (SD 9.2)	49
Saitz et al [48]	1st year university students identified as engaging in hazardous alcohol use (≥ 8 on AUDIT)	Extensive individualized brief feedback intervention n = 324	Individualised minimal brief intervention n = 326	18 and over	63.7
Walters et al [23]	1st year university students assessed within the study as “at risk” drinkers	eCHUG, personalized normative feedback program (20 minutes) n not specified	Assessment only n not specified	Not specified	48.1
Weitzel et al [46]	University students who self-identified as drinking more than 1 once of alcohol per week recruited through emails and on-campus advertising	Online daily diary and individualized tailored messages n = 20	Online daily survey n = 20	Mean 19.2, 18 and over	55

[a] Shown are baseline sample size and data. Data shown for this study in Tables 2 include only participants available at posttreatment.

[b] Intention-to-treat analysis was conducted on some or all measures.

[c] This study included a second intervention condition which consisted of Web-based feedback as well as motivational interviewing (MI). However, the motivational interviewing component was delivered face-to-face rather than via the Internet and, therefore, the effect size data from the second intervention condition is not included in calculations of mean effect sizes.

[d] Completion of AlcoholEdu program was a university-wide administrative requirement.

Effects of Interventions

Alcohol Units

Based on 5 RCTs [41-43,47,49] where a measure of alcohol units per week or month could be extracted, differential effect sizes to posttreatment ranged from 0.02 to 0.81 (median 0.54) (Table 2). Using the full samples of participants, the mean differential effect size was 0.42. If only identified problem drinkers in the Cunningham study [41] are included (rather than the full sample dataset), the effect size rose to 0.47. The pre-post differential effect size for brief personalized feedback programs [41,43,47,49] ranged from 0.02 to 0.81 (mean 0.39, median 0.33), and for the multi-session modularized programs of Riper et al [42] and Hustad et al (AlcoholEdu) [47], a pre-post differential effect size of 0.56 was obtained in each case.

Employing Cohen's effect size evaluation benchmarks [52], the effects on alcohol units consumed were generally in the small to medium range. A notable exception was the study by Hustad and colleagues [47] undertaken with a college sample. That study examined the effectiveness of 2 of the most commonly used electronic interventions for heavy drinking in college students: AlcoholEdu, an education style multi-session modularized Internet program, and Alcohol eCHECKUP TO GO (eCHUG), an intervention based on personalized normative feedback. In relation to peak drinks per occasion per month, the eCHUG personalized normative feedback intervention resulted in a large differential effect size (0.81).

Only 1 RCT allowed extraction of a follow-up effect size on alcohol units. The examination by Cunningham and colleagues [41] of the online CheckYourDrink.net website (10-minute online normative and alcohol severity feedback) resulted in a small differential effect size of 0.23 for the full sample at the 6-month follow up. When only the data from identified problem drinkers was included, a moderate differential effect size (0.43) was obtained.

Blood Alcohol Concentrations

Pre-post data on peak blood alcohol concentrations (BAC) were available from 2 RCTs [44,47] (Table 3) and resulted in a mean differential effect size of 0.66. The personalized normative feedback program of Hustad et al [47] for eCHUG and that of Neighbors et al [44] achieved differential effect sizes of 0.87 and 0.22 respectively. Interestingly, the eCHUG intervention produced a BAC effect size (0.88), comparable to that of the more extensive modularized 3-hour online alcohol program, AlcoholEdu tested in the same trial.

Other Outcome Measures

Differential effect sizes were extracted from 5 RCTs [39,43,44,49,51] in relation to number of drinks on 21st birthday [44], units of alcohol per occasion [49], peak consumption [39,43], frequency of drinking to intoxication [39,43], or 30-day quantity of alcohol use [51] (Table 3). Most studies obtained small effect sizes on these measures. However, of note is the Moore et al [51] study that employed a control group that differed from the intervention group primarily in mode of delivery (via postal services) rather than in key content. In this study, there was a greater fall in 30-day quantity of alcohol use (number of drinks per occasion) for postal delivery than for Internet delivery (differential effect size = -0.26). This, however, reflected higher consumption by the postal control group at baseline (mean 3.15 vs mean 2.49): Posttreatment alcohol quantities were comparable across the groups (postal 2.51, Internet 2.53).

Table 2. Randomized controlled trials of online alcohol interventions

Study	Treatment Group (or Treatment Group 1 if More Than One Group)					Control Group					
	Correction for Alcohol Units[a]	n	Mean (SD) Pre	Mean (SD) Post	Mean at Follow Up	n	Mean (SD) Pre	Mean (SD) Post	Mean at Follow Up	Pre-Post Effect Size (*d*)	Pre-Follow Up Effect Size (*d*)
Bewick et al [49][b]	0.80	138	b	9.62 (10.86)		179	b	11.88 (14.9)		0.02[b]	
Riper et al [42][c]	1.00	130	43.7 (21.0)	28.7[d]		131	43.5 (22.3)	40.6[d]		0.56	
Doumas et al [43][c]	1.40	46	11.42 (9.2)	6.8 (5.43)		31	9.86 (7.42)	8.1 (8.27)		0.33	
Hustad et al [47] (1) AlcoholEdu[c,e]	1.40	26	8.9 (11.62)	11.0 (15.54)		24	9.28 (12.4)	18.14 (17.25)		0.56	
Hustad et al [47] (2) eCHUG[c,e]	1.40	30	12.4 (14.29)	10.4 (11.09)		24	9.28 (12.4)	18.1 (17.25)		0.81	
Cunningham et al [41], full sample[c]	1.36	92	18.9 (14.82)	14.96 (12.38)	15.1 (12.1)	93	16.18 (13.7)	15.5 (14.0)	15.64 (14.0)	0.23	0.23
Cunningham et al [41], problem drinkers only	1.36	35	30.6 (17.14)	20.54 (15.23)	21.76 (16.2)	37	25.98 (16.3)	25.02 (16.73)	24.34 (17.0)	0.54	0.43

[a] The table displays means in 10-gram alcohol units. Calculations use stated drink sizes where available. Where a paper referred only to numbers of drinks, these were adjusted using national "standard drink" sizes [53]. Alcohol units calculated per week unless otherwise stated

[b] Baseline data presented by Bewick et al [49] is not from the posttreatment sample. The pre-post difference is based on the mean differences and related SDs from baseline to posttreatment. Analyses in that study were based on transformed data.

[c] Means were calculated using identified comparisons.

[d] Post SDs were not reported.

[e] Units of alcohol reported are per month.

Table 3. Randomized controlled trials of online alcohol interventions: Effect sizes (d) obtained across blood alcohol concentrations and other alcohol-related measures

Study and Outcome Measure	Treatment Group (or Treatment Group 1 if More Than One Group)			Control Group			
	n	Mean (SD) Pre	Mean (SD) Post	n	Mean (SD) Pre	Mean (SD) Post	Pre-Post *d*
Hustad et al [47] (1) AlcoholEdu, peak BAC	26	0.08 (0.10)	0.08 (0.09)	24	0.07 (0.08)	0.15 (0.15)	0.88
Hustad et al [47] (2) eCHUG, peak BAC	30	0.08 (0.10)	0.08 (0.08)	24	0.07 (0.08)	0.15 (0.15)	0.87
Neighbors et al [44], peak BAC on 21st birthday	150	0.11 (0.10)	0.10 (0.11)	145	0.12 (0.11)	0.13 (0.13)	0.22
Neighbors et al [44], number of drinks on 21st birthday	150	7.23 (5.29)	6.4 (6.13)	145	7.14 (5.12)	7.00 (5.57)	0.13
Bewick et al [49], units per occasion	138	[a]	6.77 (4.54)	179	[a]	7.84 (5.78)	0.23[a]
Doumas and Hannah [39], frequency of drinking to intoxication (ie, number of times drunk or high from alcohol) during the past 30 days	60	1.44(2.06)	0.85 (1.63)	73	1.19 (1.70)	1.02 (1.88)	0.22
Doumas and Hannah [39], peak alcohol consumption (number of drinks consumed on the occasion on which the individual drank the most in the previous month)	60	5.12 (5.36)	3.55 (3.91)	73	4.15 (4.80)	3.98 (4.70)	0.28
Doumas et al [43], peak alcohol consumption (number of drinks consumed on the occasion on which the individual drank the most in the previous month)	46	8.77 (4.53)	6.95 (3.92)	31	6.21 (2.77)	5.88 (3.07)	0.38
Doumas et al [43], drinking to intoxication (ie, number of times drunk or high from alcohol during the past 30 days)	46	0.84 (0.37)	0.68 (0.47)	31	0.79 (0.41)	0.71 (0.46)	0.21
Moore et al [51][b], 30-day frequency of alcohol use	53	4.74 (5.82)	3.68 (4.95)	47	5.38 (5.83)	5.02 (4.94)	0.12
Moore et al [51][b], 30-day quantity of alcohol use (number of drinks per occasion)	53	2.49 (2.55)	2.53 (2.33)	47	3.15 (2.6)	2.51 (2.33)	-0.26

[a] Baseline data presented by Bewick et al [49] is not from the posttreatment sample. The pre-post difference is based on the mean differences and related SDs from baseline to posttreatment. Data presented here are not transformed.

[b] This study's control group differed primarily in mode of delivery (via postal services) rather than in key content.

Discussion

Review of Findings

Internet interventions offer an alternative, accessible treatment option for people with alcohol-related problems. Their effectiveness, however, has not been systematically evaluated. To date, there have been a limited number of published RCTs of online alcohol interventions. The majority have been conducted with university or student populations and have employed a range of incentives and inducements to achieve an acceptable participation and retention rate. These groups tend to be young (early 20s) with a predominance of females. Given the high rates of binge drinking in this age group [7] and the fact that young people—particularly females [54]—are unlikely to access traditional face-to-face services, engagement of these students is an important achievement. However, caution should be exercised in generalizing from these findings, as student samples may not be representative of the general community on motivation, reading level, computer and Internet access, and computer literacy, among other factors.

The brevity of intervention descriptions in the published papers, variable intervention uptake and completion rates, and the heterogeneity of outcome measures and follow-up periods across studies impede the ability to generalize about the efficacy and utility of Internet-based interventions for alcohol use. Overall, online alcohol interventions (whether only involving brief personalized feedback or comprising multiple modules) appear to bring about small but meaningful differential reductions in 10-gram alcohol units consumed, blood alcohol concentrations, and a range of other alcohol-related measures. In particular, they appear more efficacious than assessment alone or general education about alcohol.

Of studies published to date, 3 stand out. Hustad and colleagues [47] undertook the only study to produce a large differential effect size (greater than or equal to 0.80) for the treatment group relative to the control. That study examined the effectiveness

of 2 of the most commonly used electronic interventions for heavy drinking in college students: AlcoholEdu, an education style Internet program, and Alcohol eCHECKUP TO GO (eCHUG), an intervention based on personalized normative feedback. However, caution should be exercised in interpreting these results as 35% of the invited participants did not consent or respond to the invitation to participate in the study.

Moore and colleagues [51] compared the efficacy and feasibility of a binge drinking prevention program for college students delivered via the Internet or via postal mail. Both modes of delivery were efficacious in reducing drinking of students who were binge drinking at baseline, but there was no significant difference in outcome between the 2 delivery modes except for 30-day quantity of alcohol use, where the postal intervention was associated with a greater reduction but a similar posttreatment mean. Replication in samples with more comparable baseline scores is needed.

The trial of Riper and colleagues [42] is also worth highlighting. That study tested a multi-component, self-help intervention for problem drinkers. A moderate pre-post differential effect size on 10-gram alcohol units consumed per week was achieved. At posttreatment, 17.2% of the intervention group had reduced their drinking levels to within Dutch guidelines for low-risk drinking compared with 5.5% of control participants. Decreases in mean weekly alcohol intake (15 units per week) were substantially greater than those in the control group (2.9 units per week). However, only 45.4% of intervention participants made use of the online intervention, and only 51.1% of controls used the psychoeducational brochure.

Conclusions

Implications for Research.

The use of online interventions for the treatment of alcohol-related problems requires more extensive research to establish the clinical appropriateness and usability of online health technologies [29], especially in nonstudent contexts. Given the potential benefit of these interventions for cost-effective delivery of interventions to large numbers of people, future research should incorporate economic analyses. As suggested by Copeland and Martin [24], the rigorous evaluation of online interventions would encourage their wider implementation and dissemination and increase their impact on public health and related service costs.

A significant challenge for this field is that advances in equipment, connectivity, and software capabilities are occurring much more rapidly than the evidence base can be fully established. In this context, recommendations for practice must necessarily rely to some extent on analogies from evidence that has been obtained on similar interventions using older forms of delivery. However, transfer of interventions to new modes of delivery run the risk of losing the key effective ingredients. It remains important that researchers respond rapidly to new technological advances, adapting treatments and routinely conducting trials to ensure that effects on alcohol use are retained.

As with all remotely delivered interventions, engagement of participants remains an issue. Internet-based interventions are likely to have greater reach if they are interfaced with targeted marketing campaigns or are embedded in routine primary care. Further research on the most effective marketing and widespread dissemination of these interventions is required.

Implications for Practice

While the current research evidence is fragmented and requires greater methodological rigor, it suggests that problematic or at-risk users may benefit from online alcohol interventions and that they may be a useful preventative and first step for groups such as women or young people who may not otherwise access more traditional AOD health services. Our confidence in these interventions is boosted by decades of research on bibliotherapies [55] and face-to-face interventions for alcohol use, including robust evidence in favour of brief interventions [56]. While further randomized controlled trials are required, there is sufficient evidence to suggest that standard health services and community campaigns evaluate and deploy online alcohol interventions to address alcohol-related problems.

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Conflicts of Interest

The writers have been involved in the development of online or telephone-based interventions for alcohol use but derive no commercial benefit from them.

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Abbreviations

AOD: alcohol and other drug
AUDIT: Alcohol Use Disorders Identification Test
BAC: blood alcohol concentrations
MI: motivational interviewing
RCT: randomized controlled trials
WHO: World Health Organization

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Viewpoint

Using Evidence-Based Internet Interventions to Reduce Health Disparities Worldwide

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Abstract

Health disparities are a persistent problem worldwide. A major obstacle to reducing health disparities is reliance on "consumable interventions," that is, interventions that, once used, cannot be used again. To reduce health disparities, interventions are required that can be used again and again without losing their therapeutic power, that can reach people even if local health care systems do not provide them with needed health care, and that can be shared globally without taking resources away from the populations where the interventions were developed. This paper presents the argument that automated self-help evidence-based Internet interventions meet the above criteria and can contribute to the reduction of health disparities worldwide. Proof-of-concept studies show that evidence-based Internet interventions can reach hundreds of thousands of people worldwide and could be used in public sector settings to augment existing offerings and provide services not currently available (such as prevention interventions). This paper presents a framework for systematically filling in a matrix composed of columns representing common health problems and rows representing languages. To bring the benefits of evidence-based Internet interventions to the underserved, public sector clinics should establish eHealth resource centers, through which patients could be screened online for common disorders and provided with evidence-based Internet intervention services not currently available at the clinics. These resources should be available in the patients' languages, in formats that do not require literacy, and that can be accessed with mobile devices. Such evidence-based Internet interventions should then be shared with public sector clinics as well as individuals anywhere in the world. Finally, this paper addresses sustainability and describes a continuum of evidence-based Internet interventions to share nationally and across the world. This approach to expanding health service delivery will significantly contribute to a reduction of health disparities worldwide, adding to the often-quoted slogan, "Think globally, act locally," a third line: "Share globally."

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KEYWORDS

Internet; online treatment; prevention; clinical trials; health disparities; consumable interventions; smoking; depression; public health; evidence-based; Internet interventions

Introduction

A Personal Comment

The author's commitment to using the Internet to help reduce disparities worldwide stems in part from his personal background. He grew up in a small community named Chosica, 40 kilometers east of Lima, Peru. When he was ten, his mother (Clara Luz Valdivia de Muñoz) informed him that the family was going to immigrate to the United States of America. His father (Luis Alberto Muñoz Camino) had a primary school education, his mother had completed high school, and they now wanted their children to attend university. Not being able to afford such in Peru, they were seeking the educational and economic opportunities available in the United States. The plan, his mother said, was for them to return to Peru after obtaining

a university education and share their knowledge with the people in Peru. As is often the case with immigrants, they did not return to live in their country of origin. But the mission she instilled in the author of sharing knowledge with as many people as possible remains an essential part of his motivation as a professional.

There are thousands of communities like Chosica throughout the world. The Internet provides an efficient conduit to convey to such communities the most effective preventive and treatment behavioral interventions in the form of evidence-based Internet interventions [1,2].

Objective

Described below are 5 types of Internet interventions. The least costly to sustain are automated self-help Internet interventions (without additional guidance by online, phone, or in-person providers). The author's experience conducting randomized controlled trials of such interventions with individuals from anywhere in the world has provided proof of concept regarding the effectiveness of such interventions for smoking cessation. This paper builds upon this experience and asks the reader to imagine how the use of evidence-based Internet interventions for this and other health problems could contribute to the reduction of one aspect of health disparities, namely, having inadequate or no access to evidence-based interventions.

Reliance on Consumable Interventions Limits Access to Health Care

There are over 1.1 billion smokers [3], over 121 million people with clinical depression [4], and over 76 million people with alcohol use disorders [5]. We will never train enough health care providers to administer adequate health care for all who need it if we continue our reliance on "consumable interventions," that is, interventions that, once used, cannot be used again. For example, a dose of medication can only be used once; the time spent treating a patient cannot be used ever again to treat another patient.

To reduce health disparities, we need interventions that can be used again and again without losing their therapeutic power, that can reach people even if local health care systems cannot or will not provide them with needed health care, and that can be shared widely without taking resources away from the populations where the interventions were developed.

Evidence-based Internet interventions meet all these qualifications. Evidence-based Internet interventions are empirically tested online methods to change individual behavior to prevent or ameliorate health problems. Medications are the active ingredient in many medical interventions; information in the form of "behavioral prescriptions" is the active ingredient in Internet interventions. Both can be standardized, evaluated using randomized controlled trials, and disseminated globally as long as users have funds to buy the medication or access the Web. Both can be used cross-culturally, as long as they are provided in a linguistically and culturally acceptable manner.

A major advantage of fully automated self-help Internet interventions is cost. Bringing a medication to market costs hundreds of millions of dollars [6] while developing an Internet intervention may cost as little as a few thousand dollars for a simple site, or, at most, several hundreds of thousands of dollars. Costs of testing a site in randomized controlled trials may run in the hundreds of thousands of dollars but, in general, require many fewer dollars per trial participant than face-to-face interventions. The differences in per-person costs of administering the intervention are even more impressive: a dose of a medication has a minimal cost even when bought in large quantities; the marginal cost of providing a self-help automated Internet intervention to one additional user eventually approaches zero. The cost of hosting the site remains a steady expense, of course, but, after the server has made the site available to say, 50,000 users, the cost of serving one more user becomes negligible. This makes it possible to share the site with people worldwide, without taking anything away from the communities where the intervention was developed.

Imagine: How Evidence-Based Internet Interventions Could Contribute to Reducing Health Disparities

Transcending Space and Time

There are health interventions that can transcend space. Traditional telemedicine consultation, for example, can connect a specialist with a primary care provider and a patient anywhere in the world. However, the time spent with a patient in another locale is time that is not being used to serve patients locally. Internet interventions transcend both space and time: they can be used simultaneously anywhere in the world, and they can be used again and again, at a time of the person's choosing, even if the specialists who developed and tested the site are no longer active professionally or even no longer alive. In this sense, Internet interventions transcend both space and time.

How Public Sector Clinics Could Use Evidence-Based Internet Interventions

Internet interventions could help extend health services to patients who are experiencing disparities in terms of care. Imagine that a Spanish-speaking patient who does not speak English arrives at San Francisco General Hospital. She is provided with a mobile device or directed to an eHealth resource room to be screened in her own language for the most common health problems (ideally using audio and video, should she not be able to read). The results would be printed in her own language and her providers' language (in this case, Spanish and English). If she meets criteria for major depressive episode, her physician might prescribe antidepressants and recommend cognitive-behavioral therapy for depression. If there are no cognitive-behavioral therapists who speak Spanish available, the patient could receive a cognitive-behavioral Internet intervention for depression in Spanish either at the eHealth resource room or, preferably, via a mobile device she could take home. Once such an intervention has been developed and tested at San Francisco General Hospital, it could be shared via the Web with any clinic anywhere in the world. A similar vignette could be described with a Quechua-speaking person going to a public sector clinic in Lima, Peru, or a Laotian-speaking patient at an Amsterdam clinic.

Live health care providers should not be replaced by Internet interventions, even evidence-based Internet interventions. Doing so would be a travesty. Each person who needs health care anywhere in the world should ideally be provided with a physician, nurse, psychologist, and so on, who are well trained to provide evidence-based interventions. Until this has been achieved, we should provide people with some intervention that is effective rather than not providing anything. Evidence-based Internet interventions are, at minimum, a temporary stopgap measure to provide needed interventions where none are available now. However, it will likely take many lifetimes, if ever, before adequate health care becomes accessible to all. Thus, efforts aimed at developing, testing, and disseminating nontraditional interventions to expand health services delivery are a good use of professional time and are sure to benefit large numbers of people [7]. Studying the comparative effectiveness of these interventions, including Internet interventions, for specific health problems in specific populations, would bring empirical evidence to bear on how best to utilize such interventions.

Addressing Unmet Needs

Internet interventions can be used:

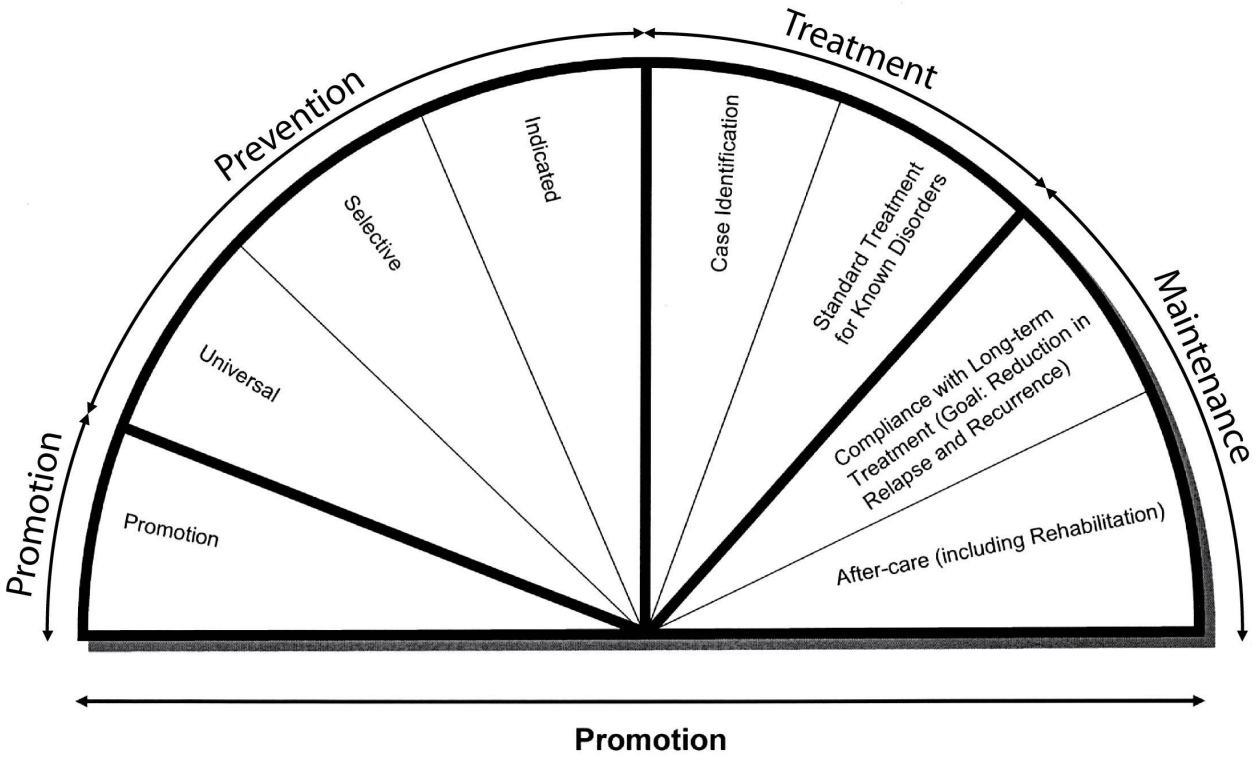
- When no other interventions for specific health problems are available
- While patients are on waiting lists, for example, during the weeks between being referred for treatment and the time a slot is open for a smoking cessation group or a depression group
- During routine treatment, as an adjunct, for example, offering an Internet cognitive-behavioral intervention as an adjunct to pharmacotherapy for depression offered in a primary care clinic
- After treatment, to prevent relapse or recurrence
- For patients who cannot travel to clinics due to distance, physical limitations, time limitations, or economic limitations
- For patients who fear stigma if they come to a mental health clinic
- For patients whose providers do not speak their language
- To extend health care beyond treatment into prevention

Beyond Treatment: Providing Preventive Interventions

The Institute of Medicine (IOM) of the United States of America has published two reports on the prevention of mental, emotional, and behavioral disorders; one, in 1994 [8] and the second, in 2009 [9]. These reports call for changes in health care policy to include prevention as a routine offering. Preventive interventions have been shown to reduce the incidence (that is, the number of new cases) of mental, emotional, and behavioral disorders. Health care systems currently spend most of their resources on treatment. They do this to reduce the prevalence of disorders, that is, the total number of cases of illness. However, one way to reduce prevalence is to reduce incidence, that is, the number of new cases. To reduce incidence, effective preventive programs must be provided. Health care administrators are in a dilemma. Facing limited budgets, they often find it hard to channel funds into prevention when they feel they are not providing adequate treatment services. Could Internet interventions help?

The 1994 IOM report argued that it is important to define prevention as interventions that occur prior to the onset of the targeted disorder (see Figure 1). Individuals with the disorder need to be identified and provided treatment. Once the acute phase of the disorder has abated, maintenance interventions should be provided to prevent relapse or recurrence or to provide rehabilitation services to reduce the sequelae of the acute episode. Prevention is itself divided into 3 levels: *universal* interventions for entire populations, *selective* interventions for subgroups at higher risk because of characteristics that are known to increase incidence (eg, poverty, trauma, or loss of a loved one), and *indicated* interventions for individuals showing early signs or symptoms of the targeted disorder but not yet meeting diagnostic criteria.

Figure 1. The mental health intervention spectrum [9] (Reprinted with permission from Preventing Mental, Emotional, and Behavioral Disorders among Young People: Progress and Possibilities, 2009, National Academy of Sciences, by the courtesy of the National Academies Press, Washington, DC.)



Let's look at a specific disorder. There are now many studies showing that prevention interventions can significantly reduce the number of new cases of major depression [10]. Yet, these interventions are not routinely offered. Even where preventive interventions have been developed and tested, once research funding ends, the institution generally does not fund ongoing prevention services. However, if the preventive intervention were an Internet intervention, maintaining the site online would not only provide access to the intervention (as tested) for the local setting, but for thousands or even hundreds of thousands of people who would otherwise not receive the benefit of preventive interventions.

Are Evidence-Based Internet Interventions Effective in Real World Settings?

The argument presented thus far assumes that Internet interventions can be effective. Is there evidence for such a claim? Isaac Marks and colleagues have reviewed an impressive collection of studies that support the contention that computer-assisted therapeutic interventions can, in fact, be effective [11,12]. Formal meta-analyses of the literature have also shown evidence of effectiveness for many health problems [13,14]. More recent reports continue to show empirical support for the effectiveness of Internet interventions [15,16] and their potential for both prevention and treatment [17,18]. Several articles have addressed the scientific foundation of Internet interventions [19-24].

The Latino Mental Health Research Program of the University of California, San Francisco, at San Francisco General Hospital, began work in this area in 1998. Until then, we had been developing and testing face-to-face individual and group interventions for the prevention and treatment of depression and for smoking cessation in English and Spanish, while some had been developed in Chinese as well. Our manuals, designed to train and help providers administer prevention and treatment interventions with fidelity to the intervention protocol as designed, are available at the UCSF/SFGH Latino Mental Health Research Program website [25] at no charge to anyone who wants to use them. We have had thousands of downloads of these materials. They are used in several countries and have been tested in randomized control trials in many settings with success [1]. However, a health care provider is needed to administer these interventions. Even where there are providers, clinicians tend to "drift" away from the treatment protocol due to time constraints, theoretical predilections, lack of experience, or simple human error [26]. Thus, even manualized interventions are often not provided as tested in randomized control trials.

Concerns that many communities have no access to trained professionals to administer our manuals prompted our group to begin experimenting with creating automated self-help Internet interventions and testing them in randomized control trials conducted on the Web. Thus, the intervention is tested exactly as it will be provided after the trial ends. This eliminates the problem of "drift." In addition, the intervention is designed to be used directly by the individual and does not require the availability of a health care provider. Nor does this approach require the difficult negotiations involved in trying to convince regional, national, or international health care systems to institute empirically supported services.

We began our research on evidence-based Internet interventions with smoking cessation interventions to determine whether we

could "match the patch," that is, obtain abstinence rates comparable to those found for the nicotine patch. Randomized trials comparing placebo patches with nicotine patches have found 6-month quit rates of 5% to 8% for placebo patches and 14% to 22% for nicotine patches [27]. Because of the well-known problem with attrition in Internet studies [28], we used the conservative "missing = smoking" convention in which a participant who does not provide data is assumed to be smoking. Using this convention, we have obtained 6-month quit rates as high as 26% [2] and 12-month quit rates of 20% [29]. Our trials thus far have involved over 60,000 consenting smokers from over 200 countries (for a report on the reach of one of our trials, see [30]). But well over 600,000 visitors have come to the site, where they can download our Guide to Stop Smoking without having to join the study. We have been able to recruit people worldwide with the help of a Google grant that allows us to post "sponsored links" (ie, Google ads) on its search engine, in English and in Spanish, all over the world.

A Proposal to Create a Central Exchange for Evidence-Based Internet Interventions

Our smoking cessation trials are proof of concept for how evidence-based Internet interventions can provide health interventions worldwide. The Latino Mental Health Research Program established the University of California, San Francisco/San Francisco General Hospital Internet World Health Research Center in 2004. Our goal is to systematically develop and test evidence-based Internet interventions to fill in a matrix of evidence-based Internet interventions for health problems by languages (see Table 1).

Table 1. Matrix for systematic development of evidence-based Web interventions: health problems by languages (our goal is to fill this matrix)

	Smoking	Depression	Pain	Diabetes	Obesity	Additional Health Problems
English						
Spanish						
Chinese						
Arabic						
Portuguese						
Additional languages						

This grid is infinitely expandable and will require the contributions of many health experts for the foreseeable future. A third dimension to the grid could represent specific subpopulations (men and women, young and old, diverse ethnic groups, preliterate and well-educated, rich and poor, and so on).

Once evidence-based Internet interventions become more numerous, we will need a system to help users choose among the many interventions that will populate the Web. The author proposes that a credible international body, such as the World Health Organization, create a Website to function as a central exchange or clearinghouse for empirical information on evidence-based Internet intervention sites. A site already exists, called "Beacon" [31], that lists Internet intervention sites and rates them on their empirical support. To expand upon this idea, a central evidence-based Internet interventions website could itself conduct randomized control trials of Internet interventions submitted to the clearinghouse. This would standardize recruitment procedures, administration of the interventions, and outcome assessments. The central evidence-based Internet intervention website would then provide a "box score" on the results. Users would be able to enter demographic data (eg, sex, age, language, and educational level) and receive outcome data for that subset of participants and the number of individuals on whom these data are based. Cost for use of commercial sites would be included, so public and commercial sites could be compared head to head.

Users could search for Internet interventions for depression, for example, and find the box score site for their demographic profile (See Table 2). Users could then decide whether the public site (Site B) would be worth trying. If they did so and site B did not help them, and if they chose to pay the price ($49), they could try site A. However, they may decide that site C might not be a good use of resources because it is both relatively expensive ($250) and its outcomes are inferior to sites A and B.

Table 2. Simplified illustration of how a central website for evidence-based Internet interventions might present data for a specific demographic profile

Website Intervention to Manage Depression	No Longer Depressed	Noticeably Improved, but Not Back to Normal Mood	Cost
A	52%	30%	$49
B	36%	54%	Public access
C	22%	20%	$250

Discussion

Sustainability

To reduce health disparities, evidence-based Internet interventions should be available worldwide at no charge. This would encourage public health clinics to maintain eHealth resource rooms for low- or no-income patients. It would also provide users who are unable to pay and who have no access to clinics with access to the evidence-based Internet interventions. The bulk of the cost of self-help automated Internet interventions is in their development and the research costs of testing them. Once found effective, keeping these Internet interventions active online requires a relatively modest expenditure. Nevertheless, the cost of maintaining these sites is not zero. Staff is needed to monitor emails from users who request help in using the site or send complaints or thank-you messages and to host and troubleshoot the site. Unless a major donor or global health organization provides ongoing funding for such sites, developers will need to create a revenue stream to maintain them.

One possibility would be to use evidence-based Internet interventions themselves to generate revenue and then funnel the revenue into the creation and maintenance of additional sites for other health problems and languages. For example, an evidence-based Internet intervention found to be effective for smoking cessation could be licensed to a health maintenance organization or a multinational corporation so the members or employees of these organizations could have special access to the site. The funds from the license could be used to maintain both the private site and a public version of the site.

Commercial versus Public Access Evidence-Based Internet Interventions

Successful commercial sites are likely to have bigger budgets, faster development times, and a profit motivation to reach more people. Disadvantages of commercial sites include perceived conflict of interest in terms of providing honest reports of participants' outcomes, similar to the concerns over pharmaceutical companies providing accurate and complete reports of the benefits and risks involved in using their products. There is also the danger that commercial sites may copyright or patent interventions that were formerly freely accessible, thus making them "proprietary." Advantages of public access sites could include becoming known for their high quality in the same way that public television programming in the United States has achieved an excellent reputation [32]. Public access sites would reach those in need regardless of their ability to pay and regardless of the local health authorities' ability or commitment to fund the sites. The outcome studies of such sites would be more credible, since financial conflict of interest would be less of an issue. Disadvantages of public access sites include the constant need to seek funding from donors, a slower pace in developing interventions, due in part to funding issues, and the possible perception of lower quality (ie, "you get what you pay for").

Five Levels of Internet Interventions

Most health care providers aspire to a world in which everyone has access to needed health care. This would include access to well-trained providers who can administer evidence-based interventions, including preventive, treatment, and maintenance interventions. This ideal is unlikely to be achieved in the foreseeable future. But it is possible to begin to approach this ideal by systematically creating a continuum of health interventions that utilize evidence-based Internet interventions.

Level 1: Automated Self-help Internet Interventions

These evidence-based Internet interventions are the most likely to contribute to the reduction of health disparities worldwide because they have the lowest ongoing cost. They consist of health behavior change interventions that are totally programmed. They can be individualized to as great an extent as programming allows, including sending individually timed educational messages (ITEMs, see [33]) or adapting the site automatically to address any number of demographic characteristics including language, gender, age, educational level, religious preferences, and so on [34]. These evidence-based Internet interventions require funding for development and for testing in outcome studies. Once this is done, they require funding for hosting, maintenance, and updating of the site, in addition to staff to respond to technical support questions. Thus, sustainability requires relatively modest ongoing support. There is no upper limit to how many people can use these interventions. They can be used worldwide even where no other health care services are available. The field of health care should endeavor to provide this type of intervention for the most burdensome global health problems as a minimal service available to anyone in the world at no charge to them. Localities with more resources could build upon this basic level by providing additional services from any of the following 4 levels.

Level 2: Guided Internet Interventions

These evidence-based Internet interventions add live support (staff-generated emails, text messages, or phone calls; advice on which elements of the site to use; encouragement, and so on). Such interventions tend to have larger effect sizes [35]. They require staff time to prepare individualized emails or phone calls, which brings them into the "consumable" arena and sets upper limits to the number of people served. Most such sites also limit the geographical reach of the site based on who is paying for the staff providing individual guidance (local, regional, or national public health entities). But they can be stand-alone services and do not rely on having an existing health care system in place.

Level 3: Internet Interventions as Adjuncts to Existing Health Care

These evidence-based Internet interventions expand available interventions in existing health care settings, helping provide services to patients on long waiting lists, supporting active treatment regimens (for example, helping patients to adhere to treatment between medical appointments), and helping reduce relapse and recurrence after acute treatment ends by reminding patients to monitor their status and continue self-care.

Level 4: Internet Interventions to Expand Health Care Beyond Current Offerings

An example of expanding health care beyond current offerings is a health care system that would use Internet interventions to move beyond treatment into both prevention and health promotion or to provide services to patients receiving inadequate care because they do not speak the languages available from local providers.

Level 5: Proactive Internet Interventions

Most current health care systems wait for people to seek help before providing it. The fifth level of intervention involves proactive identification of individuals in the community who are not already coming for services but who need interventions to prevent or manage health conditions. Internet interventions at this level would provide behavioral methods for individuals to use in the community, and, if these methods did not work, the individuals would be encouraged to seek health care at existing facilities. This level provides active case finding and preventive or treatment services in people's homes. Such services would be considered prohibitively expensive by most health care systems, which is why they are not generally available. An experimental example using face-to-face approaches is the Outcomes of Depression International Network (ODIN) project in Europe [36,37]).

To envision how Internet interventions could contribute to the reduction of disparities in access to health care worldwide, imagine the systematic development and testing of Level 1 (automated self-help) Internet interventions for the health problems that produce the largest burden of disease in the world [38]. As these evidence-based Internet interventions are made available at no charge worldwide, individuals and public sector health care settings anywhere in the world would immediately benefit from them. This alone would contribute to the global reduction of health disparities. Settings with the economic resources and political will could build upon the Level 1 (automated self-help) evidence-based Internet interventions, augmenting care to Levels 2 through 5.

Think Globally, Act Locally...and Share Globally

The often-quoted dictum to "think globally" (that is, consider issues that affect humanity) and "act locally" (begin addressing these issues where you live) can be extended by using the Internet to "share globally." For example, smoking is the number one cause of preventable death worldwide, with over five million people dying each year from tobacco-related diseases [39]. Depression is the number one cause of disability worldwide by a wide margin [38]. It is imperative that health care systems address both of these sources of unnecessary human suffering. Our research group at the University of California, San Francisco, at San Francisco General Hospital (one of our teaching hospitals) has been doing work to address these health problems with local populations for years [1]. Many individuals in San Francisco have benefited from these efforts. But once we began developing Internet interventions and testing them in randomized controlled trials, we were able to share our knowledge with hundreds of thousands of people from over 200 countries. Our outcome studies open to the entire world are difficult to categorize: are they efficacy studies or effectiveness studies? Although some of our studies are strictly randomized controlled trials, they are open to any adult in the world who wants to quit smoking. Thus, the studies are tests of effectiveness in the real world. Outcome studies in specific communities or health settings would help determine whether our findings generalize to specific locations and subpopulations. An additional benefit of Internet interventions is that they can reduce the estimated average interval between the time a health intervention is found to be effective in a research context and the time it is actually used routinely from 17 years [40] to a few hours. On the day we stopped recruitment for a recent randomized controlled smoking cessation trial, we switched our site to a participant preference trial in which any adult smoker from anywhere in the world was provided access to all active elements that had been tested in the randomized trial. Thus, the automated self-help site [41] was left up and running without charging users, while still obtaining outcome data on an ongoing fashion.

Conclusion

To reduce health disparities worldwide, the international community should develop a system to provide evidence-based Internet interventions at no cost to the users. To launch this process, funding agencies and globally minded foundations or corporations would provide ongoing support to host and maintain automated self-help Internet interventions. The number of people who could benefit from such evidence-based Internet interventions would be massive. The return on investment on Internet interventions that can be used again and again is much higher than from provision of consumable interventions whose therapeutic power is spent after one use. The geographical reach of evidence-based Internet interventions is literally worldwide. This initiative is a worthy and feasible challenge for the 21st century.

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Conflicts of Interest

None declared

Multimedia Appendix 1

Original PowerPoint presentation from Amsterdam conference on which the manuscript is based

[PPT file (Microsoft Powerpoint File), 35,151 KB - jmir_v12i5e60_app1.ppt]

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Abbreviations

ITEM: individually timed educational messages
IOM: Institute of Medicine
LMHRP: Latino Mental Health Research Program
ODIN: Outcomes of Depression International Network
SFGH: San Francisco General Hospital
UCSF: University of California, San Francisco

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Tutorial

Security Considerations for E-Mental Health Interventions

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Abstract

Security considerations are an often overlooked and underfunded aspect of the development, delivery, and evaluation of e-mental health interventions although they are crucial to the overall success of any eHealth project. The credibility and reliability of eHealth scientific research and the service delivery of eHealth interventions rely on a high standard of data security. This paper describes some of the key methodological, technical, and procedural issues that need to be considered to ensure that eHealth research and intervention delivery meet adequate security standards. The paper concludes by summarizing broad strategies for addressing the major security risks associated with eHealth interventions. These include involving information technology (IT) developers in all stages of the intervention process including its development, evaluation, and ongoing delivery; establishing a wide-ranging discourse about relevant security issues; and familiarizing researchers and providers with the security measures that must be instituted in order to protect the integrity of eHealth interventions.

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KEYWORDS

Mental health; health technology; Internet; implementation; confidentiality; data collection; privacy; computer security

Introduction

Over the past decade, there has been a rapid growth in provision of online health interventions and the scientific evaluation of their efficacy and effectiveness [1]. A high standard of data security is critical to the overall success of any eHealth project whether it is concerned with scientific research or the provision of eHealth services. However, security considerations are typically an overlooked and underfunded aspect of the development, delivery, and evaluation of eHealth interventions. Moreover, the training of eHealth researchers rarely equips them to understand the key issues and challenges associated with online data security.

Scope and Context

This paper is intended as a brief primer on data security for eHealth intervention researchers and providers. It aims to highlight the complexities and challenges associated with the security of eHealth interventions with the intention of better informing the activities of eHealth professionals who are not information technology (IT) specialists. It is not a comprehensive or systematic review of all security issues within the eHealth field and is not intended to provide specific risk mitigation solutions. Rather, it aims to highlight some key areas for consideration and to suggest measures that may help to address the major security risks of relevance to those commissioning and managing the development and delivery of interventions.

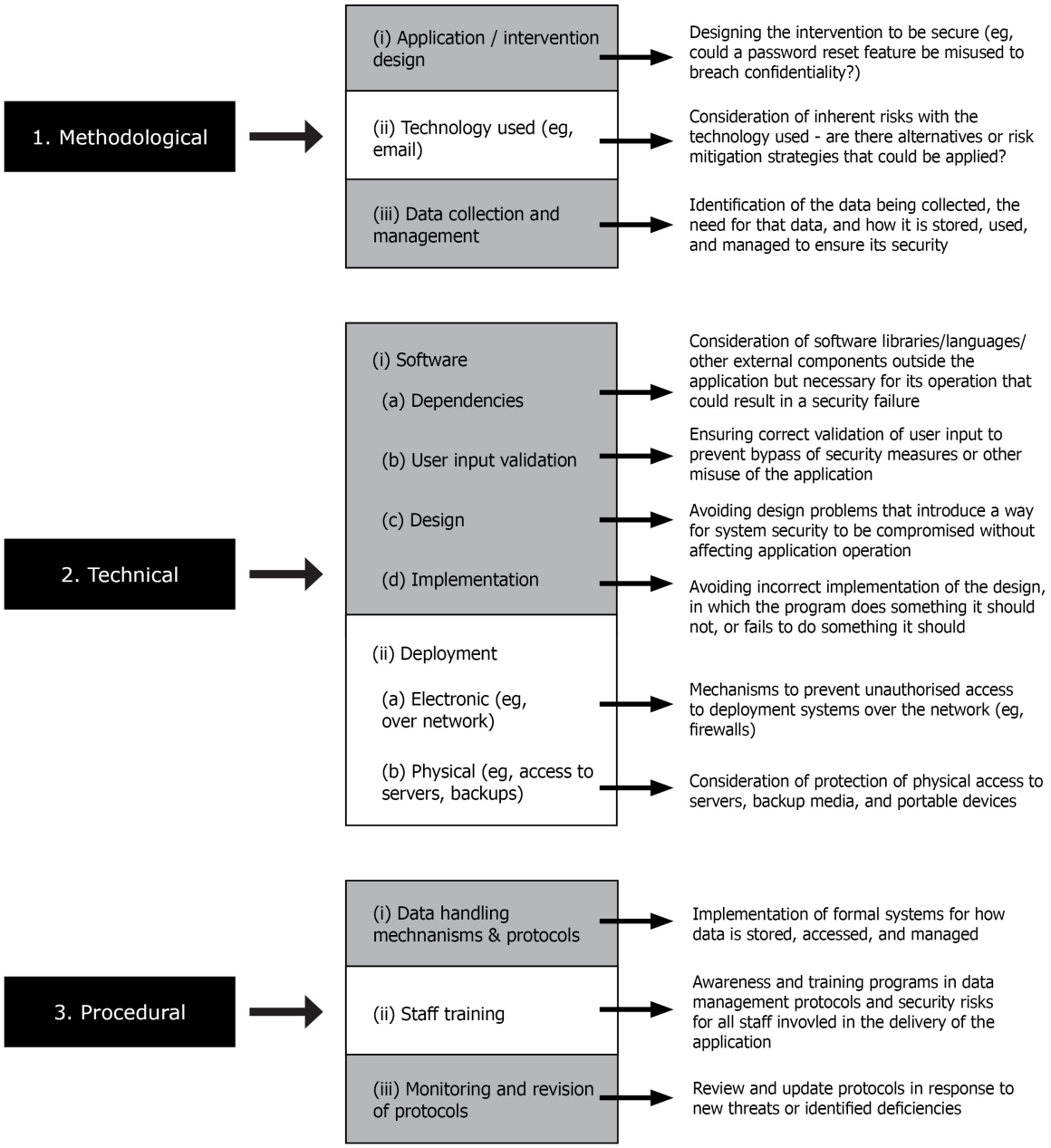
The discussion focuses on security considerations pertinent to *individual* software applications that are accessed by consumers for health prevention or treatment purposes either in research or "real-world" settings. Some of these security issues are illustrated with a focus on e-mental health interventions. This is for 2 reasons. First, the authors have many years of experience managing security issues in the e-mental health intervention domain both with respect to research and large-scale service provision. Secondly, security considerations are particularly critical in the domain of eHealth service provision and research due to the highly stigmatized nature of mental illness. The

increasing popularity and availability of e-mental health interventions over the past decade has prompted psychological societies across the world to develop specialized guidelines for psychologists engaged in e-mental health activities [2-4]. These developments promote professional and ethical practices and are important for the protection of consumers of e-mental health interventions. However the realization of ethical standards is complicated in the realm of e-delivery. In particular, protection of consumer privacy and confidentiality, a central principle of professional psychological services, evolves into wide-ranging technical and nontechnical security considerations that need to be addressed.

Definitions and Key Security Areas

For the purposes of this paper, we use the term "security" to refer to the implementation of appropriate safeguards to protect user privacy and confidentiality. In the context of eHealth interventions, this means the appropriate collection and handling of user data, the protection of data from unauthorized access or modification, and the safe storage of data. Further, we distinguish between *methodological*, *technical*, and *procedural* security (see Figure 1). Methodological security is concerned with how the overall service is designed and what types of technology are used for which purposes. Technical security relates to how the software is developed and how it operates. Finally, procedural security refers to how the operators of the intervention handle and store collected data. Each category is separately examined in the next section.

Figure 1. A summary of key security issues in the eHealth intervention environment



There are no statistics on the overall prevalence of different types of security breaches in the domain of eHealth or e-mental health. However, a recent study of identity theft in the United States identified 115 reported breaches of security in the health care sector over a 3-year period [5]. Of these, 45% were classified as “hardware” problems whereby sensitive data stored on a physical device (eg, laptop or server) was compromised through unauthorized physical access to the device. A further 43% of breaches resulted from mishandling or misuse of data (including lost or stolen documents and media, processing errors, and incorrect disposal of data) and can be classified as procedural breaches. In total, 8% of the reported security breaches arose from intentional insider misconduct, and only 4% of the reported security breaches arose from the exploitation of a vulnerability in the application or system.

These findings emphasize the importance of taking steps to avoid hardware and procedural breaches in the deployment of eHealth interventions. However, clearly all areas of possible vulnerability must be addressed given the potentially high cost of even a single breach. Moreover, failure to address one category of vulnerability can render other security precautions useless. For example, a technical compromise that enables an attacker to gain remote access to an application database bypasses even the best measures to physically protect that hardware.

Types of Security

Methodological (Design) Security

Methodological security focuses on the risks associated with how an application is designed to operate, that is, which technologies are used and for what purpose. These issues must be considered as early as possible in an application's development cycle since they are critical to much of the development process and impact on the required resources and timeline for the project.

Risk mitigation related to methodological security requires an understanding of the requirements and limitations of privacy protection in both intervention research and application development. For example, suppose an e-mental health intervention aims to facilitate online contact between a therapist and a client. In the first instance, the researcher or practitioner may conceptualize this as "email counseling." However, email technology may not be the most appropriate communication method for this purpose since it is an inherently insecure medium. Although it is possible to institute precautionary measures such as email encryption, the operation and management of such measures pose significant challenges. For example, there are practical difficulties associated with securely swapping and storing encryption keys and the need to deal with multiple encryption standards [6]. In this situation, a more appropriate approach would be to use a secure, access controlled user environment within which the client can access and post messages from and to the therapist. Since the technological development process and associated procedural and technical security considerations are very different for each approach, it is critical that this is issue be addressed at the outset.

Another methodological security consideration involves deciding which data is collected and stored by the program and for what purpose. Data may be collected to facilitate the research and evaluation aims of the program and/or user information may be required for the software to operate as intended. In both cases, the collection and storage of data and access to these data need to be informed by ethical standards of research and health care delivery. The technical and procedural considerations that arise from the collection of these data will depend on their nature and purpose.

For example, suppose a user's age is collected for the purpose of evaluating the relative effectiveness of an intervention in different population groups. Alternatively, a program may require information about the user's age range in order to tailor the content to the user. A first consideration is whether a broad age range is sufficient for the intended purpose or whether more specific information is required. The more specific the information collected, the greater the possibility that an individual may be individually identifiable. This may be particularly true if the information is collected in the context of other personal data. Information that is not identifiable in isolation may be identiable when taken together with other data. The severity of a breach increases with the sensitivity of collected data. Thus, an important risk mitigation measure involves identifying the minimum level of detail required when collecting personal data. For example a user's precise date of birth may be required in some circumstances. However, if the year of birth is sufficient, only this level of detail should be collected.

A further concern is the user's role or potential to cause a confidentiality breach, for example, by losing or otherwise exposing their account details to others including those whom they may trust. For example, a person with access to a user's email account may abuse a password-reset feature to gain access to an individual's data on an e-mental health program thereby gaining access to sensitive personal information. Consideration should be given to the potential risks and ways in which the design or the information provided to users can mitigate these risks.

Technical Security

The technical implementation and operational environment for an eHealth software application consists of many different IT and communication components. These include but are not limited to programming languages, databases, server hardware, data storage and backup systems, network switches, routers, and firewalls. Multiple IT specialties are involved in the management of this complex environment, including software engineering, system administration, database administration, and network engineering.

Although technical security considerations are complex and multifaceted, they can be broadly separated into 2 components: (1) the software application itself, and (2) the infrastructure (deployment environment) used to deliver it to end users. Each of these areas needs to be considered.

Software Application

It has long been acknowledged in the software engineering discipline that software defects arise not only as a result of coding errors, but also during the specification and design phases of a project. During the software development and testing phase, a common error is to focus solely on functional requirements (what the application will do) and ignore nonfunctional requirements such as the more difficult and specialized task of security testing [7,8]. Whereas functional testing focuses on ensuring the program does what it *is supposed to do*, security testing involves finding defects or flaws that allow an attacker to do something they are *notsupposed to be able to do*. The latter is an inherently much more complicated challenge.

Consideration needs to be given to four common types of security failures [7]. These include (1) dependency insecurities and failures, (2) unanticipated user input, (3) design insecurities, and (4) implementation insecurities. Each of these is described below.

Dependency Insecurities and Failures

Dependency insecurities and failures are problems that occur when an external component that is used by an application contains a security vulnerability, or when an external component that provides security fails or becomes unavailable. In such cases, the application itself is secure, but a component it depends on is not, and this creates a security risk for the application. Most software, particularly Web applications, are dependent on a wide range of external components and applications in their

delivery, and multiple examples of insecurity abound. As of January 2010, the US Government-operated National Vulnerability Database listed 40,260 unique vulnerabilities within operating systems, library functions, and applications that have been identified since the database began in 1999 [9]. Examples of particular relevance to eHealth interventions include database server vulnerabilities [10], Web server vulnerabilities [11,12], and faults within the programming language itself [13].

An insecurity with an external component does not necessarily mean the application can be or has been compromised. A vulnerability in a complex piece of software such as a database server may have no relevance to or impact on the application. It may be safe to delay the application of some fixes while ensuring others are urgently applied. What is important is that relevant IT expertise is used to make and act on such decisions.

All software applications depend on external components whether they are associated with the deployment of the application or are software components incorporated as part of the development of the application. In order to mitigate the risks associated with these components, it is essential that eHealth interventions are developed and deployed by IT experts with the knowledge and expertise necessary to manage issues associated with the application's external components. This includes knowledge of each library or external component that has been introduced to the application environment (such as software libraries), and the expertise to identify and resolve any security problems associated with external dependencies. This in turn requires subscription to appropriate security bulletins that provide alerts about new potential issues; a competent evaluation of the impact of the vulnerability on the application itself particularly with respect to any implications it might have for user privacy and confidentiality; and testing and immediate deployment of relevant patches in situations that are deemed to pose a risk.

It is important that such IT security expertise is available throughout the life of any intervention and not only during the development phase. Although an application may meet security requirements when it is launched and first delivered, it may be identified as being subject to serious security risks over time. In such cases, the risk is not necessarily associated with any fault in the intervention software. Rather it may be due to the emergence of a newly identified security risk in an external component.

Dependency insecurities involving components directly used by applications are often less publicized than those involving components used in the deployment of applications (such as operating systems) since they are used by fewer applications. Clearly, however, they can be just as important. This is illlustrated by a flaw in commonly used bulletin board software that allowed a hacker to determine the password hash of a user, inject that into the log-in process, and log in as the user [14,15]. For applications that use such an affected component, the security flaw and available solutions (workarounds and installation of patches) need to be examined and a risk mitigation strategy adopted as a matter of urgency. This is particularly important since many hackers will specifically target unpatched security flaws once they are reported in the public domain.

Mitigating risks of dependencies that are associated with the *deployment* of the application (such as operating system or Web server flaws) are discussed as part of deployment environment considerations.

Unanticipated User Input Problems

Unanticipated user input problems arise where a software application does not correctly identify invalid or unexpected input or fails to correctly handle it. In the context of Web-based eHealth applications, this can compromise stored data, for example, through structured query language (SQL) injection and cross site scripting (XSS) attacks [16,17]. SQL injection [16] enables an attacker to modify database commands and potentially execute completely different commands. This can lead to a data breach since checks and constraints that control access to the stored datasets can be removed. XSS attacks [16] involve insertion of additional code into a Web page that is viewed by others. This could occur for example on a bulletin board where a user writes a post that includes malicious hypertext markup language (HTML) code. When this post is displayed to other users, the code may trigger a number of undesirable and potentially serious consequences, such as embedding content from a malicious website or reporting the user's session information back to an unauthorized server. The potential impact of these kinds of attacks on the protection and integrity of user data cannot be understated. Fortunately, with appropriate software development, these risks can be (relatively easily) mitigated.

Each of these problems occurs as a result of an application failing to correctly "escape" control characters in the input (eg, quotation marks, semicolons, or html tags) that when inserted in a different context (eg, an SQL statement or an html page) have a different meaning and are executed differently. Input provided by a user should always be assumed to be potentially hostile, and any input that could represent code in a different context should be escaped or removed. More generally, software should always validate input data [18,19]. Validation should occur on length (whether too long or too short) and type (eg, integer or string), and input should be examined on syntax or range as appropriate (eg, does it match the format of an email address or a postal code). The Open Web Application Security Project advocates 3 data validation approaches: acceptance of only known data, which are validated against a white list of known "good" values; rejection of data known to be problematic, such as input containing invalid data; or sanitization of problematic data into an acceptable format [18].

All eHealth interventions should be developed to validate input data and deal with invalid data appropriately. This is an essential aspect of protecting user confidentiality and privacy that should be routinely considered as part of any application development.

Design Insecurities

Design insecurities are flaws that are introduced at the design stage. These are oversights or failures that are inadvertently designed into the application. Design flaws are often not detected during normal testing. Such flaws can be quite simple,

such as not observing that 2 systems communicate confidential data in an unencrypted form over the Internet. Often, however, they are more complicated. For example, in July 2008 the United States Computer Emergency Readiness Team identified a flaw in the way domain name system (DNS) servers verify responses that could allow an attacker to introduce fake entries such that a user would be sent to an incorrect server designed to steal confidential information or install malicious software [20]. The vulnerability relied on the attacker being able to set up his or her own DNS server and apply clever timing in order to exploit it. This flaw posed a risk with serious privacy implications for affected users.

The logical approach to mitigating design insecurities is to reduce the risk that they occur in the first place, particularly given that design flaws are difficult to detect in testing and that the earlier they are found, the less expensive they are likely to be to fix [21]. Such analysis of design is a knowledge intensive process [22]. Therefore the best approach for mitigating design flaws in eHealth interventions is to ensure that they are developed by IT specialists who have a good understanding of possible design risks within the context of eHealth. Those commissioning the development of the interventions should be aware of the need to employ specialists who can apply such approaches in the design process. Examples include Microsoft's STRIDE approach [23] (STRIDE is an acronym for spoofing, tampering, repudiation, information disclosure, denial of service, and elevation of privilege), which applies threat analysis to each component of the system model and Verdon's risk analysis process model, which is applied at the design phase [22]. Moreover, it is important to ensure that IT staff employed on an eHealth project stay informed of design flaws that are reported in other applications, such as through the publication in Common Vulnerabilities and Exposures [24].

Implementation Insecurities

Implementation insecurities are bugs in the coding whereby the application *does not correctly do something that it is designed to do* (such as performing a validation check on a certain type of input data) or where it *does something that was not intended* (such as creating a temporary file containing confidential information on the server without appropriately securing access permissions). These bugs may unintentionally disable or compromise security measures that were part of the application's design.

The employment of programmers who use appropriate software development methodologies can minimize the frequency of defects occurring in the first instance. Nevertheless, testing for implementation errors is a core element of any software development life cycle [25]. It establishes whether a coded piece of software operates as it was intended. This includes whether it protects user privacy and confidentiality. Testing processes need to be planned, efficient, and systematic to ensure bugs are detected and rectified within time and resource constraints. The testing must involve both those who commissioned the eHealth intervention and those responsible for the IT development of the software. Accordingly, researchers and providers must allocate sufficient time and resources to the iterative testing phases as part of the development process.

Deployment Environment

The deployment environment refers to how the software application is delivered—including electronic aspects (such as server operating systems and access controls) and physical aspects (such as physical location of the servers themselves). Security considerations within the deployment environment include the protection of stored data from *electronic threats* (such as unauthorized electronic access to servers or a vulnerability in an operating system) and *physical threats* (such as those that result from unauthorized physical access to a server).

As previously noted, a privacy breach associated with the electronic compromise of systems is uncommon; however, when it occurs it can have a major impact. Electronic risks can be mitigated by assigning staff with appropriate skills to the task of monitoring and managing deployment systems throughout the life of the application. This will include safeguarding against the security risks associated with external dependencies.

Physical hardware breaches occur more frequently despite the fact that they can be prevented readily. This suggests that, in practice, protection against such threats is often not appropriately prioritized. In the deployment environment, protecting against physical hardware risks involves preventing unauthorized physical access to servers and the use of backup media and other data storage devices.

Often organizations providing small-scale eHealth interventions do not directly manage the deployment environment used to deliver their programs or are responsible for only a small section of it. This is not necessarily undesirable since it may provide the eHealth provider with access to specialist skills and existing infrastructure. For example, eHealth teams based at universities may rely on their university's general IT infrastructure and staff, and small research organizations may employ professional hosting providers to deliver their programs. However, the reliance on external others does not mean that providers can ignore the security risks associated with this key component of the application's delivery.

All eHealth intervention providers should inform themselves of the types of practices that contribute to a secure deployment environment so that they can ensure that implemented strategies are commensurate with their expectations of user privacy and confidentiality protection. Providers should be aware of the common strategy of "defense in depth," that is, multiple layers of security should be implemented to ensure that a failure at one point does not compromise the system. For example, a firewall implemented on a server would guard against the failure of a firewall higher up in the network topology.

Table 1 provides a set of questions and topics that should be discussed with whoever is responsible for the deployment environment. It is not an exhaustive list, and it may be most appropriately undertaken in the context of a broader risk management analysis. However, it provides a starting point for researchers or developers who have limited knowledge of the issues of application delivery and addresses the major threats to confidentiality identified by others in the field of public health e-implementation [26]. Obviously, the inclusion of technical

staff within the research and development team will increase the specificity of the discussed safeguards, but even without this expertise, intervention providers should take responsibility for ensuring that basic measures are in place to protect the data they collect.

Table 1. Examples of questions that are relevant to the deployment environment

Area	Question	What it Means
Data: servers	Where are the servers located?	Knowledge of all physical locations where the data will reside, including off-site or redundant systems
	What are the physical protection measures for the servers?	Knowledge of the strength of physical access controls such as door locks/access cards, locks in server racks, monitored closed circuit television
	Who has access to the servers? How is this access controlled and monitored?	Knowledge of who has physical and electronic access to servers, who grants this access, and how access is revoked when no longer needed or at the end of a staff member's employment
	What is the disposal policy for old or failed hardware?	Knowledge of how old drives and media are secured is necessary. Appropriate measures include secure erasure and physical destruction.
	What remote access is there to data on the servers, and who has access to these data?	Identification of the means by which data can be remotely accessed, such as over file shares or use of remote access utilities, and who has access to these
Data: backups	Where are backups stored?	Knowledge of all physical locations where backup media will be stored, including off-site locations
	How are backups transported to storage?	If backup storage is physically separate from servers, ensuring that backups are safely transported to storage locations
	Who has access to the backups? How is this access controlled and monitored?	Identification of who can access the backups, who grants this access and how it is revoked when no longer needed or at the end of a staff member's employment
	Is encryption used? Who has access to the keys/passwords?	Encryption reduces the risk of a breach if media are lost, stolen, or disposed of incorrectly. If there is no encryption, safe physical storage becomes even more critical.
	What is the disposal policy for old/failed media?	Knowledge of how old backup media are secured is necessary. Appropriate measures include secure erasure and physical destruction.
Servers	Are server operating systems and software updated with required security patches?	Ensuring that there is a mechanism or policy in place whereby security patches are applied to servers and supporting software within an appropriate time frame
Network security	Are firewalls in use on the network, how and where?	Firewalls filter unwanted and potentially malicious traffic. Multiple layers of firewalls reduce the risk of internal attacks.
	Are mechanisms in place for intrusion detection?	Ensuring that an attack or potential attack can be identified enabling it to be prevented or handled quickly
Policies	What security policies, protocols, and processes are in place?	Establishing that a formal security policy has been adopted and that risk mitigation is a high priority
	How are security policies monitored and enforced?	Ensuring that security protocols are actively implemented is necessary. A policy or risk mitigation strategy needs to be applied in practice to be useful.

Procedural Security

Procedural security considerations concern the internal processes and mechanisms surrounding data handling. This includes who handles which data in which situations, what they do with the data, and appropriate procedures for handling a breach should it occur.

All eHealth application data is collected either through direct input by the user or through other communication mechanisms such as email, instant messaging, or telephone. All forms of potentially identifying data, including clinical notes or electronic communications with users must be appropriately handled. An intervention that has high standards of technical security quickly becomes vulnerable to privacy breaches if staff act inappropriately. Common examples of procedural failures include loss or theft of an external hard drive that contains insecure data or copying of data into insecure locations such as shared drives that can be accessed by others.

In order to protect user confidentiality and privacy, e-mental health and eHealth intervention providers need to implement comprehensive data security protocols for staff involved in the operation and deployment of the application. This may be undertaken in the context of the development of a staff security awareness and training program. Guidelines for developing such a program, together with details of helpful awareness and training resources, have been published by the US National Institute of Standards and Technology [27,28]. The importance of these measures cannot be understated, since the vast majority of health care e-privacy breaches occur as a result of procedural failures, including those caused by individuals failing to protect data stored on physically portable hardware [29]. Clearly, procedural security protocols need to be developed in the context of the ethical standards associated with provision of the intervention. However, they must also be informed by an understanding of the human factor risks that arise when staff use particular technologies.

Protocols need to be effectively implemented so that all staff and students, regardless of the size of the eHealth organization in which they are operating, understand how to deal with and protect sensitive data. Routine and ongoing monitoring of procedural risks is also required so that protocols can be adapted as required to rectify deficiencies in the existing measures and respond to new threats. Some aspects of the protocol will be specific to the application that is being delivered; others will address more general issues. As a starting point, Table 2 lists some of the most important procedural areas for consideration in eHealth intervention delivery. Again, this table is not intended to provide a comprehensive guide to procedural issues. However, it will provide the reader who has little background in procedural security issues some key issues to consider when developing protocols to protect data.

Table 2. Examples of questions and actions that are relevant to procedural security

Area	Question/Action	What it Means
Data	Are appropriate access controls applied to data?	Ensuring appropriate permissions and access controls are applied to files on network shares and any other access controls as relevant
	Encryption of portable devices such as laptops, external hard drives, and USB keys	These devices may be lost, stolen, or misplaced and thus represent a potentially significant threat to data security. If there is a chance these devices could be used to store confidential information (or data which could enable reidentification of information), then they should be encrypted. Applications such as TrueCrypt (http://www.truecrypt.org/) can support this.
	Encryption of desktop computers, if appropriate	Encrypting systems that come into contact with confidential information reduces the risk of a breach in the event of theft or incorrect disposal.
	Is identifying information really stored separately from the data?	Electronic storage means it can be difficult to physically separate identifying information from deidentified data. At the very least, electronic access controls should be set up to ensure virtual separation. It may be appropriate for a data manager to manage these access controls.
	Storage of email correspondence and other electronic records in encrypted environments	Confidential records should be stored in an encrypted format.
	Is data transferred between staff or collaborators? Under what circumstances and how is the transfer undertaken?	Staff need to understand the security risks of communication technologies such as email, and procedures needed to be implemented to address these risks in different situations. For example, email addresses and other identifying information need to be removed if forwarding user emails for discussion with colleagues, and restricted access environments should be used for transfer of data sets.
Hardware	Is there a policy and procedure in place for the disposal of old hardware and media?	Old computers and media should be securely erased before they are sold or recycled. If appropriate, storage devices should be physically destroyed.
Policy	Have processes been established for handling a breach if it were to occur?	Any breach needs to be handed effectively—knowing the steps that need to be taken is vital. This should include both steps for handling the breach itself and necessary review and rectification of processes to avoid future breaches.
	Has a policy been developed which addresses the risks of relevant technologies (email, external drives, remote access, etc)?	The tools available to an organization can pose substantial security risks if used inappropriately, but staff without an IT/security background may be unaware of this. Relevant risks need to be assessed and strategies/tools put in place to assist in mitigating them.
	Has a policy for handling staff turnover been developed?	Departure of staff from the organization needs to be handled suitably, including the return of any hardware (PDAs, external drives, laptops, etc), any documents that may be stored remotely (confidential or otherwise), and, if appropriate, the sanitization of computers.
	Are new and existing staff educated about security risks and trained to implement privacy measures?	Policies need to be communicated to all staff, including reminders on a regular basis. If security is not part of day-to-day operations, then a breach may be more likely to occur. Staff need to understand how to appropriately apply security policies in their field of work.
	Is there regular review and monitoring of relevant policies and their application?	Policies and associated outcomes need to be enforced and reviewed regularly so that they can be modified as required.

Overall Strategies: The Present and the Future

Designers and providers of eHealth interventions need to be aware of and mitigate the complex security risks associated with delivery of their applications. Ongoing risk assessment should be conducted in all of the above areas, and appropriate mechanisms, including a security protocol, must be put in place to guard against breaches [29]. In order to facilitate this process, 2 broad strategies can be used: (1) appropriate use and integration of IT staff in all stages of the project and (2) engagement in a wide-ranging discourse about security issues in eHealth interventions.

Appropriate Use of IT Expertise Across the Project Life Cycle

As discussed above, specialist IT staff need to be consulted at all project stages of the eHealth intervention research, development, and delivery to ensure privacy and confidentiality requirements are translated into practice. The security of eHealth interventions requires an understanding of the ethical obligations of the health or psychological service and, more specifically,

knowledge of how the use of different technologies can impact on meeting these obligations. There are 2 ways of meeting this challenge: by fostering the development of transdisciplinary internal experts or by relying on external expertise that is managed internally within an overall risk mitigation context.

In-house transspecialist staff can facilitate the proper consideration of methodological (design) security at an early stage of the project, manage or deliver technical measures, and contribute to the development and implementation of risk mitigation procedures relevant to the project. The use of multidisciplinary in-house teams also builds a knowledge base of which methodologies and processes work most effectively for that organization's eHealth research or delivery program [30].

If appropriate IT staff cannot be included as part of the project team, it falls to the researcher or eHealth intervention provider to ascertain that appropriate security considerations are undertaken by whoever is responsible for the development and the delivery of the program respectively and to ensure that there are provisions for ongoing management of these considerations.

Appropriate involvement of IT staff necessarily requires that budgets and timelines reflect the requirement for specialist IT expertise and processes that ensure the secure delivery of interventions, not just as part of the software development phase, but for the life of the application. Many eHealth projects do not currently progress from the evaluation stage (where their provision to study participants is evaluated) to wider availability to consumers [31]. There are many reasons for this, only some of them involving IT considerations. Nevertheless, a necessary condition for the widespread delivery of eHealth programs to the public is the involvement of suitable IT expertise to ensure the appropriate planning, design, and delivery of secure and scalable applications.

An eHealth Intervention Security Discourse: The Future

Within a rapidly changing technology environment, eHealth interventions and e-mental health interventions in particular have gained acceptance. Although the potential of these interventions is huge, they introduce a whole new set of risks to traditional health and mental health service delivery. A wide-ranging discussion is needed to enhance stakeholder understanding of the mitigation of these risks, both with respect to the e-domain in general, and the eHealth and e-mental health service types in particular. Enhanced discourse about security should include reporting of emergent risks, mitigation approaches, and breaches. Holistic or specific security measures that are introduced as part of an application's design, delivery, or evaluation need to be reported across disciplines. Privacy breaches, if they occur, should be examined in appropriate technical or procedural detail so that they can serve as a shared repository of knowledge designed to ensure that mistakes are avoided in the future. Shared discourse about strategies for coping with potential threats is also important to the development of best practices in the eHealth research and delivery domain.

To our knowledge, there are no comprehensive agreed upon standards for security in e-mental health or eHealth interventions and research specifically. However, consumer confidence in electronic health measures requires assurance and demonstration of appropriate security measures [32], and privacy and confidentiality is particularly important to consumers of e-mental health interventions. There are legislated obligations surrounding the collection and use of sensitive personal information in different legislative contexts (eg, American Health Insurance Portability and Accountability Act in the United States). However, the eHealth field needs to create standards that not only meet such requirements, but also provide the highest standards of health and mental health intervention. Useful standards that have a high applicability to the challenges of eHealth and e-mental health interventions can only be created through collaborative exploration and debate by those involved in the provision of these programs.

Conclusion

The research and development of eHealth interventions and e-mental health interventions has expanded rapidly over the last decade as the potential public health impact of innovative e-mental health delivery techniques have been demonstrated [33]. Increasingly, such interventions are being implemented in practice. However, creating an adequate, scalable, and secure eHealth intervention or e-mental health intervention requires more than a good idea, a budget, and the name of an IT company that is able to build a specified program for the allocated resources. The challenge for the developers and providers of such services is to set and meet security standards of delivery that ensure that consumers can use these services safely and with confidence.

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Conflicts of Interest

Authors KB and AB are development manager and IT manager for the e-hub research and development team, respectively, and are employed to undertake many of the strategies argued for in this paper. Author KG is codirector of e-hub and the coauthor of e-hub's e-mental health programs.

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Abbreviations

IT: information technology
XSS: cross site scripting
DNS: domain name system
HTML: hypertext markup language
SQL: structured query language

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Original Paper

Missing Data Approaches in eHealth Research: Simulation Study and a Tutorial for Nonmathematically Inclined Researchers

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Abstract

Background: Missing data is a common nuisance in eHealth research: it is hard to prevent and may invalidate research findings.

Objective: In this paper several statistical approaches to data "missingness" are discussed and tested in a simulation study. Basic approaches (complete case analysis, mean imputation, and last observation carried forward) and advanced methods (expectation maximization, regression imputation, and multiple imputation) are included in this analysis, and strengths and weaknesses are discussed.

Methods: The dataset used for the simulation was obtained from a prospective cohort study following participants in an online self-help program for problem drinkers. It contained 124 nonnormally distributed endpoints, that is, daily alcohol consumption counts of the study respondents. Missingness at random (MAR) was induced in a selected variable for 50% of the cases. Validity, reliability, and coverage of the estimates obtained using the different imputation methods were calculated by performing a bootstrapping simulation study.

Results: In the performed simulation study, the use of multiple imputation techniques led to accurate results. Differences were found between the 4 tested multiple imputation programs: NORM, MICE, Amelia II, and SPSS MI. Among the tested approaches, Amelia II outperformed the others, led to the smallest deviation from the reference value (Cohen's d = 0.06), and had the largest coverage percentage of the reference confidence interval (96%).

Conclusions: The use of multiple imputation improves the validity of the results when analyzing datasets with missing observations. Some of the often-used approaches (LOCF, complete cases analysis) did not perform well, and, hence, we recommend not using these. Accumulating support for the analysis of multiple imputed datasets is seen in more recent versions of some of the widely used statistical software programs making the use of multiple imputation more readily available to less mathematically inclined researchers.

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KEYWORDS

Missing data; multiple imputation; Internet; methodology

Introduction

Missing data is a common nuisance in eHealth research [1,2]. Subjects may be unwilling or unable to respond to some items or may fail to complete sections of questionnaires due to lack of time and interest, thus leading to data "missingness." In longitudinal studies, participants may drop out early or be unavailable during one or more data collection waves. If not addressed properly, data missingness can induce bias and corrupt external validity, which is both inevitable and uncontrolled by the researcher [3]. Because many of the statistical procedures used by researchers are designed to have complete datasets, it is important to handle missing data in a principled manner [4].

As dropout rates in eHealth studies tend to be relatively high and are even considered typical by some, addressing data missingness and dropout is of great importance. The observation that in any eHealth trial a substantial proportion of users drop out before completion has been called the "Law of Attrition" [1]. A recent review by Christensen and colleagues [2] provides an overview of dropout rates in eHealth interventions for depression and anxiety. Completion rates for online depression interventions ranged from 43% to 99%, with some trials indicating poorer retention after a longer follow-up. The results of one trial of an intervention to treat anxiety in this review reported a 6-month follow-up rate of 44% in the experimental group [2]. In reporting outcomes of a study with a considerable dropout rate, it is important to choose statistical techniques that are appropriate for the analysis of datasets with missing observations [5].

The primary concern when facing substantive missingness is that a study with high attrition rates may yield biased estimates (of the mean, for example) caused by a biased sample. Patients that leave studies prematurely have been shown to be more likely to be involved in drug use or deviant behavior [6-8], to have poorer academic performance, and to be less skillful in resisting peer pressure than other subjects [9]. Edlund and colleagues [10] found that sociodemographic characteristics associated with intervention dropout included low income, young age, and a lack of adequate health insurance coverage. Patient attitudes associated with dropout include viewing treatment as relatively ineffective and feeling embarrassed about seeing a mental health provider. Christensen and colleagues [2] identified several reasons for dropout from eHealth trials: time constraints, lack of motivation, technical or computer-access problems, a depressive episode or physical illness, the lack of face-to-face contact, preference for taking medication, perceived lack of treatment effectiveness, improvement in condition, and burden of the program. Therefore, dropout from eHealth interventions cannot be considered "random," but may be based on participants' characteristics, possibly leading to biased estimators if not addressed adequately.

In short, four key reasons for the use of missing data approaches should be recognized: (1) Missing data may compromise randomization integrity in randomized clinical trials, as drop-out rates may differ over the trial arms. (2) In all longitudinal study designs, missing data may introduce selection bias, as is made clear in the previous section. (3) An intention to treat analysis—as is requested in the consolidated standards of reporting trials (CONSORT) statement and in most other guidelines for the analysis of randomized (controlled) clinical trials (RCTs)—is a necessary step when clinical endpoints are missing for some of the participants [11]. (4) For all possible study designs, missing data may introduce a loss of power, some of which may be won back by using appropriate missing data approaches.

Remarkably, the problems encountered and the solutions implemented while solving missing data problems are rarely mentioned outside the statistical literature [11]. As resources or even a theoretical framework are sometimes lacking, researchers, methodologists, and software developers resort to editing the data to disguise an appearance of completeness. Unfortunately, ad hoc edits, or not handling missingness explicitly, and analyzing data using only complete cases may do more harm than good. These approaches could lead to results that are biased, lacking in power, and unreliable [12]. In the same vein, inappropriate use of missing data approaches will lead to biased results. This will be discussed in more detail for one of the tested approaches, although it applies to each of the other techniques as well. In general, in cases of data missingness, optimal analysis results will be obtained with the appropriate use of missing data approaches. Any other approach could lead to severe bias.

The aim of this paper is to provide a straightforward primer for eHealth researchers who seek solutions for missingness in datasets. To provide researchers with tools for working with data missingness, this paper reviews the strengths and weaknesses of the most common missing data approaches and tests the approaches in a simulation study. Theory on missingness patterns and the most widely used methods of handling missing data are comprehensively presented. The validity, reliability, and coverage of 9 different methods for dealing with incomplete datasets are presented. Some of these methods are relatively straightforward and basic, while others are more advanced and use computationally demanding algorithms to estimate missing values. Although the technical and mathematical details of the presented methods are outside the scope of this paper, those interested can consult with any of a number of references [12-16]. The primary goal of implementing any of the discussed approaches is to obtain unbiased estimators. This is achieved through the creation of datasets in which missing values are replaced by appropriate values to conserve the properties (ie, mean, variance, and distribution) of each variable. These imputed values together with the collected "real" data lead to unbiased estimates of parameters [12].

In general, 4 forms of missingness can occur in longitudinal studies: (1) In the case of initial nonresponse, no baseline data is collected for the participant, although follow-up measures may have been completed. (2) Loss to follow-up is the other way around: baseline data is collected, but (at a certain time point) the researchers fail to collect follow-up data. (3) Wave nonresponse is closely related to loss to follow-up in that data is not collected during one or more of the "waves," but data are collected during earlier and later measurement waves. Missing data has to be interpolated if this form of missingness occurs.

(4) The fourth form of missingness stems from item nonresponse. This occurs when a participant fails to respond to certain measures or questions, such as when some of the items from a questionnaire are skipped. For example, when the missing items are part of a highly correlated construct measurement (eg, one of the 16 items in a quality of life scale is missing), imputation is possible based on the other 15 collected item scores. In short, the selection of a missing data approach will in part depend on the form of missingness encountered. Although some of the presented methods may be efficacious at handling data problems, the most important determinant for preventing missing data values is to retain subjects in the study [17]. However, it often may not be feasible to invest extensive amounts of effort, time, and money to obtain nearly perfect response rates. Even then, small amounts of missing data may lead to substantial bias, depending on the pattern of data missingness.

Patterns of Data Missingness

In general, 3 mechanisms of missingness are discerned: missing at random (MAR), missing completely at random (MCAR), and missing not at random (MNAR) [13]. Each of these 3 patterns can have its own implications for the effects of missingness on parameter estimates derived from the dataset. Although these 3 terms have formal statistical definitions, their practical meaning for the purpose of this paper is best described through examples [4].

Commonly, the probability that an observation is missing depends at least in part on information that is present: missingness is dependent on observed characteristics. This type of missing data generally is referred to as missingness at random or MAR [12]. The word "random" in MAR means something rather different from what most researchers typically think of as random. The randomness in MAR missingness means that once all data have been controlled for, any remaining missingness is random [4]. As long as missingness depends on available data, but not on unavailable (missing) data, the missingness pattern is considered MAR [12]. MAR can, for example, arise when an investigator studies the predictive validity of treatment adherence on the outcome of an intervention. If patients who drop out of treatment have a propensity for missing follow-up measurements, missing follow-up data may have an MAR missingness pattern. Missingness is dependent on a subjects' characteristic (treatment adherence) that is available in the dataset.

Missing completely at random (MCAR) is a special case of MAR [12]. If cases with missing data form a truly random subset of the dataset, missing observations are considered MCAR. In essence, this means that correct parameter estimates (but not confidence intervals) can be obtained by using only the complete cases from the dataset. Typically, MCAR arises when a portion of questionnaire data from a study subject is accidentally lost. Missingness is completely random and the probability that an observation is missing is not related to any of the subjects' characteristics. Sometimes, this missing data pattern is referred to as ignorable missingness [4].

If the probability that an observation is missing depends on an unmeasured factor, this factor is partly missing itself and therefore not available, or the value of the observation predicts its own probability for missingness, the missing data pattern is called missing not at random or MNAR [12]. MNAR can be referred to as nonignorable missingness. Estimators derived from a dataset with an unaddressed MNAR missingness pattern can be biased [4]. For example, asking a subject for his or her income level without collecting data related to income may lead to forms of missingness in correspondence with this MNAR pattern. People with high incomes may be reluctant to provide information on their earnings, so it might well be that missing data are more likely to occur when the income level is relatively high. Here, the predictor for missingness is related to unobserved characteristics of the subject. Because this predictor is not measured, imputing this missing value properly is complicated; for example, one would have to specify a distribution for the missingness [12].

In general, there is no way to test whether MAR or MNAR holds in a dataset [12]. More specifically, Graham [4] indicates that pure MCAR, MAR, or MNAR really never exists: these concepts require almost untenable assumptions. In reality, often a mixture of forms will be found. Collins et al (in [12]) demonstrated that in most realistic cases, an assumption of MAR where MNAR is at hand leads to only minor impacts on estimates and standard errors. MNAR missing data approaches require the analyst to make assumptions about the model of missingness; if this assumed model is incorrect, its results are unpredictable and probably biased. Because of difficulties in the straightforward application, MNAR methods are not widely used. In this paper, we therefore do not focus on missing data approaches for MNAR patterns.

For MAR and MNAR, it should be recognized that patterns of missingness and the consequences for derived estimators are not solely a characteristic of the data, but a combination of the available data and the planned analysis. For example, if an MNAR pattern in which an unobserved or unmeasured variable is predictive of missingness (for example, left or right handedness) but is not correlated with the endpoint of the study, then the MNAR pattern does not lead to biased estimators (only to a loss of power). Another example is pointed out by Graham [4]. Suppose one develops a smoking prevention intervention. Smoking in this example is measured at two time points: before the start of the intervention (t1) and one year later (t2). Suppose missingness at t2 is dependent on t1. If an analysis or missing data approach is performed under a model in which t1 is included, missingness on t2 follows an MAR pattern, whereas t2 would follow an MNAR pattern if t1 was not included. In other words, a biased estimator as a result of missingness can only occur in reference to a specific dependent variable under a specific statistical model. Some of the more advanced missing data approaches discussed in this paper use this characteristic to estimate and impute the missing values.

Missing Data Approaches

Over the last couple of decades, several methods for handling missingness have been developed. In this section, a number of these missing data approaches are presented. The approaches that are most useful and applied most often are described below [4]. The first three approaches in this overview are considered

"basic" as they are conceptually straightforward and require minimal computations, such as complete case analysis, listwise mean imputation, and last observation carried forward (LOCF). The "advanced" approaches are newer, require more computational power, and are conceptually more complex than basic approaches. Two of these advanced approaches are imputation techniques that replace missing values in the dataset with a single approximation; these approaches are regression imputation and expectation maximization imputation. The final four approaches are multiple imputation techniques replacing a single missing observation with multiple simulated values: NORM, MICE, SPSS MI, and Amelia II. The use of these last four approaches leads to multiple instances of the original dataset with a variance in the imputed values for the missing observations that resembles the accuracy (or inaccuracy) of the missing values approximation. See also Table 1.

Table 1. Missing data approaches in this study

Approach	Description	Missingness Pattern	Type
Complete cases	Only cases without missing observations in analysis	MCAR[a]	Basic, single
Mean imputation	Imputes missing observations with listwise mean for each variable	MCAR[b]	Basic, single
LOCF	Imputes the last available observation in the current data collection wave	-	Basic, single
Regression imputation	Imputes missing observations by prediction based on other variables in a regression model	MAR, MCAR	Advanced, single
EM imputation	Imputes missing observations using expectation maximization algorithm	MAR, MCAR	Advanced, single
NORM	Multiple imputes missing observations under a normal model	MAR, MCAR	Advanced, multiple
MICE	Multiple imputes missing observations using chained equations	MAR, MCAR	Advanced, multiple
SPSS MI	Multiple imputes missing observations under a normal model in SPSS	MAR, MCAR	Advanced, multiple
Amelia II	Multiple imputes missing observations using a bootstrapping-based algorithm	MAR, MCAR	Advanced, multiple

[a] This approach will lead to unbiased point estimators (eg, means) under MCAR, but will result in lowered power and sample size.

[b] This approach will lead to unbiased point estimators (eg, means) under MCAR, but will result in biased, smaller confidence intervals.

Complete Case Analysis

The most popular and most often used missing data handling method is complete case analysis (casewise deletion). In complete case analysis, all cases with missing values are removed from the dataset before analysis. This method is straightforward in its application. This technique assumes MCAR and its application will lead to biased results under other patterns of missingness. Even under a valid assumption of MCAR data, this method is not preferential because the reduced number of cases used for the analysis leads to loss of statistical power [4].

Listwise Mean Imputation

Listwise mean imputation, in which missing values of each variable are imputed with the arithmetic mean of the available observations for the variable, attempts to overcome the loss of power of complete case analysis. Like complete case analysis, listwise mean imputation assumes the MCAR missingness pattern, which is uncommon in empirical datasets with missing observations. If the data missingness pattern is not MCAR, imputing missing values with the listwise mean will result in a biased estimation of the mean. Under all missing data patterns (also MCAR), listwise mean imputation will reduce the variance of the variable. Imputed values equal to the mean do not contribute to the total variance. This leads to decreased standard errors and artificially small confidence intervals. Because of the inadequacy of listwise mean imputation to conserve the imputed variables variance, this method is considered by some to be one of the worst missing data approaches [18].

Last Observation Carried Forward

The third most-often used method is last observation carried forward (LOCF). This approach is regularly used in epidemiological research, especially in clinical trials [19]. LOCF takes into account the individual's previous observed value on a given variable [20]. If an observation at a certain data collection wave is missing, the last observed value is then used as an estimate for this missing observation. A related method, last observation carried backward (LOCB), works according to the same approach, but imputes a newer observation in the case of a missing earlier observation of the same individual. Both carried observation methods can only be used in longitudinal research designs with at least one complete observation. Despite its wide application in clinical trials, however, recent empirical studies have cautioned against the use of this technique [21] and have demonstrated its bias [22]. This bias mainly stems from the fact that imputing previously measured values can be conservative in some situations, but not in others. LOCF assumes there will be no further improvement and, therefore, underestimates the treatment effects in an effective intervention if the intervention's effect is to change a current state (of well-being, for example). However, if the intervention's expected effect is to slow down a decline (for example in a cognitive enhancement intervention for patients with Alzheimer's disease), carrying forward a previous observation will exaggerate the found treatment effects. In RCTs, LOCF may also have unexpected anticonservative effects. In the control or placebo arm of a study, LOCF assumes no (spontaneous) change, which is not conservative because study participants in the control arm may improve as well. When there is an

assumption of no change in the control condition, but in reality there is a change, larger differences between treatment and control arms in RCTs may be artificially produced. Suddenly, LOCF is not conservative anymore [23]. In general, in studies with relatively favorable baseline measures, LOCF will project these favorable baseline scores to clinical endpoints, thus exaggerating the efficacy of the intervention. Because of these unexpected anticonservative effects, we strongly advise against the use of LOCF.

Regression Imputation

Regression imputation is the first of two "advanced" single imputation methods discussed in this paper. By adding randomly sampled "noise" from a normal distribution to a prediction model based on linear regression, the regression method imputes missing values based on the relations between variables in the dataset while preserving the variables' variance. There is some discussion about the number of predictors that should be included in the model. In general, the use of more predictor variables in the regression equation is not necessarily better. A more parsimonious model, where only statistically significant predictors are retained, is usually a better model. However, it is important to keep in mind that two types of predictor variables should be retained in the model: those predicting the variable(s) with missing observations and those that predict missingness. The latter group of predictors help to correct for differential dropout-inducing bias to the estimators. In theory, regression imputation is applicable under both MCAR and MAR missingness patterns.

Expectation Maximization Imputation

The other advanced single imputation method discussed here is based on expectation maximization (EM). The EM approach is a procedure that estimates unmeasured data and is based on iterating through two alternating steps [24]. In the expectation step, an appropriate value is calculated for the missing observation based on the available data and its distribution. In the maximization step, an appropriate value is calculated based on the current updated dataset. The model can be improved because original data will be used in addition to the proposed missing data imputations calculated during the most recent expectation step. These two steps are alternated numerous times: after each expectation step a maximization step will follow. After each iteration, a better model can be specified, leading to more accurate missing value estimations. After the final iteration, theoretically the most accurate estimation of the missing values is reached: the EM procedure will impute this value into the dataset as a replacement for the missing observation.

Multiple Imputation

In recent years, multiple imputation (MI) has emerged as a methodology for handling missing data. Originally, it was viewed as being most appropriate for complex surveys, although in the 1990s it was shown to be valuable in other settings as well [14]. Multiple imputation is an approach in which the missing values are replaced by multiple simulated versions. "Multiple" refers to the custom of replacing missing values with several different values, typically between 3 and 10 [25]. Rubin [13] has shown that unless the rate of missing information is very high, there is simply little advantage to producing and analyzing more than 10 imputed datasets. Each of these "replacement values" can be estimated using regression equations, a form of EM, the identification of a "near-neighbour" donor case with matching properties, or through a combination of these methods. In any of these methods, the correlations between the different variables in the dataset are taken into account. Based on these correlations and other variable properties, appropriate estimations for the missing values are generated.

Missing values that are replaced with more than one possible estimator will produce more than one completed dataset: each of the 3 to 10 imputations leads to a new dataset containing the original "complete" available observations and the new "generated" imputed ones. Each of the 3 to 10 datasets is first analyzed as if it were a complete dataset with no missing values. The separate results can then be combined into one final result according to specific rules. Rubin [13] presented formulae to combine the estimators and standard errors obtained from the 3 to 10 imputed datasets into one estimator and one standard error. The combined estimator is the arithmetic mean of the 3 to 10 estimators obtained from the imputed datasets; the combined standard error is based on both the standard errors and the variance of the 3 to 10 estimators of the imputed datasets. The combined estimator and standard error can be used for the calculation of, for example, *t* test statistics and analysis of variance. A more recent paper shows how a variety of other test statistics can be calculated as well [26].

From a researcher's perspective, the biggest advantage of MI is flexibility. It applies to a wide range of missing data situations and is simple enough to be used by nonstatisticians. Theoretically, this approach is superior to other models because it often produces the most robust effects. In this paper, four multiple imputation programs are compared. The first, called NORM [15], was developed for use under S-PLUS (TIBCO Spotfire, Somerville, MA, USA) or the R Statistical Programming Environment, but is also available as a stand-alone program. Using the NORM, one can perform multiple imputations of multivariate continuous data under a normal model. More information on its exact routines is presented in [15]. The second MI program is called Multivariate Imputation by Chained Equations, MICE [27], and was developed for use under S-PLUS, R, Stata (StataCorp LP, College Station, TX, USA), and as a stand-alone Windows program. MICE is an attempt to combine the most attractive aspects of MI approaches developed by [15] and [28]. The third MI program has been included in SPSS Statistics (SPSS Inc, Chicago, IL, USA) since version 17. According to the product information, this MI module allows for quick and accurate data estimates in cases where observations are missing [29]. The fourth MI program is called Amelia II, developed by Honaker and colleagues [30]. Amelia II multiply imputes missing data in a single cross-sectional dataset from time series data or from a time series cross-sectional dataset. This new bootstrapping-based algorithm it is presumed to be faster and more flexible than the other programs.

Methods

Source Data

The dataset in this simulation study was obtained from an online, self-help prospective study for problematic alcohol consumers. The online self-help program was developed by a substance abuse treatment center in Amsterdam, the Netherlands. Each new participant was invited for a measurement of alcohol consumption, quality of life, self-efficacy, and demographics. Data were collected at two waves, at baseline, and 3 months after baseline. All the cases with missing values were removed from the original dataset, resulting in a dataset with 124 cases, with 0% missing data. The dataset contains self-reported daily alcohol consumption quantities measured in standard drinking units containing 10 grams of ethanol. These consumption quantities were available at baseline and at the 3-months follow-up. For the purposes of this paper, we used only the subscale measuring alcohol consumption for the last 7 days, measured using Timeline Follow-Back methodology [31]. Currently, a randomized clinical trial (Netherlands Trial Register NTR-TC1155) on the effectiveness and cost-effectiveness of this intervention is in the process of being executed [32].

This complete (0% missing) dataset was used as a reference value for comparison of each approach. Next, one of the weekdays from the follow-up measurement was selected and an MAR missingness pattern was induced, leading to 50% MAR missingness in this variable. The operationalization of MAR applied by the execution of this macro is according to the method suggested by Scheffer [25]. Briefly, for this method two variables are necessary: (1) a variable predicting missingness and (2) a variable in which missingness will be induced. If the score of the missingness predictor variable is high, the chance that missingness will occur in the missingness variable is high; if the score of the missingnes predictor variable is low, the chance on missingness is also low. As a result, the proportion missing data in the missingness variable is correlated with the value of the missingness predictor variable.

After MAR induction, the missing data approaches were performed on the dataset with missing observations. For LOCF, data collected at baseline were carried forward to the missing follow-up measurement for the variable upon which missingness was induced. All “advanced” missing data approaches came with default software settings. It is possible to adjust these settings to change the number of iteration steps, convergence criteria, and the distribution of random error. For the presented analysis, the default software settings were used. To test sensitivity of the results to changes in these default software settings, the study was replicated using stricter, more calculation-intensive settings, that is, a larger number of iterations or stricter convergence criteria. The results obtained with these stricter settings did not differ systematically from the results obtained using the default settings.

To investigate reliability and coverage of the results obtained through these approaches, a resampling approach was performed. A total of 75 samples of n = 124 were drawn with replacement from the MAR imposed dataset, and these resampled datasets had, on average, 50% MAR missingness on the selected variable. Next, missing values from each dataset were imputed using the different approaches. Figure 2shows the arithmetic mean for the variable with imputed missing values. Each point represents the mean value of postintervention drinks, obtained from one of the 75 datasets. The area between the two dashed horizontal lines indicates the 95% confidence interval of the reference variable, which is the same variable indicating postintervention drinks but before MAR missingness is imposed. The white dot in each column indicates the mean for the repeated application of each missing data method on the 75 datasets.

Superior performance of the MI approaches over the other advanced approaches (and of the advanced approaches over the basic approaches) was expected, based on previous studies [12,25]. However, in contrast to previous publications, the approaches tested in the current study used a dataset with nonnormally distributed count data in order to mimic the everyday application of these approaches. Count data distributions are known for their deviation from the normal distribution [33].

Validity, Reliability, and Coverage

For successful application in a variety of missing data situations, it is important to test for reliability in addition to validity. For example, will the use of the presented methods lead to comparable results with repeated application? Coverage can be regarded as a combined indicator for validity and reliability. It is expected that coverage of the advanced approaches will outperform the basic methods.

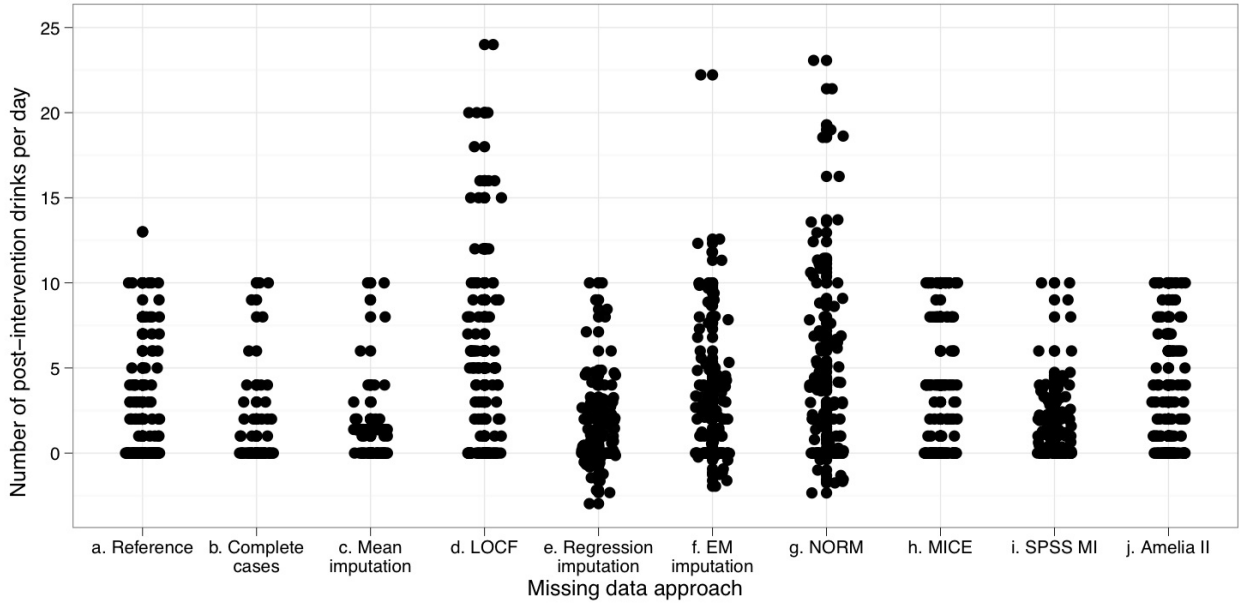
Validity was operationalized as the extent to which the estimate obtained by a missing data approach approximated the reference value. Validity (ie, test validity) was assessed by calculating *t* values and effect sizes for the differences between the reference value (mean variable score before MAR induction) and the imputed variable (mean variable score after the induction of MAR). Reliability was operationalized as the variance of the estimates obtained through repeated application of each missing data approach: the lower this variance, the smaller the confidence interval and the higher the method’s reliability. The third statistic calculated in this study was the coverage. This coverage statistic was calculated using the data obtained in the simulation study. It indicates the proportion of means within the 95% confidence interval of the mean reference value: when 70 of the 75 bootstrapped mean values for a missing data approach are within the 95% confidence interval of the reference value, the coverage is 70/75 or 93%. This coverage measure was previously used for comparable purposes, for example by Schafer and Graham [12].

Results

The complete (reference) dataset and the datasets that resulted after application of the missing data approaches are plotted in Figure 1. Each point in this figure represents a single observation (number of postintervention self-reported drinks per day for each participant). The observations for the reference are shown in the first column (a) on the x-axis. These observations are the “true” complete observations before missingness was induced.

Also shown on the x-axis (columns b to j) are the observations that were produced after the MAR 50% missingness was imposed and corrected by each of the nine missing data approaches. Some horizontal jitter was added to the strip chart to prevent equally valued observations from overlapping on the y-axis. Please note that plotting the ideal missing data approach's observations would lead to results identical to the reference plot in Figure 1. On the y-axis, the number of postintervention drinks per day is indicated. For the 4 multiple imputation approaches (columns g to j), only the first created dataset was plotted.

Figure 1. Strip chart for 9 missing data approaches and the reference value



A number of participants reported zero postintervention drinks per day; subsequently, their data points are plotted very close to each other. As is often the case for count data, observations are positive integers only and the distribution of the observations is nonnormal. Table 2 shows descriptive summary statistics for each of the methods compared with the reference. The application of complete case analysis, listwise mean imputation, regression imputation, and SPSS 17 multiple imputation led to an underestimation of the mean number of postintervention drinks. LOCF, and to a lesser extent EM imputation and NORM, led to an overestimation of the mean. Regression imputation, EM imputation, and NORM impute some negative values, which is impossible from an empirical point of view; however, these approaches could still produce unbiased estimators of mean and variance, for example. Applications of MICE and Amelia II produced the closest approximations to the reference mean value, as determined by visual analysis of the data.

Table 2. Independent samples t tests for missing data approaches against reference value

Method	Mean	SD	*t* [a]	Degrees of Freedom	*P*	Cohen's *d*
Reference	2.62	5.22	0	246	1	0
Complete cases	1.39	2.63	-2.09	176	0.04	-0.31
Mean imputation	1.39	1.73	-2.50	246	0.01	-0.35
LOCF	4.85	5.43	3.29	246	0.001	0.42
Regression imputation	1.39	2.37	-2.38	246	0.01	-0.32
EM imputation	3.09	3.85	0.809	246	0.42	0.10
NORM	3.14	9.55	0.534	246	0.53	0.07
MICE	3.06	4.30	0.730	246	0.47	0.09
SPSS 17 MI	1.49	2.03	-2.26	246	0.03	-0.31
Amelia II	2.88	3.33	0.468	246	0.64	0.06

[a] Independent samples *t* tests

To supplement the visual analysis with statistics, Table 2 shows mean, standard errors, *t* statistics, and Cohen's *d* effect sizes. The *t* and *d* values quantify the differences between the reference value and each of the imputed datasets. The lower its *t* statistic,

the more the mean value obtained after application of a missing data approach resembles the reference value. This is an indication of the validity of an imputation method. To further indicate the extent to which the imputation results differ from the reference value, effect sizes were calculated using Cohen's *d*. For this application, smaller effect sizes indicate better imputation results. The standard deviations for mean imputation, regression imputation, and SPSS multiple imputation are much smaller than the reference confidence interval. This could potentially lead to anticonservative testing results and, therefore, inflated (or increased) risk for type I error (false positives). NORM produced much larger confidence intervals; thus, NORM may lead to an increased risk for type II error (false negative).

Figure 2. Repeated application of nine missing data approaches

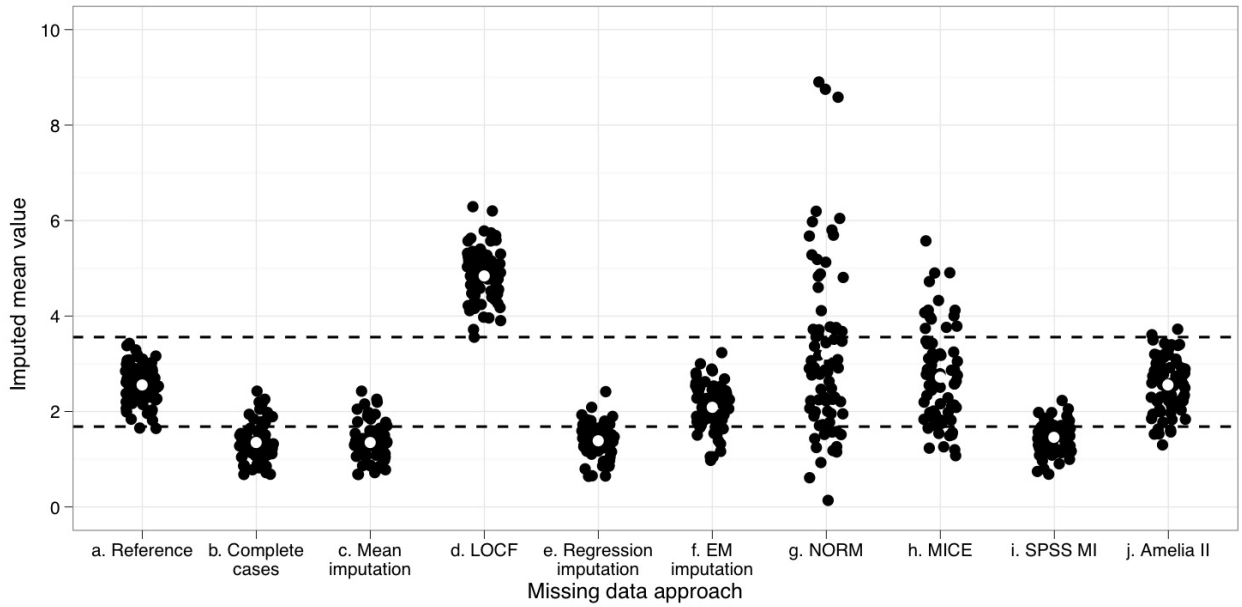


Figure 2 provides insight in the reliability of the nine missing data approaches. The white dots in this figure show the arithmetic mean of the 75 bootstrapped samples. The area between the two dashed horizontal lines corresponds to the 95% confidence interval of the reference value. Each black dot indicates the arithmetic mean of one of the bootstrapped samples. As in Figure 1, some horizontal jitter was added to improve the visual presentation of the plotted data.

The nine approaches differed remarkably in the robustness and, therefore, in the reliability of their results. The largest difference between the simulated datasets was produced by the NORM software package, with some of the highest mean values being eight times larger than the smallest. The lowest variance was seen in the complete cases, mean imputation, regression imputation and SPSS MI. LOCF, EM imputation, MICE, and Amelia II showed an average amount of inter-dataset variance.

Table 3. Coverage of the reference confidence interval for imputed means

Missing Data Approach	Coverage Proportion	Variance of Bootstrapped Sample
Complete cases	0.15	0.088
Mean imputation	0.15	0.088
LOCF	0	0.381
EM imputation	0.83	0.206
Regression imputation	0.17	0.105
NORM	0.43	3.027
MICE	0.71	0.622
SPSS MI	0.23	0.093
Amelia II	0.96	0.205

Table 3 shows the variance of the means and the coverage for each approach. For an estimation to be maximally valid and reliable, at least 95% of the means obtained from the application of an approach should be within the confidence interval of the reference value [12]. The highest coverage was obtained by the application of Amelia II. This approach was actually the only one to reach the criterion of greater than 95% coverage. From the single imputation approaches, EM imputation yielded the highest coverage proportion.

Discussion

In this paper, the application of nine approaches for handling missing data is presented and compared. The most valid result was obtained using multiple imputations from the Amelia II algorithm, closely followed by MICE, NORM, and EM imputation. However, due to the large standard errors resulting from the NORM algorithm, the power of the analysis based on this dataset was much lower than the power of an analysis using MICE or Amelia II would have been. The results obtained using the other tested approaches differed significantly from the reference value and can therefore be considered as less valid.

Although complete cases, mean imputation, regression imputation, and SPSS multiple imputation led to reliable results in the sense of small variance between the bootstrapped means (Figure 2), their application resulted in less valid parameter estimations (ie, the bootstrapped means are consistently lower than the reference mean) and their coverage was well below 95%. Optimal coverage was achieved using Amelia II, followed by EM imputation. Application of these two methods on the example dataset led to the most valid and reliable results. In general, it can be concluded that the more advanced approaches led to better results. Other authors have tested some of the presented approaches under both lower and higher missingness rates than the 50% in this study, with comparable results [ie, 12,25].

To mimic the real-life missing data problems more closely in this study, missingness was imposed on a variable containing count data (alcohol consumption counts). However, it should be noted that none of the presented approaches were specifically designed for the imputation of nonnormally distributed count data: specific missing data approaches for this type of data are currently lacking. From the Schafer suite, in addition to NORM, one could select CAT or MIX packages as an alternative, as these are intended for categorical or mixed datasets; however, these programs are also limited with regard to the imputation of missing count data. On the other hand, according to [12], excellent performance can be reached by imputing nonnormal variables under normality assumptions with no transformations. Based on the current study, it can be concluded that some methods can handle nonnormal count data well, while others perform less than optimally in such situations.

To evaluate the selected methods under more ideal conditions as well, the methods were retested using a normally distributed variable with missingness imposed under the same 50% MAR pattern (data not presented here). Differences between the methods became smaller; the less-than-optimal methods led to better results under these conditions. Multiple imputation still led to optimal results, and among the multiple imputation methods, the best results were reached using Amelia II.

Both EM imputation and Amelia II performed reasonably well in this study. EM imputation produces maximum likelihood estimates for the missing values, thus approaching true sample means and variances for an incomplete variable. However, being a single imputation method, the accuracy or inaccuracy of this estimation process is not accounted for in the variances of the resulting estimators. This leads to smaller variances, smaller confidence intervals, and therefore a greater risk of finding significant differences between variables when there are no actual differences (type I error, false positive). This shortcoming of EM imputation and other single imputation approaches marks the biggest advantage of multiple imputation. The latter captures uncertainty due to missingness of data in the variance between the generated datasets, making the estimators from multiple imputed datasets less prone to this type I error.

The main reason why MI is not used more often is probably due to the perceived complexity of its application. Working with more than one instance of the dataset may seem discouraging to researchers without extensive statistical knowledge or interest. Second, the fact that widely used statistical packages until recently did not natively support multiple imputation makes it understandable that most researchers using these software programs do not directly chose to apply this technique in case of missing data. In that sense, the introduction of multiple imputation in recent releases of statistical software (ie, the “mi” command in Stata 11 and the multiple imputation module in SPSS 17) may mark a leap forward. Positive experiences with the new “mi” command in Stata have been reported. However, under the conditions in the presented studies, the results obtained with SPSS 17 multiple imputation were less than optimal.

To conclude, this paper introduced both the implications and the practical use of data techniques to a wide, nonstatistical audience. Using the software packages tested and described in this paper, multiple imputation is feasible for any researcher in the eHealth field or related disciplines. The use of these approaches may invoke a considerable improvement of the validity of results obtained from datasets with missing values.

Acknowledgments

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Conflicts of Interest

None declared

Authors' Contributions

All authors have contributed substantially to this protocol. Matthijs Blankers constructed the design of the study and drafted the manuscript. Maarten Koeter led the overall methodological development and revised the manuscript. Gerard M Schippers is principal investigator and supervised the production of the study and manuscript. All authors have read and approved the final manuscript.

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Abbreviations

AIAR: Amsterdam Institute for Addiction Research
CONSORT: consolidated standards of reporting trials
EM: expectation maximization
LOCB: last observation carried backward
LOCF: last observation carried forward
MAR: missing at random
MCAR: missing completely at random
MI: multiple imputation
MNAR: missing not at random
RCT: randomized controlled trial

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Original Paper

Cost-Utility and Cost-Effectiveness of Internet-Based Treatment for Adults With Depressive Symptoms: Randomized Trial

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Abstract

Background: The effectiveness of Internet-based treatments for depression has been demonstrated; their cost-effectiveness, however, has been less well researched.

Objective: Evaluating the relative cost-utility and cost-effectiveness of (1) Internet-based cognitive behavioral therapy, (2) Internet-based problem-solving therapy, and (3) a waiting list for adults with depressive symptoms.

Methods: A total of 263 participants with clinically significant depressive symptoms were randomized to Internet-based cognitive behavioral therapy (n = 88), Internet-based problem-solving therapy (n = 88), and a waiting list (n = 87). End points were evaluated at the 12-week follow-up.

Results: Cost-utility analysis showed that cognitive behavioral therapy and problem-solving therapy had a 52% and 61% probability respectively of being more acceptable than waiting when the willingness to pay is € 30,000 for one quality-adjusted life-year. When society is prepared to pay € 10,000 for a clinically significant change from depression, the probabilities of cognitive behavioral therapy and problem-solving therapy being more acceptable than waiting are 91% and 89%, respectively. Comparing both Internet-based treatments showed no clear preference for one or the other of the treatments.

Conclusions: Both Internet-based treatments have a high probability of being cost-effective with a modest value placed on clinically significant change in depressive symptoms.

Trial Registration: ISRCTN16823487; http://www.controlled-trials.com/ISRCTN16823487 (Archived by WebCite at http://www.webcitation.org/5u8slzhDE)

(J Med Internet Res 2010;12(5):e53) doi:10.2196/jmir.1436

KEYWORDS

Costs and cost analysis; cost-benefit analysis; depression; Internet; computer-assisted instruction; cognitive therapy; problem solving; randomized controlled trial

Introduction

Globally, depression is one of the most prevalent mental disorders, with a large impact on peoples' well-being and with substantial economic ramifications [1-3]. Some cost-effective interventions exist for treating and preventing depression [4-9]. However, economic evaluations of Internet-based treatments are scant [10]. As far as we know, only one economic evaluation has been conducted of Internet-based treatment for depression, showing that online cognitive behavioral therapy can be cost-effective compared with usual care in primary care patients [11]. Moreover, as most Internet-based treatments are based on cognitive behavioral therapy [12], economic evaluation of other forms of Internet-based treatments is also called for.

In a randomized controlled trial for adults with depressive symptoms, Internet-based cognitive behavioral therapy and Internet-based problem-solving therapy showed superior effectiveness compared with a waiting list control group in reducing symptoms of depression and enhancing quality of life [13]. Using the same data, we now investigate the cost-utility and cost-effectiveness of Internet-based treatment. Characteristic of problem-solving therapy in this study is its short duration of only five weeks. It would, therefore, be interesting to know whether this brief intervention is superior to an 8-week cognitive behavioral therapy intervention in terms of relative cost-effectiveness. To that end, we evaluated cost-utility and cost-effectiveness for 3 contrasts: (1) cognitive behavioral therapy versus placement on a waiting list, (2) problem-solving therapy versus placement on a waiting list, and (3) problem-solving therapy versus cognitive behavioral therapy.

Methods

Full details of the study method are given elsewhere [14]. Here, we describe its main features and focus on the economic aspects.

Participants

Participants were recruited through advertisements in newspapers and via the Internet. To be included in the study, participants had to be aged 18 years or older, presenting with depressive symptoms, and willing to participate in a self-help course. Presence of depressive symptoms was ascertained with the Center of Epidemiologic Studies Depression scale (CES-D) when people scored 16 or higher on this scale [15]. No other inclusion or exclusion criteria were defined for this study.

A total of 263 participants were randomized to one of the three conditions: Internet-based cognitive behavioral therapy (CBT, n = 88), Internet-based problem-solving therapy (PST, n = 88) and a waiting list control group with unrestricted access to usual care (WL, n = 87). Block randomization was used, with each block containing 9 allocations. An independent statistician conducted the randomization. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Centre.

Interventions

The problem-solving therapy-intervention was a Dutch adaptation of Self-Examination Therapy by Bowman [16]. Problem-solving therapy consisted of 3 steps. First, the participants made a list of the most important things in their lives. Second, they wrote down their current worries and problems and divided these into important and solvable problems, important but unsolvable problems, and unimportant problems. The core element of problem-solving therapy is to address the solvable important problems following a six-step procedure: describing the problem, brainstorming, choosing the best solution, making a plan for carrying out the solution, actually carrying out the solution, and evaluation. During the third step, the participants made a plan for the future in which they described how they would try to accomplish those things that matter most to them. The course took five weeks and consisted of one lesson a week.

The cognitive behavioral therapy intervention was based on the "Coping with Depression" course [17], Dutch version [18]. Cognitive behavioral therapy in this study included psycho-education and focused on skills such as relaxation, cognitive restructuring (including coping with worrying thoughts), social skills training, and behavioral activation, specifically increasing the number of pleasant activities. Cognitive behavioral therapy consisted of 8 lessons, 1 lesson a week followed by a booster session after 12 weeks.

Participants in both interventions were supported by a life coach via email during the intervention period. Support was directed at helping the participant to work through the intervention and not at developing a therapeutic relationship or giving advice on how to cope with depressive symptoms or other problems. The average time that therapists spent on each participant providing feedback and answering questions via email was estimated at 20 minutes per week.

Outcome Measures

Generic and Clinical Outcome Measures

Participants received a baseline questionnaire prior to randomization and later at 5-, 8- and 12-weeks follow-up.

The central generic outcome was health-related quality of life derived by means of the EQ-5D of the EuroQol group. The EQ-5D consists of five health state dimensions (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression) on which the respondent has to indicate his own health state [19]. An advantage of the EuroQol is that an overall utility score of quality of life can be obtained, which facilitates comparisons with other interventions and health states in other disease areas [20]. A utility refers to the value that individuals or society may place on a particular health state. This valuation is indicated by a number between 0 (the worst imaginable condition: death) and 1 (perfect health). This study used the Dutch tariff to value generic quality of life. The utility scores of the EQ-5D are used to calculate the quality-adjusted life-years (QALYs) gained during the follow-up period by weighing the length of time spent in a particular health condition by the utility [20].

In addition, our primary clinical outcome was severity of depressive symptoms as measured by the Center for Epidemiological Studies Depression (CES-D) scale—Dutch version [15]. The CES-D consists of 20 items and the total score varies between 0 and 60 with higher scores indicating greater depressive symptom severity. The cutoff of 16 and higher is commonly used to denote a clinically significant level of depressive symptoms [15].

Measuring Service Use and Costs

Costs are defined from the societal perspective and encompass (1) intervention costs, (2) costs related to health care uptake, (3) out of pocket expenses for the family and the patient, and (4) costs stemming from production losses due to work loss days and work cutback days. Costs were calculated in Euros (€) for the reference year 2007. Information on the participants' use of health services and production losses was obtained with the Trimbos and Institute of Medical Technology Assessment

Cost Questionnaire for Psychiatry [21]. Data on service use and costs were collected for 2 periods: the 4 weeks prior to randomization and the 12 weeks following randomization. The 3 cost categories distinguished were: direct medical costs, direct nonmedical costs, and indirect nonmedical costs.

Direct medical costs consisted of intervention costs and uptake of health care services, including costs of medication. The per-participant intervention costs were estimated at € 501 for cognitive behavioral therapy and € 338 for problem-solving therapy. The largest share of the intervention costs stemmed from receiving support during the interventions. Other costs comprised maintenance costs of the websites and participants' time for working through the self-help material which was valued at € 8.83 per hour. Differences in intervention costs between the 2 interventions were mainly due to the variation in duration, with problem-solving therapy taking 5 weeks and cognitive behavioral therapy, 8 weeks. Health care services were costed by multiplying the number of health service units by their standard cost price [22] (see Table 1). The costs of antidepressants, anxiolytics, and hypnotics were calculated as the cost price per standard daily dose on a monthly basis as reported in the Pharmaceutical Compass [23]. Direct nonmedical costs consisted of costs for traveling and parking. These costs were valued at € 0.17 per kilometer and € 2.64 per hour parking time. To this we added the costs of the participants' time spent in travel, waiting, and in treatment at € 8.83 per hour (see Table 1).

Table 1. Direct medical and direct nonmedical costs by health service type

		Direct Medical Costs[a]	Direct Nonmedical Costs[a,b]		
	Unit	Cost (€)	Distance Traveled (km)	Patient's Time (hrs)	Cost (€)
General practitioner	Consultation	21.36	1.8	1	11.80
Regional mental health service	Contact	131.14	10	3	30.84
Private practice psychotherapist	Session	80.38	5	2	21.16
Psychotherapist hospital[c]	Consultation	76.08	7	3	30.31
Company doctor	Consultation	22.47	0	1	8.83
Social worker in company	Contact	50.62	7	3	30.31
Medical specialist	Consultation	103.64	7	2	21.48
Physiotherapist	Contact	24.06	1.8	2	20.63
Social worker	Contact	50.62	7	3	30.31
Consultation alcohol/drugs	Contact	131.14	10	3	30.84
Home care	Hour	32.47	0	0	0.00
Alternative care	Contact	47.00[d]	7	3	30.31
Self-help group	Session	8.83	7	3	30.31

[a] Costs are in Euros for 2007.

[b] Based on average distances (km) and travel+waiting+treatment times (hrs) for receiving treatment [22]

[c] Valued as the mean of costs for a consultation in a general or mental health hospital

[d] Costs for alternative care are variable. If unknown, the mean price of € 47 for various alternative forms of care was used.

Indirect nonmedical costs arise when production losses occur due to illness. Productivity costs were calculated according to the friction cost approach [22]. However, as our follow-up takes 12 weeks, the friction cost approach and the human capital method would produce the same results. Production losses can occur under 3 conditions. First, people can be absent from paid work due to sick leave (work loss days). To evaluate a lost day in a paid job, the average age- and gender-specific "friction costs" are used [22]. Second, production losses may occur when people are ill but continue to work with reduced efficiency (work cutback days). The number of work cutback days was estimated as the number of days actually worked when ill multiplied by a self-reported inefficiency score, which ranged between 0 (as efficient as when in good health) and 1 (totally inefficient). Third, people may also be too ill to perform domestic tasks. These costs were evaluated as the price of domestic help at € 8.83 per hour.

Statistical Analyses

All analyses were performed in accordance with the intention-to-treat principle. The expectation maximization algorithm (EM) in Statistical Package for the Social Sciences (SPSS, version 17) (SPSS, Inc, Chicago, IL, USA) was used to estimate missing values. EM employs maximum likelihood estimation to replace missing values in the data set with estimates.

Analysis of Generic and Clinical Outcomes

Missing EQ-5D scores were imputed at 5-, 8- as well as 12-weeks follow-up using EM. The rationale behind imputing EQ-5D scores for all measurements is that QALYs were

calculated for each different time period separately, that is, QALY1 was calculated from baseline to 5 weeks follow-up, QALY2, from 5 to 8 weeks, and QALY3, from 8 to 12 weeks. In this way, speed of change is taken into account as improvements often occurred in the early stages of the treatments. QALYs for the 3 time intervals were added over the total time span from baseline to the last follow-up at 12 weeks post baseline. QALYs were calculated by multiplying the utility values of the health state by the length of time spent in that health state.

Clinically significant change was determined with Jacobson's and Truax's algorithm for reliable and clinically significant change [24] while using the cutoff score of 16 on the CES-D as an indication of recovery. For a change to be clinically significant, a participant had to have recovered as well as had to have shown reliable improvement at 12-weeks follow-up.

Analysis of Costs and Economic Evaluation

Costs were determined at 5-, 8- and 12-weeks follow-up. Total cumulative costs over 12 weeks were determined by adding up the costs of each of the 3 time intervals with missing cost data imputed using the EM algorithm.

The economic evaluation consisted of a cost-utility analysis and a cost-effectiveness analysis. For both analyses, the incremental cost-effectiveness ratio (ICER) was calculated as $(C_1-C_0)/(E_1-E_0)$, where C are costs and E is the effect and the experimental and comparator conditions are indexed with the 1 and 0 subscripts. The incremental cost-utility ratio will focus on the net costs per QALY gained. The cost-effectiveness ratio focuses on the net costs per reliable and clinically significantly improved case of depression. Nonparametric bootstrap resampling techniques (with 5000 replications) were used to take into account the stochastic uncertainty of the ICER estimates. In addition, the bootstrap analysis helped to obtain the median ICER and its 95% confidence interval from all 5000 simulated ICERS. The median and its confidence interval were based on the 50^{th}, 2.5^{th}, and 97.5^{th} percentile of the distribution of the 5000 bootstrapped ICERs. As the arrhythmic mean may not provide the best estimate for the ICER, we only present the median ICER.

The scatter plots of 5000 bootstrapped ICERs on the cost-effectiveness plane were generated. This helps to produce estimates of the probability that (1) better health is generated for more costs (northeast quadrant), (2) that the intervention is inferior relative to the control condition because less health is produced at additional costs (northwest quadrant), (3) that less health is generated for lower costs (southwest quadrant), and (4) that the intervention dominates because better outcomes are obtained for lower costs (southeast quadrant). Another way of illustrating the cost-effectiveness results is the cost-effectiveness acceptability curve. Such an acceptability curve represents the probability that the intervention is cost-effective relative to the comparator condition, given varying ceilings for the willingness to pay (WTP) for one quality-adjusted life-year or for one case of depression showing reliable and significant improvement.

Sensitivity Analyses

In the main analysis, maximum likelihood estimation was used to handle missing data. Due to high attrition, we repeated analyses using multiple regression to impute missing data.

Results

Participants

The average age of the 263 participants at baseline was 45 years (SD 12.1). Most participants were female (187/263, 71%) and the majority had higher vocational education/university (168/263, 64%) or intermediate vocational education/high school (72/263, 27%). Almost all participants were Dutch (243/263, 92%). The mean score of the participants on the CES-D was 31.7 (SD 7.5, median 31.0) at baseline. Mean utility score on the EQ-5D was 0.61 (SD 0.22). There were no statistically significant differences between the three groups with respect to the demographics, depressive symptoms, or quality of life scores at baseline [13]. At baseline, total per capita costs were € 846, € 893, and € 925 for the cognitive behavioral therapy, problem-solving therapy, and waiting list groups respectively. No significant differences were found in total costs between the three groups, $F_{2, 262} = 0.10$, $P = .91$.

Clinical Outcomes

After 12 weeks, cognitive behavioral therapy and problem-solving therapy resulted in significantly higher quality of life scores and lower depression scores than waiting list placement. Full details of the main clinical outcomes are reported elsewhere [13].

The mean number of QALYs during the period of 12 weeks was 0.16 for cognitive behavioral therapy (95% CI 0.152 – 0.169), 0.16 for problem-solving therapy (95% CI 0.152-0.168), and 0.15 for wait-list (95% CI 0.142-0.159). No significant differences were found between groups, $F_{2, 262} = 1.83$, $P = .16$. Regarding clinically significant change, both cognitive behavioral therapy and problem-solving therapy tended to show more clinically significant change than waiting list placement after 12 weeks, $\chi^2_{2, 263} = 5.10$, $P = .08$. The number of participants showing clinically significant change was 25 (28.4%) for cognitive behavioral therapy, 23 (26.1%) for problem-solving therapy, and 13 (14.9%) for waiting list placement.

Health Care Service Use

Cost data were available at baseline from 252 participants (cognitive behavioral therapy, n = 83; problem-solving therapy, n = 85; waiting list group, n = 84). At 12-weeks follow-up, 147 participants returned cost data (cognitive behavioral therapy, n = 45; problem-solving therapy, n = 40; wait-listed group; n = 62). For descriptive purposes, Table 2 presents the number of participants using health care services with productivity costs due to production losses, based on the sample of participants that returned cost data at baseline and at 12-weeks follow-up.

At baseline, more than half of the participants used some form of medication. This level of medication use continued into the follow-up period. Of all participants, 30% to 40% had contact

with their general practitioner at both assessments, which happened to the same degree across all conditions. Reasons for visiting the general practitioner were, however, unknown. Frequently used services other than the general practitioner included visits to psychotherapists with a private practice, medical specialists, physiotherapists, and regional mental health services. At follow-up, visiting the private practice psychotherapist was reduced only in the problem-solving therapy group. The use of regional mental health services was reduced in both intervention groups.

With regard to production losses, a majority of the participants reported domestic costs at baseline with evident reductions reported by both intervention groups at follow-up. Reductions were also reported by both intervention groups in the number of participants that incurred costs due to work loss and work cutback in paid employment.

Table 2. Number and percent of participants using health care services and experiencing production losses

	At Baseline			At 12 weeks		
	CBT	PST	WL	CBT	PST	WL
Cost Item	n = 83	n = 85	n = 84	n = 45	n = 40	n = 62
Health care services	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Medication[a]	46 (56.1)	46 (54.1)	43 (51.2)	25 (55.6)	18 (45.0)	35 (56.5)
General practitioner	37 (44.6)	26 (30.6)	34 (40.5)	18 (40.0)	14 (35.0)	22 (35.5)
Regional mental health service	13 (15.7)	14 (16.5)	15 (17.9)	4 (8.9)	3 (7.5)	10 (16.1)
Private practice psychotherapist	22 (26.5)	29 (34.1)	21 (25.0)	13 (28.9)	8 (20.0)	14 (22.6)
Psychotherapist hospital	5 (6.1)	5 (5.9)	5 (6.0)	3 (6.7)	2 (5.0)	5 (8.1)
Company doctor	6 (7.3)	10 (11.8)	6 (7.1)	3 (6.7)	1 (2.5)	6 (9.7)
Social worker in company	4 (4.9)	2 (2.4)	2 (2.4)	0	0	1 (1.6)
Medical specialist	19 (23.2)	15 (17.6)	13 (15.5)	10 (22.2)	9 (22.5)	9 (14.5)
Physiotherapist	17 (20.7)	19 (22.4)	16 (19.0)	10 (22.2)	6 (15.0)	8 (12.9)
Social worker	2 (2.4)	2 (2.4)	3 (3.6)	0	0	1 (1.6)
Consultation for alcohol/drugs	0	0	1 (1.2)	0	0	1 (1.6)
Home care	4 (4.9)	3 (3.5)	1 (1.2)	2 (4.4)	2 (5.0)	1 (1.6)
Alternative care	10 (12.2)	12 (14.1)	17 (20.2)	3 (6.7)	4 (10.0)	7 (11.3)
Self-help group	2 (2.4)	5 (5.9)	2 (2.4)	1 (2.2)	1 (2.5)	0
Production losses						
Work loss	17 (20.7)	13 (15.3)	14 (17.7)	3 (6.7)	1 (2.5)	13 (21.0)
Work cutback	31 (37.8)	31 (36.5)	37 (44.0)	22 (26.7)	8 (20.0)	28 (45.2)
Domestic loss	59 (72.8)	69 (81.2)	68 (81.0)	23 (51.1)	16 (40.0)	49 (79.0)

[a] All types of medication are included.

Costs

Table 3 presents costs for the different cost categories based on imputed data. The majority of total costs were attributable to the indirect (productivity) costs. Indirect costs were, on average, lower by € 201 (€ 1900-€ 1701) and € 258 (€ 1900-€ 1642) for cognitive behavioral therapy and problem-solving therapy, respectively, relative to waiting list placement. The differences in total direct medical costs were largely due to the inclusion of intervention costs for both cognitive behavioral therapy and problem-solving therapy. Overall, the cognitive behavioral therapy group incurred extra costs of € 256 (€ 2814-€ 2558) compared with the waiting list group. Problem-solving therapy led to extra costs of € 147 (€ 2705-€ 2558) compared with waiting list placement. Total costs between groups were not significant, $F_{2, 262} = 0.15$, $P = .86$.

Table 3. Estimated per capita costs (in Euros) by condition during a 12-week period

Cost Item	Costs (€) for 2007		
	CBT	PST	WL
Intervention, total cost	501	338	-
Health care use, mean (SD)	441 (452)	513 (453)	472 (538)
Medication[a], mean (SD)	17 (25)	15 (26)	18 (30)
Sum of direct medical costs[b]	958 (462)	888 (461)	490 (544)
Direct nonmedical costs	156 (156)	175 (162)	168 (203)
Indirect costs	1701 (2562)	1642 (2669)	1900 (3544)
Total costs[c]	2814 (2683)	2705 (2851)	2558 (3691)

[a] Costs of antidepressants, anxiolytics, and hypnotics

[b] Includes costs of intervention, health care use, and medication

[c] Includes direct medical costs, direct nonmedical costs, and indirect costs

Table 4. Incremental cost-effectiveness ratio (ICER)

Comparison and Analysis	Cost-utility Analysis			Cost-effectiveness Analysis		
	Median [a]	Lower Bound [b]	Upper Bound [b]	Median	Lower Bound	Upper Bound
CBT vs WL						
Main analysis [c]	22,609	-322,604	428,771	1817	-9203	18,369
Sensitivity analysis [d]	-52	-144,943	223,908	19	-3856	3688
PST vs WL						
Main analysis	11,523	-285,551	401,101	1248	-18,719	23,742
Sensitivity analysis	-22,779	-105,142	41,183	-2096	-10,796	3319
PST vs CBT						
Main analysis	-21,888	-892,856	927,332	-36	-37,109	1,000,000
Sensitivity analysis	-49,963	-737,794	653,203	3164	-22,844	152,180

[a] Median ICER = 50th percentile of the 5000 bootstrap replications of the ICER.

[b] Lower and upper bounds = 2.5th and 95.5th percentiles of the bootstrap distribution.

[c] Main analysis was conducted with expectation-maximization imputation for missing observations.

[d] Sensitivity analysis was based on regression imputation.

Cost-utility: ICERs

Cost-utility analysis showed that the median incremental cost-effectiveness ratio for cognitive behavioral therapy versus waiting list placement resulted in € 22,609 per QALY gained. Hence, for each QALY gained by offering cognitive behavioral therapy instead of waiting, extra costs of € 22,609 are incurred. The left-hand panel of Figure 1 presents the distributions over the cost-effectiveness plane for the comparisons between the 2 active interventions and waiting list. Of the simulated ICERs, 28% are in the southeast quadrant, indicating a 28% probability that cognitive behavioral therapy is a better treatment because it generates more health effects for lower costs when compared with a waiting list control group. However, the majority of the simulated ICERs (67%) occur in the northeast quadrant, indicating that a health gain is produced, but at additional costs. Table 4 presents the median ICERs and their confidence intervals.

The median ICER for problem-solving therapy versus waiting list placement resulted in extra costs of € 11,523 per QALY gained by offering problem-solving therapy instead of waiting. In addition, there is a 58% probability that it is more effective in terms of QALYs at extra costs and there is a 37% probability that it is more effective at a lower cost.

Problem-solving therapy has a 35% probability of being the dominant treatment. And half of the ICERs are equally distributed over the northwest quadrant (24%) and the southwest quadrant (27%). The fact that the ICERs are almost equally divided over the four quadrants indicates no obvious preference for 1 of the 2 active interventions (Figure 3, left-hand).

Cost-utility: Acceptability

The right-hand panel of Figure 1 presents the acceptability curves for the comparisons between the 2 active interventions and waiting list placement. Regarding the active interventions versus waiting list placement, there is a 28% and 38%

probability respectively that cognitive behavioral therapy and problem-solving therapy are more cost-effective than waiting, if society places a zero value on one gained QALY. However, the probability of Internet-based therapy being more cost-effective increases when the willingness to pay for a QALY gained increases. To illustrate, with a willingness to pay ceiling of € 30,000 per gained QALY, then cognitive behavioral therapy and problem-solving therapy have a probability of 52% and 61% respectively of being more cost-effective compared with waiting.

Cost-effectiveness: ICERs

In the cost-effectiveness analysis, the incremental cost-effectiveness ratio is expressed in terms of additional costs per clinically significant change in depressive symptom severity. The median ICER for cognitive behavioral therapy versus waiting list placement resulted in € 1817, indicating that by offering cognitive behavioral therapy instead of placing participants on a waiting list, extra costs of € 1817 are incurred for a health gain of one additional reliably improved participant. There is a 69% probability that a participant will change with cognitive behavioral therapy, but at additional costs. The distributions of the bootstrapped ICERs over the cost-effectiveness plane for the comparisons between the 2 active interventions and waiting list placement are presented in the left-hand panel of Figure 2. For problem-solving therapy versus waiting list placement, ICER is € 1248 per reliably improved participant. The probability that problem-solving therapy is more effective in terms of reduced depression severity but more costly than waiting is 60%. Comparing problem-solving therapy with cognitive behavioral therapy resulted in a median ICER of -36. As for cost-utility, the four quadrants each contain an almost equal percentage of the ICERs, meaning no evident preference for 1 of the 2 Internet-based treatments (Figure 3, right-hand).

Figure 1. Distribution of bootstrapped incremental cost-effectiveness ratios (ICERs) (n = 5000) in the cost-effectiveness plane and ICER acceptability curve based on willingness to pay for one extra quality-adjusted life-year gained

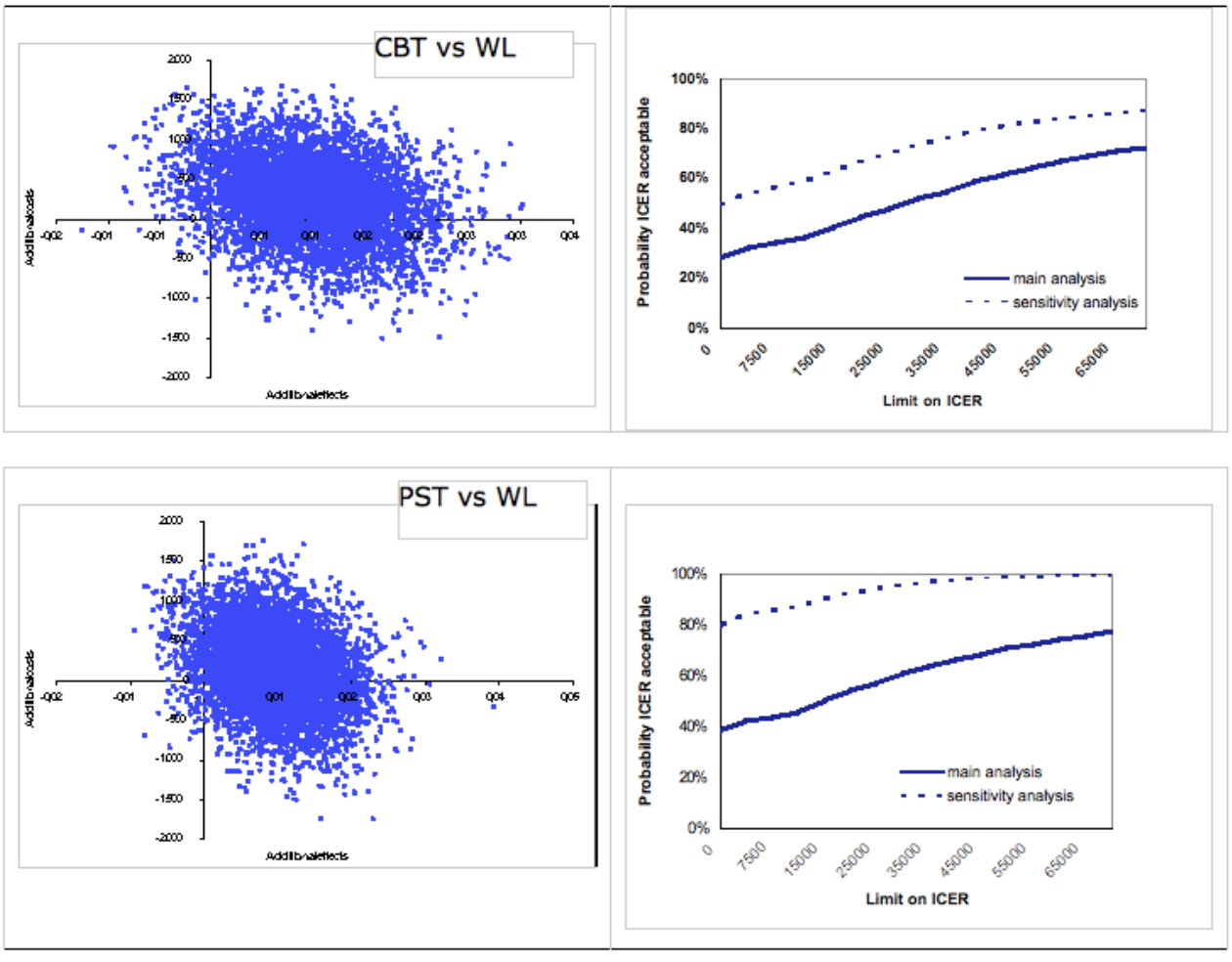


Figure 2. Distribution of bootstrapped incremental cost-effectiveness ratios (ICERs) (n = 5000) in the cost-effectiveness plane and ICER acceptability curve based on willingness to pay per clinically significant change in depressive symptoms

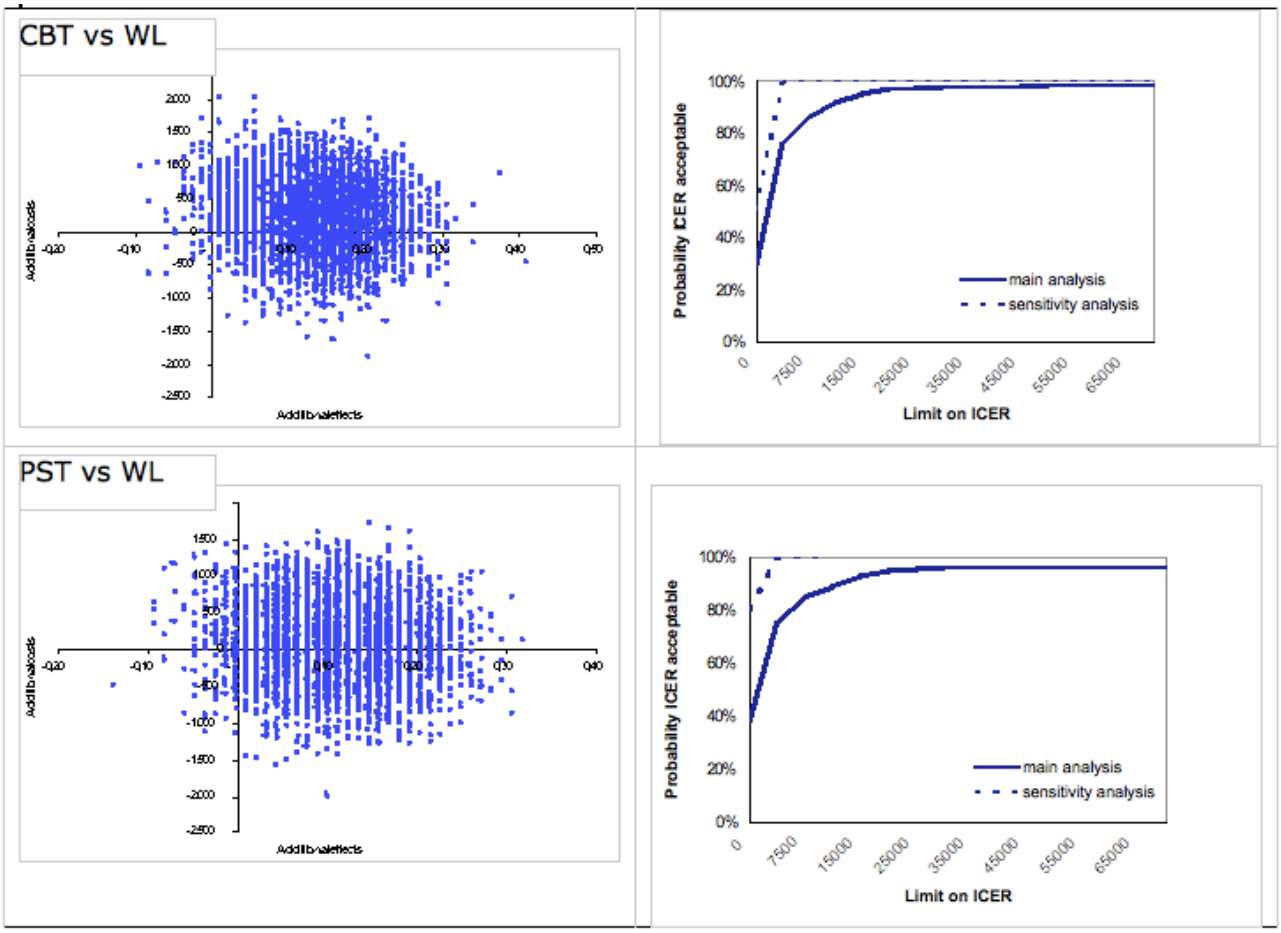
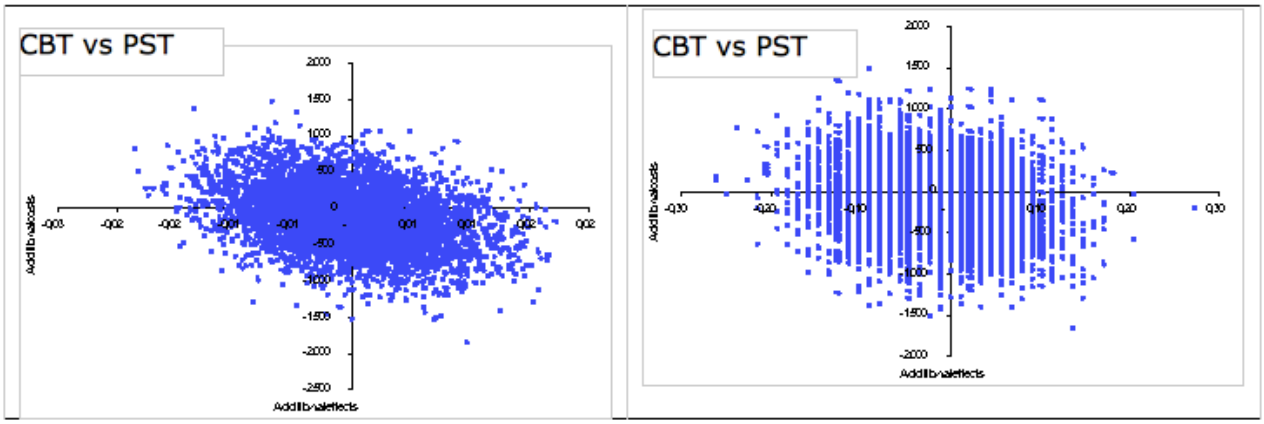


Figure 3. Distribution of bootstrapped incremental cost-effectiveness ratio (n = 5000) in the cost-effectiveness plane for quality-adjusted life-years (left-hand) and clinically significant change (right-hand).



Cost-effectiveness Acceptability

The acceptability curve for cognitive behavioral therapy versus waiting list placement showed that with no willingness to pay for one reliably improved participant, there is a 30% probability that cognitive behavioral therapy is more cost-effective than waiting (Figure 2, right-hand panel). However, the probability rapidly increases when people are willing to pay more for clinically significant improvement. With a willingness to pay of € 5000 and € 10 000, cognitive behavioral therapy has a probability of 75% and 91% respectively of being more cost-effective compared with waiting list placement. For problem-solving therapy versus waiting list placement, the probability that problem-solving therapy is more cost-effective is 38% in the case of no willingness to pay. However, WTP of € 5000 and of € 10 000 result in probabilities of 75% and 89%.

Sensitivity Analysis

Cost-utility and cost-effectiveness analyses were performed using multiple regression as an imputation method for missing

observations. Regarding cost-utility, regression imputation led to better results for both interventions compared with the main analysis (where maximum likelihood estimation was used), the probabilities that the interventions result in better outcomes at lower costs than waiting list placement are 48% for cognitive behavioral therapy (was 28% when using maximum likelihood estimation) and 79% for problem-solving therapy (was 37% when using maximum likelihood estimation). For the comparison between the two active treatments, results are in favor of problem-solving therapy with a 72% probability that problem-solving therapy leads to better outcomes in terms of QALYs at lower costs. Cognitive behavioral therapy and problem-solving therapy have high probabilities (73% and 95% respectively) of being acceptable treatments with a WTP ceiling of € 30 000 (Figure 1, right-hand panel).

In the cost-effectiveness analyses, regression imputation also resulted in higher probabilities for the interventions being cost-effective compared with waiting list placement. In this case, the probabilities that the interventions will result in more clinically significant change at lower costs are 50% for cognitive behavioral therapy (was 30% when using maximum likelihood estimation) and 80% for problem-solving therapy (was 36% when using maximum likelihood estimation). And problem-solving therapy has a high probability (77%) of producing worse clinical outcomes at lower costs than cognitive behavioral therapy. With a WTP ceiling of € 5000, the probability of cognitive behavioral therapy being acceptable is 99% from a cost-effectiveness perspective (Figure 2, right-hand panel), while for problem-solving therapy this probability is 80% in the case of no willingness to pay.

Discussion

Main Findings

At first glance, cost-utility analyses produced conservative results regarding the efficiency of Internet-based treatment. With no willingness to pay for one extra quality-adjusted life-year, cognitive behavioral therapy and problem-solving therapy had a probability of only 28% and 38% of being more acceptable than waiting. But generally, people are willing to pay for one extra quality-adjusted life-year, although there is no consensus regarding the value of one QALY [25]. When the willingness to pay was raised to € 30 000, then the Internet-based interventions had a 52% and 61% probability of being the preferred option. With the same threshold of € 30,000, sensitivity analyses based on another way of imputing missing observations showed similar or higher probabilities (≥ 73%) of cognitive behavioral therapy and problem-solving therapy being acceptable treatments, thus attesting to the robustness of our findings. From a cost-effectiveness perspective, both treatments showed high probabilities of being more cost-effective compared with waiting even when society might place modest values on one clinically significant improved patient; cognitive behavioral therapy and problem-solving therapy showed a 91% and 89% probability respectively of being more cost-effective than waiting when society was assumed to have been prepared to pay € 10,000 for recovery from depression. Comparing both Internet-based treatments indicated no obvious preference for one of the treatments.

Implications

Only a small number of depressed people are reached within traditional health care settings [26]. As Internet-based treatments are more accessible than traditional therapies, these treatments are assumed to be able to reach more people in need of treatment. Internet-based treatments for depression, mostly based on cognitive behavioral therapy, have been shown to be effective [12]. An important further step is to assess the cost-utility and cost-effectiveness of Internet-based treatments. Cost-utility analysis allows health care organizations and other stakeholders to compare the benefits of online treatment with other interventions across a range of disorders with which treatments for depression may be in competition for limited resources. The study of McCrone et al (2004) made a start by showing that computer-delivered cognitive behavioral therapy had a high likelihood of being cost-effective in primary care patients. Our study showed that two different Internet-based treatments with modest levels of therapist support were cost-effective in reducing depressive symptom severity in the general population, even in the conservative scenario that society had a limited willingness to pay for a reliably improved patient.

From a cost-utility point of view, the acceptability of the two treatments depends to a larger extent on what society is prepared to invest to achieve one quality-adjusted life-year. Differences in results between cost-utility and cost-effectiveness results can be explained by the nature of the outcomes. The quality-adjusted life-year is a measure of disease burden, including both the quality and the quantity of life lived, covering diverse health state dimensions, including mental health. The interventions were, however, directed at improving mental health, that is, reducing depression, and a depression-specific measure was used. Therefore, it cannot be expected that improvement in depression will result in across-the-board improvement in quality of life.

Besides, this study showed that a brief intervention based on problem-solving therapy seems to be a good alternative for Internet-based cognitive behavioral therapy in terms of cost-effectiveness. The generic nature of problem-solving therapy makes it suitable as a first step in a stepped care model. This would enable therapists to free up their limited resources and direct these to people presenting with more complex and severe symptomatology.

Limitations

We acknowledge the following limitations of this study. First, we were faced with a high attrition rate. The use of maximum likelihood estimation to handle missing data might have introduced some bias. It is, however, a highly recommend method [27]. In a sensitivity analysis, outcomes and costs were, in addition, calculated using multiple regression as an imputation method for missing observations. Cost-effectiveness evaluations then became more favorable for both interventions. This implies that with high attrition rates, results partly depend on the imputation method used. For our data, it was understood that

maximum likelihood estimation was the more conservative method; it was also the method used in the main analysis.

Second, the costs and effects were considered in the relatively short time span of 12 weeks. Accordingly, we do not know how the cost-effectiveness of Internet-based treatment is affected when a longer period is used, and this is a question that remains open for further research. Third, the study was not powered to detect statistically significant differences in outcomes and costs between the two Internet-based interventions. Therefore results regarding the comparison between the two active interventions should be considered explorative. Fourth, we used self-report for all measures. Self-report can be vulnerable to recall bias. The self-report of medication and care products for example, is often underestimated [28].

In light of these limitations, our findings should be interpreted with some caution.

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Conflicts of Interest

None declared

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Abbreviations

CBT: cognitive behavioral therapy
CES-D: Center for Epidemiological Studies Depression scale
EM: expectation maximization
EQ-5D: EuroQol Questionnaire
ICER: Incremental cost-effectiveness ratio
PST: problem-solving therapy
QALY: quality-adjusted life-year
WL: waiting list control group
WTP: willingness to pay

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Original Paper

Providing Web-Based Feedback and Social Norms Information to Reduce Student Alcohol Intake: A Multisite Investigation

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Abstract

Background: Unhealthy alcohol use among university students is cause for concern, yet the level of help seeking behavior for alcohol use is low within the student population. Electronic brief interventions delivered via the Internet present an alternative to traditional treatments and could enable the delivery of interventions on a population basis. Further evidence is needed of the effectiveness of Internet-delivered interventions and of their generalizability across educational institutions.

Objective: Our objective was to evaluate the effectiveness across 4 UK universities of a Web-based intervention for student alcohol use.

Methods: In total, 1112 participants took part. Participants were stratified by educational institution, gender, age group, year of study, and self-reported weekly consumption of alcohol and randomly assigned to either the control arm or to the immediate or delayed intervention arms. Intervention participants gained access to the intervention between weeks 1 to 7 or weeks 8 to 15, respectively. The intervention provided electronic personalized feedback and social norms information on drinking behavior accessed by logging on to a website. Participants registered interest by completing a brief screening questionnaire and were then asked to complete 4 further assessments across the 24 weeks of the study. Assessments included a retrospective weekly drinking diary, the Alcohol Use Disorders Identification Test (AUDIT), and a readiness-to-change algorithm. The outcome variable was the number of units of alcohol consumed in the last week. The effect of treatment arm and time on units consumed last week and average units consumed per drinking occasion were investigated using repeated measures multivariate analysis of covariance (MANCOVA). In addition, the data were modeled using a longitudinal regression with time points clustered within students.

Results: MANCOVA revealed a main effect of time on units of alcohol consumed over the last week. A longitudinal regression model showed an effect of assessment across time predicting that participants who completed at least 2 assessments reduced their drinking. The model predicted an additional effect of being assigned to an intervention arm, an effect that increased across time. Regression analysis predicted that being male or being assigned to an intervention arm increased the odds of not completing all assessments. The number of units of alcohol consumed over the last week at registration, age, university educational institution, and readiness to change were not predictive of completion.

Conclusions: Delivering an electronic personalized feedback intervention to students via the Internet can be effective in reducing weekly alcohol consumption. The effect does not appear to differ by educational institution. Our model suggested that monitoring alone is likely to reduce weekly consumption over 24 weeks but that consumption could be further reduced by providing access to a Web-based intervention. Further research is needed to understand the apparent therapeutic effect of monitoring and how this can be utilized to enhance the effectiveness of brief Web-based interventions.

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KEYWORDS

Student; eHealth; brief intervention; alcohol; Web-based interventions

Introduction

Unhealthy alcohol use among university students continues to be of concern given the immediate and long-term physical, psychological, and social consequences of this behavior [1-4]. The level of heavy episodic or binge drinking within this population [5] increases the risk of students engaging in risky, illegal, and violent behaviors [6-8]. In addition to the immediate personal and societal costs associated with alcohol misuse, heavy consumption during university is predictive of alcohol misuse and dependence in later life. Furthermore, help-seeking for alcohol problems is low [9], meaning that relatively few students access the traditional support services available.

Alcohol interventions using the Internet are being developed that build on the established brief interventions evidence base. These interventions are viewed as having potential benefit to those who have not sought traditional modes of support or treatment [10]. In addition, e-delivery may aid early self-identification of alcohol problems via the wide-scale access students have to the Internet. This combined with ability to enable confidential access at a time convenient to the user make this mode of delivery especially attractive.

Recent systematic reviews of electronic forms of alcohol intervention have indentified 17 randomized controlled trials involving young people [11,12]. A recent meta-analysis concluded that single sessions of personalized feedback, including those delivered electronically (without therapist input), can be effective in reducing problem drinking in the short-term (with follow-up up to 9 months after the intervention) [13]. Reviews suggest that interventions providing personalized feedback and social norms information can be effective [14]. Inconsistencies in outcome relate to weaknesses in the methodological quality of some evaluations [11,13-15], although over time there appears to have been a marked improvement in the quality of studies. In particular, there has been an increase in the number of studies using a randomized controlled (RCT) design and well-validated measures of alcohol consumption. Despite these advancements, published results from European trials investigating the effectiveness of Web-based interventions are relatively rare (in comparison with the number of trials published from North America and Australia). In addition, few trials explore the generalizability of effectiveness of interventions at multiple institutions. Indeed all the trials identified in a recent Cochrane review [14] were carried out at single educational institutions. Thus, there is a need to investigate if an intervention developed at one educational institution can be effective at modifying behavior of students based at other educational institutions (without the need for in-person contact during recruitment, assessment, or intervention delivery).

Our recent randomized controlled trial suggested that Web-based interventions for students, incorporating brief personalized feedback and social norms information, can be effective in reducing per occasion alcohol consumption among UK students [16]. The results showed that an electronic approach to delivering personalized feedback and social norms information could be effective in a European population. A second and larger RCT has replicated these findings and showed the reduction to be maintained at the 4-month follow-up. A limitation common to both these studies was the recruitment of students from only one educational institution. The existing evidence base says little about whether an intervention developed at one university will generalize to other educational institutions. Thus, the current research aimed to evaluate the effectiveness of a Web-based intervention developed at one educational institution for moderating the alcohol consumption of students from other educational institutions by including participants from 4 other UK universities. There is also little information on whether time of academic year affects outcome. Within the current research, it was hypothesized that the presentation of electronic personalized feedback and social norms information would reduce alcohol intake regardless of when during the academic year the intervention was available.

Methods

Procedure

The mode of student recruitment varied across educational institution; however, all used some form of e-recruitment (eg, notification included within weekly student union bulletin, posting of invitation within student portal, and direct email to students). In addition, some educational institutions posted paper-based posters around campus and provided verbal reminders to their students (eg, during induction seminars).

Interested students were invited to register during October 2007 (Time 0). The trial was conducted over a 27-week period beginning in November 2007 (Time 1).

Students who registered were asked to complete a retrospective drinking diary and the Alcohol Use Disorders Identification Test (AUDIT); these assessments are described in more detail below. At Time 0, students were also asked to provide details of their demographics including age, gender, ethnicity, graduate status, and area of study.

Only students who were consumers of alcohol and provided details of their alcohol consumption at Time 0 were eligible to enter the current study. All students who consumed alcohol at least once every 6 months were included in the current study. This was deemed important because (1) if found to be effective, the intervention would be made available to all students, and, therefore, an evaluation of the effect on those consuming below hazardous or harmful levels is required as it is possible such information could have an adverse impact, and (2) previous research has shown that misperceptions of social norms are not only the domain of those engaging in risky behavior, and,

therefore, to correct misperceptions across the population, feedback was necessary for all students.

Eligible students were stratified by educational institution, gender, age group (above or below 21 at entry to undergraduate degree program), graduate student status, and self-reported weekly consumption of alcohol (within or above sensible drinking guidelines).

Research Design

The study was an RCT with 3 arms: 1 control arm (assessment only) and 2 intervention arms (immediate and delayed access). Participants were stratified by educational institution, gender, age group, year of study, and self-reported weekly consumption of alcohol and randomly assigned to either the control or to the immediate or delayed intervention arms. Participants were not blind to their allocation.

After allocation to study arm, participants were emailed further information about the study along with an electronic link to the initial Time 1 (week 1) assessment. All contact with participants was via email. The Time 1 email contained an embedded link to either the control assessment electronic survey (completed by those in the control arm and in the delayed intervention arm) or to the intervention website (for those in the immediate intervention arm). Both websites contained identical project information and assessments (question presentation was the same between the two websites). Before completing their assessment participants were provided with a study briefing and provided informed consent online. Participants were advised that their having completed the earlier registration assessment did not mean they had to consent to taking part in the trial. Once participants in the intervention arm had completed their assessment, they received brief personalized feedback and social norms information via the website. Participants who did not complete the Time 1 assessment during week 1 were sent weekly reminders for up to 3 weeks (or until they had completed the assessment).

Participants in the immediate and delayed intervention arms had access to the intervention during weeks 1 through 7 or weeks 8 through 15, respectively. Regardless of which arm they were allocated to, participants were assessed at 5 time points.

Following the initial assessment at Time 1, additional assessments were completed at week 8 (Time 2), week 16 (Time 3), and week 24 (Time 4) (see Figure 1). The follow-up assessments (at Times 2 through 4) for intervention participants were also collected via the control assessment electronic survey. Those in the delayed intervention arm completed their Time 2 assessment via the intervention website and received personalized feedback once their assessment was completed. Delayed intervention participants follow-up assessments (at Time 3 and Time 4) were completed via the control assessment electronic survey. On completion of each Time 1 through Time 4 assessment, participants were entered into a prize draw to win a £25 Amazon voucher (ie, 4 draws per educational institution).

The study was approved by the Leeds East National Health Service (NHS) Research Ethics Committee and, where required by education institutional procedures, also by the relevant university ethics committee.

Sample Size

From previous work we ascertained that the average natural logarithm of the number of units of alcohol consumed over the last week plus 1 for students is approximately 1.3 with a standard deviation of 0.58 and, hence, a variance of 0.34. A change in natural logarithm of the number of units consumed over the last week plus 1 over the intervention period will therefore have a variance of less than 0.68 (ie, 2 times 0.34). We have taken it to be equal to 0.49 (ie, 0.7^2).

The difference in the change in the natural logarithm of the number of units consumed over the last week plus 1 between two treatment arms might be tested with a *t* test where the relevant standard deviation is 1.3. A suitable difference in change in the natural logarithm of the number of units consumed over the last week plus 1 was taken as 0.5, so that we sought a standardized difference of 0.5. For a significance level of alpha equal to .05 and a power of 1 minus beta equal to .8, a sample size of 107 participants per treatment arm was required. Given the lower power of this test compared with the analysis we proposed, this set an upper limit to the sample size as 107 participants per treatment arm or 321 participants completing the trial. To allow for attrition we aimed to recruit at least 500 participants in total.

Assessments

Participants were asked to complete a range of assessments detailing their alcohol consumption, level of alcohol dependence, readiness to change, psychological well-being and risk-taking behavior. Only those assessments of relevance to the reported analyses are described here.

Participants completed a 7-day retrospective drinking diary for the previous week at each of the 5 assessments at Time 0 through Time 4. To facilitate accuracy, participants were provided with a list of a variety of types of drinks (eg,175 milliliters red wine, 1 pint of ordinary strength lager) and asked to indicate how many of each they had consumed each day for the last 7 days. The number of drinks was then converted to standard UK units of alcohol (1 unit = 8 grams of pure ethanol) using published UK government guidelines. This retrospective drinking diary method has been previously used within a student population [16], and the approach has been recommended as a measure for groups that drink regularly [17]. The main outcome measure was total units consumed over the last week. A secondary outcome measure was the number of units consumed per average drinking occasion.

Participants completed the AUDIT at Times 0 through 4. AUDIT is a 10-item measure investigating the quantity and frequency of alcohol consumption, problems related to use, and dependence symptoms. Items are scored on a scale of 0 to 4, and a cutoff score of 8 is recommended for the identification of possible hazardous or harmful drinking [18,19]. The cross-national validation study of the AUDIT found high levels of sensitivity (.92) and specificity (.94) [20], and the measure has been widely used.

Readiness to change drinking behavior was measured (at Times 1 through 4) using a 3-question algorithm developed by Epler et al [21]. The questions investigate level of change in drinking

("Has the amount you drink changed in the past three months?"), propensity toward changing drinking behavior ("Are you interested in drinking less?"), and whether the perceived drinking level is too high ("Do you drink more than you should?") The algorithm categorizes drinkers into a precontemplation group, a contemplation group, or an action group.

Intervention

Participants in the immediate and delayed intervention arms gained access to Unitcheck (www.unitcheck.co.uk). Unitcheck provides personalized feedback on alcohol consumption and social norms information. This feedback was available every time participants visited the website and completed the online survey. The online feedback, delivered after students completed the retrospective drinking diary alongside a number of other questions outlined below, consisted of 3 main sections: (1) feedback on level of alcohol consumption, (2) social norms information, and (3) generic information.

Feedback on Level of Alcohol Consumption

Participants were presented with statements indicating the number of alcohol units they consumed per week and the associated level of health risk. Statements were standardized for each risk level and gave advice about whether personal alcohol consumption should be reduced or maintained within the current sensible levels [22]. The number of alcohol-free days was indicated alongside information stating that it is advisable to have at least 2 per week. In addition, students who consumed at least twice the daily units recommended by the UK government (ie, females who consumed 6 or more units [48 grams pure ethanol] or males who consumed 8 or more units [64 grams pure ethanol]) were advised on the number of binge episodes during the week, and it was suggested that they may want to reduce the amount they consumed per occasion.

Social Norms Information

Personalized statements were presented that summarized the percentage of university students who report drinking less alcohol than they consume. This was calculated relative to the risk level generated in section 1 of the feedback. The frequency of students within each risk level was established from data collected as part of an earlier university survey [23] and checked against the levels of consumption reported within the current sample. Information was also provided about the negative effects of alcohol intake reported by students who consume alcohol within the same risk category.

Generic Information

Generic information provided standard advice on calculating units and the general health risks of high levels of consumption and outlined sensible drinking guidelines publicized in the United Kingdom. Tips for sensible drinking and the contact details of both local and national support services were also presented.

Data Analysis

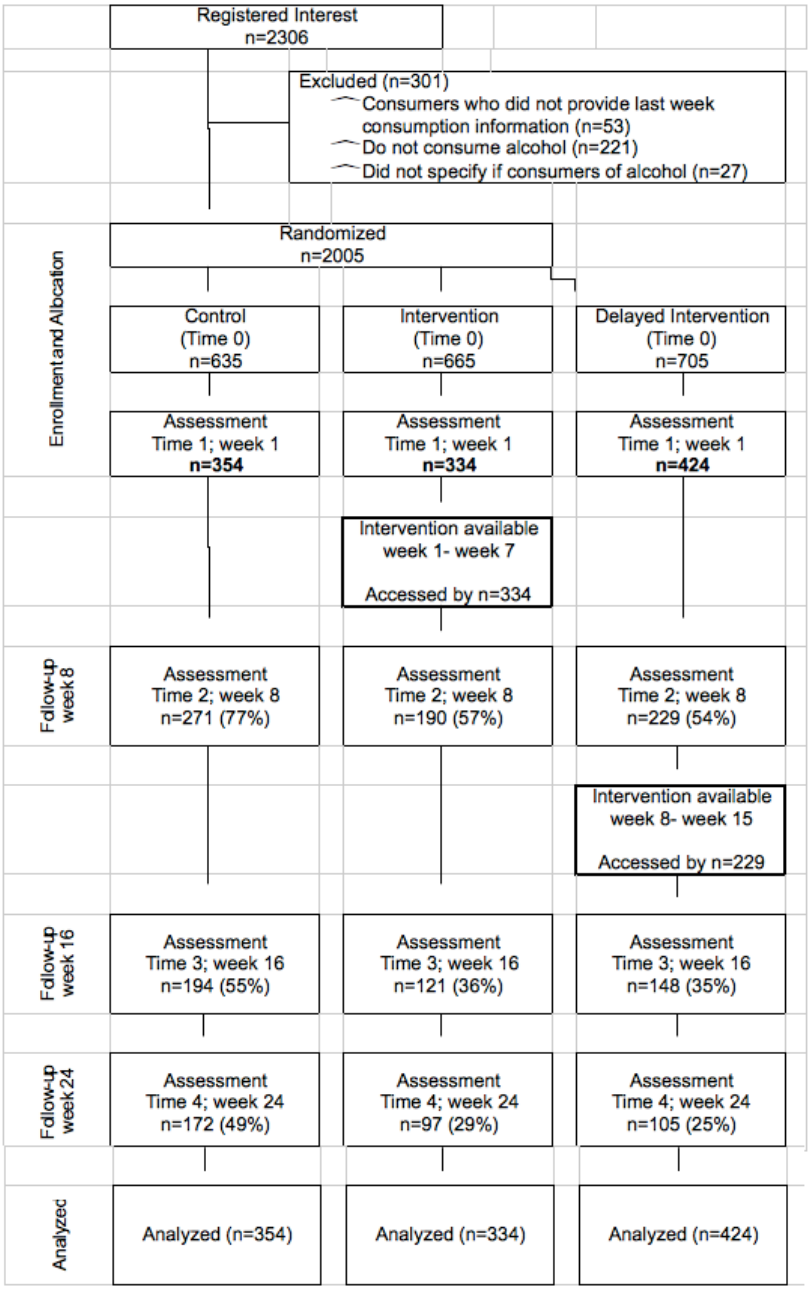
The effect of treatment arm and time on units consumed the previous week and average units consumed per drinking occasion were investigated using repeated measures multivariate analysis of covariance (general linear model) (MANCOVA). Within this analysis, the dependent variable was units consumed, the independent variable was treatment arm, and the covariate was the natural logarithm of the number of units consumed the previous week at registration. All analyses were carried out on the basis of condition allocation with the last known value brought forward. Due to the data being positively skewed, the natural logarithm of 1 plus the number of units consumed was used for all analyses. The number of units presented within the text and tables is the number of original scale units. These analyses were undertaken using SPSS, version 15 (SPSS Inc, Chicago, IL, USA).

Previous research has suggested differential attrition according to treatment arm and some trials have observed relatively high rates of attrition. These trial characteristics render the traditional repeated measures MANCOVA problematic, specifically liable to dropout bias. Therefore, an additional analysis of the primary outcome data (ie, units consumed the previous week) was planned that could accommodate these characteristics [24], namely, modeling the data using a longitudinal regression with time points clustered within students. That is, regression of the natural logarithm of the number of units plus 1 regressed upon occasion, male gender, age, and the other covariates considered. Measurements were clustered within individuals, making this a multilevel model. The model was fitted on a log scale, and this was inverted to present on the original scale of units. It was also possible that any observed effect of intervention could have been artificially produced by differential dropout, for example, heavier drinkers may have been less likely to complete assessments. To investigate this, a logistic regression was fitted to predict which students would not complete the study. Included in the regression analysis were age, educational institution, units consumed the previous week at Time 0, sex, condition arm, and readiness to change. To clarify the position with respect to previous alcohol consumption, a box plot was generated to compare noncompleters with assessment completers. This analysis was undertaken with Stata, version 11.0 (StataCorp, College Station, TX, USA).

Results

A total of 2306 students registered interest in being involved in the project. Of these, 2005 eligible students were randomized to a study arm and invited to take part (see Figure 1 for exclusion criteria). Of these, 54% (1112/2005) of students provided informed consent to be involved in the trial, a valid username, and completed the Time 1 assessment. Of the 1112 students who completed the Time 1 assessment, 690 (62%) provided Time 2 data at week 8, 463 (42%) at Time 3 at week 16, and 374 (34%) provided Time 4 data at week 24 (see Figure 1).

Figure 1. Participants flow through the trial



Of the 1112 students enrolled in the study, 816 (73%) were female. Participants' age ranged from 18 to 67 years (mean 21.45 yrs, SD 5.19). The majority of participants (95%) were undergraduate students, and 92% were predominately white/white British, based on self-reported choice from among several categories of ethnicity. Participants came from a range of subject areas, the largest of which were: medicine and health (319/1112 or 29%), sciences (175/1112 or 16%), arts (155/1112 or 14%), and social sciences (140/1112 or 13%). In all, 4 universities (3 English and 1 Scottish) took part in the study. The 4 universities were heterogeneous in terms of student populations (ie, the number of students potentially being invited to participate varied by educational institution: university A, approximately 15,000; university B, approximately 26,000; university C, approximately 5500; and university D, approximately 5000). The majority of participating students came from university A (591/1112 or 53%), followed by university B (344/1112 or 31%), university C (106/1112 or 10%), and university D (71/1112 or 6%).

Of the 1112 students enrolled in the study, 57% (637) scored 8 or more on the AUDIT and, therefore, their drinking could be considered potentially hazardous or harmful. At registration, the mean number of units of alcohol consumed over the previous week was 23.2 (SD 25.5). The majority of participants (829/1112 or 75%) reported consuming alcohol at least once a week. A further 15% (169/1112) reported fortnightly consumption with 10% (114/1112) consuming either once a month (n=80) or once every 6 months (n=34). Regarding readiness to change, at Time 1, a quarter of participants (276/1112 or 25%) were in the precontemplation phase, almost one-third (319/1112 or 29%) were in the contemplation phase, and approximately one-fifth (246/1112 or 22%) were in the action phase. The remaining participants had either missing data (196/1112 or 18%) or had at that time identified themselves

as nondrinkers (75/1112 or 7%). The demographics of participants by treatment arm are provided in Table 1.

Table 1. Demographics of participants at baseline by treatment arm allocation

	Treatment arm			
	Assessment only n = 354	Delayed access n = 424	Immediate access n = 334	Total n = 1112
Female, n (%)	265 (75%)	304 (72%)	247 (74%)	816 (73%)
Age, mean (SD)	21.3 (4.6)	21.6 (5.8)	21.4 (5.1)	21.5 (5.2)
Undergraduate, n (%)	336 (95%)	411 (97%)	313 (94%)	1060 (95%)
White/white British, n (%)	329 (93%)	388 (92%)	301 (90%)	1018 (92%)
Subject area				
Medicine and health, n (%)	106 (30%)	115 (27%)	98 (29%)	319 (29%)
Arts, n (%)	44 (13%)	66 (16%)	45 (14%)	155 (14%)
Social sciences, n (%)	46 (13%)	50 (12%)	44 (13%)	140 (13%)
Educational institution				
A, n (%)	177 (50%)	228 (54%)	186 (56%)	591 (53%)
B, n (%)	118 (33%)	125 (30%)	101 (30%)	344 (31%)
C, n (%)	36 (10%)	42 (10%)	28 (8%)	106 (10%)
D, n (%)	23 (7%)	29 (7%)	19 (6%)	74 (6%)

Alcohol consumed over the last week and per average occasion is shown in Table 2. Repeated measures MANCOVA revealed a main effect of time on units consumed over the previous week ($F_{3,3324}$ = 6.42, P < .01). Pairwise comparisons showed a significant decrease between Time 1 and all other time points (ie, Time 2 to Time 4) but no significant differences between Time 2, Time 3, or Time 4. There was however no significant time by treatment arm interaction ($F_{6,3324}$ = 1.30, P = .24).

Repeated measures MANCOVA revealed no main effect of time on average units consumed per drinking occasion over the previous week ($F_{3,3324}$ = 0.53, P = .67). There was a significant time by treatment arm interaction ($F_{6,3324}$ = 2.85 P < .001). Further analysis revealed a significant time by consumption effect for the control arm ($F_{3,1059}$ = 12.08, P < .01) with significant reductions between Time 1 and Time 2 (P < .01) and between Time 1 and Time 3 and between Time 1 and Time 4 (P < .01). There was also a significant time effect for the delayed intervention arm ($F_{3,1269}$ = 11.46, P < .01) with significant reductions between Time 1 and Time 2, Time 1 and Time 3, and Time 1 and Time 4 (P < .01). No significant time effect was observed in the immediate intervention arm ($F_{3,999}$ = 0.53, P = .66).

Table 2. Mean (SD) reported units consumed in the previous week by treatment arm and average per occasion over time

		Time 0	Time 1	Time 2	Time 3	Time 4
	n	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Units consumed over the previous week						
Control	354	23.5 (24.0)	17.5 (27.4)	13.6 (19.8)	14.6 (19.6)	15.0 (20.7)
Delayed intervention	424	23.5 (26.1)	14.7 (18.8)	13.4 (18.6)	12.8 (17.9)	11.9 (17.4)
Intervention	334	22.6 (26.4)	15.2 (20.0)	14.5 (20.2)	14.2 (21.1)	13.9 (21.7)
TOTAL	1112	23.2 (25.5)	15.8 (22.3)	13.8 (19.5)	13.8 (19.5)	13.5 (19.8)
Average units consumed per drinking occasion over the last week						
Control	354	14.3 (11.2)	11.0 (8.8)	9.5 (8.5)	9.7 (11.0)	9.3 (11.1)
Delayed intervention	424	14.2(12.9)	10.2 (8.6)	9.3 (9.0)	8.8 (8.3)	8.9 (9.0)
Intervention	334	13.7 (12.3)	8.9 (8.3)	9.1 (10.8)	9.3 (11.1)	9.0 (11.2)
TOTAL	1112	14.1 (12.2)	10.1 (8.6)	9.3 (9.4)	9.2 (10.1)	9.1 (10.3)

Included in the longitudinal regression model were monitoring status (ie, if participants completed any assessment Time 1 through Time 4), sex, and treatment arm (dichotomized to treatment/no treatment), and time since treatment (irrespective of time of initial access to the intervention). Readiness to change, if access to the intervention was immediate or delayed,

and level of consumption at Time 0 were all excluded from the final model as they did not add significantly to the prediction. The longitudinal regression model showed a significant effect of assessment (without intervention) on change across time, showing that participants who completed at least two assessments reduced their drinking (Table 3). The model also predicted an additional effect of being assigned to 1 of the 2 intervention arms, an effect that increased across time.

The model predicted that at week 24 without any assessment completion (ie. completing only Time 0 assessment), females drank 11.5 units per week while males drank 16.0 units. As can be seen in Table 3, when students completed at least 2 of the 5 assessments, predicted consumption decreased to 6.1 units for females and 8.4 units for males. When assigned to an intervention arm, there was an additional effect that increased across time with the model predicting that at week 24 females in the intervention arm had reduced their previous week unit consumption to 3.7 and males in the intervention arm had reduced their previous week consumption to 5.2 units per week. Despite the variation in individual drinking patterns across time, the data included enough observations to see an effect of the intervention. Table 4 provides details of the regression coefficients fitted in the longitudinal model. In addition, an intercept term of 2.44 corresponded to the outcome, log (1 + units consumed), for a female participant at baseline. The model yielded an overall *R2* value of 0.06 and an interclass correlation coefficient of 0.14, indicating that there was significant variation between participants and over time.

Table 3. Prediction of units consumed over the last week at each time point (longitudinal regression model)

	Units Consumed in the Previous Week	
	Females	Males
Without monitoring (ie, Time 0 assessment only)	11.5	16.0
With assessment completion but no intervention (ie, completed at least 2 of the 5 assessments)	6.1	8.4
Assigned to an intervention arm, consumption at week 8 post intervention delivery	5.5	7.6
Assigned to an intervention arm, consumption at week 16 post intervention delivery	5.1	7.1
Assigned to an intervention arm, consumption at week 24 post intervention delivery	3.7	5.2

Table 4. Table of coefficients for longitudinal regression model: log (1+units consumed over the last week) regressed on monitoring status, male sex, and duration since treatment (irrespective of when intervention was first delivered) by restricted maximum likelihood

Covariate	Coefficient	95% Confidence Interval	*P* Value
Monitored (ie, completed at least 2 of the 5 assessments)	-0.64	(-0.74 to -0.54)	< .001
Male	0.33	(0.22-0.43)	< .001
Number of weeks after intervention			
8 weeks	- 0.12	(-0.29 to 0.04)	0.14
16 weeks	- 0.17	(-0.36 to 0.03)	0.09
24 weeks	- 0.54	(-0.83 to -0.26)	.001

Regarding the possible effects of differential assessment completion, 26% (293/1112) of participants completed all 5 assessments with the remaining 74% (819/1112) of participants being classified as nonassessment completers (ie, completing between 2 and 4 assessments). Regression analysis showed that age, education institution, previous week unit consumption at Time 0, and readiness to change were unrelated to completion. The box plot summarizing units consumed over the previous week at Time 0 supported the regression analysis (Figure 2). The difference in the average number of alcohol units consumed in the previous week between those that completed all assessments and participants that did not is less than 0.4 units (with those who completed all assessments drinking slightly less). Being male or being assigned to the intervention increased the odds of not completing all assessments. Males had double the odds of not completing (odds ratio [OR] 2.10, 95% confidence interval [CI] 1.48-2.97) and those in the intervention had approximately triple the odds of not completing (immediate intervention arm OR 2.52, 95% CI 1.80-3.53; delayed intervention arm OR 3.47, 95% CI 2.49-4.85). The completion odds ratio was further supported by chi-square analysis that showed a significant association between the treatment arm and completion of all assessments ($c^2 = 67.4$, $P < .001$; see Table 5).

Figure 2. Average number of units of alcohol consumed over the previous week (expressed as the natural logarithm of the number of units plus 1) at baseline (Time 0) by assessment completion status

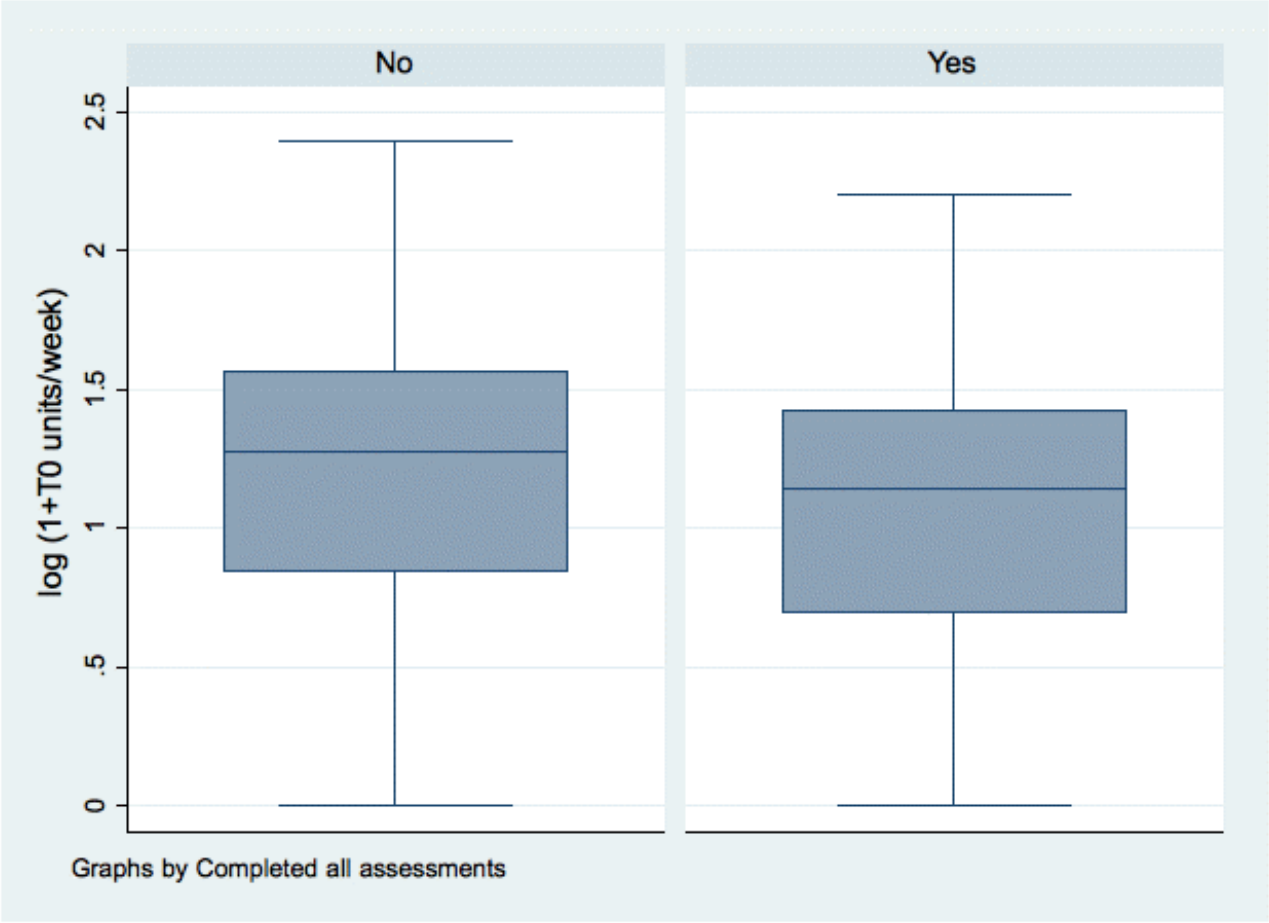


Table 5. Completion status by treatment arm

Completed All Assessments	Treatment Arm			
	Assessment Only n (%)	Delayed Access n (%)	Immediate Access n (%)	Total n (%)
Yes	150 (42%)	73 (17%)	74 (22%)	297 (27%)
No	204 (58%)	351(83%)	260 (78%)	815 (73%)
Totals	354 (100%)	424 (100%)	334 (100%)	1112 (100%)

Discussion

Principal Results

This study suggests that delivering an electronic brief intervention to students can be effective in reducing alcohol consumption. The results showed a significant effect of time and/or assessment completion. In addition, the intervention had an independent effect on reducing the number of units of alcohol consumed weekly. Neither educational institution nor time of academic year had an impact on intervention effectiveness. To the authors' knowledge, these results are the first evaluation of an electronic Web-based feedback and social norms alcohol intervention to include students from multiple universities from outside of North America.

Comparison With Prior Work

The current results are in line with previous research on electronic Web-based interventions that have reported significant decreases in total consumption per week [25-28]. In some of these studies, this decrease remained significant at the 3-month follow-up [25,26]. Unlike our earlier study [16], the current study found a significant reduction in units consumed per week where previously we found only an impact on units consumed per occasion. Within the current study, the regression analysis showed that males entered the study with a higher total number of units consumed over the last week. This finding is in agreement with other literature, which suggests that males consume more alcohol than females [23]. Being male increased the odds of not completing all assessments. Given that males have a tendency to consume higher levels of alcohol compared

with females, further work is needed to understand how best to keep male participants engaged.

According to our analysis, assessment alone had a significant effect on drinking. It is, therefore, possible that completing an assessment led participants to monitor and reflect on their own behavior leading to a decrease in consumption. Such a decrease in consumption by assessed participants is apparent in the literature [29,30]. Our results suggest that this monitoring effect did not increase alongside the number of assessments, but that the completion of 2 or more assessments predicted a similar level of reduction.

Reactivity to assessment has been documented in the literature within randomized controlled trials [31-33] and within studies designed specifically to investigate reactivity [34,35]. It is possible that the reactivity effect is due to a reporting bias (eg, social desirability may mean that participants, consciously or subconsciously, report a change in behavior without any actual behavior change). Given that this is a limitation of all self-report data, the utility of such an argument is unclear. One alternative is to suggest that monitoring alone can lead to behavior change and, therefore, given that monitoring is likely to be carried out only in the context of potential treatment, monitoring can be viewed as one of the active components in brief interventions. It has previously been suggested that comparing intervention arms to assessment only may lead to the underestimation of the impact of brief interventions—especially given that individuals who are not seeking treatment are unlikely to have their behavior monitored outside of a randomized controlled trial [32]. Within the current study, being assigned to an intervention arm further increased the reduction in weekly consumption. This suggests that while monitoring alone appears to be effective in reducing consumption, this reduction can be further enhanced by the delivery of a brief personalized Web-based intervention.

The high proportion of students identified as drinking at potentially hazardous or harmful levels suggests that students engaging in unhealthy drinking behavior are interested in engaging with Web-based resources, and this is a strength of the current study. The ability to include such students is admirable given some studies have reported engaging a greater proportion of low-level consumers (eg, [36]). This is reinforced by the finding that assessment completion was not predicted by level of alcohol consumption, especially as previous research has reported higher levels of attrition among heavier consumers of alcohol [16,37]. In addition, it is noteworthy that 75% (563/1112) of participants included in the trial who were assigned to receive the intervention engaged with the Unitcheck website on at least 1 occasion. It is also encouraging that the time of academic year made no difference to outcome.

Limitations

This study is the first outside of North America to engage students from multiple educational institutions and to include medium-term follow-up. A number of limitations need to be considered, however, when interpreting the results. First, although 75% of intervention participants accessed the intervention, the percentage that engaged with follow-up assessments was considerably lower, with only 26% (293/1112) completing all 5 assessments. Second, while participants from 4 educational institutions were involved, the relatively low number from some educational institutions highlights the difficulties in multisite interventions. In particular, it draws attention to the need to understand further how to engage students from universities that have not traditionally delivered health information to their students and who are perhaps not as receptive to receiving brief interventions via this medium. Third, while there was a 4-month follow-up period, these results say little about the longer term impact of the intervention. The long-term impact of electronic brief interventions is still uncertain. Nor is it understood how, if at all, repeated access to such interventions is likely to support behavior change. This is of particular importance to Web-based interventions that can be a repeated source of feedback to students at a time that they choose. It is a potential strength of e-interventions that students could be encouraged to repeatedly access feedback while incurring minimal additional costs. Fifth, the longitudinal regression analysis cannot determine if it is monitoring or willingness to be monitored that accounts for the reduction in consumption. The analysis attempted to account for this; however, we cannot rule out that willingness to be monitored (rather than engaging in the monitoring process itself) is an alternative explanation.

Conclusions

This RCT confirms that Web-based interventions for alcohol can be effective in student samples. That the effect does not appear to vary across educational institutions is encouraging. It is hypothesized that differences in levels of recruitment across educational institutions are likely to be related to use of the Internet to deliver health information to students. Further work is needed, however, to understand how contextual factors can best be optimized in order to engage students. Within this study, much of the observed effect was apparently due to self-monitoring, but there was an additional effect of the intervention. Research is needed to understand how the individual elements of the personalized feedback interact with this self-monitoring effect in order to enhance the effectiveness of Web-based interventions.

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Conflicts of Interest

In the past, authors Bewick, Barkham, Hill, Gill, and O'May have received funding from the European Research Advisory Board. Author Bewick, as a keynote speaker, has received reimbursement of travel expenses from Anheuser-Busch. Authors Gill and O'May have previously received funding from the Portman Group.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
NHS: National Health Service
RCT: randomized controlled trial

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Original Paper

Effectiveness of a Web-Based Brief Alcohol Intervention and Added Value of Normative Feedback in Reducing Underage Drinking: A Randomized Controlled Trial

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Abstract

Background: Current insights indicate that Web-based delivery may enhance the implementation of brief alcohol interventions. Previous research showed that electronically delivered brief alcohol interventions decreased alcohol use in college students and adult problem drinkers. To date, no study has investigated the effectiveness of Web-based brief alcohol interventions in reducing alcohol use in younger populations.

Objective: The present study tested 2 main hypotheses, that is, whether an online multicomponent brief alcohol intervention was effective in reducing alcohol use among 15- to 20-year-old binge drinkers and whether inclusion of normative feedback would increase the effectiveness of this intervention. In additional analyses, we examined possible moderation effects of participant's sex, which we had not a priori hypothesized.

Method: A total of 575 online panel members (aged 15 to 20 years) who were screened as binge drinkers were randomly assigned to (1) a Web-based brief alcohol intervention without normative feedback, (2) a Web-based brief alcohol intervention with normative feedback, or (3) a control group (no intervention). Alcohol use and moderate drinking were assessed at baseline, 1 month, and 3 months after the intervention. Separate analyses were conducted for participants in the original sample (n = 575) and those who completed both posttests (n = 278). Missing values in the original sample were imputed by using the multiple imputation procedure of PASW Statistics 18.

Results: Main effects of the intervention were found only in the multiple imputed dataset for the original sample suggesting that the intervention without normative feedback reduced weekly drinking in the total group both 1 and 3 months after the intervention (n =575, at the 1-month follow-up, beta = -.24, *P* = .05; at the 3-month follow-up, beta = -.25, *P* = .04). Furthermore, the intervention with normative feedback reduced weekly drinking only at 1 month after the intervention (n=575, beta = -.24, *P* = .008). There was also a marginally significant trend of the intervention without normative feedback on responsible drinking at the 3-month follow-up (n =575, beta = .40, *P* =.07) implying a small increase in moderate drinking at the 3-month follow-up. Additional analyses on both datasets testing our post hoc hypothesis about a possible differential intervention effect for males and females revealed that this was the case for the impact of the intervention without normative feedback on weekly drinking and moderate drinking at the 1-month follow-up (weekly drinking for n = 278, beta = -.80, *P* = .01, and for n = 575, beta = -.69, *P* = .009; moderate drinking for n = 278, odds ratio [OR] = 3.76, confidence interval [CI] 1.05 - 13.49, *P* = .04, and for n = 575, OR = 3.00, CI = 0.89 - 10.12, *P* = .08) and at the 3-month follow-up (weekly drinking for n = 278, beta = -.58, *P* = .05, and for n = 575, beta = -.75, *P* = .004; moderate drinking for n = 278, OR = 4.34, CI = 1.18 - 15.95, *P* = .04, and for n = 575, OR = 3.65,

CI = 1.44 - 9.25, *P* = .006). Furthermore, both datasets showed an interaction effect between the intervention with normative feedback and participant's sex on weekly alcohol use at the 1-month follow-up (for n = 278, beta = -.74, *P* =.02, and for n = 575, beta = -.64, *P* =.01) and for moderate drinking at the 3-month follow-up (for n = 278, OR = 3.10, CI = 0.81 - 11.85, *P* = .07, and for n = 575, OR = 3.00, CI = 1.23 - 7.27, *P* = .01). Post hoc probing indicated that males who received the intervention showed less weekly drinking and were more likely to drink moderately at 1 month and at 3 months following the intervention. For females, the interventions yielded no effects: the intervention without normative feedback even showed a small unfavorable effect at the 1-month follow-up.

Conclusion: The present study demonstrated that exposure to a Web-based brief alcohol intervention generated a decrease in weekly drinking among 15- to 20-year-old binge drinkers but did not encourage moderate drinking in the total sample. Additional analyses revealed that intervention effects were most prominent in males resulting in less weekly alcohol use and higher levels of moderate drinking among 15- to 20-year-old males over a period of 1 to 3 months.

Trial Registration: ISRCTN50512934; http://www.controlled-trials.com/ISRCTN50512934/ (Archived by WebCite at http://www.webcitation.org/5usICa3Tx)

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KEYWORDS

Web-based brief alcohol intervention; adolescents; normative feedback; moderate drinking; alcohol use

Introduction

Numerous studies have indicated that early drinking onset and excessive alcohol use can have detrimental consequences for adolescents' current and future health status [1-4]. Compared with adults, adolescents appear more susceptible to the harmful effects of alcohol due to biological, psychological, and social developmental changes that typically occur during the adolescent life stage [5,6]. In addition, findings suggest that alcohol consumption can harm the developing adolescent brain, which eventually could lead to deficits in neurocognitive functioning [7,8]. The accumulating insights into alcohol-related health hazards for adolescents have caused great concern among national and international health authorities and have resulted in plans for action to reduce underage and hazardous drinking among youth [9,10]. Recent evidence suggests that these intensified alcohol prevention activities seem to pay off by showing a steady decline in alcohol consumption levels among adolescents in the United States [11] and also in the Netherlands [12]. However, despite these recently reported decreases in alcohol prevalence rates, the proportion of early and heavy drinking adolescents is still considerably high. For example, data from the European School Survey Project on Alcohol and Other Drugs (ESPAD) conducted in 2007 suggest that 43% of 15- to 16-year-old European students engaged in heavy episodic drinking during the past 30 days, and at least 50% of students reported having tried alcohol before the age of 13 [13]. Recent data on alcohol prevalence rates among US youth aged 12 to 20 years indicated that about 17.4% engaged in binge drinking in the past month and 5.5% were heavy drinkers [14].

Moreover, several meta-analyses of the efficacy of alcohol prevention programs indicate that the effects of current alcohol preventive approaches are fairly small [15-17]. To enhance the efficacy of alcohol prevention programs, new and advanced strategies are warranted. A promising endeavor may be the application of electronic media to deliver alcohol preventive materials. This delivery mode presents an opportunity to widely disseminate interventions in an easy and cost-effective way [18,19]. Moreover, since the majority of adolescents in Western countries have access to the Internet [20] and make frequent use of Internet technologies [21,22], Web-based interventions may be particularly suitable to target adolescent audiences.

Over the past years, Web-based delivery modes have successfully been applied to administer brief alcohol interventions [23-28]. These types of interventions can generally be described as short-term preventive consultations to detect problematic alcohol use in an early stage and to motivate nontreatment-seeking heavy drinkers to change their behavior or seek treatment. A core element of brief alcohol interventions is the presentation of discrepancies between what the client reports and what the client wants or what would be beneficial for him or her. The purpose is to increase motivation to change or modify his or her behavior. Therefore, most brief alcohol interventions consist of a screening procedure followed by personalized feedback that participants receive based on their answers to the screener questions. According to the literature, this tailored approach might be more effective than the delivery of a more general prevention message due to the fact that the receiver of the intervention is more likely to identify with personally relevant information and pay more attention to person-related information than to general information [29].

Initially, brief alcohol interventions were delivered in health care settings during face-to-face contact with a health professional [30]. More recently, other modes of delivery have been employed such as postal mail methods [31] and electronic methods via computer programs [32] as well as the Internet [23]. The latter Web-based approach may be more beneficial than the more traditional delivery methods because it allows easy access to large audiences and gives participants the opportunity to access the intervention at their own convenience, which may enhance participants' feelings of privacy and anonymity. Furthermore, the inclusion of tailored information can be accomplished in an easier and more cost-effective way [19].

Previous trials suggest that Web-based brief alcohol interventions can reduce drinking in nonclinical adult populations, that is, problem drinkers [23], drinkers in the

workplace [33], and heavy drinking [25,28,34] or mandated college students [24]. As indicated by these previous findings, Web-based brief alcohol interventions were effective in the short-term and midterm by reducing adults' and young adults' drinking rates at approximately 1 to 12 months after the intervention. Besides the preventive impact on adult and young adult drinkers, Web-based interventions may also hold potential for alcohol prevention among adolescents. Further insight into this topic is of great importance since early intervention in adolescents' drinking careers might reduce the risk of escalation to more problematic drinking patterns. A short, personalized, Web-based intervention may specifically appeal to adolescent drinkers and may, therefore, effectively motivate them to modify their alcohol consumption. In spite of the potential benefits of Web-based brief alcohol interventions to target adolescent drinkers, previous studies have not addressed this topic to this date.

To our knowledge, the present study is the first to test the short-term effectiveness of a Web-based brief alcohol intervention among a sample of adolescents and young adults aged 15 to 20 years. Our objective was to additionally test the contribution of normative feedback to the effectiveness of this Web-based brief alcohol intervention. Normative feedback involves the presentation of comparative information about personal drinking levels and drinking levels of a relevant comparison group, such as same-aged peers. This prevention strategy was developed in response to a comprehensive body of literature showing that college students tend to overestimate their peers' drinking levels [35]. According to the social norms approach, correction of these overstated perceptions about peers' alcohol consumption levels will have an impact on youngsters' alcohol use [36]. Although the effectiveness of providing normative feedback on peer alcohol use has been demonstrated in research on college samples [37], it is not clear whether this strategy would reduce alcohol use in adolescents. Moreover, it is possible that normative feedback might generate stronger effects in males than in females [36] due to the degree of specificity of the provided normative feedback [38] or due to differences in the flexibility of normative perceptions between girls and boys [39]. Therefore, a Web-based brief alcohol intervention could have a differential effect on drinking patterns in females and males in this age group. Notably, current interventions show some diversity in the type of normative information that is presented, which may affect the effectiveness of this component [36]. These differences exist mainly in the choice of reference group, which can vary in degree of specificity, that is, peers in general versus first year graduate students or same-sex peers. There is some evidence suggesting that prevalence information about specific reference groups has a stronger impact on college students' normative perceptions and personal drinking behavior than does more general prevalence information [36]. In keeping with these preliminary findings, we aimed to test the impact of age- and gender-specific normative feedback on alcohol consumption levels in 15- to 20-year-old youths. In sum, the objective of the present study was to test the following research questions: (1) Is a Web-based brief alcohol intervention effective in reducing weekly drinking and encouraging moderate alcohol use in 15- to 20-year old youths? (2) Does inclusion of normative feedback contribute to the effectiveness of this Web-based brief alcohol intervention? (3) Does the impact of a Web-based brief alcohol intervention differ between males and females in this age group?

Methods

Study Design

The present study was a 3-arm randomized controlled trial in which participants screened as binge drinkers received 1 of 2 Web-based brief alcohol interventions or were assigned to the control group.

Participants and Procedure

Volunteer members of an online access panel between 15 and 20 years of age were invited to complete an online survey on lifestyle and health behavior. We informed all participants that the assignment would occur by chance and that some participants did not need to evaluate an intervention but just had to answer some questions.

This online panel was set up and maintained by Flycatcher, a full service research agency affiliated with Maastricht University, the Netherlands. This agency is registered by the Dutch Data Protection Authority (number 1007001) and follows the European Society for Opinion and Marketing Research (ESOMAR) privacy policy stated by the European branch organization of research agencies. The research agency uses a double "opt in" procedure, which means that potential participants first indicate on a website that they would like to become a panel member by providing their email address. These potential panel members receive an email with information and a link to confirm or reject their membership. This double opt in procedure is regarded as a form of informed consent. Registered panel members can receive invitations by email with study information and a possibility to reject or confirm study participation. According to the Dutch and European research guidelines, at age 15 adolescents may be included in research if they grant their personal informed consent; parental consent is not required for this age group.

A total sample of 1012 participants was included and received an online questionnaire at baseline that contained items on demographic characteristics and alcohol use. Of these adolescents, 575 fulfilled the following inclusion criteria: 15 to 16 year old youths engaging in binge drinking at least once a month, or 17 to 20 year old youths engaging in binge drinking at least once a week. For females, binge drinking was defined as drinking more than 4 alcoholic consumptions per occasion and for males, more than 6 [12]. All included participants were randomly assigned to 1 of the following conditions: (1) Web-based brief alcohol intervention without normative feedback, (2) Web-based brief alcohol intervention with normative feedback, or (3) a control group. At 1 month after baseline, all participants received a short questionnaire with questions similar to those on the pretest. In addition, the 2 experimental groups received an email with a link to their assigned Web-based brief alcohol intervention. To assess the effectiveness of the 2 interventions, we conducted 2 posttests at 1 month and 3 months after the delivery of the interventions. At these posttests, both intervention groups and the control

group received online questionnaires with questions about alcohol use. After each measurement or intervention, participants were sent 1 reminder after 4 days informing them that they had 1 week to complete the intervention or questionnaire. After completion, participants received vouchers to buy gifts, books, or movie tickets. No ethical approval was sought for this study.

Randomization

An independent research agency assigned participants randomly to the conditions. The randomization was generated using a randomization function in Excel. Recruitment was stratified by sex, age, and educational level to obtain equal groups.

Intervention

Description of the Web-based Interventions

The Web-based brief alcohol interventions consisted of 2 parts: (1) a questionnaire including items addressing participants' drinking patterns, drinking motives, and health risk status and (2) personalized feedback based on participants' answers to the earlier posed questions on the questionnaire including advice about moderate drinking. The advice for young adults aged 18 to 20 years was in line with the guidelines of the Dutch National Health Council recommending that men should not drink more than 2 drinks of alcohol per day and women, 1 drink of alcohol per day [40]. Adolescents under the age of 16 years received advice to abstain from alcohol. Adolescents aged 16 to 17 years were advised to abstain from alcohol, and if they drank alcohol, they were advised to drink moderately (not more than 1 or 2 drinks per occasion). The time to complete the intervention, which included filling out the screener questions and reading the personalized feedback, was estimated at 15 minutes.

Topics of the Interventions

The feedback was tailored to participant's age (under 16, 16 to 17 years of age, and 18 years of age and older) and gender and organized along 4 topics for the intervention without normative feedback group, and 5 topics for the intervention with normative feedback group. These topics are described below.

Personal Drinking Behavior and Related Health Risks

Participants received a summary of the quantity and frequency of their drinking behavior. If participants' alcohol use exceeded moderate drinking limits, they received information about how this could affect their health.

Drinking Motives and Suggestions to Reduce Alcohol Use

Drinking motives and suggestions to reduce alcohol use were instigated by risk-conducive motives, such as drinking to forget problems or to conform to peer pressure [41,42]

Risk of Developing Problematic Alcohol Use or Alcohol Dependence

Participants who showed increased risk due to specific physical reactions in response to alcohol [43], symptoms of physical dependence, or problematic alcohol use [44] were informed about their risk status and received suggestions to moderate their drinking and directions to seek further help.

Personal Perceptions About Own Alcohol Use and Related Risks

A summary of participants' objective personal health risks was presented and set against their self-reported personal risk perceptions and motivation to engage in moderate drinking

Normative Feedback

The version of the drink test with normative feedback additionally provided an overview of how much participants thought their age mates would drink, how much their age mates actually drank, and how much the participants drank themselves. This information was presented in a bar chart showing each participant's own weekly alcohol use, the actual prevalence rates of Dutch adolescents' weekly alcohol use matched according to the participant's sex and age, and the prevalence rates of Dutch adolescents' weekly alcohol use as estimated by participants. The data on peers' actual alcohol consumption levels were retrieved from alcohol prevalence estimates among same-age groups found in a nationally representative sample of high school students (included in feedback for adolescents aged 15 to 17 years) and the general population (included in feedback for young adults aged 18 to 20 years) [12,45]. Only participants who over estimated their peers' alcohol consumption received prevalence rates pertaining to their peers' actual alcohol use. If estimations were correct or lower than the actual prevalence rates, participants were informed that they had provided the correct estimation.

Outcome Measures

Weekly alcohol consumption was assessed using the Dutch version of the Alcohol Weekly Recall [46]. Participants were asked to indicate retrospectively for the past 7 days, how many standard units they had consumed. For example: "Yesterday it was … (fill out the name of the day) and I consumed … standard units." To ensure standardized responses, we provided for various beverages an overview of standard units.

The measure for moderate drinking was based on the item for weekly alcohol consumption, which was recoded as 0 = "no moderate drinking" and 1 = "moderate drinking." Participants aged 15 to 17 years were labeled as "moderate drinkers" if they consumed no alcohol in the past week. Males aged 18 to 20 years were regarded as moderate drinkers if they consumed less than 14 alcoholic drinks in the past week, and same-aged females were regarded as moderate drinkers if they consumed less than 7 alcoholic drinks in the past week.

Strategy of Analyses

Possible differences between the 3 conditions at baseline were tested using chi-square tests for sex, educational level, and moderate drinking and analyses of variance (ANOVA) for age and number of drinks a week, where 1 standard drink is equivalent to 10 grams of pure alcohol. The number of drinks per week (mean 14.91, SD 13.23) had a skewed distribution and a high level of kurtosis (skewness 1.86, kurtosis 6.40). We applied a log transformation on the number of drinks plus 1. The mean (SD) of the transformed variable was 2.37 (SD) 1.01, skewness became -0.78, and kurtosis was reduced to 0.14.

The randomized sample consisted of 575 respondents. However, 297 participants did not respond during the intervention period, which resulted in a sample of 278 participants who adhered to the intervention. We compared this sample with the dropout group with respect to sex, age, educational level, and alcohol use in the past week by conducting a logistic regression analysis and including group membership (0 = completers and 1 = dropouts) as the dependent variable. No differences were found for sex (odds ratio [OR] = 0.91, *P* = .58, 95% confidence interval [CI] 0.63 - 1.29) or weekly alcohol use (OR =1.10, *P* = .28, 95% CI 0.92 - 1.31). However, the samples differed on age (OR = 0.89, *P* = .05, 95% CI 0.79 - 0.99) and educational level (OR .66, *P* = .001, 95% CI 0.53 - 0.82) caused by a higher dropout rate among the younger participants and those with lower education levels.

The effects of the brief alcohol interventions (with or without normative feedback) on (the log transformation of) weekly alcohol consumption were tested with linear regression analyses. The intervention effects on moderate drinking were tested with logistic regression analyses. The intervention without normative feedback was represented by a dummy variable with 0 = control group and intervention group with normative feedback and 1 = group without normative feedback. The intervention with normative feedback was represented by a dummy variable with 0 = control group and intervention group without normative feedback and 1 = group with normative feedback. We also examined whether the intervention effects differed according to participant's sex by including interaction terms of sex with both dummy variables (females = 0 and males =1). Participant's age and educational level were included as covariates in all analyses. For the interpretation of interaction effects we used the SPSS macro MODPROBE [47]. This procedure allows the probing of interaction effects while controlling for other covariates and provides the coefficients of the conditional effects for each level of the moderator. Unfortunately, it was not possible to apply this analytic strategy to multiple imputed data. Therefore, we only conducted post hoc analyses for the completers-only sample.

To compare the control group with each of the 2 experimental groups, intention to treat (ITT) analysis is an adequate strategy for randomized controlled trials and is interpreted as including all respondents belonging to the original randomized groups [48]. In our case, we had high levels of dropout. Of the 575 randomized respondents, only 278 respondents completed both posttests (at the 1-month and 3-month follow-ups). These figures suggest a dropout rate of 51.6%, in terms of not filling in questionnaires. In our ITT analysis, we used the multiple imputation procedure of PASW Statistics 18 to deal with these missing values. We applied this procedure to the baseline sample of participants that fulfilled the criteria for inclusion in our study (n = 575). In addition, we analyzed the data for participants who completed both posttests at 1 month and 3 months, that is, the 278 participants in the completers-only group.

Results

Participants Flow

The flow of the participants through the trial is illustrated in Figure 1. Of the 1012 participants who completed the baseline, 575 participants fulfilled the inclusion criteria and were randomly assigned to 1 of 3 conditions. Of these potential participants, only 320 responded. At follow-up, 1 and 3 months after the intervention period, 278 completed both posttest measurements.

Figure 1. Trial schema

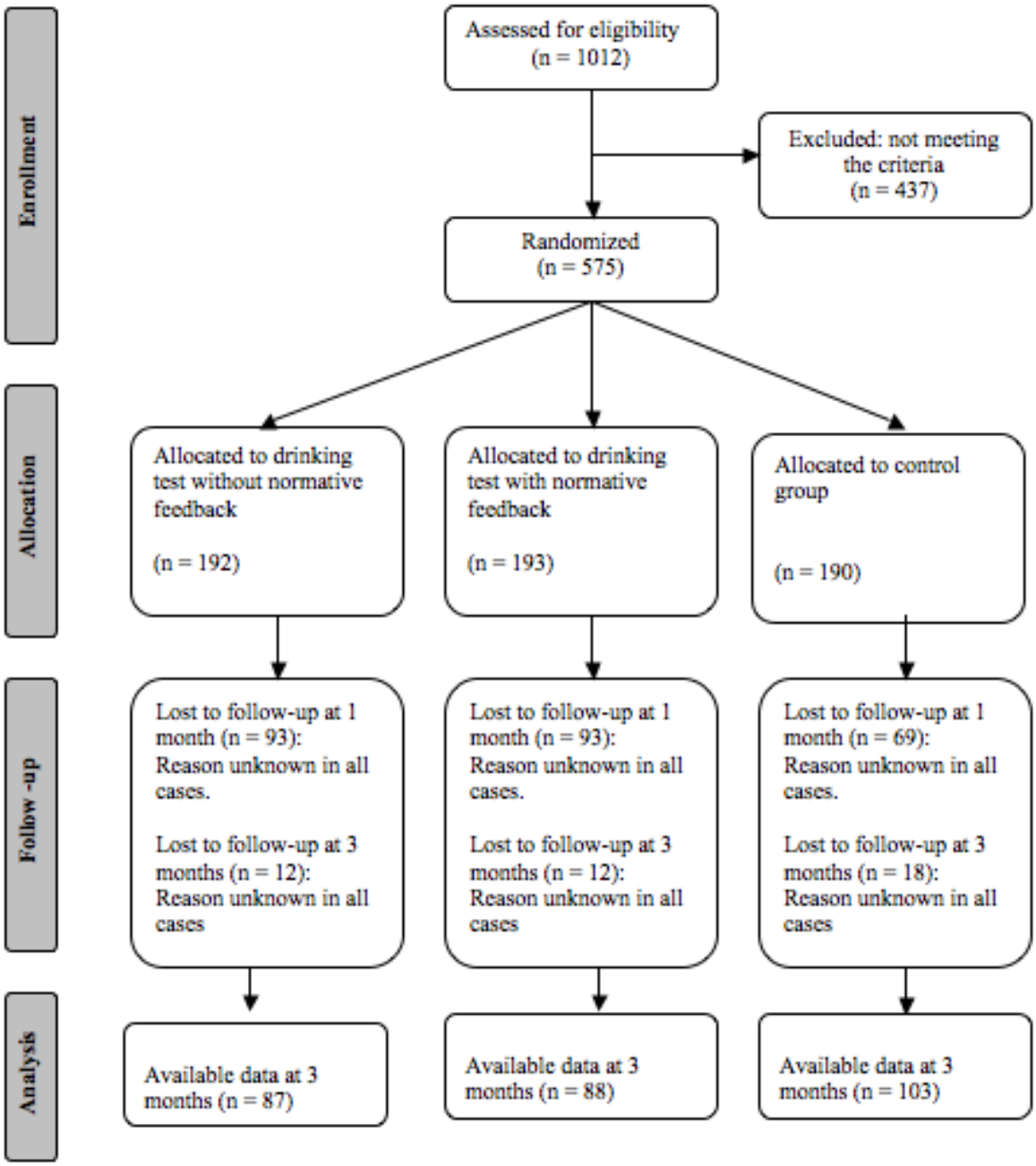

Table 1. Differences in demographic characteristics and alcohol consumption patterns among participants at baseline (n = 575)

Variable	NNF[a] (n = 192)	NF[b] (n = 193)	Control Group (n = 190)	Test Result	*P*
Sex				χ^2_2 1.57	.46
Males, n (%)	74 (38.5)	82 (42.5)	69 (36.3)		
Females, n (%)	118 (61.5)	111 (57.5)	121 (63.7)		
Mean age (SD) in years	18.16 (1.55)	18.05 (1.54)	18.11 (1.59)	$F_{2,572} = 0.26$	.77
Educational level				$\chi^2_4 = 1.95$	.75
Low, n (%)	54 (28.1)	47 (24.4)	49 (25.8)		
Medium, n (%)	72 (37.5)	71 (36.8)	66 (34.7)		
High, n (%)	66 (34.4)	75 (38.8)	75 (38.5)		
N drinks of alcohol in past week, mean (SD)	14.2 (12.2)	15.1 (13.4)	14.8 (13.7)	$F_{2,572} = 0.23$	.80
Moderate drinking, n (%)	106 (55.2)	96 (49.7)	97 (51.1)	$\chi^2_2 = 1.25$	.53

[a] NNF= Intervention without normative feedback

[b] NF = Intervention with normative feedback

Sample Characteristics

Participants' demographic and clinical characteristics assessed at baseline are summarized in Table 1. No differences were found between the 3 conditions, indicating that the randomization was successful. Of the 575 participants, 225 (39.1%) were male. Mean age (SD) of the participants was 18.1 years (1.56). Most of the participants had intermediate or high education levels (150 or 26.1% had low levels, 209 or 36.3%, intermediate, and 216 or 37.6%, high) and almost all (553 or 96.3%) were born in the Netherlands. The majority of participants (496 or 86.2%) were students, 6.1% (35) had a job and 7.7% (44) combined their study with a job.

Weekly Alcohol Consumption

At baseline, participants (n = 575) had consumed on average 14.7 drinks of alcohol in the past week (11.5 for females, 19.7 for males). Participants' weekly drinking rates at the 2 posttests (n = 278) were 11.9 drinks (8.6 for females, 17.0 for males) at the 1-month follow-up and 13.1 (9.6 for females, 18.5 for males) at the 3-month follow-up.

We conducted linear regression analyses to test whether the Web-based brief alcohol interventions reduced participants' weekly alcohol consumption at 1 and 3 months after the intervention. In these analyses, we additionally tested possible moderation effects of participant's sex by including the interactions between intervention and sex in the third step. Results of the third step of the equations are presented in Table 2. We controlled for demographic characteristics, that is, sex, age, and education level by including these variables in step 1 of the equations. When inspecting results of the first step, we found that only age was related to participants' weekly alcohol use, suggesting that the older the participants, the higher their weekly drinking levels.

To determine whether the interventions had an overall effect on participants' weekly drinking rates, we inspected the findings of the second step (not presented in Tables). Our data for the completers-only sample (n = 278) did not show any main effects. However, the multiple imputed dataset (n = 575) indicated that both interventions reduced weekly drinking at the 1-month follow-up (intervention without normative feedback, beta = -.24, *P* = .05; intervention with normative feedback, beta = -.34, *P* = .008) and the intervention without normative feedback reduced weekly drinking at the 3-month follow-up (beta = -.25, *P* = .04).

According to further analyses presented in Table 2, results of the third step showed significant interaction effects between sex and the Web-based brief alcohol intervention without normative feedback on participants' weekly alcohol use at the 1-month follow-up (completers only, beta = -.80, *P* = .01; multiple imputed, beta = -.69, *P* = .009) and at the 3-month follow-up (completers only, beta = -.58, *P* = .05; multiple imputed, beta = -.75, *P* = .004). These findings suggest that the impact of the Web-based brief alcohol intervention without normative feedback on weekly alcohol use at the 1- and 3-month follow-up differed between males and females. For the further interpretation of these interactions, we used the SPSS Macro MODPROBE and calculated the coefficients of the focal predictor (Web-based brief alcohol intervention without normative feedback) at both levels of the moderator (participant's sex). These post hoc analyses suggested that males who received the intervention without normative feedback were more likely to reduce their weekly alcohol use at the 1-month (beta = -.43, *P* = .08) and 3-month follow-up (beta = -.45, *P* = .049). In contrast, females who received the intervention without normative feedback were more likely to increase their weekly alcohol use at the 1-month follow-up (beta = .37, *P* = .06). If we express these estimates in number of drinks, results would imply that the intervention without normative feedback reduced the weekly drinking rate at the 1-month follow-up in males by 5 drinks of alcohol (from 12.8 to 7.8 drinks) and increased the weekly drinking rate in females by 1.6 drinks (from 3.8 to 5.4

drinks). The estimated effect of the intervention without normative feedback on males' weekly alcohol use at the 3-month follow-up amounted to a reduction of 5.3 drinks (from 13.5 to 8.2 drinks).

Regarding the intervention with normative feedback, our results showed interaction effects with participant's sex on weekly alcohol use at the 1-month follow-up for the completers-only group (beta = -.74, *P* = .02) and at both time points for the multiple imputed sample (at 1 month, beta = -.64, *P* = .01, and at 3 months, beta = -.65, *P* = .01) suggesting that the impact of the intervention differed between males and females. Post hoc analyses showed that males who received the intervention with normative feedback were more likely to reduce their weekly alcohol use at 1 month (completers only [n = 278], beta = -.49, *P* = .03). This implies that the intervention with normative feedback reduced weekly alcohol use in males by 5.6 drinks (from 13.5 to 7.9). Unfortunately, it was not possible to test the interaction effect on weekly drinking at the 3-month follow-up in the multiple imputed sample.

Table 2. Multiple regression analyses predicting weekly alcohol consumption at the 1-month follow-up and the 3-month follow-up

	Weekly Alcohol Consumption at the 1-Month Follow-up						Weekly Alcohol Consumption at the 3-Month Follow-up					
	Completers Only n = 278			Multiple Imputed n = 575			Completers Only n = 278			Multiple Imputed n = 575		
	Beta	SE	*P*	Beta	SE	*P*	Beta	SE	*P*	Beta	SE	*P*
Sex (males)	1.16	.21	< .001	0.80	.18	< .001	1.01	.20	< .001	0.86	.11	< .001
Age	0.15	.04	< .001	0.13	.03	< .001	0.21	.04	< .001	0.15	.03	< .001
Education	0.07	.08	.37	0.23	.07	< .001	0.29	.08	< .001	0.32	.06	< .001
NNF[a]	0.37	.20	.06	0.01	.16	.95	0.13	.18	.49	0.02	.16	.89
NF[b]	0.25	.20	.21	-0.09	.16	.56	0.18	.19	.34	0.03	.16	.83
Interaction NNF by sex	-0.80	.31	.01	-0.69	.26	.009	-0.58	.30	.05	-0.75	.26	.004
Interaction NF by sex	-0.74	.31	.02	-0.64	.26	.01	-0.34	.29	.25	-0.65	.25	.01

[a] NNF= Intervention without normative feedback

[b] NF = Intervention with normative feedback

Moderate Drinking

Tables 3 and 4 present findings about the effect of the Web-based brief alcohol interventions on participants' levels of moderate drinking at the 1- and 3-month follow-up. In our analyses, we controlled for participant's sex, age (continuous variable), and education level (continuous variable). Although the Tables only present the coefficients of the third step, we also inspected the main effects of participants' demographic characteristics and of the intervention in the earlier 2 steps. Results indicated that older participants were more likely to show moderate drinking at the 1-month follow-up and the 3-month follow-up. In addition, our data showed a borderline significant effect of sex on moderate drinking at the 3-month follow-up, suggesting that females were more likely to engage in moderate drinking than males.

Further, analyses based on the multiple imputed sample (n=575) indicated a borderline significant main effect of the Web-based brief alcohol intervention without normative feedback on responsible drinking at the 3-month follow-up suggesting that participants who received the Web-based brief alcohol intervention were slightly more likely to engage in responsible drinking 3 months after the intervention (beta = .40, *P* = .07).

Our findings further showed a significant interaction between sex and Web-based brief alcohol intervention without normative feedback at the 1-month follow-up for the completers-only group and a borderline significant interaction for the multiple imputed sample (completers only, OR = 3.76, *P* = .04, 95% CI 1.05 - 13.49; multiple imputed sample [n = 575], OR = 3.00, *P* = .08, 95% CI .89 - 10.12). At the 3-month follow-up, we found significant interactions between the Web-based brief alcohol intervention without normative feedback and participant's sex for both samples (completers only, OR = 4.34, *P* = .04, 95% CI 1.18 - 15.95; multiple imputed sample, OR = 3.65, *P* = .006, 95% CI 1.44 - 9.25).

Post hoc probing of these interactions for the completers-only group demonstrated that males who received the intervention without normative feedback were more likely to engage in moderate drinking but only at the 3-months follow-up (beta = 1.21, *P* = .02). In contrast, data for females showed that those who received the intervention without normative feedback were less likely to engage in moderate drinking at the 1-month follow-up (beta = -.82, *P* = .046). Post hoc analyses further demonstrated that males who received the intervention with normative feedback were slightly more likely to engage in moderate drinking at the 1-month follow-up (beta = .83, *P* = .09). At the 3-month follow-up, the effect of the intervention with normative feedback on responsible drinking differed for males and females, but closer inspection showed that there were no significant changes in the likelihood to engage in moderate drinking in males or females.

Table 3. Logistic regression analyses predicting moderate drinking at the 1-month follow-up (intention to treat analysis)

	Moderate Drinking at the 1-Month Follow-up					
	Completers Only n = 278			Multiple Imputed n = 575		
	OR	95% CI	*P*	OR	95% CI	*P*
Sex (males)	0.52	(0.22 - 1.21)	.13	0.61	(0.27 - 1.38)	.23
Age	1.40	(1.17 - 1.67)	< .001	1.37	(1.16 - 1.62)	< .001
Education	0.95	(0.68 - 1.32)	.75	0.97	(0.70 - 1.32)	.83
NNF [a]	0.44	(0.19 - 0.99)	.05	0.53	(0.25 – 1.14)	.11
NF [b]	0.74	(0.33 - 1.62)	.45	0.96	(0.46 – 1.99)	.92
Interaction NNF by sex	3.76	(1.05 - 13.49)	.04	3.00	(0.89 - 10.12)	.08
Interaction NF by sex	3.12	(0.90 - 10.76)	.07	2.22	(0.69 - 7.14)	.18

[a] NNF = Intervention without normative feedback

[b] NF = Intervention with normative feedback

Table 4. Logistic regression analyses predicting moderate drinking at the 3-month follow-up (intention to treat analysis)

Moderate Drinking at the 3-Month Follow-up						
	Completers Only n = 278			Multiple Imputed n = 575		
	OR	95% CI	*P*	OR	95% CI	*P*
Sex (males)	0.35	(0.14 - 0.89)	.03	0.40	(0.21 - 0.75)	.004
Age	1.16	(0.97 - 1.38)	.09	1.00	(0.89 - 1.13)	.96
Education	0.56	(0.40 - 0.79)	.001	0.55	(0.43 - 0.69)	<.001
NNF [a]	0.77	(0.35 - 1.68)	.05	0.91	(0.52 - 1.61)	.75
NF [b]	0.55	(0.24 - 1.26)	.45	0.77	(0.44 - 1.37)	.38
Interaction NNF by sex	4.34	(1.18 - 15.95)	.04	3.65	(1.44 - 9.25)	.006
Interaction NF by sex	3.10	(0.81 - 11.85)	.07	3.00	(1.23 – 7.27)	.01

[a] NNF= Intervention without normative feedback

[b] NF = Intervention with normative feedback

Discussion

Principal Results and Comparison With Prior Research

The purpose of the present study was to test the effectiveness of a Web-based brief alcohol intervention in reducing weekly alcohol use and promoting moderate drinking among 15- to 20-year-old drinkers and to determine whether inclusion of normative feedback would increase its effectiveness. The study findings showed some main intervention effects, but these were primarily found for weekly drinking and only in the multiple imputed data of the original sample. Moreover, at the 3-months follow-up, the inclusion of normative feedback did not contribute to the effectiveness of the brief alcohol intervention since only the intervention without normative feedback resulted in a decrease in participants' weekly drinking rates, 3 months after exposure to the intervention.

Additional analyses for both datasets suggested that the impact of the Web-based brief alcohol interventions differed for males and females. According to findings from both datasets, males who received the Web-based brief alcohol intervention showed lower levels of weekly alcohol use and were more likely to have engaged in moderate drinking at the 1- and 3-month follow-up. The estimated effect of the intervention without normative feedback on males' weekly drinking rates amounted to a reduction of 5 drinks of alcohol at the 1-month follow-up and 5.2 drinks at the 3-month follow-up. For females, the intervention did not yield any effects, except that we found a small unfavorable effect of the intervention without normative feedback 1 month after the intervention. More specifically, females who received the intervention without normative feedback were less likely to engage in moderate drinking and showed an estimated increase in weekly drinking of 1.6 drinks of alcohol at the 1-month follow-up. In addition, our data indicated that the brief alcohol intervention with normative feedback increased responsible drinking in male drinkers but only at the 1-month and not at the 3-month follow-up. The estimated effect of the Web-based brief alcohol intervention with normative feedback on males' weekly drinking levels at

the 1-month-follow up amounted to a reduction of 5.6 drinks of alcohol.

Our finding that a Web-based brief alcohol intervention increased moderate drinking in males aged 15 to 20 years is encouraging for the further implementation of brief alcohol interventions among late adolescents. However, it should be noted that we used a short follow-up of 3 months. Moreover, it is striking that our intervention reduced alcohol use predominantly in males and hardly in females. The latter finding contradicts outcomes from previous research showing either an overall effect of brief alcohol interventions [49,50] or an even stronger effect in women [37,51]. As shown by a review of the impact of alcohol abuse interventions on drinking in college samples, interventions were more effective in reducing alcohol-related problems if the sample contained more women [50]. However, the evidence for greater effectiveness of brief alcohol interventions in females compared to males stems from research on brief interventions that were delivered face-to-face or by postal mail, whereas our intervention was Web-based. A recent study demonstrated that female college students receiving a face-to-face intervention showed greater reductions in alcohol use than female students who received a computer intervention [52]. These findings suggest that female drinkers are less responsive to computer-tailored brief alcohol interventions. However, this explanation does not account for the contrasting evidence between the present study and earlier research showing the effectiveness of Web-based brief alcohol interventions in a total sample of both males and females [28]. Since it is not clear whether the sex-specific effect of our intervention was due to our younger sample or other factors, we recommend further research on this issue.

Surprisingly in our study, males who were exposed to the brief alcohol intervention with normative feedback showed decreases in weekly drinking but no increases in moderate drinking levels at the 3-month follow-up. In contrast, males who received the brief alcohol intervention without normative feedback showed decreased weekly drinking 1 month and 3 months after the intervention and higher levels of moderate drinking 3 months after the intervention. Thus, our data suggest that the inclusion of normative feedback does not contribute to the effectiveness of the tested brief alcohol intervention in adolescent male drinkers in the long term. This finding is not in line with previous research demonstrating the effectiveness of normative feedback, particularly for males [53]. Logically, the lower impact of the brief alcohol intervention with normative feedback cannot be explained by the fact that we used age-specific and sex-specific normative feedback, since previous findings suggest that information about specific reference groups would increase and not decrease the effectiveness of normative feedback. However, a possible explanation might be that we tested a younger sample than has been examined in previous research. To date, the effectiveness of normative feedback in reducing alcohol use in adolescent drinkers has not been addressed in previous research. It might be the case that the presentation of normative comparison information has fewer long-lasting effects in adolescent drinkers compared with college students. To gain further insight into this matter, more research is needed on the effectiveness of normative feedback in adolescent samples.

Limitations

Several limitations need to be considered when discussing the implications of our study. First, it is important to note that our findings are based on a convenience sample with some inevitable dropout, particularly among the younger and less highly educated participants. Also, since we used a convenience sample of online panel members who were binge drinkers, it is not clear whether our findings would generalize to more clinical samples. Importantly, 51.6% of the panel members who agreed to participate in the research did not respond after being allocated to the intervention or control condition. Unfortunately, we do not have any information about what caused this high dropout rate. It is possible that a substantial portion of the recruited participants were not interested in the intervention. This is likely since participants were not selected on the basis of their own treatment motivations but were included if they met criteria for binge drinking. These high dropout rates suggest that a considerable part of the adolescent population might not use or benefit from Web-based brief alcohol interventions. This is an important issue for the further implementation of Web-based brief alcohol interventions and should be further investigated in future research. Second, we used self-reported data to assess participants' alcohol consumption levels. This type of measurement may show response bias due to social desirability concerns and memory effects. However, a number of studies confirmed the validity of self-reports of alcohol use [54-57] suggesting that self-reports can be used to assess drinking behavior. Still, to further improve the assessment of participants' drinking levels future studies could, for instance, include other types of measurements such as Ecological Momentary Assessment (EMA) or direct observations. Finally, the utility of the tested intervention should be further examined by testing its effectiveness in the longer term after repeated exposure and among light drinkers.

Conclusion

Present findings suggest that a Web-based brief alcohol intervention can be effective in reducing weekly alcohol use and encouraging moderate drinking in 15- to 20-year-old males over a period of 1 to 3 months. Inclusion of normative feedback does not seem to enhance the effectiveness of the intervention in encouraging moderate drinking 3 months following the intervention. Moreover, the interventions do not seem effective in females in this age group, and the intervention without normative feedback even showed small unfavorable effects at the 1-month follow-up.

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Conflicts of Interest

None declared

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Abbreviations

ANOVA: analyses of variance
EMA: Ecological Momentary Assessment
ESOMAR: European Society for Opinion and Marketing Research
ESPAD: European School Survey Project on Alcohol and Other Drugs
ITT: intention to treat

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Original Paper

Feasibility of an eHealth Service to Support Collaborative Depression Care: Results of a Pilot Study

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Abstract

Background: Treatments and organizational changes supported by eHealth are beginning to play an important role in improving disease treatment outcome and providing cost-efficient care management. “Improvehealth.eu” is a novel eHealth service to support the treatment of patients with depressive disorder. It offers active patient engagement and collaborative care management by combining Web- and mobile-based information and communication technology systems and access to care managers.

Objectives: Our objective was to assess the feasibility of a novel eHealth service.

Methods: The intervention—the “Improvehealth.eu” service—was explored in the course of a pilot study comparing two groups of patients receiving treatment as usual and treatment as usual with eHealth intervention. We compared patients’ medication adherence and outcome measures between both groups and additionally explored usage and overall perceptions of the intervention in intervention group.

Results: The intervention was successfully implemented in a pilot with 46 patients, of whom 40 were female. Of the 46 patients, 25 received treatment as usual, and 21 received the intervention in addition to treatment as usual. A total of 55% (12/25) of patients in the former group and 45% (10/21) in the latter group finished the 6-month pilot. Available case analysis indicated an improvement of adherence in the intervention group (odds ratio [OR] = 10.0, P = .03). Intention-to-treat analysis indicated an improvement of outcome in the intervention group (ORs ranging from 0.35 to 18; P values ranging from .003 to .20), but confidence intervals were large due to small sample sizes. Average duration of use of the intervention was 107 days. The intervention was well received by 81% (17/21) of patients who reported feeling actively engaged, in control of their disease, and that they had access to a high level of information. In all, 33% (7/21) of the patients also described drawbacks of the intervention, mostly related to usability issues.

Conclusions: The results of this pilot study indicate that the intervention was well accepted and helped the patients in the course of treatment. The results also suggest the potential of the intervention to improve both medication adherence and outcome measures of treatment, including reduction of depression severity and patients becoming "healthy."

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KEYWORDS

Depression; patient care management; information systems; Internet; treatment outcome; medication adherence; pilot study; feasibility study; collaborative care

Introduction

Depressive disorders are the second leading cause of disability worldwide with prevalence ranging from 16% to 18% during the entire life span [1]. The majority of people with depression are treated in primary health care [2,3]. It has been shown that treatment of depression in the primary care setting is far from optimal [4-6].

To improve the outcome of depression treatment, we need to improve patient adherence to therapy [7-9] and the care process itself using, for example, collaborative care, which is characterized by enhanced collaboration between the patient and health care professionals involved in the treatment process [10-12]. Glied has shown that particularly in collaborative care it appears possible to sustain net benefits using less costly interventions [10]. The question we asked was: Can we develop eHealth interventions to treat depression in which the net benefits are sustained while further reducing resource utilization and cost?

New eHealth tools and interventions promise to provide care process support (helping patients and health care professionals to comply with the defined care process with less effort) and to actively engage the patients, thus reducing resource usage [13,14]. Online self-treatment interventions have already proven their clinical value [15], and literature also describes eHealth solutions to support collaborative care in depression treatment [16] including eHealth solutions that have already demonstrated significant improvement of outcomes [17,18].

An eHealth system for active patient engagement and care management, called RecoveryRoad, has been described by Robertson [19]. Its features included secure e-consultations, progress-monitoring questionnaires, psycho-education, and evidence-based therapy. It also offered access to patients' data, automated reminders for patients, and support for case management. In reports of preliminary findings, Robertson described high adherence to the system (53% to 84%) and self-reported medication adherence (over 90%) with a large effect size (Cohen's d = 1.0) on average depression severity decline [19].

In this paper, we report the results of a pilot study to assess the feasibility of a novel eHealth intervention to support treatment of patients with depression.

Methods

Improvehealth.eu Intervention

The intervention, "Improvehealth.eu" service [20], consisted of (1) a Web-based information and communication technology system, referred to as "the ICT system," designed to support collaborative care management and active patient engagement, and (2) online and phone-based care management performed by trained psychologists.

The intervention was administered via the Internet (accessible using personal computers and smart phones) and mobile phones. The ICT system, available 24/7, aimed to (1) actively engage the patients in the process of care; (2) increase the availability of information to all involved health care professionals (psychologists/care managers, general physicians, and psychiatrists); (3) automatically detect patient issues like poor or missing treatment response, unwanted side effects, emergence of suicidality, and nonadherence to medication regimens; and (4) provide timely response by care managers [21]. Care managers were available by telephone during service hours (3 hours per day on workdays), and their email response time was not longer than 2 working days. Upon starting the intervention, patients were informed that in case of imminent suicidality outside the intervention's service hours they were to contact existing urgent psychiatric care providers. Care managers reported all patient-related activities in the ICT system, and physicians were asked to do the same.

Patients were actively engaged by submitting self-reporting questionnaires on symptoms and drug therapy side effects at least once per week in the acute phase (lasting from week 0 to week 9 after the start of therapy) and at least once per month in the continuation phase (lasting from week 10 to week 23). Submitted questionnaires provided real-time evaluation data for the ICT system and care managers.

The ICT system defined and assigned the tasks in the care process automatically for each patient. Some administrative and clinical tasks with well-defined trigger rules were performed by the ICT system in an automated way using rule sets and an evaluation matrix [21,22]. These tasks included (1) sending reminder text messages to patients and/or care managers if patients forgot to submit questionnaires on due dates, (2) quantitatively analyzing submitted questionnaires, and (3) creating questionnaire-related tasks for care managers (ie, to call a patient who had discontinued treatment).

The ICT system could only be accessed using secure hypertext transfer protocol (HTTPS) and digital certificates. All data were stored on the University of Primorska server in an encrypted

file system. Access of health care professionals to data was only granted on patient consent.

Generic functionalities available to all users (patients, care managers, and care providers) included a personal calendar; an internal messaging system (a system of mailboxes); a forum as well as questions and answers; personal profile settings; information on depressive disorder, treatment, and emergency facilities; and the ICT system instructions.

Additional functionalities of the ICT system were available to patients, care managers, and care providers. These are shown in Table 1. A schematic description of functionalities available to patients is given in Figure 1 (not all are shown). In addition, a screenshot of "Improvehealth.eu" in which a patient is submitting a questionnaire is depicted in Figure 2.

Table 1. Additional functionalities of the ICT system available to patients, care providers, and care managers

Additional Functionalities	Descriptions
For patients	
Online self-assessment questionnaires (on depression symptoms, treatment side effects, suicidality, and medication adherence)	· composed of 46 questions over 2 pages with fixed question order · utilized adaptive questioning, that is, additional in-depth questions that appeared when certain answers were chosen · a completeness check upon each page submission · no review steps, that is, users could review the submitted questionnaire after submission in their record history but could not change it · available by using a link on the homepage · information from all completely submitted questionnaires used in the analyses
Automated personalized interpretations	· provided to the user by the ICT system instantly after the online questionnaire submission · included a tailored reinforcement message · provided analysis of deviations such as lack of symptom improvement or emergence of side effects
Access to a psychologist/care manager	· available over internal messaging and phone during predefined hours · no psychotherapy offered apart from unstructured conversations (in contrast to RecoveryRoad [19])
Automated text message reminders	· sent to patients' mobile phones in case of overdue tasks such as booking an appointment with their physicians or submitting a questionnaire
An individual patient record	· included submitted questionnaires and reports of patient-professional interaction by care managers and physicians sorted by time · internal to the ICT system · by clicking on a particular entry, the entry would expand to show all stored information
For care managers and care providers	
Dashboard	· provided a patient list with status indicators (symptoms, suicidality, medication adherence, etc) · included task lists for at-a-glance overview
Semi-automated care management	· triggered by an automated analysis of each self-assessment questionnaire upon which specific tasks were automatically assigned to care managers by the ICT system
Activity forms for reporting of performed tasks	· supported monitoring of timely execution · different forms for different professionals
An e-learning module:	· provided the latest treatment guidelines and a related online test for physicians to earn continuing medical education points

Figure 1. Simplified patient view of the intervention in which arrows describe the direction of information flow, boxes represent ICT system functionalities, and icons above arrows denote available channels (personal computer, mobile phone)

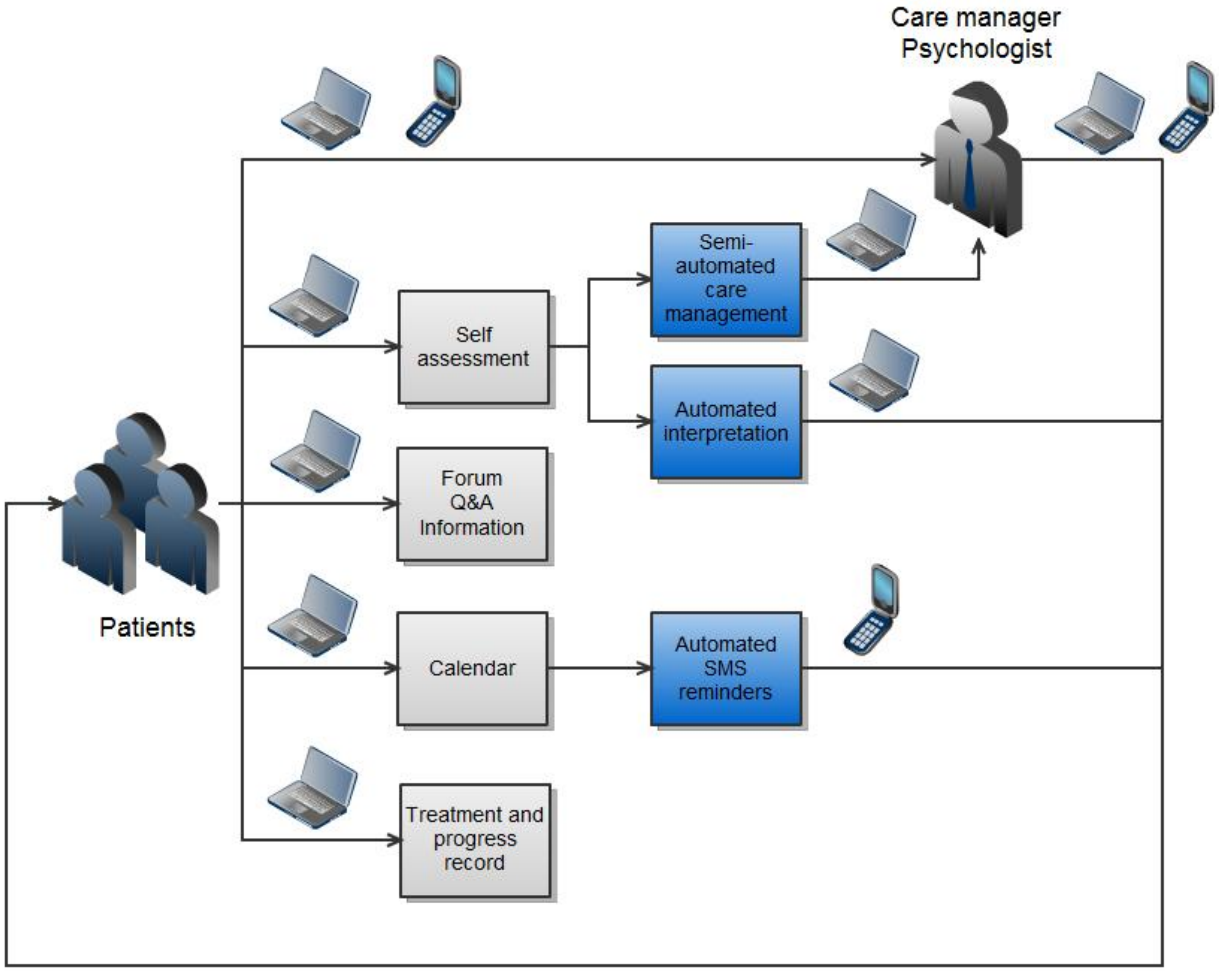
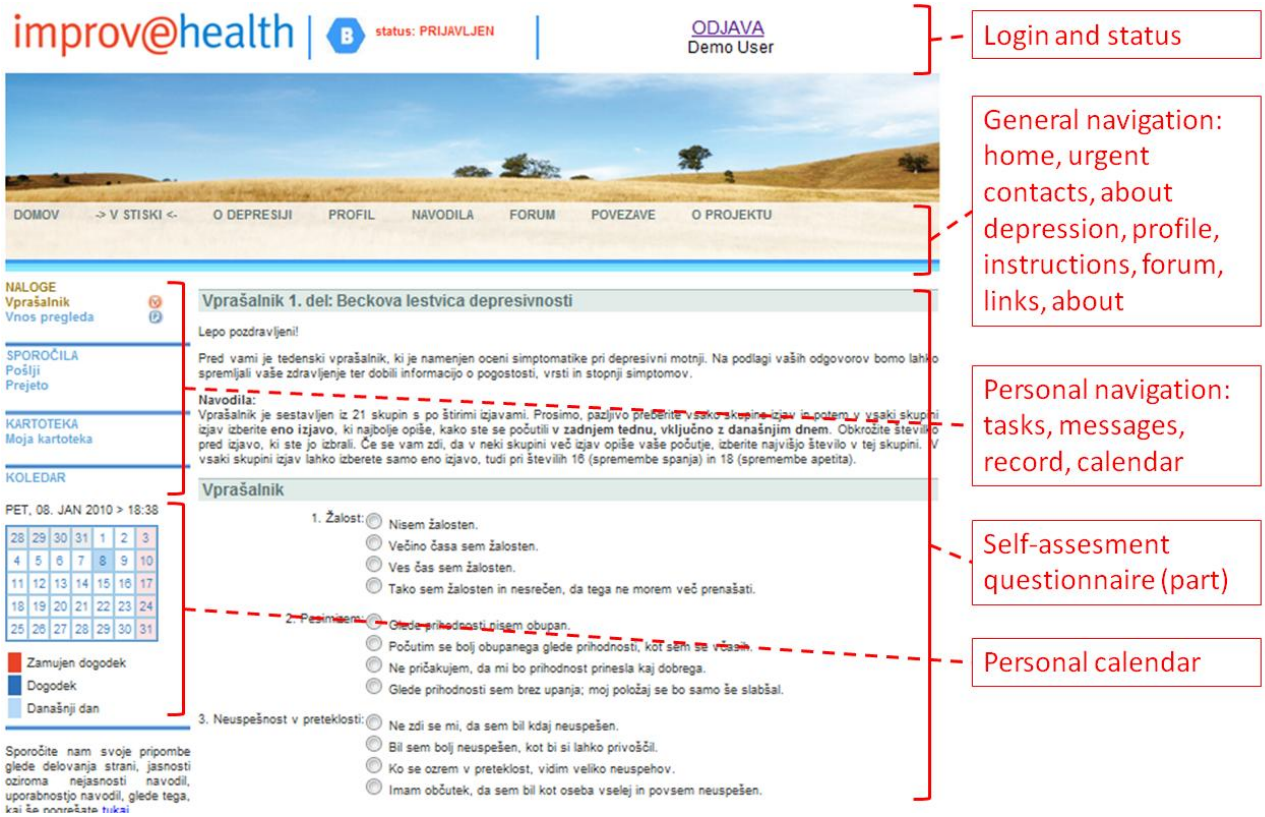


Figure 2. Screenshot of "Improvehealth.eu" in which a patient is submitting a questionnaire (the red semibrackets indicate particular modules, explained in boxes on the right hand side)



Study Design

The pilot study to explore the feasibility of the intervention was approved by the Slovene National Medical Ethics Committee. Inclusion criteria were: a diagnosis of depression (ICD10 group F32) or mixed anxiety and depression disorder (ICD10 code F41.2) for the first time or after a remission of at least 6 months; introduction of antidepressant treatment in the last 10 days; regular use of Internet and mobile phone; 14 or more points on Beck Depression Inventory-II (BDI-II) questionnaire [23,24].

The control group received treatment as usual, that is, physician visits and antidepressant treatment. The intervention group received the intervention "Improvehealth.eu" service as an addition to treatment as usual. Systematic alternating order (unweighted even-odd distribution) without blinding was used to assign patients to the control group or to the intervention group [25].

After giving informed consent, the patients filled in 2 paper questionnaires, one at the beginning of the pilot (referred to as Time 0) and the other after 24 weeks, that is, at the end of the pilot (referred to as Time 1). The Time 0 assessment consisted of a questionnaire assessing demographics and BDI-II [23,24]. The Time 1 assessment consisted of a repeated BDI-II assessment and a 26-question questionnaire exploring the duration of antidepressant therapy, side effects, adherence, patients' perceived quality of care, and, for the intervention group only, the overall perception of the intervention.

Patients were recruited and enrolled by 7 physicians upon initial assessment. The observation period for each individual patient was 6 months. Primary outcome measures were patients' medication adherence and clinical outcome measures (reduction in depression severity according to BDI-II and reaching "healthy" criteria, described below). User acceptance and usage patterns were explored as secondary outcome measures. No incentives were offered to patients for finishing the pilot.

Demographics and Pilot Participation

Demographics included age, gender, marital status, education, and employment. Attrition rate was measured as the share of patients responding to the Time 1 questionnaire.

Medication Adherence, BDI-II Improvement, and Outcome Measures

For self-assessment of medication adherence at Time 1, we used a questionnaire combining 3 previously reported measures: (1) regularity of administration over the defined medication period, (2) taking the medication at the same time of the day, and (3) regular use of correct dosage [26-28]. "Adherent" was defined as adherent to 2 or 3 of these criteria.

To assess reduction in depression severity, we calculated the difference between patient-reported Beck Depression Inventory-II (BDI-II) scores at Time 0 and Time 1 [23,24]. To assess clinically important change (the patient becoming "healthy"), we used a combination of BDI-II score of less than 14 points at Time 1 and at least 8 points improvement in BDI-II score from Time 0 to Time 1 as suggested in previous research (rounded from 14.29 and 8.46, respectively) [29-31].

Usage Patterns

Additional data were acquired from the database to explore the duration and frequency of intervention usage and workload on

care managers, including time between registration and last submitted questionnaire, number of submitted questionnaires, and number of tasks performed by care managers.

Patient Feedback

For qualitative assessment, the patient questionnaires at Time 1 included open-ended questions on overall satisfaction with the intervention. They also included 12 Likert-type items (statements) on patient perception of care quality, access to care, and access to information.

User Experience With the ICT System

Initial usability testing of the ICT system was performed before the pilot by 6 healthy individuals and 1 usability expert. Users had to perform tasks like registering, filling in the questionnaire etc. Usability issues regarding the ICT system arising during the pilot were reported and listed as such.

Statistical Analysis

Choice of tests was dependant on variable type. Two-sided significance testing was used in all cases. To compare demographic characteristics of the two groups we used the Fisher exact test, the Mann-Whitney test, and the chi-square test. For adherence, Mantel-Haenszel odds ratio estimate was used. For BDI-II improvements, we performed available case analysis using paired and unpaired *t* tests and Cohen's *d* for effect size. For outcome measures, we used the Fisher Exact test and odds ratio estimates.

We employed a simple sensitivity analysis to assess variability due to dropouts' missing data: available case and intention-to-treat analyses were performed, the latter using simple imputation scenarios [32]. These scenarios were: (1) "healthy" (ie, an assumed BDI-II score of less than 14 and symptom reduction of at least 8) early quitters in the intervention group were also healthy at Time 1, and the average frequency of healthy dropouts in the control group was the same as in the intervention group; (2) all drop-outs in either group were not healthy; or (3) all dropouts in both groups were healthy. These 3 scenarios imputed the same risks in both groups, pulling effect estimates towards the null hypothesis [32], thus avoiding the overestimation of intervention effect. We also added a pessimistic scenario (4) in which all missing patients in the intervention group were imputed as "not healthy," whereas in the control group they were imputed as "healthy."

Usage patterns were assessed using Kaplan-Meyer analysis. The 2 scenarios used were (1) treating all patients as events and (2) treating "healthy" quitters (patients quitting with last reported BDI-II values reaching "healthy" criteria) as censored events. Care manager usage patterns were listed depending on classification of tasks.

For patient feedback, the qualitative answers were categorized and compared with the aims of the intervention, whereas Likert-type items were analyzed using the Mann-Whitney test.

Results

Demographics and Pilot Participation

There were no significant differences between the intervention and control groups at the beginning of pilot (Time 0 in Table 2) and after 6 months (Time 1) for age, gender, marital status, education, and employment. Of the 46 patients, 25 (54%) were allocated to control group and 21 (46%) to intervention group. The response rate at 6 months (Time 1) was slightly higher in the intervention group (12 out of 21, 57%) versus the control group (10 out of 25, 40%), but the difference was not statistically significant ($\chi^2_1 = 1.34$, $P = .38$).

In the intervention group, the reasons patients gave for dropping out were dissatisfaction with the intervention (1 patient) and early significant clinical improvement (8 patients). For those who said they dropped out because they were much improved, it is unknown whether they were still healthy at Time 1. Reasons for high attrition at Time 1 in the control group were not known.

Table 2. Group characteristics at Time 0

	Intervention n = 21	Control n = 25	*P* value[a]
Age, median (mean ± SD)	36 (35.71 ± 12.11)	37 (40.04 ± 17.07)	.44[b]
Female gender, n (%)	18 (86%)	22 (88%)	.99[c]
BDI-II symptom severity			
Mild, n (%)	2 (10%)	4 (16%)	
Moderate, n (%)	8 (38%)	9 (36%)	
Severe, n (%)	11 (52%)	12 (48%)	.81[d]
Married or partnered, n (%)	15 (71%)	17 (68%)	.99[c]
University degree, n (%)	8 (38%)	7 (28%)	.53[c]
Currently employed, n (%)	15 (71%)	12 (48%)	.14[c]

[a] Comparison of the intervention group and the control group

[b] Mann-Whitney test

[c] Fisher exact test

[d] Chi-square test

Medication Adherence, BDI-II Improvement, and Outcome Measures

In the control group, 3 out of 9 (33%) patients were adherent to antidepressants compared with 10 out of 12 patients (83%) in the intervention group ($\chi^2_1 = 5.45$, $P = .03$, odds ratio [OR] = 10.0, 95% confidence interval [CI] = 1.28-78.1).

Both groups demonstrated significant within-group reduction of mean BDI-II score from Time 0 to Time 1 (control group: paired $t_9 = 3.95$, $P = .003$, Cohen's $d = 1.23$; intervention group: paired $t_{11} = 7.23$, $P < .001$, Cohen's $d = 2.57$), with intervention group seeming to indicate a greater effect size, which is further supported by the between-group comparison shown in Table 3.

Table 3. Between-group comparison of BDI-II for available cases

	Intervention Mean (SD) n = 12	Control Mean (SD) n = 10	Difference	Two-sample t_{20}; *P* value	Effect Size: Cohen's *d* (95% CI)
BDI-II at Time 0	29.50 (8.15)	28.70 (8.34)	-0.80	0.23; $P = .82$	
BDI-II at Time 1	9.83 (8.05)	17.80 (7.91)	7.97	2.33; $P = .03$	1.00 (0.09-1.88)

In outcome sensitivity analysis (Table 4), available case analysis and the 3 intention-to-treat (ITT) scenarios with equal risk imputation [32] resulted in odds ratios in favour of intervention, seeming to indicate an improvement of outcome in the intervention group. The last, pessimistic scenario was insignificantly in favour of the control group. Confidence intervals were wide due to small sample sizes and high dropout ratios.

Table 4. Outcome measures: available cases and intention-to-treat (ITT) analysis scenarios

	Intervention	Control	χ^2_1, *P* Value	Odds Ratio (95% CI)
Healthy at Time 0, n (%)	0/21 (0%)	0/25 (0%)		
Healthy at Time 1, n/available cases (%)	9/12 (75%)	1/10 (10%)	9.3, *P* = .004	27 (2.3-310)
Intention-to-treat scenarios				
Healthy at Time 1, n (%): ITT 1[a]	17/21 (81%)	15/25 (60%)	2.4, *P* = .20	2.8 (0.73-11)
Healthy at Time 1, n (%): ITT 2[b]	18/21 (86%)	17/25 (68%)	2.0, *P* = .19	2.8 (0.64-12)
Healthy at Time 1 (%): ITT 3[c]	9/21 (43%)	1/25 (4%)	10.1, *P* = .003	18 (2.0-159)
Healthy at Time 1 (%): ITT 4[d]	9/21 (43%)	13/25 (68%)	2.9, *P* = .14	0.35 (0.12-1.2)

[a] realistic in that "healthy" early quitters in the intervention group were healthy at Time 1, and the average frequency of healthy dropouts in the control group was the same as in the intervention group

[b] all missing patients from either group are assumed "healthy"

[c] all missing patients from either group are assumed "not healthy"

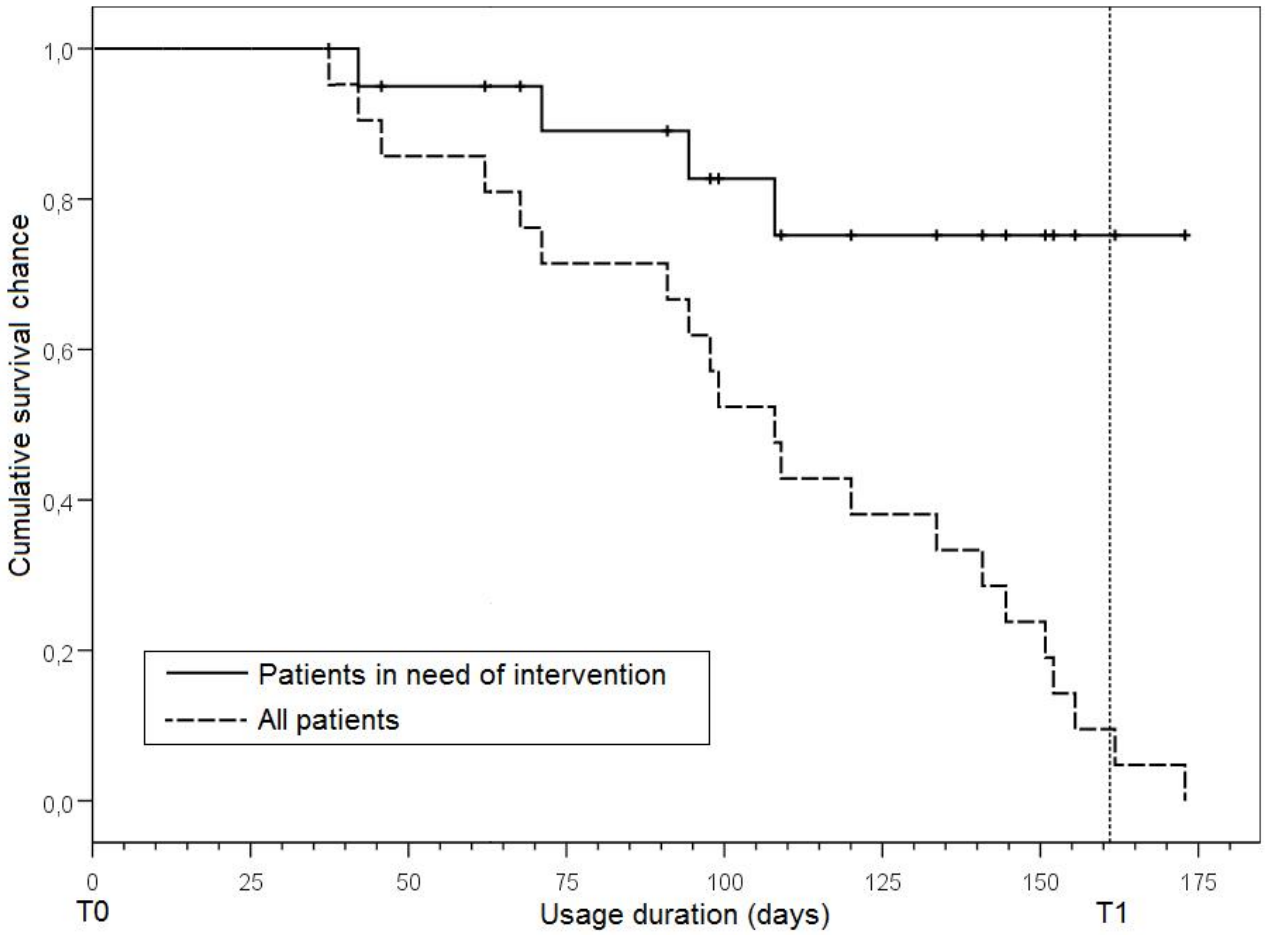
[d] pessimistic in that all missing in the intervention group assumed "not healthy" and all missing in control group assumed "healthy"

Usage Patterns

In Figure 3, the Kaplan-Meyer plot depicts the chance of a patient reaching a certain duration of intervention usage. Shown are 2 scenarios: (1) all patients and (2) only patients in need of further intervention where only nonhealthy patients at any given time were taken into account (by treating healthy quitters as censored events). The mean duration of intervention usage by all patients was 107 days (95% CI 90-125 days); for patients in need of further intervention the mean duration was 150 days (95% CI 131-170 days).

The patients submitted a total of 431 questionnaires online of which 198 (46%) were complete. The average number of complete questionnaires per patient was 9.9 (SD 3.35, range 3-14). The remaining 229 submitted questionnaires were only partially completed and were treated as unsuccessful submissions. The patients were required to fill in the missing answers and resubmit the questionnaires.

Figure 3. Kaplan-Meier survival analysis for use of intervention (dotted vertical line denotes Time 1 at beginning of the 24th week)



Of the 21 patients in the intervention group, 6 (29%) required guided registration over the phone by the care manager. Care managers submitted 46 task-resolution reports related to 16 of the 21 patients (76%) (see Table 5).

Table 5. Care manager tasks

Reason	Number of Tasks	% of Tasks	Patients Involved, n (%) (n = 21)[a]
Questionnaire overdue: phone patient	15	33%	9 (43%)
Reported side effects of medication: phone patient	6	13%	2 (10%)
Reported suicidality: phone patient	3	7%	2 (10%)
Confirm change of therapy: contact physician	2	4%	2 (10%)
Missing symptoms improvement: phone patient	5	11%	5 (24%)
Due date of control visit: phone patient	9	20%	6 (29%)
Exit/dropout: phone patient	6	13%	3 (14%)
Total	**46**	**100%**	**16[a] (76%)[b]**

[a] The number of total patients involved in task resolution (16) is less than the number of patients in the intervention group (21) as for some patients no tasks were assigned to the care manager.

[b] As some patients required that care managers undertake tasks for more than one reason, the sum of total patients involved is less than the sum of involved patients by reasons.

In addition, care managers reported that 33 assigned tasks were not resolved because the patient did not answer the phone or reply to an email. Of these, 88% (29/33) were requested for patients who dropped out. The average number of tasks performed was 2.2 per patient and 2.9 per patient actually requiring that the case manager undertake a task. In addition, 1 of the 7 physicians involved in the pilot reported patient visits in the ICT system, and none of the 7 physicians performed the e-learning test.

Patient Feedback

No significant differences were detected between the control group and the intervention group in perception of care quality or accessibility to care and information. Qualitative feedback regarding the intervention provided by patients from the intervention group is shown in Tables 6. Of the 21 patients, 17 (81%) gave positive feedback whereas 7 (33%) gave negative feedback.

Table 6. Positive feedback provided by patients in the intervention group: categories and examples

Category of Intervention Benefit	Number of Replies (n = 17)	Example
Increased control of their disease and improved overview	6 (35%)	I could monitor my progression.
Provided an incentive	3 (18%)	It was reminding me of regular antidepressant intake.
Useful information, increased knowledge	2 (12%)	Improved knowledge of depression and how to fight it.
Available and responsive	2 (12%)	Quick coordination, quick advice, quick transfer of information.
Treatment barrier reduction	2 (12%)	Much easier to communicate over the internet than live.
Overall usefulness	2 (12%)	I liked everything.

Table 7. Negative feedback provided by patients in the intervention group: categories and examples

Category of Intervention Drawback	Number of Replies (n = 7)	Example
Annoying	2 (29%)	Annoying text messages
Repetitive	2 (29%)	Same questionnaire repeating all the time
Computer literacy required	2 (29%)	Some computer literacy is needed; digital certificate installation difficulty
Lack of content	1 (13%)	Empty forum, empty question and answer

User Experience With the ICT System

Some areas for improvement were identified during the pilot. The following 4 required increased resource utilization and called for a future modification of work processes: (1) Digital certificates (electronic documents required by the ICT system from each user for authentication) required time and were somewhat difficult for both patients and care managers to manage. Further simplifications of certificate handling are necessary and human resources are required to help patients register. In the future, we anticipate that digital certificate "literacy" among users will reduce the importance of this issue. (2) A significant proportion of the care manager workload was due to dropouts not responding to calls and emails. More efficient strategies for interaction with these patients are needed. (3) Physician usage of the ICT system was poor, requiring specific motivational strategies (ie, a reimbursement scheme). (4) Frequently asked questions were available but not used, as the protocol that required the care manager to post these was not strictly enforced.

An additional 4 areas were identified that require changes in the ICT system functionality: (1) The feedback provided when a patient does not complete a questionnaire needs to be improved (ie, that directs users to missing answers). (2) Automated text messages were seen as a disturbance for a minority of patients who experienced fast clinical improvement and wished to finish the intervention early. The solution is for the care manager to have the ability to deactivate these messages for individual patients. (3) The knowledge base of the ICT system needs to be upgraded to increase the pool of available interpretations when questionnaires are submitted. The reason for this is to reduce repetitive answers that are possibly perceived as impersonal by patients. (4) Because the forum was poorly used and the clinical value of forums is unclear [33,34], consideration should be given to discontinuing of this function.

Discussion

The main findings were that (1) user feedback confirmed the ICT system's alignment with the initial objectives (active patient engagement and improved care management) and (2) the results of the pilot indicate the intervention's likely influence on improvement of medication adherence and the outcome measures, namely the reduction of depression severity and patients becoming "healthy."

Overall usability was good, with some feature enhancements necessary to further improve it. Patient feedback about the benefits of the ICT system was in line with the intervention goal and its design. The intervention seemed to support collaborative care [16,35] and active engagement [36] if usability issues are addressed properly in future [37].

We noticed that medication adherence for treatment as usual was low (33%) and comparable to values reported previously (21%) [38]. The intervention group had a significantly higher adherence rate (83%), likely due to the intervention.

The effect size of improvements in scores on the BDI-II in the intervention group compared with the control group was in line with the results of the study by Robertson et al [19] (in both cases Cohen's $d = 1$). This seems to indicate an effect of the intervention on treatment success and is further supported by improved outcome measures for intervention group. No significant changes in treatment quality perception were observed.

Limitations

Even though we employed tests that gave the highest statistical power for a given variable type (parametric where applicable, nonparametric otherwise), small sample sizes in most analyses and the additionally high dropout ratio for intention-to-treat analyses resulted in wide confidence intervals. The fixed allocation sequence with even-odd randomization and no blinding [25] likely contributed to bias, and other contributing factors such as depression severity and comorbidities were also not taken into account. We suggest larger sample sizes and more robust methodology (with improved dropout prevention, full randomization, and use of advanced imputation techniques) for further research of the topic.

Conclusions

This pilot study has shown that the intervention—a novel eHealth service offering collaborative care management and active patient engagement—was well received by potential users, seeming to indicate increased patient engagement and feelings of control over treatment progress. The pilot also seems to indicate a likely positive effect of this type of intervention on medication adherence and outcome measures in depression treatment, possibly further improving outcome in addition to interventions offering online cognitive behavioral therapy [39-41].

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Conflicts of Interest

None declared.

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Abbreviations

HTTPS: secure hypertext transfer protocol
ICT: information and communication technology
ITT: intention-to-treat
BDI-II: Beck Depression Inventory-II

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Original Paper

Online Group Course for Parents With Mental Illness: Development and Pilot Study

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Abstract

Background: Children of parents with mental illness (COPMI) are at greater risk of developing mental disorders themselves. Since impaired parenting skills appear to be a crucial factor, we developed a facilitated 8-session preventative group course called KopOpOuders (Chin Up, Parents) delivered via the Internet to Dutch parents with psychiatric problems. The goal was to promote children's well-being by strengthening children's protective factors via their parents. To reach parents at an early stage of their parenting difficulties, the course is easily accessible online. The course is delivered in a secure chat room, and participation is anonymous.

Objective: This paper reports on (1) the design and method of this online group course and (2) the results of a pilot study that assessed parenting skills, parental sense of competence, child well-being, and course satisfaction.

Method: The pilot study had a pre/post design. Parenting skills were assessed using Laxness and Overreactivity subscales of the Parenting Scale (PS). Sense of parenting competence was measured with the Ouderlijke Opvattingen over Opvoeding (OOO) questionnaire, a Dutch scale assessing parental perceptions of parenting using the Feelings of Incompetence and Feelings of Competence subscales. Child well-being was assessed with the total problem score, Emotional Problems, and Hyperactivity subscales of the Strengths and Difficulties Questionnaire (SDQ). Paired samples *t* tests were performed, and Cohen's *d* was used to determine effect sizes. Intention-to-treat analyses and analyses of completers only were both performed. Course satisfaction was evaluated using custom-designed questionnaires.

Results: The sample comprised 48 parents with mental illness. The response rate was 100% (48/48) at pretest and 58% (28/48) at posttest. Significant improvements were found on PS Laxness and Overreactivity subscales ($P < .01$) and on the OOO Feelings of Incompetence and Competence subscales ($P < .01$) in analysis of completers only as well as by intention-to-treat analysis. Effects were moderate on the PS ($d = .52$ and $d = .48$) and were large and moderate on the OOO ($d = 0.61$ and $d = 0.46$). At pretest, 75% and 64% of PS scores were in the clinical range, which declined to 43% and 39% at posttest. No significant changes were found for child well-being. Scores for approximately two thirds of children were not in the clinical range at both pretest and posttest. The mean course satisfaction score was 7.8 on a 10-point scale. Of all participants, 20% (10/48) followed all the sessions.

Conclusion: This online group course on parenting skills is innovative in the field of e-support and among interventions for mentally ill parents. The pilot results are promising, showing moderate to large effects for parenting skills and parental sense of competence. Test scores at baseline indicating parenting problems were largely in the clinical range, and baseline scores indicating problems among the children were in the nonclinical range, suggesting that parents were reached at an early stage. Course satisfaction was high. Future research should focus on cost effectiveness and course adherence.

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KEYWORDS

Parenting support; health promotion; parents with mental illness; online group course; Internet

Introduction

Parenting is a complex social skill, and it can be heavily undermined by mental illness [1]. Parental mental illness is a widespread phenomenon. One in four to five adults experience mental health problems at some stage of their lives [2,3], and a considerable proportion of them are bringing up children at the time. Every year in the Netherlands, 864,000 parents suffer psychopathology according to Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria, and together they have 1.6 million children under 22 years of age [4,5]. Children of parents with mental illness are themselves at risk of developing mental disorders such as depression, anxiety, and alcohol or drug dependence [5]. They are more likely than other children to have poorer communication skills and relationship or intimacy problems [6-11]. The risks are substantial: children who have a parent with psychiatric problems are 1.5 times more likely to develop a mental disorder at some point in their lives than children without such parents (50% versus 30%), and as many as 66% develop disorders if both parents are mentally ill [4,5]. Despite this risk, a considerable number of children do not develop disorders, indicating that parental psychopathology alone does not explain the problem. The precise mechanisms through which children develop mental health problems are still unknown, but a combination of genetic, biological, social, and psychological risk and protective factors is generally assumed to be the cause [12].

Risk Factors

The presence of risk factors in children of parents with mental illness is associated with an increased probability of onset of major health problems as well as greater severity or longer duration of these problems [13]. Knowledge of risk factors is crucial to illness prevention programs, as some factors can be alleviated or eliminated. Well-known risk factors that cannot be influenced directly by preventive intervention are the child's age at the onset of a parental disorder [13], genetic factors [14,15], and the severity and duration of parental illness [16]. Yet the medical literature has also drawn attention to several types of risk factors that can be mitigated by preventive intervention. These are described below.

Dysfunctional Parent-Child Interaction

Parents with mental illness interact differently with their children than other parents. The parenting styles of mothers with unipolar depression, for instance, may be characterized by a flatter affect and less physical contact, lower levels of expressed approval or spontaneity, and more frequent anger [9,17,18]. Anxious parents exhibit high levels of control, disapproval, and overprotection towards their children [14,19]. Alcohol-dependent parents often show neglect and unpredictable behaviors [6,20]. A further danger is the increased risk of child abuse by parents with mental illness [20,21]. Parents may put age-inappropriate responsibilities on children, resulting in "parentification" of the child [22-24]. In addition to behaviors and symptoms stemming from their mental illness, parents also experience feelings of shame and fears of losing custody of their children; these may also negatively affect parent-child interaction and may inhibit parents from seeking help [25,26].

Conflicts Between Parents

In addition to the parents' individual problems, there may be problem-related conflicts between parents, for instance conflicts about an alcoholic parent's drinking. Parental stress and conflicts show associations with undue pressure and disapproval exerted on children [27]. Conflicts and stress can have a negative impact on the children [11].

Partners and Lone Parents

A mental disorder in one parent can put growing pressure on the well partner. If the partner can meet the challenge, the consequences for the family and the children may remain limited [28]. Growing up in a single-parent family is in itself a considerable risk factor to children for developing mental disorders, and the combination with parental mental health problems adds extra weight [29].

Protective Factors

From the point of view of mental illness prevention, protective factors are at least as important as risk factors. Protective factors are conditions that improve an individual's resistance to risk factors and illness; they have been defined as "those factors that modify, ameliorate, or alter a person's response to some environmental hazard that predisposes to a maladaptive outcome" [13]. Although the evidence base on protective factors is still limited [6], the following factors have been identified in the literature:

- If a parent and child have a good relationship despite the parental disorder, the child's prognosis is significantly improved [23,24].
- Strong support of the child by the unaffected parent may compensate for a deficit in support from the affected parent. In broader terms, a good relationship with at least one parent is a strong protective factor: a child can then cope with considerable difficulties without necessarily developing psychopathology. Social support from the unaffected parent, a sibling, or a support network or trusted person outside the family can help protect the child. Emotional and practical support are both important [23,30-32].
- Realistic self-appraisal on the child's part is crucial [30,33,34].
- A clear understanding of the parent's problems can be very helpful [4,23].

Parenting Support Programs

According to a study by Goodman and Brumley [35] that compared depressed (n = 25), schizophrenic (n = 53), and well mothers (n = 23), parenting style is a decisive factor for children's outcomes. The study showed that effects of a mother's illness on a child are mediated mainly through the quality of parenting as she practices it. Affectional involvement and parental responsiveness are particularly important for a child's social functioning.

Parenting style can be improved by parenting support programs. Many studies have shown that preventive parenting support has positive effects on parents' skills and sense of parental competence as well as on child well-being [36-41]. A well-known parenting program is the Triple P Positive Parenting

Program. Level 4 of this program is indicated if the child has multiple behavior problems in a variety of settings and there are clear deficits in parenting skills. A meta-analysis examining the effects of level 4 of Triple P showed a moderate effect on the Parenting Scale (overall effect size d = 0.51) and a large effect on the Parenting Sense of Competence Scale (overall effect size d = 0.67). These are validated scales measuring dysfunctional discipline styles and parents' view of their competence as parents. [40]. In addition, moderate positive effects were found on the Behavior Problem scale as measured by the Eyberg Child Behavior Inventory (overall effect size d = 0.42) [41].

Parenting Support Programs for Parents With Mental Illness

Evidence-based parenting programs for parents with mental disorders are less common [12,42]. Also, the parental role remains an underexposed issue in the field of mental health treatment [43] even though it constitutes a fundamental part of a parent's identity. There are indications that parents' recovery from mental illness can be facilitated by a strengthening of their parental role [44].

According to a review by Fraser and colleagues [12], one of the few well studied, effective programs for parents with mental illness is the Preventive Family Intervention (FPI) from the United States [45], an intensive program that includes home visits to parents with mood disorders and their families. It is designed to improve communication about the disorder and its consequences for the children as well as to strengthen the children's resilience. A study [45] of 36 families that had a nondepressed child between the ages of 8 and 15 and a parent who had experienced affective disorder were randomly assigned to either the FPI intervention or a lecture discussion group. Children in the FPI group reported significantly greater understanding of parental affective disorder. Furthermore, children and parents had significantly better adaptive functioning in terms of changes in illness-related behaviors and attitudes (eg, increased communication with and understanding of the children). This intervention has also been implemented in the Netherlands.

Less intensive parenting support programs that are easily accessible and can reach parents at an early stage of parenting problems and children's problems are not yet available for parents with mental illness. The preventative intervention KopOpOuders (Chin Up, Parents), an online group course, is intended to fill this gap. The advantages of an online group intervention for this target group are that it is anonymous (important because participants may feel shame or may fear losing custody of their children), requires no traveling time or babysitter, and enables contact with other parents in similar situations. KopOpOuders may also reach parents who are not in touch with mental health services.

The KopOpOuders intervention is an innovative intervention in several ways. Online group courses are still rare in the entire field of e-support. Only two online studies have been reported worldwide [46,47]. These have involved chat room courses for adolescents with internalizing problems, and they have been associated with favorable effects using a pretest-posttest design. In one of the few studies of online parenting support, Taylor and colleagues [48] reported that a computer-based course combined with home visits and telephone coaching was associated with positive outcomes. Of a total of 128 goals set by 90 participants, 100% progress was made on 68 goals. Adherence to the program, which has been flagged as a potential disadvantage of e-interventions [46,47,49], was acceptable, with two thirds of participants completing all program elements. Finally, in the field of interventions for mentally ill parents, KopOpOuders is innovative because it is based on systematic evidence of risk and protective factors and parenting support theories.

Objective

This paper describes the design and method of the online group course KopOpOuders and reports on the results of a pilot study that assessed parenting skills, parental sense of competence, child well-being, and course satisfaction.

Methods

The Parenting Support Course KopOpOuders.nl

The purpose of the KopOpOuders intervention for parents with mental illness is to enhance their children's psychosocial well-being and to protect the children from developing mental health problems by improving their parents' skills. We based KopOpOuders on recognized theories relevant to parenting support—social learning theory [50], the theory of developmental psychopathology [51], and the contextual theory [52]—and we linked course components to the identified risk and protective factors. This is consistent with Fraser's [12] call to develop theory-based interventions for this target group. As our central focus was on the risk and protective factors for children that can be influenced by giving parenting support to their parents, we chose the following focal points for the preventative intervention [4,22-24,34]:

- strengthening parent-child interaction
- supporting the unaffected parent
- ensuring a support network or trusted person for each child
- reinforcing children's coping and social skills
- explaining the parental mental illness to the children.

Textbox 1 shows how we operationally defined these focal points.

Textbox 1. Objectives of the online KopOpOuders course and their operational definitions

(1) Good parent-child interaction

- Parent feels less guilt and shame about the mental illness and about the consequences for the home situation.
- Parent knows what effects their own mental illness could have on the children.
- Parent knows which protective factors exist for the child and is able to strengthen these.
- Parent can articulate their own limitations and needs with respect to their parental role and can discuss these with a partner or trusted person.
- Parent learns general parenting skills (eg, setting limits, dealing with conflicts), puts these into practice, and has a realistic idea of "good-enough parenting."

(2) Support from the well parent

- Well parent feels less guilt and shame about the problems in the family.
- Well parent knows how to keep functioning well and cope with the situation.
- Well parent knows partner's limitations and needs with respect to the parental role and can discuss these with the partner.
- Well parent is able to support the partner in actively improving the partner's parental role.

(3) Support network or trusted person

- Parent knows his or her own support network and enlists its help when needed.
- Parent allows children to seek support from others.
- Parent has "emergency plan" in case of relapse.
- Parent is familiar with services available to self, partner, and children and knows how to seek help there if needed.

(4) Children's coping skills and social competence

- Parent knows the children's age-specific development tasks and gives them sufficient room to perform them.
- Parent allows children to seek support from others.
- Parent informs children in age-appropriate ways about the mental illness and absolves them of responsibility.
- Parent gives children room to express their feelings.
- Parent is familiar with available services for children and knows how to seek help from them if necessary.

(5) Children's understanding of themselves and of the parental problems

- Parent informs children in age-appropriate ways about the mental illness and absolves them of responsibility.

The KopOpOuders course is based on three mutually supportive principles. First, it facilitates the parents' learning potential by highlighting and addressing their shame and guilt about their illness. Second, it teaches some general principles of parenting as well as more specific skills needed in the unique situation in which the parents and children find themselves. Third, the participants practice and consolidate this knowledge. Chat sessions, videos, and home exercises are provided to support participants as they put into practice parenting skills such as talking to children about psychological or addiction problems, listening to children, and setting limits. Consolidating the knowledge is facilitated by having participants record what they learn in a "plan of action" and fill in a "parenting atmosphere meter" every day.

The online course consisted of eight 90-minute weekly sessions in a secured chat room facilitated by one or two trained health promotion workers from four Dutch mental health organizations. (If the facilitator was highly experienced, one was sufficient.) Each course group had a maximum of six participants with mental illness. Between sessions, parents did homework and practiced parenting skills in structured home exercises. Participants were encouraged to invite their partners to read the session transcripts on the screen and to help carry out the homework exercises. The course focal points listed in Textbox 1 were addressed systematically in the eight sessions. Session topics were as follows: (1) getting acquainted and discussing the family situations; (2) "good-enough parenting"; (3) communicating with your child; (4) child development and "parentification"; (5) giving attention to your child; (6) setting limits and dealing with conflicts; (7) social network and emergency plan; (8) preserving your gains and farewell.

The chat room in which the course was delivered was part of the public website www.kopopouders.nl, which provided written information and videos about mental illness and parenting, a user forum, and an email service through which users could get individual support from a health promotion professional. The secured chat room screen had two parts: the left part was for chatting, and in the right part, the facilitator could post short videos to enhance recognition or other information such as the session agenda or an outline or diagram. The chat room screen included emoticons that participants could use to add a feeling to a message. To sign up for the course, participants completed

online questionnaires. When accepted, participants received a log-in code. Registration was anonymous, but participants were asked to supply a mobile phone number to which an automatic text reminder could be sent half an hour before each weekly session.

Sample

From March 3, 2008, through May 13, 2009, 94 parents with mental illness, 88% of them female, enrolled in the KopOpOuders program. The parent's average age was 37 years with a range of 25 to 52 years (SD 6.8), and their children's average age was 7.7 years, with a range of 1 to 21 years (SD 4.8). Accepted for the intervention were 85 parents with mental illness; 6 others did not respond further after completing the initial questionnaires, and 3 were excluded because of the longtime placement of the child out of the home, there were no parental psychological problems, or the children were over 21 years of age. Of those parents accepted, 26 withdrew before the course started citing reasons that included an unstable home situation (divorce, relocation, starting a rehabilitation, training, or reintegration program), postponement of participation, or no reason. Ultimately, 59 parents with mental illness began the intervention, 48 of whom gave informed consent to take part in the pilot study. The reasons that 11 parents failed to provide consent are unknown, but these parents were all female, 8 (73%) lived in single-parent families, 11 (73%) had intermediate or lower vocational education, and most reported that they experienced a mood disorder or a borderline personality disorder.

In the informed consent group (n = 48), 41 (85%) participants were female with a mean age of 37 years (SD 6.8); the mean age of their children was 6.7 years (SD 5.3). The following mental health problems were reported: depression or bipolar disorder (41%), personality disorder (38%), post-traumatic stress disorder (19%), attention-deficit/hyperactivity disorder (8%), anxiety disorders (6%), psychosis (6%), eating disorders (4%), alcohol addiction (4%), and autism (2%). Comorbidity was reported by 33% (16/48). Of the 48 participants, 28 (58%) lived in two-parent families or stepfamilies, 40 (83%) had one or two children, 27 (56%) were married, 43 (90%) were of Dutch ethnicity (the others were Belgian, Turkish, and Danish), 20 (42%) had intermediate and 13 (27%) higher vocational education, 25 (52%) had jobs or attended reintegration programs, and 45 (93%) had received professional psychological help from a mental health service. The partners of the mentally ill parents were not involved in the study.

Recruitment and Screening

Parents with mental health problems were recruited via the website, www.kopopouders.nl, or through recruitment materials distributed by four implementing mental health agencies, both internally, and to other mental health services in their regions. These included general practitioners, social services, and homecare services in four rural and urban regions in the Netherlands. Parents applied for the course via the website by completing questionnaires about their childrearing situation and the nature of the problems. Parents accepted for the course were also asked for their consent to take part in the study. Exclusion criteria for course acceptance were long-term placement of the children out of the home, severe personality or behavioral problems of children, the presence of acute crisis situations, and insufficient proficiency in Dutch.

Measures and Design

At the start of the course (at pretest), parents completed questionnaires on parenting practices, child behavior, and sociodemographic background. The course comprised eight 1.5-hour sessions. At the end of the eighth session (posttest), participants completed questionnaires on course satisfaction, parenting practices, and child behavior.

Parenting Skills

To assess parenting practices, we used 12 questions from the Laxness and Overreactivity subscales of the Dutch version of the Parenting Scale (PS) [53-55]. These scales measure the parenting style during the last two months on a 7-point scale. Subscale Laxness measures the degree in which parents apply a permissive parenting style. An example of the questions in the subscale Laxness is: "When I say my child can't do something…I let my child do it anyway." The response choices range from 0, "never or rarely" to 7, "I stick to what I said." The subscale Overreactivity measures the degree of authoritarian parenting style and a parent's appropriate reaction to child behavior. An example is: "When my child misbehaves, I spank, slap, grab, or hit my child." The response choices range from 0, "never or rarely" to 7, "most of the time." Both subscales consist of 6 items. The corresponding scores sum up to a total subscale score with a range of 6 to 42. A low score means use of effective parenting skills, and a high score indicates a dysfunctional parenting style. Both subscales, Laxness and Overreactivity, tested as reliable with Cronbach alpha (Laxness .79; Overreactivity .88). The original Parenting Scale in English included an additional subscale, Verbosity, intended to measure the degree of verbalization of parenting reactions. The internal consistency of this subscale has been found to be unsatisfactory [56-59]. Therefore, this subscale was not included in the study. Without including a score for the subscale Verbosity, the total problem score in the short Dutch PS is not reliable [54,55]. Therefore, the total score was not included in the analyses. The parenting scale has cutoff scores that can be used for a clinical assessment of dysfunctional parenting. For Laxness, the clinical cutoff score is 2.8 and higher, and for Overreactivity the cutoff score is 3.0 and higher [54,55]. The percentage of parents with scores within the clinical range of the questionnaire is reported in the "Results" section.

Parental Competence

Sense of parental competence was measured with a Dutch scale assessing parental perceptions of parenting: the Ouderlijke Opvattingen over Opvoeding questionnaire (OOO). The OOO has 11 questions that can be divided into two subscales: Feelings of Incompetence (6 items) and Feelings of Competence (5 items). Answers are rated on a 6-point scale with categories ranging from 1, "completely disagree" to 6, "completely agree." The 6-item Incompetence scale of the OOO is a subscale taken from the Nijmegen Parenting Stress Index, short version [60]. The scores for this subscale range from 6 to 36; the higher the score, the more incompetent a parent feels. An example is:

"Parenting my child is more difficult than I thought it would be." The 5-item Competence scale of the OOO is taken from the Parenting Self-Agency Measure [61]. The scores range from 6 to 30; the higher the score, the more competent a parent feels. An example is: "I feel confident in my role as parent." Both OOO subscales were reliable (Incompetence, alpha = .79; Competence, alpha = .74). There are no clinical cutoff scores available for this questionnaire.

Child Behavior

The official Dutch 25-item Strengths and Difficulties Questionnaire (SDQ) [62-65] was used to assess child behavior. It has 5 subscales and a total of 25 items each of which can be rated 0, "not rue," 1, "partly true," or 3, "true." Subscales are Emotional Problems Scale, Behavior Problems, Hyperactivity, Peer Problems, and a Pro Social Behavior scale. Range of scores per subscale are 0 to 10, and the range of the total problem score is 0 to 40 (Pro Social scale is not included in the Total Problem score.) A higher score indicates more problem behaviors except for subscale Pro Social Behavior where a higher score means less problem behavior. The first subscale measures the emotional problems of the child. An example item from this subscale is, "My child often complains of headaches, stomach aches." The clinical cutoff score is 5, meaning that scores above 5 indicate clinical problems, in this case abnormal emotional problems, which may be an indication for professional intervention. The second subscale measures the conduct problems of the child. An example item of this subscale is, "My child often has temper tantrums or hot tempers." The clinical cutoff score for this scale is 4. The third subscale measures hyperactivity. An example item of this subscale is, "My child is restless, overactive, cannot stay still for long." The clinical cutoff score for this scale is 7. The fourth subscale measures peer problems. An example item of this subscale is, "My child has at least one good friend." The clinical cutoff score is 7. The final subscale measures pro social behavior. An example item of this subscale is, "My child is considerate of other people's feelings." The clinical cutoff score is 4, and in the case of this subscale, scores of 4 and below indicate that there are abnormal social behavior problems that may be an indication for professional intervention. Finally, the total problem score has a clinical cutoff score of 14, meaning that scores above 14 indicate abnormal emotional and behavior problems [66]. Two of the subscales, Emotional Problems and Hyperactivity, and the total problem score were reliable in the present study. Cronbach alphas for these scales were .86, .72, and .79, respectively. Cronbach alphas for the subscales Behavioral Problems, Peer Problems, and Pro Social Behavior were .33, .43, and .55, respectively, were considered not reliable, and were omitted from further analysis. The SDQ has Dutch clinical cutoff scores presented above, and the percentage of scores within the clinical range of the questionnaire are reported in the "Results" section.

Family Background

A sociodemographic questionnaire gathered background data on the participants, such as family features, socioeconomic status, work status, number of children, problems within the family, and the motives for taking the course. An example item was, "What describes your family best?" The choices were: (1) regular family, that is, both parents are biological or adoptive parents; (2) stepfamily, that is, two parents one of whom is a stepparent; (3) single-parent family; (4) other.

Course Satisfaction

Participants' overall satisfaction with the intervention was measured at posttest on a 10-point scale using a custom-designed evaluation questionnaire in which 10 represented highly satisfied and 1 represented highly dissatisfied. Satisfaction was also evaluated through questions on course techniques, organization, and content. Example items were, "Did you encounter technical problems using the chat room?" "How satisfied are you with the content of session 1, session 2, and so on." Items were rated from 1 to 10.

Statistical Analyses

KopOpOuders is an innovative e-parenting support intervention designed for a specific group of parents. Though negative results were not expected, two-sided paired samples *t* tests were conducted for conservative reasons. These results from a completer analysis of completers (ie, participants who completed the course) are reported in Table 1. We also conducted analyses based on the intention-to-treat-principle, using the conservative "last observation carried forward" method in which missing values at posttest were replaced by the value at pretest, in addition to an analysis using regression imputation where all missing values were imputed. The later was implemented in Stata version 9.4 [67]. Effect sizes were calculated as Cohen's *d* that is, mean at pretest minus mean at follow-up divided by the standard deviation (SD) at pretest. Values of *d* less than 0.32 were interpreted as small effect sizes, values from 0.33 to 0.55 as moderate, and values from 0.56 to 1.20 as large [68,69]. Using the SD at pretest to divide the calculated difference between the pre and post mean score is more conservative than using the mean pre/post SD. Descriptive statistics were used to determine how satisfied participants were with the content and design of the course. Responses to open questions on the evaluation forms were coded as quantitative data.

Results

Response Rate

The sample comprised 48 parents with mental illness who consented to study participation and took part in one or more course sessions. Response rate at pretest was 100% (48/48) and at posttest 58% (28/48). A logistic regression analyses with dropout at posttest as the dependent variable was executed. Participants who completed the course did not significantly differ from participants who dropped out of the study on any of the measured variables.

Table 1. Short-term intervention effects on parenting skills, sense of parenting competence as measured by Ouderlijke Opvattingen over Opvoeding (parental beliefs about parenting-questionnaire) and child well-being as measured by the Strengths and Difficulties Questionnaire (n = 28)

	At Pretest			At Posttest			*t* test		
Test and Subscale	Mean	SD	Scores in the Clinical Range %	Mean	SD	Scores in the Clinical Range %	*t*	*P* Value	d
Parenting skills									
Laxness	3.41	1.08	75%	2.85	0.79	43%	2.90[a]	.007	0.52
Overreactivity	3.71	1.56	64%	2.97	1.12	39%	4.02[a]	.000	0.48
OOO									
Feelings of incompetence	26.32	5.62		22.88	5.01		3.13[a]	.004	0.61
Feelings of competence	18.57	4.66		20.70	3.69		2.81[a,b]	.009	0.46
SDQ									
Emotional problems	4.36	3.08	36%	3.75	2.61	32%	1.57	.13	
Hyperactivity	5.75	2.50	39%	5.01	2.97	25%	1.97	.06	
Total problems	15.11	6.20	36%	13.67	6.91	36%	1.88	.07	

[a] $P < .01$

[b] The negative result is consistent with prediction and represents a positive change since parents feel more competent.

Effects on Parenting Behavior

Table 1 summarizes the results of the completers-only analyses. The parents' laxness and overreactivity ratings decreased significantly in the course of the intervention; effect sizes were moderate ($d = 0.52$ and $d = 0.48$). The Dutch Parenting Scale defines clinical cutoff scores; the percentages of parents scoring in the clinical range declined from 75% to 43% for laxness and from 64% to 39% for overreactivity. Feelings of parenting incompetence also diminished significantly from pretest to posttest, reflecting a large effect ($d = 0.61$). Feelings of competence grew and showed a moderate effect size ($d = 0.46$). The negative *t* test value is consistent with predictions of increased competence of parents. No clinical range has been defined for the OOO scale. Both intention-to-treat analyses (with missing values imputed according to the "last observation carried forward" and "regression imputation" methods) confirmed the outcomes of the reported completers-only-analyses.

Effects on Child Behavior

Results of the completers-only analyses are presented in Table 1. Parental reports indicated some trends in effects on their children's behavior. Hyperactivity and total problems declined but not significantly ($P < .10$); effect sizes were small ($d = 0.30$ and $d = 0.23$). No significant effects were found for emotional problems. The results from the intention-to-treat analyses were consistent. Slightly over one-third of children had scored in the clinical range on each SDQ subscale at pretest, and this remained unchanged at posttest except for a nonsignificant decrease on the hyperactivity subscale.

Course Satisfaction

The course satisfaction questionnaire was completed by 27 parents at the end of the intervention. Their overall mean satisfaction rate was 7.8 on a 10-point scale. The highest-rated course topic was "giving better attention to your child" (mean score 8.0). Most parents indicated that the intervention had met their expectations well. The best-met expectation was "learning to deal better with feelings of shame, guilt, and incompetence," which was cited by 100% (14/14), followed by "finding sympathy and recognition by sharing experiences," cited by 73% (11/15) of parents. Satisfaction with the course facilitators was high: 78% (21/27) of parents found facilitators involved and supportive. A large majority of parents, 74% (20/27), considered the online intervention a better way to receive professional help than a face-to-face intervention. Most parents, 70% (19/27), responded that they would definitely recommend the intervention to other parents. Satisfaction was also expressed with the anonymity of the course, the opportunity to participate without leaving home, and the fact that no child care was needed. Most parents, 78% (21/27), were satisfied with the duration of the sessions, and 89% (24/27) with the interval between them; 52% (14/27), were satisfied with the number of sessions, but 44% (12/27) would have preferred more sessions. The course homework, including the practicing of parenting skills, was deemed fairly relevant to relevant by 100% (27/27) of the parents. Points for improvement were also suggested, with 41% (11/27) desiring more personal email contact with facilitators and a few participants wanting telephone or face-to-face contact. Some 30% (8/27) of parents expressed dissatisfaction with the number of dropouts from the course; others valued the greater personal attention in the smaller stay-behind groups.

Course Adherence

Of the 59 parents who began the course, 42% (25/59) took part in fewer than four sessions, and 57% (34/59) in four sessions or more; 37% (22/59) attended seven or eight sessions, and 20% (12/59) all eight sessions. The reasons reported for dropping

out during the course were varied, but often involved unstable home situations (eg, relational problems and divorce, relocation, or starting a reintegration program). As reported above, completers did not significantly differ from participants who dropped out of the study on any of the measured variables, indicating that loss-to-follow up was random.

Discussion

Principal Results

At the onset of the study, many parents scored in the clinical range on parenting skills, indicating that they were facing serious childrearing problems. At the conclusion of the course, a large proportion of parents had moved out of the clinical range; the percentages of parents in clinical ranges for laxness and overreactivity at pretest (75% and 64%) had decreased by posttest to 43% and 39%, respectively.

Parenting skills of laxness and overreactivity (d = 0.52 and d = 0.48) decreased, parental sense of competence (d = 0.61) increased, and feelings of incompetence (d = 0.46) decreased, indicating that parents were less likely to overreact or underreact to child behavior, that parents were responding to behavior appropriately on the basis of its severity, and that parents felt more empowered in their parenting and thus less likely to generate insecure attachment styles and poor outcomes for the children [70]. The effect sizes on parenting skills and sense of competence were comparable to those seen in studies of level 4 of the parenting program Triple P.

In terms of children's problems, the pilot results showed a decline, though not significant, on the SDQ scores. This contrasts with a significant finding for behavior problems from the Triple P level 4 program, which showed significant, moderate effects on the Eyberg Child Behavior Inventory (overall effect size d = 0.42) [41]. The difference in outcome may be explained by the fact that children's problems at baseline in the Triple P study were in the clinical range, while those in our study were largely in the nonclinical range.

The fact that baseline parenting problems were largely in the clinical range and child problems in the nonclinical range suggests that parents were reached at an early stage of their parenting difficulties. The course satisfaction was high, with a mean score of 7.8 (10-point scale). The course adherence seemed to be a point for improvement and further research; 57% (34/59) followed half of the sessions or more, and only 20% (12/59) of the parents followed all the sessions. Finally, 93% (45/48) of the participants had received professional psychological help from a mental health service. This indicates a limited achievement of the aspiration to reach parents who had not been in contact with a mental health service. It is unknown, however, when these contacts took place; if this was long before the course attendance, the potential benefit of this online intervention might have been realized.

Limitations

The most significant limitation of the study was the lack of a comparison group, making it impossible to conclude whether the significantly improved parenting competence was attributable to the course or to some other fact. The effect sizes from the trial may well have been inflated because they constituted the effects of spontaneous recovery and of nonspecific effects. It is thus likely that effect sizes in a well-controlled trial would be considerably smaller. A second limitation of this pilot study was the relatively small size. This precluded undertaking specific subanalyses, for example, to predict outcome from parent and child factors. A third limitation was the self-report nature of the quantitative parenting data. However, in keeping with the digital and anonymous nature of the intervention, independent observations were not feasible. Data on child behavior were based on reports of the parents rather than independent raters, and may have been biased. A final limitation was the lack of data from the period following the intervention so that it is not known whether the observed improvements continued, strengthened, or diminished in the longer term.

Implications for Future Research Directions

Future research on KopOpOuders will involve a controlled trial for measuring the effects of the intervention, including longer-term effects, on parenting and on child wellbeing. Cost-effectiveness analyses will be undertaken. The costs of the online course in terms of facilitator time are about the same as costs for face-to-face courses, but these costs are lower compared with costs of individual or family counselling. The expected short-term and long-term savings of online parenting courses lie in lower costs associated with work absenteeism and eventual treatment or care for parents and children.

Because the sample included a group of parents with mixed diagnoses, further analysis will examine diagnostic, symptom, and other variables that predict outcome. Future research should also target the role of the other partner or well partner and measure well-being. Finally, another area to explore is how the target group could be better reached.

Course adherence has been found to be associated with the success of a range of mental health programs [71], yet little research has been done to analyze adherence to these programs or the factors that can improve adherence [49]. We monitored course adherence in the present study, but little other material on online parenting support is available for comparison. The study of Taylor and colleagues [48] reported on a computer-based parenting course combined with five home visits and telephone coaching. The course adherence was as follows: 66% (59/89) completed all of the program elements and 76% (68/89) completed more than half of the program. These results are more favourable than those of our study in which 20% (12/59) of the parents followed all the sessions and 57% (34/59) followed half of the sessions or more. The higher course adherence in the study by Taylor et al may be explained by different factors. First of all, in the study by Taylor et al, the participants were not anonymous and the program comprised probably fewer elements than the KopOpOuders intervention. Also, the better mental condition of the parents may be an explanatory factor. In our study, parents often cited their unstable home situation, which usually appeared linked to their mental illness, as a motive for stopping. Similarly, Dutch experiences with face-to-face courses for mentally ill parents indicate that unstable situations at home often prompt

participants to drop out. Another explanatory factor that may have led to better course adherence in the study by Taylor et al is the personal contact with a counselor through home visits and telephone coaching. This corresponds to our satisfaction survey in KopOpOuders, which revealed a desire by the parents for more personal contacts with the facilitator via email, which might have strengthened participants' commitment to the course. Future research should focus on factors that could improve course adherence and on the impact of adherence on the outcome.

Implications for Policy and Practice

In view of the increasing numbers of children now in care [72], early preventative interventions need to be provided to at-risk groups in order to keep parenting problems from escalating. KopOpOuders.nl should fit well into low-threshold illness prevention programs. If the course is shown effective, its reach could be greatly extended by offering more courses and by intensifying recruitment efforts. One prerequisite for increasing delivery capacity is a clear funding structure for COPMI interventions as is now being developed in the Netherlands. Recruitment might be improved by advertising on relevant websites and in other media, as well as by embedding interventions like these in the continuum of youth services, thus enabling an effective referral pathway to the intervention.

The anonymity of the course was valued by the parents. This anonymity, however, does not fit with the established procedures of many health insurance companies, which require that parents are identified. A new funding structure for online services that preserve anonymity is proposed in the Netherlands. The funding structure for online interventions is now brought to the attention of several stakeholders under the Dutch Ministry of Health. We think the anonymity may be of great importance. Such anonymity may lower the barriers to seeking help and might probably help to lower the risk of child abuse. According to the Netherlands Mental Health Survey and Incidence Study of 7076 Dutch people [21], the risk of child abuse is two to three times higher for children of mentally ill parents as for other children. This includes all forms of abuse: physical, psychological, and sexual abuse, and emotional neglect. Given the clear association between child abuse and parental mental illness [20,21], and in view of these parents' feelings of shame and their fears of losing custody of their children [25,26], the anonymity of online parenting support might breaking down barriers to their seeking help. On the other hand, what actions should course facilitators take if they suspect that child abuse is occurring? A protocol is now being drawn up by the developers of KopOpOuders to address this important issue; it will be submitted for approval to the professional sectors involved and to the Netherlands Health Care Inspectorate.

Conclusions

Our pilot study gives reason for cautious optimism about the prevention of mental health problems in a large at-risk group—children of parents with mental illness (COPMI). The objectives of the online intervention, KopOpOuders, appear to have been nearly achieved: reaching mentally ill parents at an early stage of their parenting difficulties and enhancing their children's well-being by improving the parents' childrearing competence.

Future research, with a randomized controlled design, should examine the short- and long-term effectiveness of this intervention on parenting, child well-being, and the well-being of the parents. Future research should also focus on cost-effectiveness of the intervention and on course adherence and the factors that can improve it.

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Conflicts of Interest

Karlijn Arntz and Rianne van der Zanden are the authors of the online group course, KopOpOuders.nl.

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Abbreviations

COPMI: children of parents with mental illness
DSM: Diagnostic and Statistical Manual of Mental Disorders
FPI: Preventive Family Intervention
OOO: Ouderlijke Opvattingen over Opvoeding (parental perceptions of parenting questionnaire)
PS: Parenting Scale
SDQ: Strengths and Difficulties Questionnaire

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Original Paper

Community Attitudes to the Appropriation of Mobile Phones for Monitoring and Managing Depression, Anxiety, and Stress

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Abstract

Background: The benefits of self-monitoring on symptom severity, coping, and quality of life have been amply demonstrated. However, paper and pencil self-monitoring can be cumbersome and subject to biases associated with retrospective recall, while computer-based monitoring can be inconvenient in that it relies on users being at their computer at scheduled monitoring times. As a result, nonadherence in self-monitoring is common. Mobile phones offer an alternative. Their take-up has reached saturation point in most developed countries and is increasing in developing countries; they are carried on the person, they are usually turned on, and functionality is continually improving. Currently, however, public conceptions of mobile phones focus on their use as tools for communication and social identity. Community attitudes toward using mobile phones for mental health monitoring and self-management are not known.

Objective: The objective was to explore community attitudes toward the appropriation of mobile phones for mental health monitoring and management.

Methods: We held community consultations in Australia consisting of an online survey (n = 525), focus group discussions (n = 47), and interviews (n = 20).

Results: Respondents used their mobile phones daily and predominantly for communication purposes. Of those who completed the online survey, the majority (399/525 or 76%) reported that they would be interested in using their mobile phone for mental health monitoring and self-management if the service were free. Of the 455 participants who owned a mobile phone or PDA, there were no significant differences between those who expressed interest in the use of mobile phones for this purpose and those who did not by gender ($\chi 2_1$, = 0.98, P = .32, phi = .05), age group ($\chi 2_4$, = 1.95, P = .75, phi = .06), employment status ($\chi 2_2$, = 2.74, P = .25, phi = .08) or marital status ($\chi 2_4$, = 4.62, P = .33, phi = .10). However, the presence of current symptoms of depression, anxiety, or stress affected interest in such a program in that those with symptoms were more interested (χ^2_1, = 16.67, P < .001, phi = .19). Reasons given for interest in using a mobile phone program were that it would be convenient, counteract isolation, and help identify triggers to mood states. Reasons given for *lack* of interest included not liking to use a mobile phone or technology, concerns that it would be too intrusive or that privacy would be lacking, and not seeing the need. Design features considered to be key by participants were enhanced privacy and security functions including user name and password, ease of use, the provision of reminders, and the availability of clear feedback.

Conclusions: Community attitudes toward the appropriation of mobile phones for the monitoring and self-management of depression, anxiety, and stress appear to be positive as long as privacy and security provisions are assured, the program is intuitive and easy to use, and the feedback is clear.

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KEYWORDS

Mobile phones; monitoring; self-help; depression; anxiety; stress; Internet intervention

Introduction

Reducing the burden of mental disease requires a combination of effective prevention, early intervention, treatment, and self-management, and a critical aspect of these functions is for individuals to monitor their mental health. Self-monitoring brings about actual improvements in mood and behavior and enhances individuals' compliance with treatments [1,2].

Historically, paper diaries have been the primary mode of monitoring, but patients can find them cumbersome. Noncompliance is also common, as demonstrated by Stone et al [3] who compared patients' actual and reported compliance with diary keeping. By embedding a photosensor into the binder containing the paper diary forms that detected light and recorded when the binder was opened and closed, the researchers ascertained that actual compliance was 11%, whereas participant-reported compliance was 90%. In contrast, compliance with an electronic diary was 94% [3]. However, computer-based monitoring also has inherent limitations in that it relies on users being at their computer at scheduled times, which can be inconvenient, and, as a result, nonadherence after short periods of time is also common with this delivery channel. Retrospective recall of symptoms, mood, or behavior can also be unreliable [3]. To be maximally effective, individual self-monitoring needs to take place regularly and in real time to reduce recall bias and increase accuracy.

Mobile phones offer a solution. Their take-up has reached saturation point in most developed countries and is increasing in developing countries; they are carried on the person and they are usually turned on. A further advantage is that mobile phones allow the gathering of frequent instantaneous reports of mood and behavior while people go about their everyday business. Termed Ecological Momentary Assessment, or EMA, mobile phone monitoring has been shown to more accurately represent the true natural history of transitory states than dispersed measurements and may decrease user burden [4]. With mobile phones, users can be prompted to respond, and these "just-in-time" prompts can be scheduled for key times. Mobile phone monitoring is also potentially more convenient than paper- or computer-based recording.

Mobile phones have been used for monitoring within behavioral health applications such as alcohol consumption [5] and gambling [6]. They have also been used to deliver simple interventions, for example, to manage migraines [7], enhance physical activity [8], cease smoking [9], and control weight [10]. However, the use of mobile phones in mental health monitoring and management is in its infancy.

Furthermore, community attitudes toward the use of mobile phones as a mental health tool are unknown. Until recently, mobile phones were primarily viewed as tools of communication and social identity, but increasingly they are evolving into a personal multipurpose tool for their owners, with routine functions now including reminders for medical appointments, timekeeping, and note taking. While preliminary research has been undertaken exploring community attitudes toward the use of mobile phones for health monitoring, such as for asthma [11], attitudes to the appropriation of mobile phones for mental health monitoring and management have not yet been investigated.

Derived from the field of marketing, the term "appropriation" refers to the processes that take place when new uses are invented for existing technologies and when these uses develop into routine practices and spread within a user community [12]. The aim of this study was to investigate community attitudes toward the appropriation of mobile phones for mental health monitoring and management as groundwork for the development of a digital tool for self-monitoring and self-management of depression, anxiety, and stress.

Methods

A mixed method approach was used consisting of an online survey, focus group discussions, and interviews. The target population was Australian adults over 18 years of age with or without depression, anxiety, or stress. Participation was voluntary and anonymous in all 3 study components.

Development and Administration of Study Tools

Questions for the online survey, focus group discussions, and interviews were generated, reviewed, and amended by the research group in consultation with the members of the community program team at the Black Dog Institute, a mood disorders unit in Australia. The final set of questions explored the following issues:

- current usage of mobile phones
- attitudes toward using a program on mobile phones or the Internet for monitoring and managing depression, anxiety, or stress
- possible ways in which participants might use such a program
- any key features that such a program should have
- demographic information and mental health history of participants

The survey was pilot tested using QuestionPro [13]. The survey's usability and functionality were assessed and improvements made prior to it being posted on the website of the Black Dog Institute [14]. The website provides information and tools about mood disorders for the public, health professionals, and workplaces. A broad cross section of the public uses the site, including those with mood disorders and those without (eg family, carers, friends, students, and interested individuals). The site is consistently in the top 5 Google ranks for mood disorders in Australia.

The survey was voluntary and was open to any site visitor. Initial contact with potential participants was made on the Internet. The survey consisted of 46 questions over 12 Web

pages. Some pages had more items than others, although the maximum number of items per page did not exceed 7. Forty-four of the 46 items were mandatory, each was highlighted, and it was not possible for respondents to proceed to the next page until they had completed the mandatory items. Because there was no back button, respondents were unable to review or change their answers. To prevent multiple entries, a cookie was placed on the participant's computer. There was no Internet protocol (IP) check or log file analysis. As this was an open survey, no log-in or registration was required. The data were collected over a 3-month period from May to August 2009.

Focus group participants and interviewees were recruited through community organizations, a variety of companies, and the Black Dog Institute community programs. Similar questions to those in the online survey were used in the focus group discussions and the interviews to facilitate later triangulation of results. To protect participants' confidentiality within the interviews and focus groups, demographic information and mental health history were completed anonymously by a paper and pencil questionnaire that participants sealed in an envelope and gave to the researcher. An experienced moderator conducted each of the focus groups with 1 or 2 observers present who took notes. The sessions were audio taped for later transcription and analysis.

Informed Consent Process

Individuals who clicked on the link to the online survey were provided with a statement about the study that included its purpose, the length of time to complete the survey (approximately 15 minutes), how the data were being stored (initially on the secure QuestionPro server then in password-protected files in the university's secure server for 7 years), and the name of the chief investigator (author JP), before being invited to give their informed consent online and to access the survey. The survey was anonymous. However, those who wished to enter a draw to win an iPod Nano for completing the survey were invited to separately provide their name, phone number, and email address. This information was stored in a secure password-protected file on the QuestionPro server and then transferred to the university's secure server for long-term storage.

The informed consent process for the focus group discussions and interviews was similar. Individuals who expressed interest in being interviewed or participating in the focus group discussions were provided with a written outline of the study which included its purpose, the length of time the interview/focus group would take (approximately one hour), how the data were being stored (audiotaped for later transcription and storage for 7 years in password-protected files in the university's secure server) and the name of the chief investigator (author JP). They were then invited to give their informed consent to participate in the interview or focus group. No identifying information was collected.

The study was approved by the University of New South Wales Human Research Ethics Committee.

Advertising and Recruitment

The online survey, focus group discussions, and interviews were advertised simultaneously through Facebook, the websites of the University of New South Wales and Black Dog Institute, and the intranets of a variety of companies and consumer organizations. The advertisement for the online survey can be found in Multimedia Appendix 1. The advertisements for the interviews and focus groups had similar wording to the advertisement in Multimedia Appendix 1 with the exception that participants were reimbursed A$50 for their time and travel expenses instead of being given the opportunity to enter into the draw for the iPod Nano.

Participants

From May to August 2009, 655 unique visitors accessed the online survey of whom 48 were ineligible because they were either under 18 years old (n=13) or did not live in Australia (n=35). Of the 607 eligible respondents, 525 (86.5%) completed the survey.

In all, 6 focus group discussions involving 47 participants (70% female) were conducted from June to August 2009; 4 groups were held in urban areas and 2 in rural towns in New South Wales, Australia. Of the urban groups, 2 specifically targeted young people aged 18 to 28 years. A further 20 people were involved in the interviews, all of whom lived in Sydney, Australia.

Table 1 provides demographic and mental health data for the participants involved in the 3 related studies.

Table 1. Participants' characteristics

	Online Survey (n = 525)		Focus Group Discussions (n = 47)		Interviews (n = 20)	
	%	n	%	n	%	n
Gender						
Female	67.6	355	70	33	60	12
Age category						
18-24	16.6	87	53	25	25	5
25-34	31.8	167	13	6	20	4
35-49	38.1	200	21	10	45	9
50-59	10.3	54	6	3	5	1
60+	3.2	17	6	3	5	1
Employment status						
Employed full-time	43.6	229	14.9	7	50	10
Employed part-time	14.9	78	17	8	5	1
Self-employed	8.2	43	14.9	7	25	5
Full-time student	13.3	70	38.3	18	10	2
Unemployed	3.8	20	6.4	3	10	2
Retired	1.7	9	6.4	3	0	0
Home duties	6.7	35	2.1	1	0	0
Temporarily unable to work due to illness or injury	6.1	32	0	0	0	0
Permanently unable to work due to illness or injury	1.7	9	0	0	0	0
Relationship status						
Single	37.7	198	66	31	35	7
De facto relationship	16.6	87	6.4	3	15	3
Married	36	189	23.4	11	30	6
Divorced/separated	9.5	50	2.1	1	15	3
Widowed	0.2	1	2.1	1	5	1
English spoken at home						
Yes	92	483	93.6	44	75	16
Mental health						
Current depression	60.2	316	23.4	11	30	6
Current anxiety	49.1	258	19.1	9	25	5
Current stress	51.8	272	19.1	9	45	9
Current treatment for depression	54.3	285	23.4	11	10	2
Current treatment for anxiety	30.5	160	10.6	5	20	4
Current treatment for stress	17.9	94	6.4	3	5	1
Lifetime depression	92	483	83	39	60	12
Lifetime anxiety	65	341	46.8	22	25	5
Lifetime stress	77.7	408	66	31	55	11

Analysis

Data from each component of the study were analyzed separately and then triangulated. Triangulation involves the exploration of a research question by using multiple data gathering methods in order to get a better understanding of the subject matter, to cross-check the research findings, and to increase their validity [15]. In our studies, we also used the information from the focus group discussions and interviews to shed light on and illustrate the findings of the online survey. Descriptive analyses and tests

of group differences within the survey data were conducted using PASW Statistics Version 18 (SPSS Inc, Chicago, IL, USA). Within the interviews and focus group transcripts, salient themes and principles were identified using the "thematic analysis" technique, a qualitative method for identifying, analyzing, and reporting patterns of meaning within data [16]. Data are organized and described in rich detail within a theoretical framework. In this study, an existentialist or realist framework was used whereby the experiences, meanings, and the reality of participants were identified and reported as expressed, in contrast to other frameworks which focus on, for example, the manner in which participants' meanings are "constructed" within the broader context of society [16].

Results

Current Mobile Phone Behavior

The majority of survey respondents (455/525 or 86.7%) owned a mobile phone or personal digital assistant (PDA) of whom 83.3% (379/455) reported using it at least daily. Making and receiving calls and sending and receiving short message service (SMS) messages were the predominant functions used (see Figure 1). Other functions commonly used included the Internet (for downloading songs and videos, listening to music, accessing email and Facebook, and listening to the radio: see Figure 2), camera, alarms, memos and reminders, calendar and appointments, clock, games and calculator.

Figure 1. Most common uses of mobile phones by online survey respondents

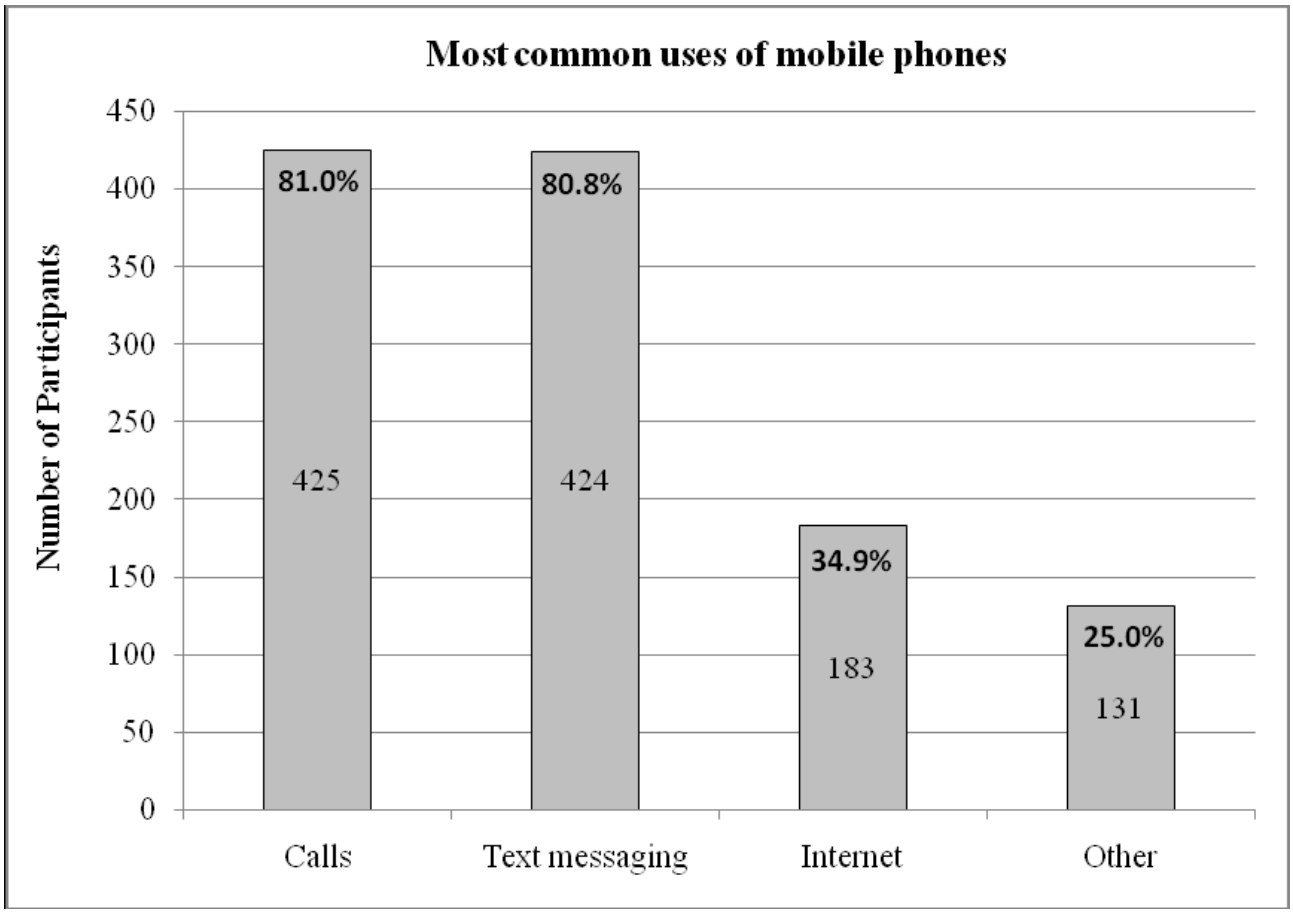
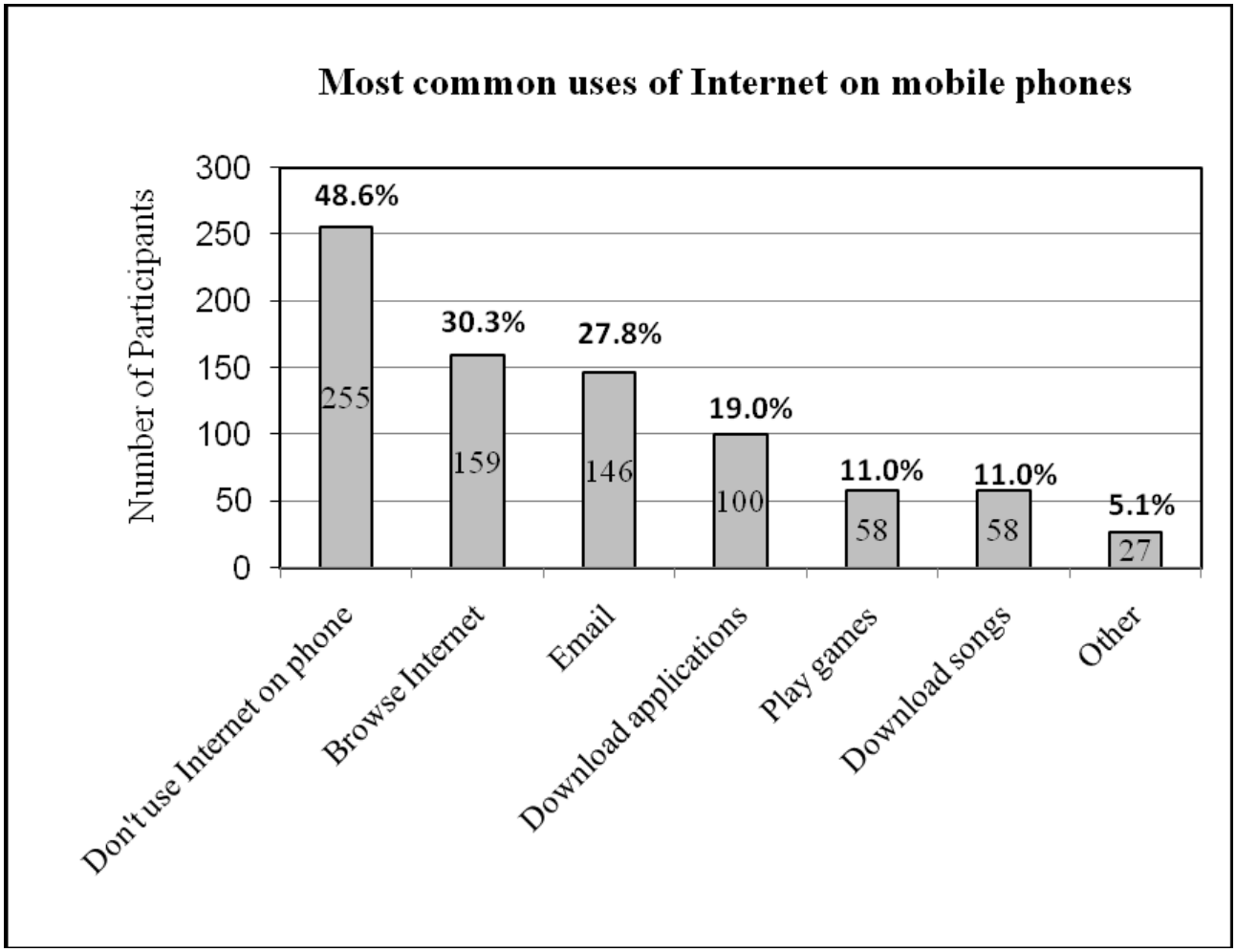


Figure 2. Most common uses of the Internet on mobile phones



Nearly half (255/525 or 48.6%) indicated that they did not use their mobile phone to access the Internet. Reasons included the cost (150/525 or 28.5%), lack of need because they have Internet access on a computer (169/525 or 32%), their mobile phone is not Internet-enabled (66/525 or 12.6%), they haven't had the need (67/525 or 12.7%), or a variety of other reasons, such as not knowing how to access the Internet via the mobile phone, finding it too difficult or complicated, or because the phone is poor quality with a small screen.

Focus group and interview findings converged with those of the online survey, with the exception of accessing the Internet. All focus group participants owned a mobile phone and the majority (39/47 or 83%) said they used it every day, predominantly for social reasons, but 72% (34/47) said they also used their mobile phone for work. However, only 18/47 (38%) accessed the Internet on their mobile phone and this was primarily for email, Facebook, Twitter, music, directions, games, Google, and Internet browsing. Reasons participants gave for not using the Internet on their mobile phone included the cost, not knowing how to use it, having no need to use it, or the Internet was not available on their mobile phone.

Responses from interviewees were similar. While all owned a mobile phone or PDA, usage varied widely from a few times a week to more than 50 times a day. However, similar to the survey respondents and the focus group participants, the majority (19 of the 20 interviewees) reported using their phone at least once a day. The different uses to which their mobile phones were put were also similar: all participants reported making phone calls, 18/20 (90%) used text messaging, and a minority used their mobile phone for checking emails, taking photos, and other functions such as a clock, a calculator, a calendar, or an alarm or to set reminders. However, 13/20 (65%) did not use the Internet on their phone, and a similar proportion reported that they did not know how to download a program or application on their phone. The reasons participants gave for not using the Internet on their mobile phone were that they had Internet access at home or work, the cost was too high, or their phone didn't allow Internet access.

Attitudes Toward Using a Mobile Phone for Mood Monitoring and Self-help

Interest in Using a Mobile Phone Program for Monitoring and Self-management

The majority (399/525 or 76%) of survey respondents indicated that they would be definitely be interested (245/525) or likely (154/525) to be interested in using a program on their mobile phone to monitor and manage their mood, anxiety, or health. Among the 455 respondents who owned a mobile phone or PDA, there were no significant differences between those who were interested in using their mobile phones in this way and those who were not by gender ($\chi 2_1$, = 0.98, P = .32, phi = .05), age group ($\chi 2_4$, = 1.95, P = .75, phi = .06), employment status

($\chi 2_2$, = 2.74, P = .25, phi = .08) or marital status ($\chi 2_4$, = 4.62, P = .33, phi = .10). However, the presence of symptoms of depression, anxiety, or stress was associated with reported increased interest in using such a program (χ^2_1, = 16.67, P < .001, phi = .19). Specifically, standardized residuals indicated that among participants who stated that they were not interested in using the program, there were fewer with current mental health symptoms than expected (and an overrepresentation of participants with no symptoms; P < .05 and P < .01, respectively). Of the 9.9% (45/455) of respondents who reported current symptoms of depression, anxiety, or stress and were not interested in the program, 68.9% (31/45) indicated that they did not think using a mobile phone program to track moods could help people to manage their depression, anxiety, or stress.

These results were supported by information from the focus group discussions. The majority (33/47 or 70%) of focus group participants also said they were interested in the notion of using their mobile phone to track their mood, anxiety, or health. Reasons given included speed, convenience, ease of access, the importance of being able to monitor and reflect on mood changes during the day, the opportunity to improve self-awareness, self-management, and well-being, access to support when it was not possible to get to a doctor, the view that it would be less confronting than face-to-face consultation, and the possibility of helping isolated people feel connected. Comments included:

> *A mobile phone application would be a highly convenient, portable, and discreet way of tackling one's condition.*
>
> *Everyone uses the Internet and mobile phones.*
>
> *It could help those who are isolated and have mental health issues.*
>
> *You have your phone with you most of the time, so you would be able to record moods more accurately.*

Reasons given by those who were not interested in using their mobile phone to monitor their mental health included not liking to use their phone or technology, concerns that it would be too intrusive or privacy would be lacking, and not seeing the benefit of tracking mood and behavior. For example:

> *If the technology is too difficult, then it only adds to the stress and a sense of failure.*
>
> *It seems impersonal and too generalized to be able to capture the emotions of each individual.*
>
> *I can't see the connection between tracking mood and lowering anxiety, stress, [or] depression.*

Mode of Using the Program

Of the 399 survey respondents who indicated they were interested in using a monitoring and management program delivered via their mobile phone, 93.7% (374) indicated that they would want a username and password to log on. The length of time per session for which they would be prepared to use such a program ranged from 1 to 90 minutes (median = 5 minutes). The mean number of mood dimensions that participants were interested in tracking at any one time was 5.6 (SD 3.2). Most of these respondents (329/399 or 82%) thought that they would use the program at least daily, some suggesting multiple times per day (196/399 or 49.1%). However, there were significant differences in the expected mode of use according to whether respondents reported current symptoms or not. The participants who were without current symptoms (96 out of 399) indicated that they would use such a program less often ($\chi 2_1$, = 4.52, P = .03, phi = .11) and for shorter periods (mean 7.28 minutes, SD 6.03) than the 303 respondents with current symptoms (mean 10.7 minutes, SD 11.28; t_{301} = 3.82, P < .001 [two-tailed]).

Information presented in the interviews illustrated the online survey findings. For example, comments from the 13 (of 20) interviewees who reported that a program to monitor depression, anxiety, or stress would definitely be helpful included:

> *It is text savvy and good for the younger generation.*
>
> *Yes, it would be great, another avenue to use and to help people feel that they are not alone.*
>
> *It could be a great motivational tool for people to look after themselves better.*
>
> *Maybe [it would be good] if someone cannot afford psychological treatments or for people who like to keep their feelings to themselves.*

In addition, 5 interviewees felt that such a program might be helpful, but with caveats. For example, one asked, "If someone such as a doctor is already helping to manage one's moods, why would you use the Internet?" Another 2 interviewees thought that face-to-face contact with a professional would be more beneficial.

In response to the question of whether they would use the program themselves if there were no cost, 17 answered positively, and the majority said that they would use it at least once a day.

> *I would be very interested [in using the program] because it's a new tool and not intrusive, and it would be handy.*
>
> *I would be interested, not for my moods but for my health.*

Other reasons given included "my phone is always with me."

Of the interviewees who reported that they would not use a mobile phone mental health program, the reasons given included that they use their mobile phone only for basic functions like phone calls and they did not see how monitoring moods or behavior would help them if they were depressed, stressed, or anxious.

Key Functions and Features Required

In answer to questions about the key functions required in such a program, 78.7% (314/399) of the survey respondents interested in using the program said they would find it helpful to receive SMS reminders to track their moods; 93% (371/399) nominated that they would want to receive feedback about the information they had entered into such a program; and 89% (355/399) were interested in receiving self-help suggestions (Figure 3). Comparison of respondents with (303/399) and without (96/399) current depression, anxiety, or stress showed that significantly

more of those with symptoms indicated that they would find it beneficial to receive SMS reminders to track their moods and behaviors ($\chi 2_1$, = 9.98, P = .002, phi = .165). However, there was no significant difference between those with and without current symptoms in whether they saw feedback on monitoring information as a requirement ($\chi 2_1$, = .01, P = .91, phi = -.02) or whether they would want to receive self-help suggestions ($\chi 2_1$, = .51, P = .47, phi = -.04).

Figure 3. Preferred functionality of program: online survey respondents

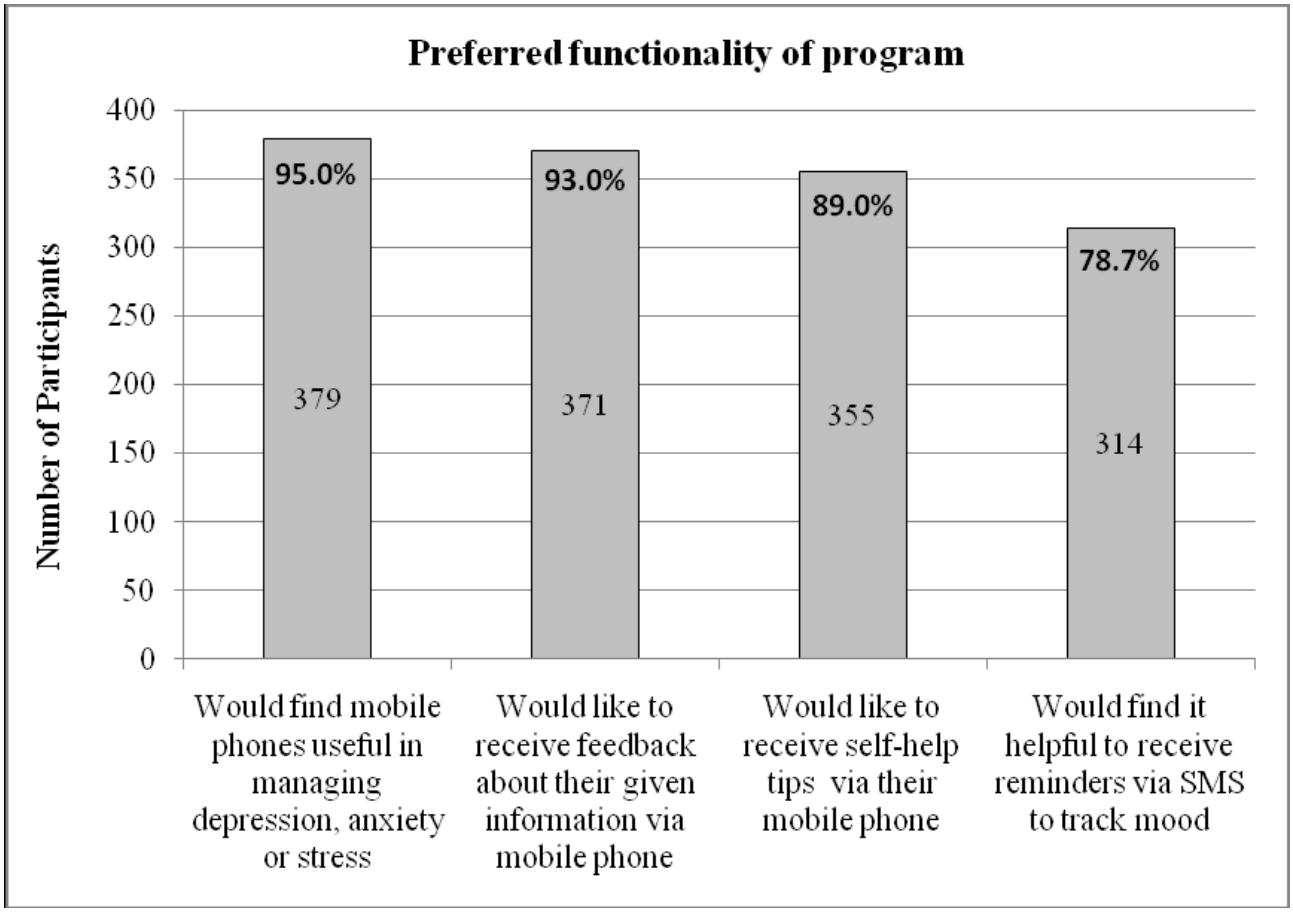
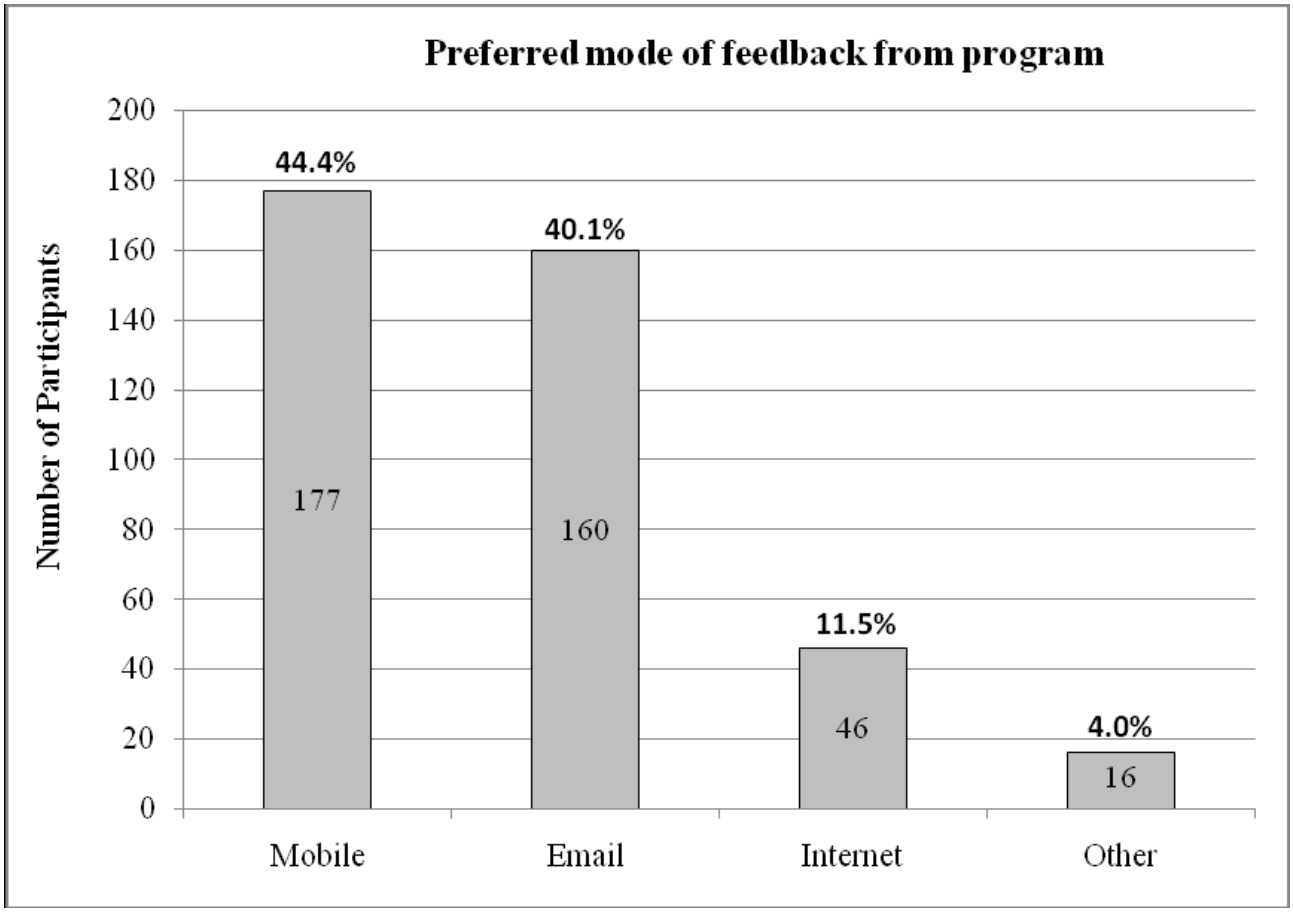
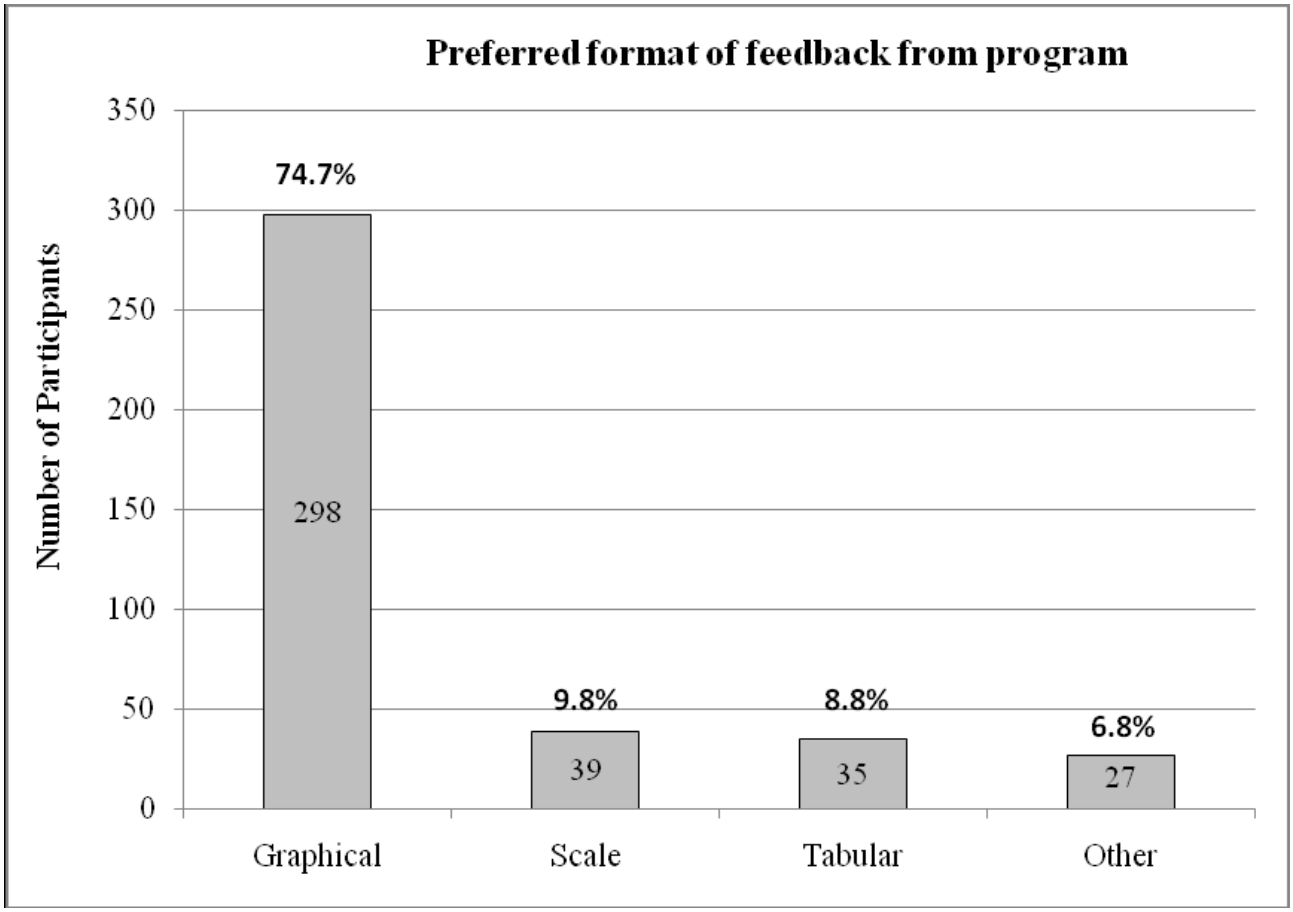


Figure 4. Most preferred modes of feedback from program among online survey respondents



As can be seen in Figure 4, choice of delivery channel to receive the feedback and self-help suggestions was mixed: 44.4% (177/399) opted for their mobile phone, 11.5% (46/399) chose the Internet, and 40.1% (160/399) chose email. Figure 5 illustrates that the preferred format for such feedback was graphs (298/399 or 74.7%) rather than tables or scales. In answer to the question of whether they would be more inclined to use the program if it had games or fun activities, nearly two-thirds (257/399 or 64.4%) of survey respondents interested in using a mobile phone mental health program said no. However, a similar proportion (250/399 or 62.7%) said they would want the option of personalizing the program with colors, background, logos, and so on.

Figure 5. Most preferred formats of feedback among online survey respondents



Detailed discussion took place in the focus groups about what constituted necessary features of a mobile phone mental health program. Privacy was highlighted as an issue of significant importance and the majority said that a secure log-in comprising username and password should be a mandatory feature. The need for the program to be simple to use and "foolproof" was also emphasized. Usage should be quick (maximum 10 minutes) and easy; one participant suggested that the benchmark for its ease and privacy of use was whether it could be used on public transport. SMS reminders were seen as helpful as long as users had the option of varying their delivery so that they did not become intrusive. Feedback was deemed to be very important, and data presented in graphical form was the most popular format suggested. Functionality allowing day-to-day and week-to-week comparison was also seen as important. Participants suggested that entering data on the mobile phone and receiving it via computer would be an acceptable method that would also resolve some issues of privacy. Allowing users flexibility of choice regarding how much information is to be fed back and over what time frame was also seen as key.

Interviewees reported similar attitudes. They highlighted the importance of privacy and security of information, and the majority said they would want a username and password to access the program. A majority also indicated that they would want to receive short message service (SMS) reminders to track their moods/behaviors. The minority who did not want reminders indicated that they would find them annoying and bothersome.

If given the choice, 86.2% (344/399) of survey respondents interested in using a mobile phone mental health program indicated that they would allow their doctor to access or receive information about their moods and behavior from the program. Interviewees were similarly minded, saying that "it would be good to have a human on the end to make sense of the data I enter," and "yes, it would be a helpful, precise, and efficient way of tracking what's happening." Of the 91 survey respondents who were against the idea, the major reason given was that it would constitute a breach of privacy for them, while others explained that they don't have a doctor whom they see regularly. There was an even split between those with current symptoms (48/91 or 52.7%) and those without. One interviewee said he did not see the point because "if I am seeing a doctor for my health or mental illness, I would already be telling him what is going on."

Discussion

This study explored, for the first time, community attitudes toward the appropriation of mobile phones for mental health monitoring and self-help. Triangulation of results from the 3 study components suggests that, overall, participants were positive about the idea of conceptualizing mobile phones as a mental health tool but the acceptance was conditional upon a number of key features being included. These included the need for the program to be simple and straightforward to use and the need for its security and privacy to be guaranteed, especially for information sent to the mobile phone. A user name and

password were considered to be mandatory. Text message reminders were seen as helpful as long as they were not intrusive, and feedback graphs were deemed to be important.

However, there were differences in expected mode of use between participants with current depression, anxiety, or stress and those without. Respondents with current symptoms indicated that they would be prepared to use a mobile phone program more often and for longer periods, and they were also significantly more likely to want to receive SMS reminders to track their moods and behaviors. Nevertheless, both groups indicated that they would want feedback on monitoring information and to receive self-help suggestions from such a mobile phone program.

Thus, while there appears to be a community willingness to accept a broadening of the conceptualization of mobile phones to embrace functions associated with improving mental health, there are caveats to the appropriation of mobile phones for the new functions. The implications for clinicians and eHealth providers are clear. Most mental health programs, whether delivered face-to-face, by telephone, book, or computer, rely on their clients monitoring their symptoms or activities, either as an integral component of the service or as a complement to it. The information is useful for individuals to help them gain control of their condition and for service providers to review the effectiveness of their service. However, to successfully facilitate self-monitoring and self-management via mobile phones, clinicians and eHealth developers must place additional importance on ensuring that the mobile phone programs are secure, private, and easy to use.

A further implication arising from the data concerned the apparent lack of understanding about the rationale for and benefits of mood tracking among some respondents. Nearly 10% of the sample, the majority of who reported current depression, anxiety, or stress, indicated that they did not see how a mobile phone program for monitoring moods would help people manage their depression, anxiety, and stress. It is not known if they were expressing doubt about monitoring per se or monitoring specifically on a mobile phone. If the former, then considering that the recent National Survey of Mental Health and Wellbeing in Australia [17] found that 65% of people with mental health conditions do not access services, our results suggest that a health promotion campaign outlining the benefits of self-monitoring for mental health may be helpful.

Limitations

Having been recruited primarily through the websites of the University of New South Wales and the Black Dog Institute, the intranets of a variety of companies and consumer organizations, and via Facebook, the convenience sample for the online survey is likely to be unrepresentative of the broad population. Visitors to the site were self-selected, and because Internet access is not equal among all socioeconomic and demographic groups, biased estimates on variables related to socioeconomic status may have resulted [18]. Nevertheless, we felt it was justified to recruit from these online sources because our research questions pertained to the use of electronic technologies. Post hoc inspection of the survey sample indicates that ownership and usage of mobile phones was representative of the Australian population. However, there was a stronger representation of survey respondents with current or lifetime depression, anxiety, or stress compared with the Australian population. Another limitation was that our studies took place only in Australia and, although the prevalence of mental health problems in Australia is similar to that in other developed countries and mobile phone penetration is as high, the results may not generalize to populations in other developed countries.

The Future

In line with the results of our research, we are now developing a mobile phone monitoring and self-help program at the Black Dog Institute. The “myCompass” system will provide users with a tool to monitor and manage depression, anxiety, and/or stress via the Internet on their mobile phone or computer. With the assistance of optional screening questions, users can receive tailored suggestions about mood and behavior dimensions they might find helpful to monitor, or they can select from a menu of monitoring dimensions themselves. They can also choose the time of day they want to monitor and whether they would like to receive regular SMS or email messages to prompt them. Both real time and retrospective assessment of moods, events, and behavior will be available, and users will be able to receive graphical feedback of their data with situational information if desired. They may also choose to receive brief self-management modules (involving interactive cognitive-behavioral strategies), motivational messages, stories, information, and tips to help them to manage depression, anxiety, and stress. Alternatively, the system will offer a selection of strategies derived from algorithms based on user data. The program is designed as a stand-alone tool for the public that is secure and easy to use.

Once the digital program is fully developed and pilot tested, a large-scale randomized controlled trial is planned to measure outcomes arising from use of the program.

Conclusion

Mobile phones are the way of the future. Ownership has reached saturation point in most developed countries, and in developing countries it is increasing exponentially. The simplification and rapid development of digital technology together with the way in which mobile phones are carried on the person and switched on and positive community attitudes make the mobile phone a useful vehicle for enhancing access to evidence-based monitoring and self-help for people with mild to moderate high-prevalence mental health conditions.

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Conflicts of Interest

The myCompass program is being developed at the Black Dog Institute.

Multimedia Appendix

Advertisement for the online survey

[PDF file (Adobe PDF), 78 KB - jmir_v12i5e64_app1.pdf]

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Abbreviations

EMA: Ecological Momentary Assessment
IP: Internet protocol

PDA: personal digital assistant
SMS: short message service

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Original Paper

Multimodal E-Mental Health Treatment for Depression: A Feasibility Trial

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Abstract

Background: Internet interventions for depression have shown less than optimal adherence. This study describes the feasibility trial of a multimodal e-mental health intervention designed to enhance adherence and outcomes for depression. The intervention required frequent brief log-ins for self-monitoring and feedback as well as email and brief telephone support guided by a theory-driven manualized protocol.

Objective: The objective of this feasibility trial was to examine if our Internet intervention plus manualized telephone support program would result in increased adherence rates and improvement in depression outcomes.

Methods: This was a single arm feasibility trial of a 7-week intervention.

Results: Of the 21 patients enrolled, 2 (9.5%) dropped out of treatment. Patients logged in 23.2 ± 12.2 times over the 7 weeks. Significant reductions in depression were found on all measures, including the Patient Health Questionnaire depression scale (PHQ-8) (Cohen's $d = 1.96$, $P < .001$), the Hamilton Rating Scale for Depression ($d = 1.34$, $P < .001$), and diagnosis of major depressive episode ($P < .001$).

Conclusions: The attrition rate was far lower than seen either in Internet studies or trials of face-to-face interventions, and depression outcomes were substantial. These findings support the feasibility of providing a multimodal e-mental health treatment to patients with depression. Although it is premature to make any firm conclusions based on these data, they do support the initiation of a randomized controlled trial examining the independent and joint effects of Internet and telephone administered treatments for depression.

(J Med Internet Res 2010;12(5):e48) doi:10.2196/jmir.1370

KEYWORDS

Depression; Internet; feasibility; telephone; telemedicine

Introduction

Epidemiological studies have shown that 6.7% to 10.1% of the general population suffers from a depressive or mood disorder in a 12-month period [1,2]. Over the past 8 years, a number of Internet interventions have been developed to treat depression [3]; however, these interventions have often resulted in high rates of attrition [4]. (Note that in this paper, attrition and adherence refer to dropping out or staying in treatment and not to loss to follow-up for study assessments.) For example, studies examining open access to stand-alone Internet treatments find that fewer than 10% of patients return after a first visit and as few as 1% complete treatment [4]. Studies that use recruitment and screening procedures consistent with face-to-face trials find

better adherence for stand-alone sites, although the mean number of log-ins remains in the 2 to 4 range for a 7- to 8-module intervention [5,11]. Many studies have found that email support can significantly improve adherence [3]. For example, a trial comparing two different Internet treatments supported by coaching emails reported that between 56% and 72% of participants completed 4 sessions, although only approximately 38% completed the entire Internet treatment [6]. Adherence and outcomes for Internet interventions are generally poorer for depression compared with Internet interventions for other mental health problems such as anxiety disorders [3,4]. This is perhaps not surprising, given that depression reduces motivation for and compliance with recommendations for traditional treatments as well [7,8]. Thus, while adherence to Internet treatments is a problem generally [9], it appears to be more common among patients with depressive disorders.

This paper describes the results of a feasibility trial of a multimodal e-mental health intervention, in which an Internet treatment for depression was supported by brief weekly calls from a "coach." These calls were designed to maximize adherence to the Internet intervention for depression.

We used 3 basic frameworks in designing the e-mental health and telephone intervention. First, we designed the structure of the website based on the persuasive technologies framework [10], which outlines the principles through which computer technology can be used to persuade individuals to change their behavior. The following principles were used: (1) Simple, brief tools that provide monitoring and feedback are most likely to be useful. Indeed, length and complexity of Internet modules have been suggested as one cause of dropout [11]. (2) Technologies that can be inserted into daily routine are more likely to be persuasive and to promote adherence. Accordingly, most of the patient's work on the website was designed to require less than 3 to 5 minutes and involved self-monitoring and feedback. The site and the coach suggested website visits daily or every other day. (3) Tools should simplify tasks, in this case those associated with behavioral activation and cognitive restructuring. (4) Feedback should be tailored to the individual. (5) Media such as video can be effective at promoting vicarious learning. (6) Users view interactive websites as social actors. Thus, specific features that affect human relationships can also improve acceptability of a website. These include attractiveness of the site, "personality" of the site, (eg, whether information is provided in a highly directive or more nondirective manner), credibility, and reciprocity (eg, whether the site provides something of value in return for asking the user to provide information or engage in tasks).

Second, Internet interventions for depression show better outcomes and adherence when accompanied by human support. While the role of human support in promoting adherence has been repeatedly confirmed [3,4], there is surprisingly little theoretical or empirical exploration in psychology or psychiatry into why or how human support improves adherence. We have begun developing a framework for understanding how human support increases adherence. This is based on a branch of accountability theory, which describes specific mechanisms by which adherence can be obtained [12]. Accountability refers to the implicit or explicit expectation that an individual may be called upon to justify his or her actions or inactions. Borrowing from accountability theory, the following basic principles would likely be important in a protocol for maintaining adherence via human support. Providers must: (1) be seen as trustworthy, benevolent, and having the necessary expertise, (2) frame the relationship as one containing reciprocity in which the patient can expect to receive definable benefits from the coach, (3) be specific about which outcomes are expected, (4) focus expectations on processes rather than outcomes, (5) monitor adherence and inquire when the patient is nonadherent, (6) specify accountability processes at the beginning of treatment with adequate justification and with patient agreement, and (7) reward and encourage success in meeting goals. We therefore developed an interface to allow a provider or coach to monitor patient activity on the site. We also developed a coaching protocol based upon these principles.

Third, different telecommunications technologies vary in their potential to sustain adherence and outreach [13]. Internet interventions on their own are associated with high attrition [3], likely because these interventions rely principally on patient initiative for engagements and have limited capacity for outreach. The addition of email to these interventions improves adherence and outcomes [3,4]. Telephone interventions are associated with adherence rates of more than 92% [14]. Accordingly, we delivered the coaching protocol via telephone and email.

This paper reports on the adherence and depression outcomes from the feasibility testing of a multimodal eHealth intervention for depression. Our goal was to examine feasibility in terms of recruitment, adherence, and depression outcomes. Secondary outcomes included anxiety and positive affect. We also examined the relationship between adherence and depression outcomes.

Methods

Participants

From December 11, 2008, through March 25, 2009, participants were recruited through advertisements posted on a popular online community, Craigslist.org, which features classified advertising. Recruitment was conducted in Chicago, Illinois, USA. Those who were interested in participating were directed to the study Web page where they completed the Patient Health Questionnaire depression scale (PHQ-8) [15]. Respondents who scored 10 or above on the PHQ-8 were invited for a telephone screening interview. Those who were interested in participating received a "verbal informed consent," in which a research assistant described the study over the telephone, as well as a written consent, which was emailed and could be electronically signed. This study was approved by the Northwestern University Institutional Review Board.

The inclusion criteria were: (1) a score of 10 and above on the PHQ-8, as this is the criterion recommended by the MacArthur Depression Group for referral to psychotherapy or counseling [16], (2) possession of an email account, (3) access to a telephone, (4) access to a computer with broadband access to the Internet, (5) ability to speak and read English, and (6) age

18 years or older. Participants were excluded if they (1) had a hearing or voice impairment that would prevent participation in the coaching sessions and study assessments, (2) had visual impairments that would prevent the use of the website and completion of study assessment materials, (3) met screening criteria for dementia, (4) had a severe psychiatric disorder, including psychotic disorders, bipolar disorder, bulimia or anorexia, or posttraumatic stress disorder (PTSD), (5) reported severe suicidality (eg, plan and intent) or had a history of suicide attempt in the past five years, (6) were currently or planning to receive psychotherapy during the 7-week treatment, (7) had initiated treatment with an antidepressant in the last four weeks, or (8) planned to be out of town for 2 weeks or more during the 7-week treatment phase.

Study Design

This was a single arm feasibility trial. Because this is the first test of a novel intervention, a single arm trial testing feasibility rather than efficacy is an appropriate design [17]. Eligible patients were provided log-in information for the moodManager website and were contacted by their assigned coach. Outcomes were assessed at baseline, mid-treatment, and end of treatment (week 7).

Intervention

The moodManager Website

The depression management skills training website, which we called "moodManager," was based on cognitive behavioral principles [18,19] and consisted of six learning modules and four tools. The learning modules were intended to teach basic concepts of cognitive behavioral therapy and to participants how to use the tools. Content included text, video, and audio material. Modules were designed to require 15 to 20 minutes to complete. Learning modules (and associated tools) included the following: (1) "Getting Started," which was an introduction to the basic principles of cognitive behavioral therapy (CBT); (2) "Monitoring Activities," which described the relationship between activities and mood and introduced the "Activity Diary" tool, which allowed participants to track and rate daily activities; (3) "Scheduling Positive Activities," which taught participants to use the "Activity Scheduler," a tool used to plan and schedule positive activities; (4) "Identifying Thoughts," which described the effects of thoughts on mood and taught participants to use the "Thought Diary" tool to monitor automatic thoughts; (5) "Challenging Thoughts," which expanded the Thought Diary tool by teaching participants to develop alternative thoughts; (6) "Maintaining Gains," which summarized the skills learned and encouraged participants to continue using the tools for relapse prevention. Tools were designed to support implementation of cognitive behavioral skills, to require only a few minutes to complete, and were intended to be completed every day or every other day. Tools were partially "scaffolded": the Activity Monitoring tool was incorporated into the Activity Scheduling tool, and the Thought Diary tool was incorporated into the Challenging Thoughts Diary tool. Participants were required to complete a tool three times before the next learning module would open, to ensure that the concept was learned. The moodManager site included mood rating and tracking features for self-monitoring by patients.

The moodManager site also contained a provider interface that allowed the coach to observe the patient's activity on the site, including dates and times of site visits, content of patient's entries into tools (eg, activity diaries and thought records), depression monitoring ratings, and alerts for suicidality.

The Coaching Protocol

Participants were assigned a coach who contacted them once per week by telephone and once per week by email. Based on principles of accountability theory [12], self-determination theory [20,21], and motivational interviewing, we designed a brief telephone coaching program that we called Telephone Coaching to Support Adherence to Internet Interventions (TeleCoach). In accordance with the theory and principles described in the "Introduction" section above, TeleCoach included the following elements. Coaches must (1) present themselves as trustworthy, benevolent, and having the necessary expertise in coaching an online intervention, (2) frame the relationship as one containing reciprocity in which the patient can expect to receive definable benefits from the coach, (3) be specific about which outcomes are expected (eg, logging into moodManager), (4) monitor adherence through the coach interface and inquire when the patient is nonadherent, (5) specify accountability processes at the beginning of treatment (eg, that the coach can see when the patient uses the site) with adequate justification and with patient agreement, and (6) reward and encourage success in adherence.

TeleCoach included an initial "engagement session," which was intended to last approximately 30 minutes while subsequent conversations with the coach were intended to be 5 to 10 minutes in length. Participants were also permitted to email their coaches with questions during the week. (A copy of the TeleCoach protocol is available at http://www.preventivemedicine.northwestern.edu/researchprojects/telecoach.htm.)

Coaches

The two coaches were PhD-level licensed psychologists. While the protocol is designed so as not to require specialized training, a higher level of expertise was required at this early developmental stage to ensure patient safety. Coaches were blind to outcome assessments but did have access to mood tracking within the moodManager site.

Measures

Adherence

Adherence was measured in two ways. Adherence to the Internet portion of the intervention was defined by the number of log-ins. Adherence to the TeleCoach program was defined by whether or not the coaching phone call was completed. Dropout from the intervention was determined to have occurred at the last point of contact with the website or coach, if it occurred more than one week before the end of treatment period.

Study assessments were completed at baseline, week 4, and week 8. Consistent with standard clinical trial methodology in depression, assessments were performed both by clinical interview administered via telephone and self-report administered online. The telephone interviews were administered

by trained clinical evaluators who were blind to the coaching component of the study, site usage, and other data collected by moodManager, such as the depression ratings. Research assistants received extensive training on assessment protocols. All telephone evaluations were audiotaped and reliabilities were periodically checked by having two or more clinical evaluators rate the same tapes (see report of reliabilities below). To ensure separation of the treatment and the evaluation, self-reported outcomes were administered via SurveyMonkey.com separately from the moodManager program. To minimize loss to follow-up, participants were paid up to US $80 for completion of assessments. Participants were clearly informed that payment was not for use of the website to ensure that payments did not influence treatment adherence.

Mini International Neuropsychiatric Interview

The Mini International Neuropsychiatric Interview (MINI) [22] is a structured interview to evaluate Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) Axis I disorders, including Major Depressive Episode (MDE), as well as most other major diagnoses. The full MINI was administered by telephone at screening, but only the MDE section was administered at follow-up telephone evaluations.

Hamilton Rating Scale for Depression

The Hamilton Rating Scale for Depression (HRSD) was administered at all time points to provide an objective, interview-based measure of depressive symptom severity consistent with trials of face-to-face psychotherapy and pharmacotherapy. A telephone administered version of the 17-item HRSD, developed for the Medical Outcomes Study [23], was administered by a clinical evaluator. Clinical evaluators' average interrater reliability, using interclass correlations, was .95 (range .81-.99).

Personal Health Questionnaire

The Personal Health Questionnaire (PHQ-9) [24] is a 9-item self-report measure of depressive symptoms that closely matches the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for MDE and was administered online at all time points. To address concerns raised by the IRB, the PHQ-8 [15], which excludes the item measuring suicidality, was used for screening only, prior to patient enrollment in the study. The PHQ-9 was used as the self-report outcome measure.

Perceived Barriers to Psychological Treatment

The Perceived Barriers to Psychological Treatment (PBPT), administered at baseline, is a 25-item measure that identifies barriers to access to face-to-face psychological care [7]. It has been shown to predict decreased utilization of face-to-face services.

The moodManager Depression Tracking

In contrast to the HRSD and PHQ-9, which were administered independent of the treatment site, this assessment was administered to the patient at each site visit to moodManager. Also, unlike all other assessments, coaches had access to the depression tracking tool ratings and were expected to review them. Patients were asked to rate the two questions (mood and anhedonia) on a 0 to 10 Likert scale, where 0 = no symptoms and 10 = worst possible symptom. These items were adapted from the PHQ-2 [25]. The assessments were intended to help the participant track mood during treatment and were not intended for outcome assessment; however, they were used in secondary analyses as described below. The total depression assessment score had a potential range of 0 to 20.

Generalized Anxiety Disorder Scale

The Generalized Anxiety Disorder Scale (GAD-7) [26] is 7-item self-report measure of anxiety symptoms that closely matches the DSM-IV criteria for GAD.

Positive Affect

We included only the 10 self-report items from the Positive Affect Scale of the Positive and Negative Affect Scale (PANAS) [27].

Telephone Interview for Cognitive Status

The Telephone Interview for Cognitive Status (TICS) is a widely used telephone assessment that has demonstrated reliability and validity in identifying dementia resulting from Alzheimer's and stroke [28]. It was administered at screening.

Demographics

Demographics were collected via online self-report.

Exit Interview

Upon completing the final assessments, an unstructured interview was conducted in which patients were asked to review each of the components of the site and intervention, to describe specific problems or critiques, and to provide us with a general overview. These data were collected primarily to assist the team in improving future versions of moodManager and the intervention.

Statistical Methods

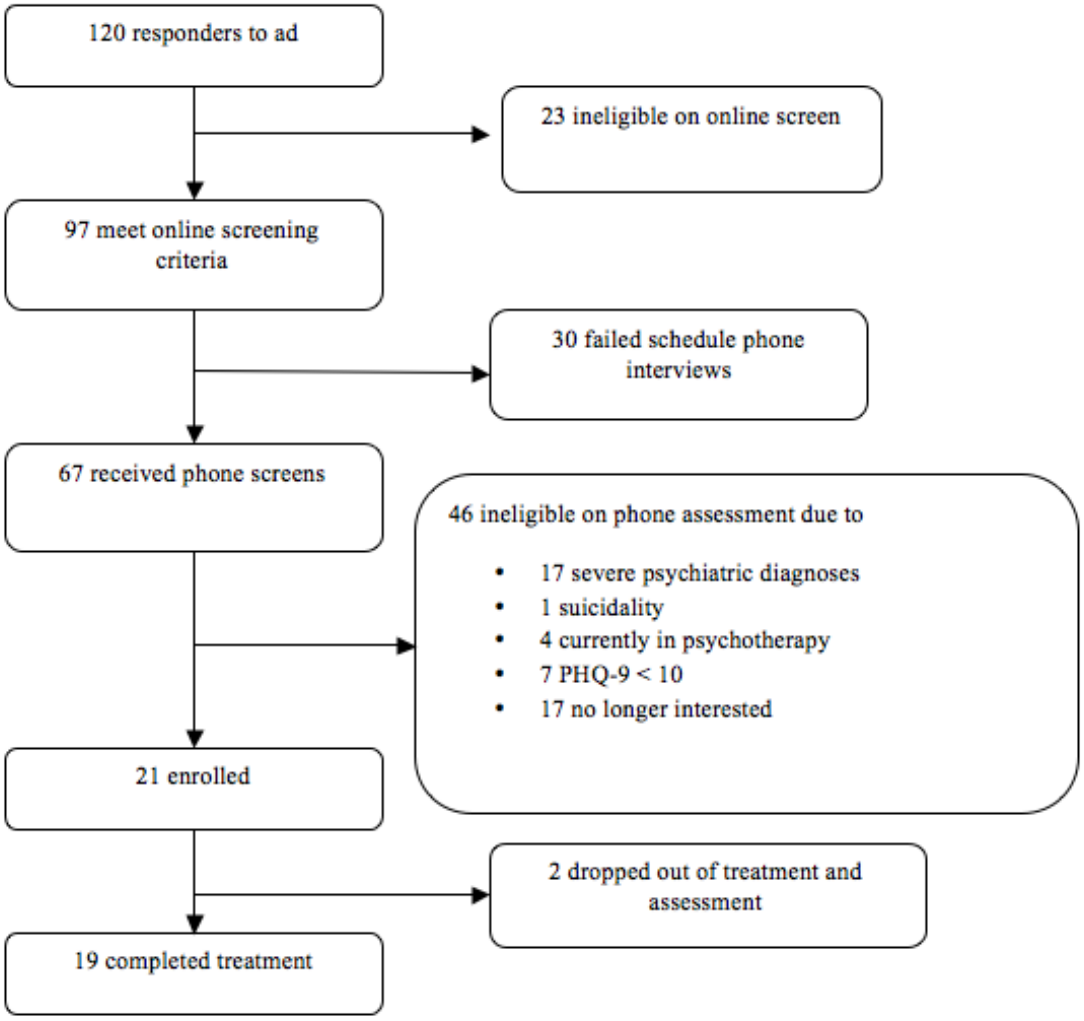
All analyses were conducted on an intent-to-treat basis. Outcome and utilization analyses were conducted by random intercept mixed-effects regression models using the maximum likelihood method for continuous outcome and generalized estimating equations model by SAS Proc Genmod procedure (SAS Institute Inc, Cary, NC, USA) with an exchangeable working correlation structure for binary outcomes. For analyses using moodManager tracking, depression measures were averaged over a one-week period. For the purposes of these analyses, missing data were assumed to be missing completely at random and therefore were ignored.

Results

Recruitment

During recruitment, 120 individuals responded to the online classified ad, 97 met preliminary criteria and were contacted via email for an eligibility assessment, and 21 were enrolled. The flow of patients through the study is displayed in Figure 1.

Figure 1. Flow of patients through recruitment, screen, and intervention



Participant Characteristics

Baseline characteristics of participants can be found in Table 1. Of the 21 enrolled patients, 17 identified barriers on the PBPT that would prevent access to face-to-face treatment.

Table 1. Demographics

Demographics	Measure n = 21
Age, mean (SD)	32.90 (9.97)
Female, n (%)	17 (81%)
Married, n (%)	5 (24%)
Race	
African American, n (%)	3 (14%)
Asian, n (%)	4 (19%)
Caucasian, n (%)	14 (67%)
Diagnoses	
Major depressive disorder, n (%)	17 (81%)
Agoraphobia, n (%)	4 (19%)
Social phobia, n (%)	1 (5%)
Highest level of education	
Completed high school, n (%)	1 (5%)
Some college, n (%)	4 (19%)
Associate's degree, n (%)	1 (5%)
Bachelor's degree, n (%)	9 (43%)
Master's degree, n (%)	4 (19%)
Advanced degree, n (%)	2 (10%)
Current employment status	
Employed, n (%)	14 (67%)
Unemployed, n(%)	4 (19%)
Disability, n (%)	1 (5%)
Declined to respond, n (%)	2 (10%)

Among patients who met preliminary screening criteria (n = 97), patients who were enrolled (n = 21) did not differ significantly from patients who were not enrolled on any available data including age (P = .43), gender (P = .53), race (P = .50), or score on PHQ-8 (P = .59).

Outcome Measures

Adherence

In total, 19 (91%) participants completed all treatment modules and continued to log in to moodManager throughout all weeks of the treatment. Of 21 participants, 2 (less than 10%) did not complete the intervention; 1 dropped out following the initial engagement session with the coach but without logging on to the website and the other participant dropped out after the 3rd week. Patients who dropped out of treatment also refused to continue assessments and were lost to follow-up.

The mean number of visits to the site over the course of the 7-week treatment program was 23.16 ± 12.16 (Range 7-49). Visits were more frequent in the first week (3.8 ± 1.33) and declined over time but continued through the final (7th) week (2.0 ± 1.28). The 19 patients who completed treatment also completed all 8 TeleCoach calls. In addition, 5 (26%) continued to log in to the site after completion of the trial.

Outcomes for Depression, Anxiety, and Positive Affect

The means, standard deviations, and effect sizes for outcome measures are shown in Table 2. Significant improvements were seen in all measures, including the HRSD (t_{37} = -5.37, P < .001), the PHQ-9 (t_{37}= -7.37, P < .001), the GAD-7 (t_{37}= -7.48, P < .001), the PANAS-PA (t_{37}= 5.10, P < .001) and MDE (beta = -2.27, Z = -4.70, P < .001). At baseline, 17 of 21 (81%) patients met criteria for MDE, with 5 of 19 (24%) at week 4, and 1 of 19 (5%) at week 8.

Table 2. Means and standard deviations of outcome measures

Measure	Baseline Mean (SD) (n = 21)	Week 4 Mean (SD) (n = 19)	Week 8 Mean (SD) (n = 19)	Effect Size (Cohen's *d*)	*P*
HRSD	21.2 (6.42)	14.4 (6.41)	12.0 (6.54)	1.34	< .001
PHQ-9	15.0 (3.70)	8.2 (5.18)	5.6 (5.74)	1.96	< .001
GAD-7	10.8 (4.59)	5.3 (3.23)	3.6 (3.85)	1.70	< .001
PANAS-PA	20.6 (5.27)	27.6 (7.74)	29.4 (9.14)	1.16	< .001

Relationship Between Adherence and Depression

Site Visits and Depression.

We examined the week-to-week relationship between utilization and depression by examining the number of site visits and the moodManager depression tracking assessment obtained at each site visit. Poorer mood was associated with a greater number of site visits during the same week (Estimate = 0.11, t_{95} = 3.06, *P* = .003). When weeks were lagged so that depression predicted number of site visits in the following week, there was no significant effect (*P* = .91). When depression was lagged to predict subsequent site visits, there was also no significant effect (*P* = .17).

Coaching and Depression

The mean amount of time for the initial engagement calls was 28.5 ± 7.22 minutes, and the mean amount of time for subsequent calls was 9.9 ± 6.40 minutes. The length of the coaching call was not significantly related to scores on the moodManager depression tracking tool during the following week (*P* = .36). Similarly, moodManager depression ratings did not predict the length of the following coaching call (*P* = .63).

Coaching and Utilization

Length of the coaching call was not significantly related to subsequent number of site visits (*P* = .23), and number of site visits did not significantly predict the length of the coaching call (*P* = .15).

Exit Interview

Overall, participants reported that the site was helpful and enjoyable to use. Tracking features, specifically activity scheduling and mood ratings, were reported as highlights of the site. Patients also consistently liked the content of the learning modules, and some indicated that more content would be welcomed. General problems reported were mostly usability related issues including critiques regarding navigation and confusion related to rules and requirements for progression through the program. Some patients did not always use tools as taught (eg, many patients used thought records as a free form "journal"), although these participants were still enthusiastic about using the features.

Discussion

This study examined the feasibility of a multimodal treatment approach to depression. The Internet treatment required more frequent log-ins than are typically required. The telephone coaching support was developed based upon accountability theory and is, to the best of our knowledge, the first manualized telephone support program for an Internet intervention. The trial showed good overall treatment adherence. The attrition rate of under 10% is similar to the 8% rate of attrition seen in telephone administered therapies [14] and compares favorably with the 25% to 50% attrition rates seen in face-to-face psychotherapy and the 35% to 90% attrition rates seen in stand-alone and email supported Internet interventions [4]. In addition, log-in rates to the website averaged nearly 4 per week in the early phase of treatment and remained at twice per week in the final week. While the numbers of log-ins in the later weeks were somewhat lower than recommended, the mean of 23 log-ins over 7 weeks in treatment is, as best we know, higher than other Internet treatments have achieved. Reductions in both diagnosis of depression and severity of depressive symptoms were in the range seen in randomized controlled trials (RCTs) of psychotherapy and antidepressant medications [29,30]. Overall, the finding that patients adhered to the treatment at a high rate and improved suggests that using multiple telecommunications technologies to support Internet interventions for depression is feasible and acceptable to patients.

We examined within treatment relationships between depression and adherence variables. Poorer mood in any given week was associated with a greater number of site visits. However, mood did not significantly predict the number of site visits the following week, nor did number of site visits predict mood. While it is difficult to make inferences about causality, we speculate that poorer mood increased utilization since the alternative, that utilization decreased mood, is inconsistent with the overall positive outcomes. Thus, these findings suggest that patients may titrate their treatment to meet their own needs.

The TeleCoach intervention protocol was designed and developed so that it is easy to learn and ultimately could be used by providers who do not have any specific training in cognitive behavioral therapy, or in psychotherapy more generally. The intent is that nurses, social workers, or other persons serving in the role of care managers could be trained to implement the protocol. The coaching sessions were intended to be 5 to 10 minutes. In fact, the session length mean was approximately 10 minutes. There was considerable variability in length, with many sessions being considerably shorter but many also being much longer. However, there was no support for the ideas that session length was a response to poorer mood or that the length of the session affected mood. Indeed, our experience was that the

"chattiness" of the patient was the principal driver of session length.

The patients who enrolled in the study met criteria for anxiety disorders at a much higher rate than seen in the general population [1]. This finding, which was unexpected but not surprising, suggests that Internet interventions may reach populations who commonly are not seen in standard face-to-face psychological interventions. For example, patients with agoraphobia might find it difficult to get to a clinic, while patients with social anxiety may find it uncomfortable to engage in psychotherapy. Indeed, this was borne out by spontaneous comments from patients to the coaches indicating that they would never seek help from a therapist. A posthoc analysis found no evidence that patients with symptoms of agoraphobia or social anxiety performed any better or worse than patients without these symptoms. The potential for Internet interventions to reach such undertreated or untreated populations remains an area with great research and clinical potential.

The primary impetus for this study was the problem of attrition in Internet intervention. Adherence to Internet interventions has repeatedly been identified as a major problem requiring the development of a "science of attrition" [9,31]. Much of the work on attrition has focused on understanding how the reach of the Internet might increase enrollment of patients at greater risk of attrition, incorporating components into trial design to prevent this effect (eg, through the use of run-ins), and understanding patient characteristics associated with attrition [4]. In addition, there have been numerous attempts to reduce attrition through modifications to Internet interventions, but this has been done without much theoretical underpinning. These modifications have included the addition of postcard reminders, email, telephone calls, and online discussion groups [32,33]. While initial attempts to find solutions to the problem of attrition may benefit from investigator intuition and trial-and-error approaches, the area of Internet intervention has advanced to a stage where it could benefit from more refined and better specified models, which define the components of human interaction and support that contribute to adherence. Such a conceptualization could be used to develop more refined intervention solutions to the problem of attrition.

Limitations

This study is a preliminary feasibility trial and, as such, it has all of the problems associated with such studies. Without a control condition, we cannot rule out the possibility that the improvements in depression were due to the natural course of the illness or to other factors independent of the intervention. Without controlling for telephone and/or website treatments alone, it is also impossible to determine the relative contribution of each to either adherence or depression outcomes. Given the large number of people who did not follow up after initial contact, it is possible that there was some sample selection bias. While the numbers selected out are similar to those seen in other trials of Internet interventions for depression [32,34], the possibility that our results are due to selection bias cannot be ruled out. In addition, the small size of the sample increases the likelihood that the sample is not representative of the population from which we recruited. Finally, while study staff clarified at each assessment point that payment was for assessments and not for moodManager use, it is possible that the adherence to the treatment was influenced by these payments.

Conclusions

Given these limitations, we emphasize that the results of this feasibility trial should in no way be used to suggest that the moodManager website or the TeleCoach support have any effect on depression or adherence. However, these results are very promising. As the first study of a manualized coach support program for an Internet intervention, this study opens a line of research that has the potential to improve our understanding of how to enhance adherence to Internet interventions. Based on the encouraging results of this study, we have initiated a pilot 3-arm RCT comparing (1) moodManager and TeleCoach, (2) moodManager alone, and (3) a wait-listed control group for the treatment of major depressive episode.

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Conflicts of Interest

David C Mohr, PhD, and Martin McCarthy Jr, PhD, hold copyrights to an earlier version of moodManager.

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Abbreviations

CBT: cognitive behavioral therapy
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition
GAD-7: Generalized Anxiety Disorder Scale
MDE: Major Depressive Episode
MINI: Mini International Neuropsychiatric Interview
PANAS: Positive and Negative Affect Scale
PHQ-8: Patient Health Questionnaire depression scale
PTSD: posttraumatic stress disorder
RCT: randomized controlled trial
TICS: Telephone Interview for Cognitive Status

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Original Paper

Ethical Dilemmas in Online Research and Treatment of Sexually Abused Adolescents

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Abstract

Background: In a recent uncontrolled trial of a new therapist-assisted Web-based treatment of adolescent victims of sexual abuse, the treatment effects were found to be promising. However, the study suffered a large pretreatment withdrawal rate that appeared to emanate from reluctance among the participants to disclose their identity and obtain their parents' consent.

Objective: Our objectives were to confirm the effects of the online treatment in a controlled trial and to evaluate measures to reduce pretreatment withdrawal in vulnerable populations including young victims of sexual abuse.

Methods: The study was designed as a within-subject baseline-controlled trial. Effects of an 8-week attention-placebo intervention were contrasted with the effects of an 8-week treatment episode. Several measures were taken to reduce pretreatment dropout.

Results: Pretreatment withdrawal was reduced but remained high (82/106, 77%). On the other hand, treatment dropout was low (4 out of 24 participants), and improvement during treatment showed significantly higher effects than during the attention placebo control period (net effect sizes between 0.5 and 1.6).

Conclusions: In treatment of vulnerable young populations, caregivers and researchers will have to come to terms with high pretreatment withdrawal rates. Possible measures may reduce pretreatment withdrawal to some degree. Providing full anonymity is not a viable option since it is incompatible with the professional responsibility of the caregiver and restricts research possibilities.

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KEYWORDS

Childhood abuse; adolescence; sexual abuse; codes of ethics; consent; anonymity; posttraumatic stress disorder; cognitive behavior therapy; cognitive behavior therapy methods; Internet; exposure; social sharing

Introduction

More than a decade of research has shown that therapist-assisted Web-based treatment may provide an effective alternative to standard (face-to-face) treatment for a wide range of psychological disorders [1,2]. However, most of the evidence has been collected among adult populations. Further research is needed to establish the efficacy of such treatment for vulnerable children and adolescents.

In 2007, the Rutgers Nisso Group, a Dutch expert center on sexuality, initiated the development of a protocol for the online treatment of adolescent victims of sexual abuse and sexual violence. Dutch epidemiological research among 12 to 25 year old children, adolescents, and young adults had estimated the prevalence of sexual abuse to be 18% among girls and 4% among boys [3]. Other studies demonstrated that many victims do not disclose their experiences and that the accessibility of professional help was poor due to long waiting lists [4]. Clearly, there was a need for more accessible psychological help for this group. In their online project, Rutgers Nisso aimed to increase the availability of evidence-based care. They conjectured that adolescent victims would more readily seek online treatment,

given their extensive use of the Internet and their tendency to disclose their feelings and thoughts more freely on the Internet [5].

Rutgers Nisso, the Interapy group—a Dutch center for research, development, and Internet treatment of psychological disorders—and the University of Amsterdam developed an online treatment based on an existing therapist-guided Web-based treatment of posttraumatic stress [6-10]. This protocol was adapted to victims of sexual abuse, and its effects were tested in an uncontrolled clinical trial. In that study, treatment dropout was low (all but one completed treatment), and the effects for those who started treatment were favorable. At posttreatment, participants reported substantial reductions on measures of posttraumatic stress and general psychopathology (.7 < d < 1.1). However, pretreatment withdrawal was very high (90%): only 8 of the 82 eligible applicants (10%) actually started treatment. Applicants withdrew in large numbers during the online screening prior to a diagnostic telephone interview [11]. Analyses of the pretreatment withdrawal suggested that the researchers' obligation to ascertain parental consent and the supposed loss of anonymity for the participants discouraged many applicants from participating in the study.

The study raised several dilemmas:

Is it responsible to forgo biographical information that might be essential in the case of a personal crisis of the client? What is the responsibility of the care provider in that case? Obviously, the moral aspects seem to be the most compelling, but there may be financial consequences if claims of neglect are brought against the care provider. Legal questions may present themselves in countries such as the Netherlands where care providers are obliged to obtain and register the "Citizen Service Number" of all clients.

On the other hand, what are the ethical implications of withholding a promising treatment from the most vulnerable group?

How will outcome research suffer given the absence of the biographic information that is needed to conduct long-term follow-up, dropout analyses, and analyses of moderators of treatment effect?

Dilemmas associated with the requirement for parental consent and the loss of anonymity are not confined to treatment studies. In survey research, nonresponse increases considerably when anonymity is lifted, and informed consent is made obligatory [12]. After a general health examination with youngsters between 12 and 17 years of age, Lothen-Kline and colleagues [13] experimented with 2 exit questionnaires. The questionnaire informing the respondents that their data would be shared with parents or guardians showed significantly less affirmation regarding suicidal ideation and use of alcohol than the consent form that did not mention this. Some authors have discussed the age level up to which parents or guardians have to be informed. Some of them advocate lowering the age level because the cognitive development of youngsters is sufficient for them to decide themselves whether to participate [14]. The recommendations vary from "researchers should be responsible and know when to deviate from the normal age restrictions" to "researchers should adhere to the law with regard to the age of parental control" or "try to get dispensations." However, issues of law and responsibility are often neglected as well. In a systematic review of 34 outcome studies regarding substance abuse, Smith et al found that in 59% the consent procedures were not reported adequately [15].

As noted by Childress [16], if the identity of a client cannot be verified, the caregiver runs the risk of treating minors without the knowledge and consent of their parents or guardians. Full anonymity does not seem to be a viable option in guided online treatment. Anonymous treatment may jeopardize the professional responsibility of the caregiver [17] and will restrict research possibilities. In general, two options seem feasible. First, one can reduce the anxiety about nonanonymity in the participants. This is especially important for potential clients who do not need parental consent but who nevertheless are hesitant to participate without strict anonymity. Second, if possible, one can change the designs of studies in such ways that parental consent might not be required.

In the next section, we present the design and outcome of a study that was conducted to obtain a controlled estimate of the effects of online treatment for young victims of sexual abuse. In this study, several measures were taken to reduce pretreatment withdrawal. The discussion reflects on the outcome for those who started treatment and the lessons that were learned with regard to pretreatment withdrawal.

Methods

Design

Several studies have demonstrated the effectiveness of the therapist-assisted Web-based treatment in adults [6-10]. A previous study confirmed these findings in an adolescent population [11]. Under Dutch law, in experimental (randomized) studies, parental consent is not needed for participants of 18 years and over. However, if the study is a nonrandomized evaluation of an existing treatment, this is lowered to 16 years and over. For that reason, the present study was designed as a treatment evaluation study, in a within-subject, baseline-controlled format. The baseline-control period consisted of a placebo intervention of 8 weeks comprising attention by providing fortnightly outcome measurements and encouraging messages. The treatment period followed and comprised 8 weeks of intervention, with 4 fortnightly outcome measurements. Since there was no randomization, participants who were 16 years or older did not need parental consent. The design was approved by the ethical committee of the Department of Psychology of the University of Amsterdam.

Treatment

The Protocol

The treatment protocol was based on an existing cognitive behavioral treatment of posttraumatic stress in adult populations [6-10] and on previous research that suggested that victims of rape or other forms of sexual abuse often refrain from disclosing their experiences. In a large survey study, Lange et al [18] found

that reactions to disclosure were critical in this association. Negative reactions, inducing shame and guilt, explained more of the variance in psychopathology than the "objective" severity of the abuse. The original treatment comprises 10 structured writing assignments [7,19] implementing 3 therapeutic modules: exposure, cognitive reappraisal, and social sharing.

Several changes were made to adapt the protocol to the treatment of victims of sexual abuse. First, an additional feedback occasion was included in the exposure module to provide extra guidance at this difficult stage [20,21]. Second, an extra module was added that comprised participants' writing about the impact of the sexual abuse on their physical functioning, on their body image, and on their intimate relationships and sexuality. Third, at the end of treatment, instructions were added to generate a "personal toolkit," that is, a document in which participants listed the treatment elements they found most useful. In this document, clients formulated how they would use these elements should they sense impending relapse. Finally, extra psycho-education was added concerning the specific problems participants might have encountered, such as shame, social anxiety, or lack of assertiveness. The treatment comprised 11 virtual contacts during the 8 weeks of treatment.

Setting

The full therapeutic procedure was conducted without face-to-face contact. Participants used a common Web browser to follow the procedure, including the completion of the questionnaires and the therapeutic assignments.

Privacy

Several measures were taken to secure the privacy of the participants. First, only the therapist and the participant were given access to the treatments. Participants and therapists were given an account to a private password-protected website. In addition, the website included a Web mail system, which allowed participants to contact their therapist outside the treatment regime. Thus, participants who shared an email account with others (eg, family members) did not have to use this shared account during treatment. Third, all communication with the website was encrypted with the Hypertext Transfer Protocol over Secure Socket Layer. Fourth, the Web server was protected by a firewall and remotely administered through an encrypted communication channel.

Participants

Recruitment

In the previous study of treatment of victims of childhood sexual abuse [11], many applicants were excluded because they were older than 18 years of age. Later, strong indications from the field suggested that help was equally needed for young adults and for adolescents. Accordingly, the upper age level in the present study was raised to 25 years. Dutch media provided free publicity to the study in response to a press release. Potential clients were referred to a public website that provided background information about the study. This website contained an online application form.

Screening

The screening started with standardized self-report instruments administered through the secure website. To ease the fear of losing anonymity, the biographic questions (name, gender, telephone number, names of parents and general physician, and insurance data) were not posed at the beginning of the online screening, but in separate steps at later stages.

The online screening was followed by a diagnostic telephone interview conducted by graduated clinical psychologists. Applicants who were not willing to submit to the telephone interview were given the option of being interviewed through online text-based chat. To be included in the study, participants had to score at or above the clinical cutoff [24] for posttraumatic stress disorder (PTSD) on the Impact of Event Scale (IES) [22-24], described below. To establish whether the respondents experienced sexual abuse in the past, the Childhood Unwanted Sexual Experiences Questionnaire [25,26] was adapted for use with adolescents. It provides information about the type of the abuse, severity, feelings of guilt and shame, degree of disclosure, location, and the relationship with the perpetrator.

Risk of psychosis was determined by means of the Dutch Screening Device for Psychotic Disorder (SPDP) [27]. The Somatoform Dissociation Questionnaire-5 [28] was used to determine the degree of dissociation. Suicidal ideation was determined with the Dutch adaptation of the Suicidality Questionnaire [29]. The Dutch adaptation of the Self Harm Inventory [30] was used to establish the presence and degree of auto-mutilation. Applicants were excluded if they scored above the cutoff scores of these instruments. They were also excluded on grounds of any of the following: ongoing sexual abuse in the family; a prevalent disorder other than PTSD diagnosis; concurrent treatment; anorexia nervosa (body mass index [BMI] < 18); use of neuroleptica; prior admission into a psychiatric hospital; or substance abuse. Excluded respondents received personalized referrals to agencies providing face-to-face treatment in their region.

Outcome Measures

The Impact of Event Scale

The Dutch adaptation of the IES was used to measure the degree of traumatization [22,23]. The IES consists of 15 items and comprises the subscales Intrusion (8 items) and Avoidance (7 items). Cronbach alpha varies between alpha = .66 and alpha = .78 for the Avoidance scale and between alpha =.72 and alpha = .81 for the Intrusion scale [31]. In the control period and during treatment, the IES was administered every 2 weeks.

Depression Subscale of the Symptom Checklist-90-Revised

To establish the degree of depression, the Dutch adaptation of the Depression subscale of the revised Symptom Checklist-90 (SCL-90-R) was used [32,33]. This scale comprises 16 items, which are scored on a 5-point Likert scale (0 to 4), indicating the rate of occurrence of depressive symptoms over the past week. The scale has good internal consistency (Cronbach alpha = .90) and good convergent and discriminant validity. The

depression measure was administered 3 times: prebaseline, postbaseline/start treatment, and posttreatment.

Invalidation and Strength

Based on the methodology of Routine Outcome Monitoring [34], during the study, participants were repeatedly asked to express the degree to which their symptoms interfered with their functioning (ie, Invalidation) in the past week, on a scale from 1 (low) to 10 (high). Similarly, participants monitored their Strength, that is, the degree to which they had been able to cope with their symptoms in the past week. Correlations between Invalidation and Strength were calculated on all measurement moments. As to be expected, the correlations were negative, statistically significant (P = .005), and fairly high: the mean correlation was r = -.55 and ranged from r = -.30 to r = -.71. These associations became stronger in the second part of the study when the scores started to be affected by the therapeutic impact. These findings suggest that the measures, though associated, measure distinct constructs.

Client Satisfaction

At posttest, participants answered questions regarding their satisfaction with the treatment in general and with its specific parts. In addition, they rated the therapeutic alliance, the nature of the online contact, whether they missed the face-to-face contact with their therapists, and their perceived effectiveness of the treatment.

Statistical Analyses

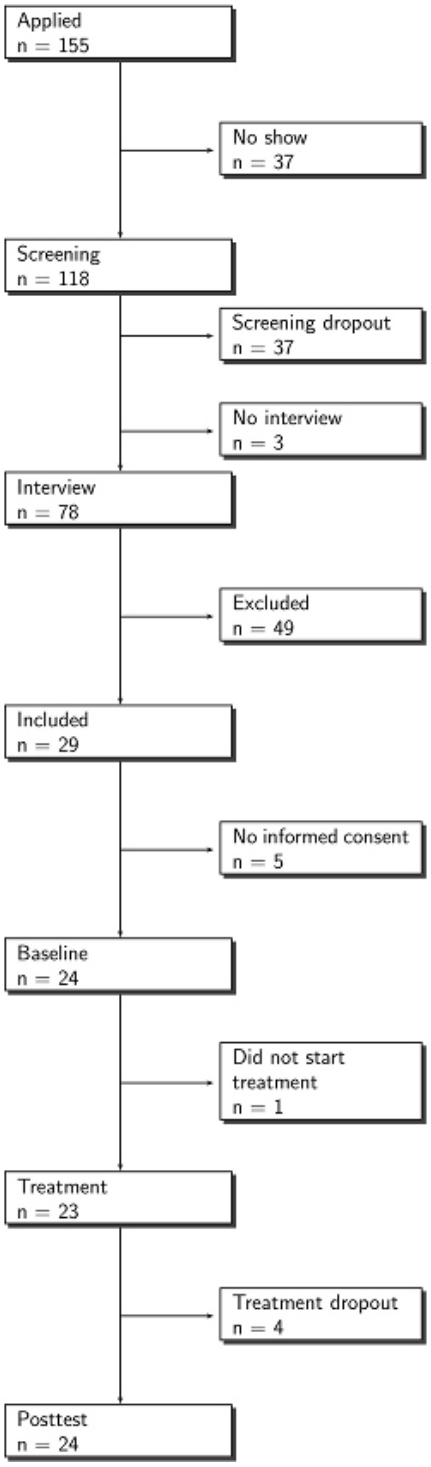
Improvement was calculated for the baseline-control period and the treatment period separately. The differences between improvements during the control and treatment period were tested for each of the 4 outcome measures, using two-sided paired t tests. All participants, including those who did not complete the treatment, provided outcome data. Hence, the effects could be ascertained for all participants, including the dropouts (intention to treat), without statistical imputation techniques being necessary. The effect sizes were expressed in Cohen's d [35] for both periods separately by dividing the mean improvement scores by the standard deviation of the first assessment. Net effect sizes were calculated by subtracting the effect size of the control period from the effect sizes of changes during the treatment period.

Results

Participant Flow

Overall, as shown in Figure 1, this study also suffered from considerable pretreatment withdrawal. Of the 106 applicants that were not excluded by the researchers, 77 % (82) did not start the baseline-control period.

Figure 1. Flowchart of participation



No Show

Of the 155 applicants, 24% (37) did not start the screening. Since we have no data for these respondents, we could not establish their age or their reasons for withdrawing.

Screening Withdrawal

In total, 118 applicants started the screening. Of these, 40 (34%) did not complete the screening. Most of the withdrawal (37 applicants) occurred during the online part of the screening. The online screening comprised 21 steps. Of these, 3 steps included biographic questions. Of those who withdrew during the online screening, 49% (18 out of 37) did so at one of these three steps.

Of the 81 applicants who completed the online screening, 3 did not commit themselves to the interview. Accordingly, 78 respondents were interviewed by telephone or chat. In total, 71 participants accepted the telephone interview, while 7 participants opted for the online chat.

Exclusion

Of the participants who completed the screening and were interviewed, 63% (49/78) met the criteria for study exclusion.

The main reasons for exclusion were ongoing abuse within the family (n = 20) or being in concurrent treatment (n = 9).

Informed Consent

Of the 29 participations who were admitted to the study, 24 returned the completed informed consent form and were subsequently registered for participation in the treatment; 5 did not return the informed consent form. There was no difference in withdrawal percentage at this stage between those who had committed themselves to a telephone or chat interview.

Treatment Dropout

Of the 24 starting participants, 1 withdrew after the baseline-control period, and 4 dropped out during the treatment phase. All 24 starting participants completed the posttest.

Age and Withdrawal

Table 1 presents the various forms of pretreatment withdrawal (screening dropout, refusing interview or chat, no informed consent) in different age groups. The table indicates that the younger groups showed higher rates of withdrawal than the older ones. Of the 65 applicants who had provided information about their age and were not excluded, the withdrawal was highest (7/8 or 87%) among the age group 14 to 15 years. The group aged 16 to 17 years old showed a withdrawal rate of 75% (12/16), whereas in the oldest group, 22 out of 41 (54%) withdrew before treatment started.

Table 1. Type of withdrawal by age group of applicants who were not excluded

	Age Group					
	14 -15 (n = 8)		16-17 (n = 16)		≥ 18 (n = 41)	
Type of Withdrawal	n	%	n	%	n	%
Screening dropout	5	62%	8	50%	20	49%
No interview	2	25%	1	6%	0	0%
No consent	0	0%	3	19%	2	5%
Total withdrawal	7	87%	12	75%	22	54%
Started baseline	1	12%	4	25%	19	46%

Effects of Treatment

Baseline Characteristics

On average, participants who started treatment were 20 years old (range 14-25, SD 3.5). One participant was younger than 16, four were between 16 and 17 years old, and 19 participants were between 18 and 25 years old. An average of 5 years had passed (SD 4) since the occurrence of the traumatic events.

Outcome

Table 2 presents the averages of the participants on the outcome measures at screening, postcontrol/pretreatment, and at the end of treatment. The table shows large effect sizes for decrease in Invalidation and increase of Strength during treatment, while there were no or only small improvements during the control period. Accordingly, Table 2 shows large *net* effect sizes (difference in effect size between treatment and control) as well for Invalidation, Depression, and Strength. However, the net effect sizes on trauma symptoms as measured by the IES were moderate (d = .5) and not significant (P = .28).

Table 2. Means and standard deviations of outcome measures administered at the screening, at postcontrol period, and at posttreatment, effect sizes d, and t values resulting from the paired t tests of the differences in improvement during control and during treatment

	Screening/ Precontrol n = 24		Postcontrol/ Pretreatment n = 24			Posttreatment n = 24			Test of Difference	
Measure	Mean	SD	Mean	SD	*d*	Mean	SD	*d*	t_{23}	*P*
IES[a]	49.5	9.1	35.7	15.2	1.5	17.5	15.4	2.0	1.1	.28
DEP[b]	43.7	13.3	41.8	12.0	.1	29.3	11.6	.9	3.3	.01
Invalidation	7.0	1.4	6.5	1.1	.4	3.6	1.7	2.0	3.7	.01
Strength	5.2	1.7	5.2	1.6	.0	7.1	1.6	1.1	3.2	.01

[a] IES = Impact of Event Scale

[b] DEP = Depression subscale of the revised Symptom Checklist-90

Overall, from screening to posttreatment, the effect sizes were very high, with Cohen's d varying from d = 1.1 (strength) to 3.5 (trauma symptoms). Regarding the IES, all participants improved. According to the criteria of Jacobson and Truax [36], of the 24 participants, 2 (8%) changed only marginally, 5 (21%)

reported reliable improvement, and 17 (71%) reported scores reflecting a reliable and clinically significant improvement.

Repeated Assessments

Figure 2 shows the process of change during control and treatment by the results of the fortnightly measurements of traumatic stress (IES), Invalidation and Strength. The figure displays the development of the standardized means over time: mean pretest scores were subtracted from the mean score at each measurement occasion and divided by the pretest standard deviation.

Figure 2. Standardized mean change in Impact of Event Scale (IES) scores and single-item assessments of Invalidation and Strength as measured weekly during the screening, the baseline control period (C1-C4), and the treatment period (T1-T4)

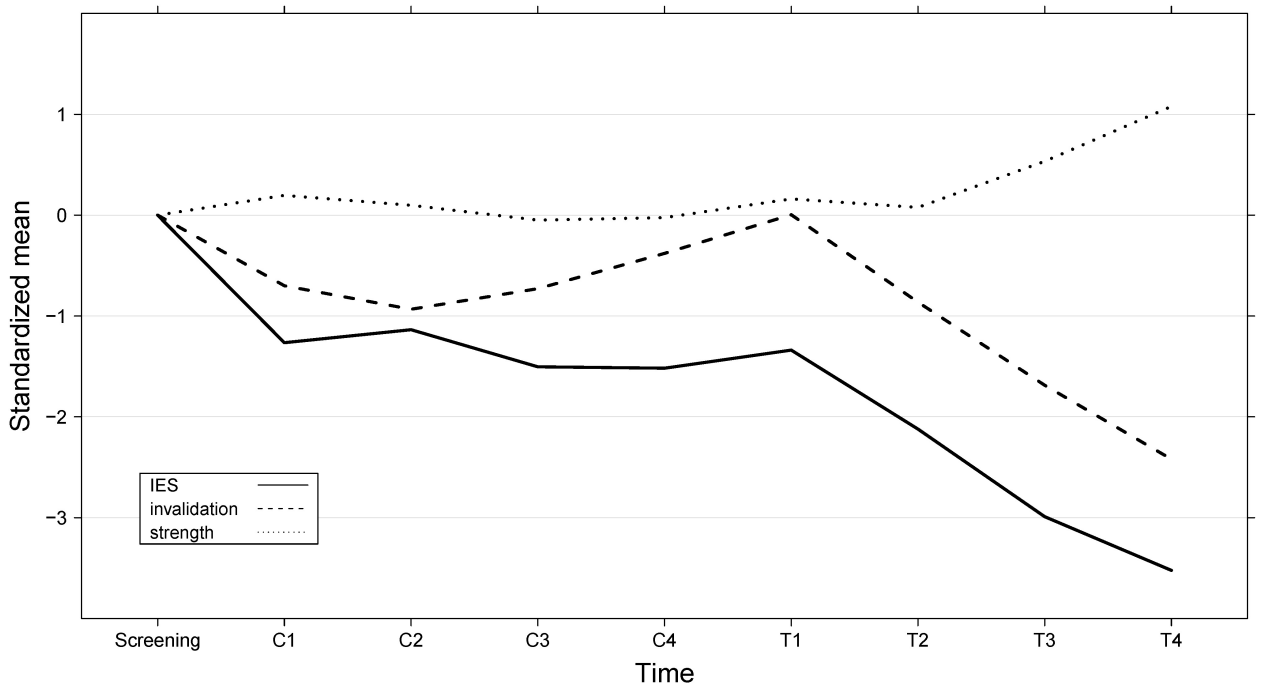


Figure 2 suggests that the large reduction in IES scores in the control period should be attributed to the screening. The screening included many questions that required the participants to focus on their trauma and on their present situations. In combination with the psycho-education and the expectation of the forthcoming treatment, this might have resulted in increases of awareness and hope. This ad hoc explanation is supported by Figure 2. The drop in IES right after the screening is very steep (this decrease represents an effect size of $d = 1.3$). After this, there is no further decrease in the IES scores during the baseline-control. When treatment started, the decrease started again, and persisted, during the whole treatment period.

In exploratory analyses, the change in trauma symptoms during the baseline-control period was again compared with the change during treatment. This time, the IES improvement scores were not calculated on the basis of the measurements taken during the screening but on the basis of the measurements taken at the start of the baseline-control, that is, at C1, the first measurement during the baseline-control period. This resulted in a significant difference between improvements in IES Scores made during treatment and the baseline-control period of $P < .001$, with a net effect of $d = 1.8$.

Client Satisfaction

As shown in Table 3, participants expressed general satisfaction with the treatment and their therapists. Although 22% of the participants did miss face-to-face contact, they were highly satisfied with their therapists, and 91% (21/23) stated that they would recommend the treatment to others. Treatment modules were evaluated favorably, in particular the exposure part of the writing. The new “Body” module, targeting bodily symptoms, received the lowest rating.

Table 3. Client satisfaction with treatment and therapists

Aspect	Response n = 23
Satisfaction with Treatment (scale of 1 to 10)	
Overall, mean (SD)	7.9 (1.3)
Writing/exposure phase, mean (SD)	8.1 (1.3)
Body phase, mean (SD)	6.7 (2.1)
Cognitive reappraisal phase, mean (SD)	7.3 (2.5)
Taking leave/social sharing phase, mean (SD)	6.8 (2.9)
Satisfaction with therapist , mean (SD)	8.6 (1.0)
Missed face-to-face contact, n (%)	5 (22.2%)
Internet therapy is an effective method, n (%)	20 (87%)
Would recommend the treatment to others, n(%)	21 (91%)

Discussion

The first part of the discussion focuses on the outcome of the controlled study for those participants who started treatment. The second part focuses on the pretreatment withdrawal. Finally, we formulate on the basis of our results a set of recommendations regarding the ethical dilemmas concerning the online research into the treatment of young and vulnerable populations.

Effects of Treatment

The data showed strong decreases in posttraumatic stress symptoms, depression, and subjective invalidation, and a strong increase in subjective strength. The tests between improvements in the baseline period and the treatment period were highly significant. The graphs of Invalidation and Strength showed gradual improvements that started after the first module and continued until the end of treatment.

At screening, the average IES score was well above the cutoff score for PTSD, and, at final posttest, the IES score was clearly below the cutoff score. From prebaseline (screening) to posttreatment, reductions in symptoms were significant and very large in terms of effects sizes. Taking these results into account, it is worth considering incorporating the screening and baseline period into the treatment itself. In future randomized trials, the effects of treatment with or without this baseline period should be investigated.

Ratings of the modules were generally high. Surprisingly, the lowest rating was given to the module that was specially generated for this population, psycho-education on somatic symptoms that might occur after sexual abuse. This might have been caused by specific frightening parts of the module comprising monitoring of behaviors including self-harm, obsessive cleanliness, and fear of being touched. Nevertheless, as shown in Figure 2, the relatively low satisfaction with this module did not interrupt the gradual improvements; there are indications that the module might even have given positive incentives to the next module of cognitive reappraisal.

The study is characterized by several strengths. In most experimental studies of the treatment of posttraumatic stress, the measures of the effects are expressed in terms of decrease in trauma symptoms. The present study confirms that treatment effect may also be expressed in the increase in feelings of strength. Our findings support the general suggestion to care providers and researchers to not focus entirely on the reduction of illness behavior, but to also target increase in self-esteem and empowerment [37,38]. Finally, the encouraging messages and repeated measures rendered the control period an attention placebo condition.

The content of the intervention was well established in prior research [6-10] and adapted to this special population in collaboration with an institution that is specialized in treating sexual problems in adults and adolescents. The protocol included many motivational techniques that inspired clients and therapists in bringing about a positive bonding [39-41]. The manner in which the online protocol was implemented allowed for strict control of treatment integrity.

Of course, this study also had its limitations, in addition to the considerable pretreatment withdrawal. First, only one male participated. The underrepresentation of males may be due to the greater incidence of sexual abuse among women. Also, a greater fear of disclosure in male victims may discourage them from seeking treatment [42,43]. We will have to find ways to encourage victimized male adolescents to seek evidence-based help. A second limitation is the absence (at the time of writing this report) of follow-up measurements. The follow-up measures will be ascertained up to one year after the posttest.

Pretreatment Withdrawal

Of the 78 participants who completed all steps in the screening, 49 (62%) had to be excluded, a large proportion of them because the abuse was ongoing within the family or because they were already in treatment elsewhere. This demonstrates the vulnerability of this population.

In the previous study [11], many eligible applicants withdrew before treatment. In the present study, several measures were taken to reduce pretreatment withdrawal. First, the study was designed as an evaluation of treatment rather than an

experimental randomized study. In this design, parental consent was obligatory only for applicants under 16 years of age instead of 18 years. Second, the upper age level for participation in the study was increased from 18 to 25 years. Thus, the population of potential participants who did not require parental consent was expanded. Third, participants were offered the alternative of a structured interview by chat if they were reticent to answer questions on the telephone.

The previous study showed a withdrawal rate of 90%. In the present study, the pretreatment withdrawal rate was 77%, a reduction of 13%: a total of 82 out of 106 applicants, who were not excluded by researchers, withdrew before treatment, while 24 (23%) started treatment. The present withdrawal rate is still high, but we should keep in mind that online treatment studies involving less sensitive populations also show considerable pretreatment withdrawal, varying from 19% to 46%, with an average of 37% [6-10].

The procedures during the screening permitted us to inspect at what stages withdrawal occurred. This inspection revealed that screening withdrawal was strongly associated with the posing of biographic questions. This again suggests that anonymity is probably the decisive factor, especially since the older participants—who did not need parental consent—also withdrew in high numbers when the biographic questions came up. We also learned that the youngest group (aged 14 to 15), who needed parental consent, withdrew nearly totally. Only 1 of the eligible applicants of that group started treatment (6%). The group of 16 to 17 years old did slightly better; 4 (25%) started treatment. The lowest pretreatment withdrawal was found in the oldest group, of which 46% of the eligible applicants started treatment.

Of course, caution is warranted in inspecting these results as they are based on relatively small numbers. But altogether, the data suggest that fear of losing anonymity is important for both young and old participants, whereas the fear of needing parental consent is more or less decisive for the younger age groups. Arranging the study as a treatment evaluation probably permitted the 16 to 18 years olds to participate in somewhat higher numbers since they did not need parental consent. The relatively low withdrawal in the oldest group supports this reasoning as well.

Conclusion and Possible Approaches

Although pretreatment withdrawal occurs in most online treatments, it is worrisome that we are at present unable to reach a greater number of potential participants in the present type of vulnerable population. The measures taken to reduce pretreatment withdrawal seemed to have had some effects, but they were modest. Providing full anonymity is not an option since it is contrary to the professional responsibility of the caregiver, does not allow payment by insurance companies, and restricts research possibilities. However, high pre-treatment dropout should not discourage efforts to treat vulnerable groups. After all, the present study also revealed good adherence: having started the online treatment, few participants dropped out. Furthermore, in the treated group, the positive effects were large. The present procedures and findings should motivate us to find more effective ways of lowering the participation threshold without relaxing the clinical and scientific standards to which we subscribe. Even without the guarantee of anonymity, the following measures may reduce pretreatment withdrawal in so far as it is caused by fear of nonanonymity and the obligation of parental consent.

Loss of Anonymity

Determine which information is minimally necessary to carry out responsible interventions, for example, age, name, insurance details. Providers of health interventions could confine themselves to this minimally necessary information.

Provide information on the homepage about the necessity of gathering these biographic data. The most effective phrasing and timing of this information is an important issue that requires careful consideration.

During the screening, biographic questions should be preceded by an explanation of why each question is asked, and why the answer is optional or obligatory.

If biographic data are asked for scientific reasons only, make sure that clients are informed why the questions are asked and do not oblige them to answer those questions.

Increase the participant's feeling of anonymity. This is especially important for those potential clients who do not need parental consent but are nevertheless reluctant to participate if anonymity is not guaranteed. Anonymity could be enhanced by posing fewer biographical questions. Information concerning actual identity could be requested at later stages in the program.

If parental consent is not needed, make sure that clients are informed that data are not shared with others.

Parental Consent

Seek dispensation regarding parental consent. For example, dispensation could be made conditional on the client's disclosure to specially trained general practitioners [44]. Consent of one of these should then be sufficient to initiate the screening and ultimately start the online treatment. Note that in most countries, this would require a change in the law. Mental health institutions, political, and governmental institutions would have to make a concerted effort to realize the necessary changes to the law.

In countries in which the obligation of parental consent is stricter in research than in evaluation of treatment, one may facilitate participation by designing the study so that it, in effect, satisfies the definition of treatment evaluation.

If possible, consider changing the format from treatment to self-help. The present study comprised a full-fledged therapist-guided online treatment. Completely automated self-help programs might raise less anxiety about loss of anonymity. Many of the content protocols, such as those presented here, could be used in self-help programs. Yet, this option may still leave unresolved some legal and responsibility problems. Furthermore, there is growing evidence that the effects of pure self-help are different from the effects of guided self-help or online treatment [1,45,46].

Final Remarks

We may simply have to accept that even when all measures described above are taken, the chances of encountering relatively high pretreatment withdrawal will remain considerable. Future studies should address this problem and describe the measures that were taken to reduce pretreatment withdrawal and the rates of withdrawal at various stages.

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Conflicts of Interest

Alfred Lange is professor at the University of Amsterdam and scientific advisor to Interapy PLC. Jeroen Ruwaard is a PHD student at the University of Amsterdam and system engineer at Interapy PLC.

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Abbreviations

PTSD: posttraumatic stress disorder
IES: Impact of Event Scale
SPDP: Screening Device for Psychotic Disorder
BMI: body mass index
SCL-90-R DEP: Depression subscale of the revised Symptom Checklist 90

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Original Paper

How Patients With Schizophrenia Use the Internet: Qualitative Study

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Abstract

Background: The Internet is an important source of health information for people with psychiatric conditions. Little is known about the way patients with schizophrenia use the Internet when it comes to issues related to their illness. Data on their specific needs, difficulties, and the consequences related to Internet use are lacking.

Objective: Our objective was to investigate the nature and subjective consequences of health-related Internet use among patients with schizophrenia.

Methods: In all, 26 individual semistructured interviews were conducted and analyzed qualitatively in groups of 4 until theoretical saturation was achieved.

Results: Study results suggest that the Internet is an influential source of illness-related information for patients with schizophrenia. Many aspects of their behavior around the Internet resemble those of individuals not afflicted by mental illness. Importantly, problems specific to patients with schizophrenia were stimulus overflow, an inability to deal with the abundance of information, difficulties with concentration, lack of energy, paranoid ideas, symptom provocation, and the need to distance themselves from illness-related topics as part of the recovery process. Internet information was subjectively perceived as having the potential to significantly change patients' attitudes toward medication and their relationships with doctors.

Conclusions: These findings provide insight into how individuals with schizophrenia handle illness-related Internet information. The data could contribute to the continuous development of Internet-based interventions and offer novel approaches to optimizing traditional treatment options.

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KEYWORDS

Schizophrenia; psychosis; Internet; attitudes; behaviors

Introduction

Private use of the Internet as a source of information is increasing worldwide. Today, in Austria, 70% of households have access to the Internet, and 67% of the general population regularly uses the Web [1-2]. Likewise, the Internet is of growing importance specifically as a source of health information [3]. How it is actually used and the importance attributed to online health information varies among different patient groups, such as cancer, gynecology, or general practice patients [4]. Due to its anonymity and easy access, however, the Internet is a particularly important source of information

and opportunity for peer exchange for those suffering from chronic or stigmatizing conditions [5-6].

A representative survey of the general population in Great Britain found that 18% of all Internet users access information on mental health issues [7], and, as revealed in a survey among psychiatric outpatients in Switzerland, about 68% of those with various mental health problems use the Internet as a source of information related to their diagnosis [8]. A further study of people with a major mental illness in the United States found that about one-third use the Internet and about half of these access health information online [9]. Despite the fact that online health information is of varying quality and readability [10-12], the Internet may exert considerable influence on its users by enhancing coping strategies, empowerment, and self-efficacy; by decreasing the feelings of anxiety and isolation; and by affecting the doctor-patient relationship as well as health-related behaviors and decisions, as has been shown in qualitative and quantitative studies with participants suffering from both common and severe mental illness [3-4,13-15].

Due to their often-marked interpersonal difficulties, people with schizotypal personality disorder have been found to be especially likely to use the Internet, with a particular interest in social interaction on the Web [16]. Similar considerations apply to schizophrenia, given the stigma and the interpersonal communication problems frequently associated with this illness. The resulting social anxiety and retreat may make the Internet a particularly important realm of possibility for this group of patients. However, symptoms of schizophrenia such as attention deficit or delusional interpretations may become a barrier to Internet use, especially since websites containing information on schizophrenia are usually difficult to read, as found in a recent study on patient information for schizophrenia on the Web [11].

These complex preconditions indicate that Internet use related to issues concerning schizophrenia may be associated with certain difficulties, needs, and consequences specific to patients suffering from this illness. However, currently available knowledge on the effects of Internet use on patients has been largely generated in medical fields other than mental health. Psychiatric research in this area has so far focused mainly on depression and anxiety disorders [17-24] or mixed psychiatric patient groups [25]. Some of these studies using a qualitative approach have found, for example, that people with mood disorders increasingly turn to the Internet to make health care decisions, but are also often merely looking for emotional support, sympathy, social companionship, and help with getting through the day [17-18]. At the same time, the Internet offers a stage for pretenders seeking attention by faking illnesses such as depression, and this may have profound negative consequences for patients using online interaction in a spirit of honesty [17]. Cross-sectional quantitative research suggests that user-selectable peer support may actually aggravate psychological burden and thus have the potential to trigger a downward depressive spiral [19]. By the same token, longitudinal quantitative research found that using the Internet for health purposes may be associated with increased depression, attributable to increased rumination, unnecessary alarm, or overattention to health problems and self-selected online health resources [20]. On the other hand, various Web-based interventions, ranging in their focus from self-help to structured professionally led therapies, have been shown to reduce symptoms of depression and anxiety [21-23]. Overall, however, the methodological quality of such intervention studies is low, and high-quality randomized controlled trials are needed to inform the practice of consumers, practitioners, and policy makers [24].

When it comes to severe mental illnesses such as schizophrenia, the impact of the broad availability of illness-related information from the Internet on patients with schizophrenia remains almost entirely unknown. Hence, as a first step, this study aims to uncover the complex and differentiated experiences and insights of people with schizophrenia and the potential subjectively experienced consequences of Internet use on illness-related attitudes, behaviors, and relationships with doctors.

Methods

Sample

Participants were eligible for inclusion if the following criteria applied: (1) diagnosis of schizophrenia or schizoaffective disorder according to *the International Classification of Diseases, Tenth Revision* (*ICD-10*) [26], (2) age 18 to 65, (3) being stable enough to participate in the interview, and (4) current or past use of the Internet. Purposive sampling was used to maximize the likelihood of obtaining a broad range of views. Hence, the target group consisted of people of different age ranges, sociodemographic backgrounds, and varying levels of Internet use overall and for illness-related information or interaction in particular. Participants were recruited from the outpatient department and the day clinic of the Department of Psychiatry and Psychotherapy at the Medical University of Vienna, from community psychiatrists, and Promente, a low threshold community mental health organization that also confirmed the patients' diagnoses. The study was approved by the responsible ethics committee, and all participants gave written informed consent for participation before the interview. A consultant psychiatrist was available during and after the interviews in case a participant might feel burdened or distressed as a result of the interview. None of the participants requested any intervention.

Qualitative Interviews

A semistructured interview style was employed because previous research in other fields suggested a number of areas of interest. Semistructured interviews allowed those areas to be covered while at the same time providing the flexibility to explore emerging themes and individual issues in detail. Accordingly, an interview guide was generated from a literature review, with the initial topics including the extent of Internet use as a means to gain information about the illness; illness-related interaction with others on the Internet; reasons for and against using the Internet for these purposes and consequences thereof; and communication with others about Internet information and its consequences. Questions were open-ended and revised iteratively, allowing for further exploration of new issues raised. For example, the topic of how to personally assess the quality

and reliability of Internet information was introduced by participants and actively explored in subsequent interviews.

In the interviews, participants had the opportunity to extensively talk about their views, attitudes, and experiences. Probes according to the interview guide where used when the participants' narratives came to an end or significantly deviated from the topic of interest. Interviews were conducted at a venue of the participants' choice, which included a quiet room at the outpatient department, cafés, and people's homes. Interviews were conducted by a researcher (author BS) who was not involved in the participants' treatment. Interviews lasted 15 to 60 minutes. All were recorded on audiotape and transcribed verbatim. In addition, data were collected on a number of sociodemographic and illness-related variables.

Data Analysis

For content analysis, QRS NVivo 7 software (QRS International Pty Ltd, Doncaster, Victoria, Australia) was used [27]. In all, 3 researchers (authors BS, IS, and MA) read the first 4 transcripts repeatedly to immerse themselves in the data. They independently separated the data into meaningful fragments identifying emerging themes and labeling them with descriptive codes. The individual coding frames were then compared and discussed until consensus was reached. BS and IS then applied the constant comparison method independently to chunks of 4 further transcripts at a time, applying and refining the coding frame by splitting broad themes into smaller fragments and merging smaller themes into broader categories as appropriate. The independent coding results were compared and discussed regularly, with BS applying the respective refined coding frame to the interviews that had been coded earlier. After 16 interviews had been coded in this way by BS and IS, MA independently coded another 4 interviews and discussed her findings with the other 2 researchers to validate the existing coding frame. All remaining interviews were then independently coded and compared by BS and IS, and ideas about themes and codings were discussed at regular intervals throughout the analysis. Recruitment, data collection, and analysis occurred simultaneously until theoretical saturation was reached.

Specific Methodological Considerations

Repeated comparison and adaptation of the coding among researchers aimed to maximize the credibility of the results; that is, the fit between respondents' views and the researchers' reconstruction of the same. Dependability was ensured by a rigorous and traceable research process with all steps of the analysis being fully documented. Transferability is addressed in this report by providing background characteristics of the individual participants, confirmed by the provision of numerous verbatim quotes (see below), all of which contribute to the study's validity and reliability [27-28].

Results

Characteristics of the Participants

Of the 26 participants whose data were required for theoretical saturation, 14 (54%) were male. The age range of all participants was between 18 and 52 years (mean 33). Sociodemographic characteristics of the participants are displayed in Table 1.

The majority of participants, (20/26 or 77%) reported their main diagnosis to be schizophrenia, while the remaining 23% (6/26) reported schizoaffective disorder. For all participants, the age at first onset of illness was between 11 and 44 years (mean 22). All but 2 participants had been hospitalized at least once.

Table 1. Sociodemographic characteristics of the study participants

Characteristic	(n = 26)	%
Gender		
Male	14	54
Female	12	46
Marital status		
Single	16	62
Partnership/married	6	23
Separated/divorced	4	15
Employement status		
Unemployment benefit	4	15
Social welfare benefit	1	4
Student	3	12
Disability pension	11	42
Employed (including sick leave)	5	19
other	2	8
Living situation		
Own household (with partner/family)	9	35
Own household (alone)	9	35
Flat share	2	8
Parents' household	3	12
Supported housing	3	12
Education (highest level completed)		
No formal education	1	4
Compulsory schooling[a]	5	19
Primary education[a]	7	27
Secondary education (including college and university)[b]	13	50

[a] Different streams of basic education

[b] Beginning at age 18 or 19

Internet Use

General Internet use ranged from sporadic to several hours a day. Of all participants, 15 reported use of the Internet on a daily basis, 8 reported regular use, and 3 reported that they used the Internet only rarely. Of the 26 participants, 22 reported having searched for illness-related information on the Web. Of these, 5 regularly used the Internet for illness-related issues, while 17 did so occasionally. In addition, 14 had used chat rooms or networking sites; 5 had exchanged illness-related information there. Favored online sources were common search engines, Internet encyclopedias, and service-related websites.

Thematic Analysis

We found that 7 key themes emerged from the data: (1) specific topics of interest on the Web, (2) reasons for and against using the Internet as a source of illness-related information, (3) subjectively perceived effects of information from the Internet, (4) communication with doctors about Internet content, (5) interaction about the illness on the Internet, (6) reliability and quality of Internet information, and (7) wishes and suggestions for improvement. All themes are outlined below together with some essential quotes. Additional quotes to support the results can be found in Multimedia Appendix 1. The emerging themes are summarized in Table 2 together with the number of participants talking about each topic and the total number of quotes coded within each category.

Table 2. Codes applied, number of people quoting the respective topic, and number of quotations within each category

Key Themes	Number of Participants	Number of Quotes
Specific topics of interest on the Web		
Unspecific illness-related information	15	35
Medication and side effects	14	43
Diagnosis/symptomatology	14	18
Services provided	13	21
Risk factors and illness causes	6	10
Prognosis and course of illness	5	6
Reasons for and against using the Internet as a source of illness-related information		
Reasons for using the Internet for illness-related information	22	69
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Specific Topics of Interest on the Web

Frequently, interviewees reported having looked for general information with some association to their illness, and they often had problems defining the issues they had been interested in more precisely.

Medication was among the most frequently searched issues. Requests dealt with general information, for example, that lithium is a salt or the definition of generic drugs as well as personally relevant information such as side effects. The Internet was used to check whether side effects experienced were attributable to specific medication in the hope of finding better medication with fewer side effects.

> *If somehow something new is on the market now again, if there is a new class that has no side effects at all...* [Patient #26, male, age 35, schizophrenia since age 16]

Participants were conflicted between interest in the topic and the fear of finding out more about potential side effects. Many did not want to know too much about their medication and reported that they preferred relying on their doctors.

> *And then I am afraid, because I don't like to take medication that gives me cardiac death or apoplexy or stroke and there is a higher risk for diabetes as well.* [Patient #4, female, age 35, schizophrenia since age 10]

Another important interest pertained to diagnostic criteria, symptomatic categories, and statistics, mainly to define one's own illness and to verify one's diagnosis.

Interviewees also talked about their Web searches for a variety of services, which they had conducted mainly to help them find a suitable facility or to better evaluate services before deciding to use them. Overall, they felt that such information reduced the barrier to actually accessing psychiatric help.

> *I mainly wanted to know about the outpatient clinic, like what the opening hours are, when you can be admitted, or when you can speak to a doctor. So in the end, that's exactly why I actually came here [to the outpatient department], because I found it fairly quickly [on the Internet]…here, it's not really a problem to speak to a doctor.* [Patient #24, male, age 29, schizophrenia since age 2]

When it comes to risk factors and illness causes, some potential psychosocial causes were mentioned (especially stress or predisposing personality factors), but, overall, biological illness models prevailed, especially drugs and assumed genetic and biochemical causes. These biological explanatory factors appeared to provide relief in dealing with the illness. Only a few participants remembered that they had read about prognosis and the likelihood of recovery, and, overall, such information was regarded as rather delicate.

Reasons for Using the Internet to Find Illness-Related Information

Apart from general advantages such as easy access, speed, and the broad spectrum of information, illness-related motives for using the Internet also became apparent. These included the anonymity and absence of hierarchy on the Web, which we found to be associated with a lower perceived threshold to accessing information and with gaining confidence for overcoming problems with social interaction.

> *Another advantage is that, that the Internet has a flat shape, that it is accessible to all of society.* [Patient #19, male, age 44, schizophrenia since age 23]

Apart from positive incentives for Internet use such as anonymity and egalitarianism, negative incentives could also be identified, including dissatisfaction with therapy, problems communicating with the doctor, and the opportunity to find individually suitable answers.

> *It's also a source of information for people that are just starting on antipsychotics and who perhaps don't get the information they want from their doctor, and it gives you the feeling that you got all the information.* [Patient #4, female, age 35, schizophrenia since age 10]

Reasons Against Using the Internet to Find Illness-Related Information

General reasons cited by interviewees against using the Internet to find illness-related information were lack of access to a computer, financial problems, difficulties using technology, fear of computer viruses, fear of Internet addiction, preference for other sources of information, and the expectation of low quality of Internet information. Further important reasons were that the demand for information had already been satisfied, lack of interest, and the wish to rely on a doctor.

> *I don't know, I somehow don't believe that using the Internet can help. I trust my doctor.* [Patient #25, male, age 26, schizophrenia since age 6]

The prominent illness-related reasons against Internet use were stimulus overflow and the inability to deal with the abundance of information, problems with concentration, lack of energy and depressive symptoms, paranoid ideas and fear of symptom provocation, and the wish to distance oneself from illness-related topics as part of the recovery process.

> *…that it is overstressing, that the inconsistencies within the information are strongest on the Internet…when you have too many opinions, you are lost in psychosis.* [Patient #11, female, age 43, schizoaffective disorder since age 19]

> *I try to get over that on my own, and I don't want all this influence…I want to deal with things the way I want and not be blinded by some Internet report.* [Patient #15, male, age 30, schizoaffective disorder since age 11]

> *And this is also a part of my illness, well, a part of my recovery to distance myself a little from that.* [Patient #12, female, age 35, schizophrenia since age 12]

Subjectively Perceived Effects of Information From the Internet

Positive Effects

Overall, positive effects may best be summarized as supporting empowerment by getting knowledge and improving access. Specifically, Internet information was considered to help patients better understand themselves and the illness, providing clarification and orientation.

> *It [illness-related information on the Internet] has simply clarified a lot. And it was important for me to see how other people deal with it [schizophrenia] and how I could perhaps deal with it.* [Patient #18, male, age 26, schizophrenia since age 8]

The possibility to anonymously tell one's own story and to discover that other people reported similar experiences was perceived as a relief. This applied to direct exchange with others, for example, in chat rooms but also applied to the simple finding and reading of illness-related information.

> *…that I have the feeling not to be alone with the problems I have.* [Patient #20, male, age 52, schizoaffective disorder since age 22]

Information in itself had a reassuring effect, reducing fears (eg, of becoming addicted to medication) and helping to better integrate one's situation and redefine one's identity.

> *The positive thing is, about the information, in principle, that you don't get stuck in this "okay, now I'm nuts," but that this is a disorder…there are biochemical causes and everything is quite simple in my opinion.* [Patient #8, female, age 34, schizophrenia since age 5]

Negative Effects

Negative experiences were the provocation or aggravation of symptoms and aversive emotional responses, especially fear, sadness, and hopelessness, for example, in relation to dramatic illness stories.

> *You can get Internet-induced psychosis from that [searching for illness-related information on the Internet]; you can simply freak out.* [Patient #9, female, age 46, schizoaffective disorder since age 26]

> *A negative effect was that you become scared, there is a lot more, ahem, there are not enough success stories on the Web, I'd say, and you get a lot of negative things.* [Patient #8, female, age 34, schizophrenia since age 5]

Effects on Behavior and Attitudes

Internet information was found to have the potential to stimulate changes in behavior or attitudes. These were positive in most cases, for example, better coping strategies or lower thresholds for seeking help.

> *To better cope with the illness and avoid situations, like drugs, for example, or excessive stress, or that you simply learn to take better care of yourself.* [Patient #18, male, age 26, schizophrenia since age 8]

Negative effects on attitudes referred mainly to medication. Specifically, Internet information was described as leading to a more critical attitude toward one's own medication.

> *If you read all that, you can't take the meds anymore anyway, because they have more side effects than they have main effects.* [Patient #11, female, age 43, schizoaffective disorder since age 19]

Communication With Doctors About Internet Information

Reasons not to talk to doctors about information from the Web were numerous. Among the most important fears were that doctors could feel criticized or have an unchangeable preconceived view and it wouldn't be worth discussing things anyway.

Information from the Internet had the potential to significantly change the relationship with the attending doctors, with the most important aspect being a shift of the subjectively perceived hierarchy.

> *Well, that it is not such a downhill grade anymore, where he [the doctor] has the information about everything and I am there being fed by him and don't really know why and what I am getting something for and what effects that can have and so on. This downhill grade is something that I have managed to level out, in terms of having power and becoming assertive as a patient.* [Patient #20, male, age 52, schizoaffective disorder since age 22]

The way doctors' reactions were read by patients when talking about Internet information mainly depended on the quality of the patient-doctor relationship. In a good relationship, reactions were mostly judged as positive even when the doctor's reply was evasive or even openly critical of the Internet search.

> *Yes, she [the doctor] said there are so-called hypochondriacs who extensively surf the Web and imagine all kinds of illnesses and so on and that I should be careful with this kind of information. Yeah, and then I somehow thought she is right. I really don't need to read all kinds of rubbish that doesn't even affect me…* [Patient #7, female, age 38, schizophrenia since 19 years]

Occasionally patients felt left with uncertainty, doubt, and disappointment, for example, when the conversation did not lead to a satisfactory explanation or desired change. One interviewee recounted having found a new drug on the Internet not yet known to his doctor. While trying to avoid interpreting this incidence in the interview, the frustration it caused was obvious.

> *Yes, basically I am content with [my doctor], well, except for this one time, when he didn't know that [the new medication]… if that is their specialist area they have to know about it, otherwise they can't attend to patients.* [Patient #26, male, age 35, schizophrenia since age16]

Interaction With Others About the Illness on the Internet

In all, 5 interviewees reported exchange of information with other people about the illness on the Web. All stressed the advantage of not being confronted with insecurities in personal contact and appreciated the special content of the information gathered in this way.

> *People who really have someone in their family who has exactly the same illness, or who have it themselves, I think the things they can tell you are more interesting than when you ask the doctor.* [Patient #7, female, age 38, schizophrenia since age 19]

The illness-related interaction on the Web was assessed positively throughout. Overall, 3 major effects were found: self-help or mutual help in coping with the illness, boosting self-esteem and self-validation through helping others, and reassurance through sharing one's story.

> *It is also about taking care of each other: How are you? How am I? What advice can I give you when you are unwell? Yes, and through that exchange you learn to deal with your illness and avoid situations that are bad, for example.* [Patient #18, male, age 26, schizophrenia since age 8]

Participants who had never used the Internet for illness-related exchange talked about their reasons against it. Relevant obstacles were, again, problems with technology but also illness-related apprehensions, especially fear of becoming addicted, distrust of unknown people, and the necessity to protect oneself against other people's illness stories.

> *I think I would be very careful there, because I don't know if that is a private person who's logged in there,*

> *I mean, I don't know if you can believe everything people write.* [Patient #7, female, age 38, schizophrenia since age 19]

> *Yes, there are also funny psychoses, but I think they are the minority, and most things people are experiencing are really dramatic, and I want to protect myself against that a little.* [Patient #8, female, age 34, schizophrenia since 5 years]

Reliability and Quality of Internet Information

Information was described as interesting, rational, good, and credible but also as superficial, trivial, incorrect, of lesser quality, and bad, and even when information was perceived as satisfactory overall, often some skepticism remained about its quality and credibility.

Even though several interviewees had never thought about the reliability of Internet information, most were able to comment on potential strategies to assess its credibility. Often, the judgment was a personal, emotional, or intuitive decision that had to do with a "generally reputable impression" of a given Web page on which nothing should appear "strange" or that should not contain "flashy advertisements." A further technique was to determine the provider, with more credibility being attributed to "official pages," such as universities or magazines than to "private pages" or chat rooms.

> *You have to check the sender; I mean if that is a medical university, for example, or just someone and you don't know who it is. I think that way you can differentiate very easily what is serious or professional and what isn't.* [Patient #20, male, age 52, schizoaffective disorder since age 22]

Others evaluated the information according to its perceived comprehensibility, usefulness, and transparency. Comparison with one's own experiences was another strategy, and congruency resulted in trust.

> *…I have my own lived experience, and I can agree with that or not.* [Patient #3, female, age 25, schizophrenia since age 9]

The appraisal by doctors, family, and friends also helped interviewees to form an opinion. Finally, technical features such as cookies, spyware, or the virus scan activation were mentioned as indicators of poor quality.

Wishes and Suggestions for Improvement

Attributes of information wished for were that the information should be clear, objective, scientific, and actively destigmatizing. There was a demand for more reflected viewpoints of users and positive case histories, as well as more education about drugs such as cannabis.

> *…you are most satisfied as a patient when you get really scientific explanations; that helps.* [Patient #7, female, age 38, schizophrenia since age 19]

> *[I would like] more positive case histories because actually you never read, for example, about people who managed to live completely normal lives again.* [Patient #8, female, age 34, schizophrenia since age 5]

One of the wishes was for doctors to recommend good Internet sites and talk more about information obtained from the Web. Another suggestion was that doctors should explain on the Internet how they usually communicate with patients and that patients should be able to ask doctors specific questions directly on the Web.

Discussion

Parallels With the General Population

The participants in this study stated that they value the same advantages of the Internet that the general population values, notably, the easy and quick access, the broad spectrum of available information, and the anonymity of Internet use [3,29]. Strategies described for searching for information and assessing its quality also closely resembled those of the average Internet user [3]. Although the assessment of content was largely based on intuition and not restricted to specific indicators of quality, most interviewees reported personal strategies for assessing the quality and reliability of information. Similar to the general population, they were often concerned about the quality of content on the Internet, which, however, did not prevent them from using it [3,29].

Similarly, a number of arguments against Internet use for illness-related information that have been made by the general population were also made by the participants in the study. Among these were problems with technology or expectations of poor quality but also having sufficient information through other sources or preferences for direct personal information from professionals [3,30].

Parallels With Other Patient Groups

While reasons against using the Internet were a prominent topic throughout the interviews and a lot of skepticism was expressed toward Internet contents, the Internet was still described as an influential source of illness-related information. Similar to patients with other diagnoses such as pain, interviewees reported that frequently sought information included diagnosis, medication, and specific services and that forums or chat sites were infrequently visited [31]. Retrieved information was perceived as helpful for better understanding oneself and the illness, as has been shown among people with poor health status in general [6,15]. Gaining the knowledge of not being the only person affected and anonymously learning how others deal with problems was a source of relief, and online health information in general led to a reduction of barriers to seeking professional help [5-6]. However, for the participants in our study, the retrieved information, especially dramatic illness stories, was also frequently perceived as disturbing, causing sadness, despair, and hopelessness or worsening the attitude toward medication.

As has been shown in studies involving people with somatic conditions [15,31-32], participants reported that they rarely spoke to their doctors about the results of their Internet searches, partly due to the fear that the doctors might feel criticized. However, Internet information increased participants' confidence to talk to their physicians about concerns [15], and

talking to their physicians about illness-related information from the Web facilitated an improvement in their relationships with their physicians [15,33]. For patients with schizophrenia in our study, a particularly important change was the perceived shift in the hierarchy to a more equal relationship. At the same time, a certain frustration and resignation concerning doctor-patient communication became apparent, especially when questions were not answered properly or did not result in a change of treatment.

Psychosis Specific Issues

Among the specific illness-related reasons for using the Internet elucidated in this study were the anonymity and absence of hierarchy on the Internet, which has similarly been found among healthy individuals [29] but especially among people with chronic and stigmatizing conditions [5-6]. In this respect, a specific advantage for patients with psychosis, who often have pronounced fears and uncertainties in social interaction, was not having to face another person but still being able to gain information and interact with others without feeling devalued or unsafe. However, while a different study showed that people with schizotypal personality disorder specifically value information exchange connected with social interaction on the Web [16], our participants with schizophrenia attached higher importance to general information displayed on the Web and were rather skeptical about information from forums or chats. Another specific advantage for patients with schizophrenia was the opportunity to find idiosyncratic explanations and meaningful ways to express themselves in the context of the illness, for example, by accessing, producing, and combining pictures, music, and text from diverse sources.

Knowledge of specific illness-related problems or arguments against using the Internet among this patient group was one of the most significant findings of this study. Problems that were expressed included stimulus overflow and inability to deal with the abundance of information, difficulties with concentration during psychosis, lack of energy, paranoid ideas and fear of symptom provocation, and the necessity to distance oneself from illness-related topics as part of the recovery process. Participants also mentioned the possibility of an overabundance of information. It became evident that patients with schizophrenia may perceive only a certain amount of information as reasonable and feel the need to guard themselves against excess information. Overall, there was some ambivalence regarding the need for information and a struggle to achieve a subjectively adequate distance from illness-related topics and from other people with the same disorder and their stories.

Limitations

The percentage of participants with secondary education shows that a large proportion of our sample was well educated. Given the diverse sample that was recruited not only from the university hospital but also from community psychiatrists and a low threshold community mental health organization, this may reflect the fact that among people with schizophrenia, those with higher education are more likely to use the Internet, as has also been shown for the general population and people with other disorders [8-9,15,34]. Moreover, people with higher education may simply be more inclined to participate in research.

Some of the participants referred to Internet use that had occurred long ago. This may have been especially true for those who were facing problems with the Internet leading to reduced Internet use. Hence, in these participants a memory bias may have impaired the recall of experiences with the Internet.

Implications

The results of our study clearly show that the Internet is an important and influential source of information for patients with schizophrenia. Those who participated in our study wished for more communication with their doctors about information they have retrieved from the Internet. Research in different medical disciplines, however, shows that doctors only rarely integrate the Internet into their daily routine [4,35]. Such integration of the Internet into consultations was not only an explicit wish of the interviewees in our study, it also seems especially important for patients with schizophrenia given their specific problems with Internet use. Whether this increased wish for communication applies to patients with different background characteristics such as lower education remains to be investigated in larger quantitative studies.

Given the potential for change in health care utilization behavior or in attitudes toward treatments and doctors, patients' Internet use may also have an indirect impact on mental health professionals which health professionals should be aware of in their general practice. Since this qualitative study revealed effects subjectively perceived by participants, the results can serve to generate informed hypotheses, while quantitative and prospective studies in particular are needed to empirically establish the potential effects of illness-related Internet use. Our study may also provide a basis for the development of a questionnaire as a foundation for the quantitative investigation of Internet use and its consequences among patients with schizophrenia.

Moreover, in recent years there has been an increasing tendency to use information technology, including the Internet, for patient education and therapeutic interventions for people with psychotic disorders [36-38]. In the design of such interventions, the specific problems, needs, and consequences of Internet use for people with schizophrenia should be carefully considered. Our study creates a first empirical basis to inform the continuous development of Internet-based interventions for this population.

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Conflicts of Interest

None declared

Multimedia Appendix 1

Additional quotes to support the study results

[PDF file (Adobe PDF), 70 KB - jmir_v12i5e70_app1.pdf]

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Abbreviations

ICD-10: International Classification of Diseases, Tenth Revision

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Original Paper

Content and Functionality of Alcohol and Other Drug Websites: Results of an Online Survey

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Abstract

Background: There is a growing trend for individuals to seek health information from online sources. Alcohol and other drug (AOD) use is a significant health problem worldwide, but access and use of AOD websites is poorly understood.

Objective: To investigate content and functionality preferences for AOD and other health websites.

Methods: An anonymous online survey examined general Internet and AOD-specific usage and search behaviors, valued features of AOD and health-related websites (general and interactive website features), indicators of website trustworthiness, valued AOD website tools or functions, and treatment modality preferences.

Results: Surveys were obtained from 1214 drug (n = 766) and alcohol website users (n = 448) (mean age 26.2 years, range 16-70). There were no significant differences between alcohol and drug groups on demographic variables, Internet usage, indicators of website trustworthiness, or on preferences for AOD website functionality. A robust website design/navigation, open access, and validated content provision were highly valued by both groups. While attractiveness and pictures or graphics were also valued, high-cost features (videos, animations, games) were minority preferences. Almost half of respondents in both groups were unable to readily access the information they sought. Alcohol website users placed greater importance on several AOD website tools and functions than did those accessing other drug websites: online screening tools (χ^2_2 = 15.8, P < .001, n = 985); prevention programs (χ^2_2 = 27.5, P < .001, n = 981); tracking functions (χ^2_2 = 11.5, P = .003, n = 983); self help treatment programs (χ^2_2 = 8.3, P = .02, n = 984); downloadable fact sheets for friends (χ^2_2 = 11.6, P = .003, n = 981); or family (χ^2_2 = 12.7, P = .002, n = 983). The most preferred online treatment option for both the user groups was an Internet site with email therapist support. Explorations of demographic differences were also performed. While gender did not affect survey responses, younger respondents were more likely to value interactive and social networking features, whereas downloading of credible information was most highly valued by older respondents.

Conclusions: Significant deficiencies in the provision of accessible information on AOD websites were identified, an important problem since information seeking was the most common reason for accessing these websites, and, therefore, may be a key avenue for engaging website users in behaviour change. The few differences between AOD website users suggested that both types of websites may have similar features, although alcohol website users may more readily be engaged in screening, prevention and self-help programs, tracking change, and may value fact sheets more highly. While the sociodemographic differences require replication and clarification, these differences support the notion that the design and features of AOD websites should target specific audiences to have maximal impact.

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KEYWORDS

Alcohol; drugs; Internet; online survey; stress; health; website interactivity; website trustworthiness; Web-based interventions

Introduction

It is estimated that over a quarter of the world's population use the Internet [1] and that 75% of Internet users have searched for health or medical information on the Web [2]. While the health sector has primarily employed the Internet as a psycho-educational portal, advances in interactive technology have increased the potential of the medium to be used to deliver targeted health interventions and other behavior change programs [3].

While there is a growing trend to use the Internet to deliver alcohol and other drug (AOD) information and resources, little is known as to how best engage "at-risk" populations, such as young people, or how to optimize its access and utilization. Given the appeal of the Internet to young people [4,5] and that this is a group that frequently engages in problematic drinking and does not typically access standard AOD services, targeted programs on the Internet may be a medium that could be employed to great effect in this area.

Much of the published literature concerning online AOD interventions is descriptive [6], providing only general information on program evolution, application, and usage [eg, 5,7-11]. Overall, the findings have underscored the scope and access this medium can offer relating to AOD information, as well as the potential of the Internet for the dissemination of screening, assessment, and intervention programs. Some studies [eg, 10,11] have found that individuals unconstrained by geographic location, access Internet-based AOD information and resources in numbers that would overwhelm a traditional face-to-face health service. For example, a naturalistic Internet-based tobacco cessation study by Saul et al [9] reported that in 2 months 100,000 people visited the program website and over 23,000 registered with the program. A study by Linke et al [12] reported an average of 1039 visits per month to the "Down Your Drink" website drawn from over 41 countries. Furthermore, Internet-available information and services appeal to diverse populations including women and young people, who do not necessarily access standard face-to-face AOD services. For example, Koski-Jännes et al [13] found that 61% of those who accessed the "Drinking Habit Test" were women.

In relation to the reasons for use of online AOD resources and materials, out-of-hours availability has been found to be important [5,14]. Other reasons for use of online AOD resources include ease of access to a computer, the anonymity and privacy afforded by the medium, and not having to attend face-to-face meetings [14]. However, Internet programs that require repeated access or extended periods of engagement on the site experience high dropout rates [5,15].

Research into how people search and engage with health websites suggests that the typical user explores only the first few links on a search engine and assesses website credibility by the source of the information cited on the Web page and the professionalism of the website program design [16]. Eysenbach and Köhler [16] noted that in observational studies, Internet users rarely checked the "about us" sections of websites, investigated who the authors or owners of the site were, or read disclaimers or disclosure statements. Perhaps even more telling was the finding that very few Internet users remembered which websites they had retrieved information from or who had developed the sites [16].

The way in which the information is presented can mediate the duration and frequency of visits to a website. For example, the website itself, along with the navigation configuration, needs to be attractive and easy to use [17,18]. Less structured websites do not hold visitors, and websites that do not change over time attract fewer repeat visits [19]. Individuals have been found to be more likely to stay longer at sites that provided personalized feedback as well as relevant and reliable information [18].

While general Internet health access and usage is an important starting point for AOD website design, currently there is a lack of information on users' knowledge, experience, and opinions of AOD websites. There is a need to gain an understanding of site users' preferences and perceived gaps or deficiencies of existing sites if this medium is to be of optimal value as an AOD health promotion, prevention, and intervention tool. The aim of the current study was to address this gap in the existing research and investigate the experiences of AOD website users and their views about the content, functionality, and utility of these websites.

Methods

An open-access online survey was developed to examine Internet use and opinions of AOD and health-related websites. The current paper focuses on results relating to AOD websites only.

Development of Survey Themes and Specific Questions and Pretesting

Initial development of the survey involved face-to-face, teleconference, and email discussion between members of the research team in order to formulate the themes and specific questions. The draft survey was submitted to the project advisory group, consisting of government and nongovernment AOD, youth, and primary care representatives, for review and comment. The final survey explored the following themes:

1. General Internet usage
2. AOD website Internet usage and search behaviours
3. Most-visited AOD websites
4. General website features
5. Interactive website features
6. Judging website trustworthiness
7. Preferences regarding AOD websites tools and functions
8. Preferences for AOD online treatment modalities and support

The survey was pilot tested online (via Survey Monkey) by members of the research team and several independent community members. Usability and functionality were improved prior to online administration.

Online Survey Design and Administration

Adaptive questioning features were employed to avoid survey respondents having to answer unnecessary questions. The presented questions, therefore, depended on answers to prior questions (eg, if respondents had never visited an AOD website, they were not asked further questions about theses websites). There were no more than four questions to a Web page (averaging two questions per page), spanning a potential 84 Web pages. Although there were 188 questions in the total survey, the adaptive questioning procedures meant that the maximum number of questions presented to a respondent was 118. All questions were forced choice, that is, to proceed to the next Web page, all responses to all questions on the preceding page were required. As there was no “back” button offered, respondents could not change answers on previous Web pages. Survey Monkey captured question responses automatically and placed them into an electronic database (Excel) that could only be accessed by the account creator.

Consent Process and Advertising

The survey was voluntary, anonymous, and took 10 to 15 minutes to complete. Upon entry to the survey home Web page, respondents were provided with an explanatory statement outlining the study (eg, purpose of the study, funding source, name of the chief investigator, length of survey, data storage, and ethics committee approval) and were asked to provide online informed consent prior to accessing the survey questions. Respondents were also offered the chance to enter a draw to win an 8GB iPod Nano for completing the survey if they provided their name and an email address. Respondents were informed that identifying information would be stored separately from their survey data. Survey data was collected in a one-month time frame (March-April 2009). Ethics approval was obtained from the Queensland University of Technology Human Ethics Research Committee.

The survey and Web link was advertised via Facebook, AOD and health-related websites, and a range of industry, consumer, and tertiary institutional email lists. A copy of the survey announcement can be found in Multimedia Appendix 1.

Results

Response Rate

To be eligible to participate, respondents were required to be an Australian resident and at least 16 years old. (Ages of respondents ranged from 16 to 70 years.) Of the 3313 people who accessed the survey, 305 were excluded for the following reasons: discontinuation at the information statement (n = 11); failure to give consent (n = 124); not responding to any survey questions (n = 167); resided overseas (n = 2); and being under 16 years of age (n = 1). Of 3008 respondents, 1794 had visited health-related websites but had not previously visited an AOD website. These respondents were therefore not included in the analyses reported in this paper. The remaining 1214 respondents had endorsed visiting either an alcohol website (448/1214, 36.9%) or a drug website (766/1214, 63.1%), were unique visitors (based on their IP addresses), and had responded to at least one survey question. The majority completed the entire survey (882/1214, 72.7%).

Demographic Information

Table 1 provides demographic data for the drug and alcohol website user groups.

Table 1. Percentages and n values for gender, education, relationship status, employment status, English as a first language, and age of drug website users and alcohol website users

Demographic Variable	Type of Website Accessed					
	Drug Website Users			Alcohol Website Users		
	%	n		%	n	N
Gender						
Male	35	193	32.4	108	34	301
Female	65	359	67.6	225	66	584
Completed secondary education	91.5	505	92.2	307	91.8	812
Level of tertiary education						
None	7.8	43	6.3	21	7.2	64
Apprenticeship/trade	1.6	9	1.5	5	1.6	14
Other certificate	3.1	17	3.9	13	3.4	30
Diploma	5.3	29	3.6	12	4.6	41
Current undergraduate	57.8	319	59.6	198	58.5	517
Completed undergraduate	12.7	70	11.7	39	12.3	109
Current postgraduate	1.3	7	0.9	3	1.1	10
Completed postgraduate	10.1	56	12.3	41	11.0	97
Other	0.4	2	0	0	0.2	2
Relationship status						
Single	46.4	225	49.1	163	47.4	418
Married/cohabitating with partner	28.4	156	26.2	87	27.6	243
In relationship, not cohabitating	23.3	128	22.9	76	23.1	204
Divorced/separated and single	1.8	10	1.8	6	1.8	16
Widowed and single	0.2	1	0	0	0.1	1
Employment status						
Employed full-time	18.3	101	20.8	69	19.3	170
Employed part-time/casual	53	292	52.1	173	52.7	465
Home duties	2.4	13	2.4	8	2.4	21
Disability support	0.4	2	0.6	2	0.5	4
Unemployed	12	66	10.2	34	11.3	100
Retired	0.2	1	0.6	2	0.3	3
Student	10.5	58	10.2	34	10.4	92
Student and working	2.2	12	2.1	7	2.2	19
Self-employed	0.7	4	0.6	2	0.7	6
Other	0.4	2	0.3	1	0.3	3
English as a first language	85.3	469	88.3	293	86.4	762
Age category						
16-24	65.9	405	63.3	228	64.9	633
25-33	17.6	108	18.1	65	17.7	173
34-43	6.5	40	8.3	30	7.2	70
44-52	7.3	45	6.1	22	6.9	67
53-61	1.6	10	3.1	11	2.2	21
62-70	1.1	7	1.1	4	1.1	11

There were no significant differences between the alcohol website users and the drug website users on any demographic variable: gender (Fisher exact test $\chi^2_1 = 0.6$, $P = .46$, n = 885); education ($\chi^2_9 = 4.9$, $P = .80$, n = 884); relationship status ($\chi^2_4 = 1.3$, $P = .86$, n = 882); employment status ($\chi^2_9 = 2.7$, $P = .98$, n = 883); English as a first language (Fisher exact test $\chi^2_1 = 1.6$, $P = .23$, n = 882); age category ($\chi^2_5 = 3.95$, $P = .56$, n = 975). There was also no difference in the mean ages in years of the users of the alcohol website (26.3, SD 10.4) and the users of the drug website (26.0, SD 9.9) ($t_{1,973} = .205$, $P = .65$). The median age of both the alcohol and drug groups was 22.0 years.

General Internet Usage

Drug and alcohol website users reported primarily accessing the Internet from home (959/1214, 79.4%) or at university, school, or work (232/1214, 18.7%), via cable broadband (306/1214, 39.9%), ADSL (243/1214, 20.0%), or ADSL2 (185/1214, 24.2%). Respondents commonly accessed the Internet daily (1178/1214, 97.0%) and were typically online for periods ranging from 5 to 30 minutes (217/1214, 17.9%), 30 to 60 minutes (316/1214, 26.0%), 1 to 2 hours (315/1214, 25.9%), or 2 or more hours (366/1214, 30.1%). Daily online activities were email (1060/1209, 87.7%), social networking, (eg, Facebook and MySpace) (688/1203, 57.2%), news (574/1197, 48%), and random "surfing" (506/1200, 42.2%). Over 90% (1112/1214, 91.6%) said they felt comfortable/confident when using the Internet. There were no significant differences between the alcohol and drug website user groups on any of these general Internet usage variables.

Alcohol and Other Drug Websites Usage and Search Behaviours

Most respondents found the websites via search engines (610/766 or 79.6% of drug website users and 341/448 or 76.1% of alcohol website users). Both groups were primarily interested in finding information about effects of the substance used (688/740 or 93.0% of drug group and 307/421 or 72.9% of alcohol group).

When respondents chose to specify the information they looked for on websites, 74 drug website users reported searching for information on the chemical composition of drugs, firsthand drug user accounts, why people used drugs, health risks and side effects of using drugs, harm minimization strategies, referral links to supports, online assessment, self-help programs, general usage statistics, or drug sentencing laws. The responses of 60 alcohol website users stated that they were looking for information about standard drinks, alcohol content in cocktails and safe drinking limits, alcohol use in pregnancy, alcohol and violence, effects of combining drugs and alcohol, short and long term health issues associated with drinking, hangover cures, relapse prevention information, or reasons why people drink.

Finding the desired information appeared to be difficult for respondents searching alcohol websites. Rating the success of their search on a 3-point scale (yes, somewhat, no), almost half (211/431, 49%) reported they were only somewhat successful in finding what they wanted, and only 47.3% (204/431) said they did find it. Percentages for respondents searching drug-related websites were similar (348/745, 46.7% somewhat; 392/745, 52.6% yes). Just over half of respondents in the drug group (408/736, 55.4%) and alcohol group (232/414, 56.0%) reported being able to source information they wanted within 5 to 15 minutes.

Most Visited Alcohol and Other Drug Websites

AOD website users were presented with 14 AOD websites (see Multimedia Appendix 2 for AOD website list). They were asked if they had visited each site, and if so, were asked to rate how easy it was to use, its attractiveness, and trustworthiness as very, somewhat, or not at all. The two most visited AOD websites across groups were the Australian Government National Drugs Campaign website (170/727 or 23.4% of the drug group and 110/421 or 26.1% of the alcohol group visited this site) and the National Drug and Alcohol Research Centre website (232/736 or 32.0% of the drug group and 95/421 or 22.6% of the alcohol group visited this site). Interestingly, although both groups rated these websites as very or somewhat easy to use and trustworthy, the ratings regarding the attractiveness of these websites were far lower.

General Website Features

The drug and alcohol website user groups were presented with a series of general website features and asked to rate how important (very, somewhat, or not at all) they thought these features were for AOD and health-related websites. As shown in Table 2, seven of the listed features were considered very important by the majority of respondents from both groups, with a glossary and sitemap receiving the lowest importance rating. There were no significant differences between the groups on any of the general website features.

Table 2. General website features rated very important

General Website Features Rated Very Important	Drug Website Users		Alcohol Website Users	
	% (n)	N	% (n)	N
Easy navigation	88.5 (676)	764	88.3 (392)	444
Open access	87.1 (666)	765	86.2 (381)	442
The right amount of information	82.1 (624)	760	81.2 (358)	441
Internal search function	79.4 (608)	766	79.1 (351)	444
Easy to understand language	75.7 (575)	760	77.9 (346)	444
No need for extra software	73.9 (564)	763	73.5 (324)	441
Interesting Web pages	50.7 (386)	762	56.0 (248)	443
Does not require a high bandwidth	46.3 (353)	761	47.3 (209)	442
Attractive website layout	40.1 (307)	765	45.9 (204)	444
A glossary	30.6 (232)	758	34.2 (151)	442
A sitemap	27.9 (212)	761	26.4 (117)	443

There were no significant differences in the preferences of men and women for general website features. However, the relative importance of a site map (χ^2_{10} = 19.8, P = .03, n = 969) varied according to age group categories. This result indicated that those aged 44 to 61 years valued site maps significantly more than the other groups. Respondents holding an “other certificate” as their highest education qualification valued easy navigation the least of the education categories (χ^2_{16} = 27.5, P = .04, n = 879).

Interactive Website Features

The drug and alcohol website user groups were presented with a series of interactive website features and asked to rate how important (very, somewhat, or not at all) they thought these features were for AOD and health-related websites. As Table 3 shows, being able to print or download information, being able to ask a question, external links, and pictures and graphics were valued most highly, followed by automated personal feedback, video, quizzes, and flash animations. Games, blogs, SMS, or email reminders were less common preferences. There were no significant differences between the two groups on any interactive website feature.

Table 3. Interactive website features rated very important

Interactive Website Features Rated Very Important	Drug Website Users		Alcohol Website Users	
	% (n)	N	% (n)	N
Print/download information	68.8 (526)	765	72.5 (321)	443
Being able to ask a question	57.3 (437)	763	58.2 (258)	443
External links	52.5 (400)	762	54.9 (242)	441
Pictures and graphics	46.8 (357)	763	51.8 (230)	444
Automated personal feedback	23.6 (179)	759	26.9 (119)	442
Video	16.1 (123)	762	17.0 (75)	442
Quizzes	15.3 (117)	763	19.7 (87)	442
Flash / Animations	11.3 (86)	760	10.6 (47)	442
Audio	11.3 (86)	763	10.9 (48)	442
Access to a chat room	11.1 (85)	763	12.7 (56)	441
SMS or email reminders	7.7 (58)	757	9.6 (42)	437
Blogging	8.7 (66)	759	6.8 (30)	439
Games	4.5 (34)	758	7.0 (31)	441

Of the all respondents, 31 specified other important general and interactive website features not listed in Table 2. The most common responses were being able to post comments, access to a chat room with an expert to answer questions, online forums to ask anonymous questions, a “frequently asked questions” section, peer testimonials, real facts, polls and votes, and a “where to get help” section.

Preferences for specific interactive website features did not differ according to gender or educational level. However, being able to ask a question was influenced by age group ($\chi^2_{10} = 36.1$, $P < .001$, n = 968). The youngest age group valued being able to ask a question most highly, and those between 44 and 61 years of age valued this feature the least. The youngest age group also significantly valued chat room access the most, and those between 44 and 52 years of age valued it least ($\chi^2_{10} = 38.9$, $P < .001$, n = 968). Similarly, the option to blog was most important to respondents between 16 and 24 years of age and least important for those aged 25 to 33 ($\chi^2_{10} = 53.3$, $P < .001$, n = 962). Furthermore, respondents 16 to 24 years of age valued games the most, and those aged 25 to 33 years old valued them least ($\chi^2_{10} = 27.8$, $P = .002$, n = 965). In contrast, the youngest age category valued downloading of information least, and those between 33 and 43 and those between 53 and 61 years of age valued it most ($\chi^2_{10} = 18.6$, $P = .046$, n = 968).

Judging Website Trustworthiness

Respondents were asked to rate the importance (very, somewhat, or not at all) of a number of trustworthiness indicators when they judged whether or not they could trust a website. The percentage of trustworthiness indicators judged as very important are provided in Table 4.

Table 4. Indicators of website trustworthiness judged very important

Indicators of Website Trustworthiness Judged Very Important	Drug Website Users		Alcohol Website Users	
	% (n)	N	% (n)	N
It provides evidence for its claims	86.8 (664)	765	87.3 (385)	441
It says where it got its information from	81.3 (621)	764	81.9 (363)	443
There is enough information to tell whether the writers are experts	71.7 (548)	764	75.5 (335)	444
It tells you when it was created or last updated	70.4 (539)	766	72.7 (322)	443
I can easily find who owns and wrote the website	67.9 (518)	763	73.3 (324)	442
It tells you it has a privacy policy	55.5 (422)	761	58.1 (257)	442
It tells you whether sponsors are involved	52.7 (400)	759	53.2 (236)	444
Past experience	50.4 (384)	762	51.8 (228)	440
Has reference or links to other websites	46.4 (354)	763	50.3 (222)	441
It displays a quality seal of approval (eg, HONcode)	44.3 (337)	761	47.1 (209)	444
It has been recommended to me by my peers	37.9 (289)	762	42.1 (187)	444
It has been recommended to me by my family	32.8 (249)	760	37.2 (165)	443
Another site said it was good	18.2 (138)	757	20.1 (89)	442

Over 80% of respondents identified the provision of evidence for claims made on a website and statements describing the source of information provided as very important factors for judging website trustworthiness. No significant differences were found between the two groups on any indicator of trustworthiness.

In addition, 25 respondents were able to specify other important indicators of trustworthy websites not listed in Table 4. The most common responses were: the website was recommended to them by pharmacists, doctors, or counsellors; the website was government affiliated; the contact details of the website owner were provided; the website had a certain ”look and feel” and a “serious tone” and the content was objective and unbiased.

Opinions About Preferred Website Tools and Functions When Using Alcohol and Other Drug Websites

Alcohol and drug website user groups were asked to consider whether they would use a range of website tools/functions and how important (very important, somewhat, or not at all) these features would be. The percentages of respondents endorsing the tool/function as very important are presented in Table 5.

Table 5. Alcohol and drug website tools/functions rated very important

Website Tools/Functions	Drug Website Users		Alcohol Website Users	
	% (n)	N	% (n)	N
Downloadable fact sheets for consumers	55.6 (348)	626	62.2 (224)	360
A Web portal site that has information on the best site and treatment options	49.5 (308)	622	51.5 (185)	359
Online tests or other tools to help gauge if there is an AOD problem[c]	42.6 (266)	624	52.6 (190)	361
A quick and easy user profile system that tailors information to need	42.7 (268)	628	44.2 (159)	360
Downloadable fact sheets for friends[b]	37.4 (232)	620	44.9 (162)	361
Prevention programs for those “at risk” of developing an AOD problem[c]	34.9 (217)	622	48.5 (174)	359
Downloadable fact sheets for family or carers[b]	35.7 (222)	621	45.9 (166)	362
An online treatment program with assistance (phone, IM, email or webcam)	32.0 (199)	622	32.7 (118)	361
A tracking function[b]	26.8 (167)	624	35.9 (129)	359
An online self-help treatment program [a]	25.7 (160)	622	33.1 (120)	362
A consumer information sharing hub to share experiences	29.5 (184)	624	25.3 (92)	363
Material/text presented in a different language	10.9 (68)	623	12.5 (45)	360
A chat room	9.8 (61)	625	8.9 (32)	361
Being able to start up your own online support group	8.9 (55)	619	9.2 (33)	358

[a] P < .05

[b] P < .01

[c] P < .001

Alcohol website users were significantly more likely to endorse a range of tools/functions as very important in comparison with the drug website users, specifically: online screening tools (χ^2_2 = 15.8, P < .001, n = 985); prevention programs (χ^2_2 = 27.5, P < .001, n = 981); tracking functions (χ^2_2 = 11.5, P = .003, n = 983); self help treatment programs (χ^2_2 = 8.3, P = .02, n = 984); downloadable fact sheets for friends (χ^2_2 = 11.6, P = .003, n = 981); and family (χ^2_2 = 12.7, P = .002, n = 983). In addition, 24 respondents added the following other important tools/functions: the provision of a blend of positive and negative personal testimonials, good information, and peer reviewed journal articles.

Preferences for specific website tools or functions did not vary by gender. However, several significant differences were found for age and higher educational level. Age group impacted on the Web portal feature (χ^2_{10} = 29.1, P = .001, n = 962) with respondents between 16 and 24 years of age valuing a Web portal least and those between 44 and 61 years valuing it most. Those in the youngest age group also valued access to a chat room most, and those aged 44 to 52 years placed least importance on this feature (χ^2_{10} = 30.4, P = .001, n = 967). The youngest age group also valued a consumer hub the most, and those aged 33 to 52 years valued it least (χ^2_{10} = 34.6, P < .001, n = 968). Those in the youngest age category valued the ability to start up an online support group most, and those aged 44 to 52 placed the least importance on this feature (χ^2_{10} = 26.97, P = .003, n = 958). However, being able to download fact sheets for family and carers was most important to those aged 43 to 52 and least important to those aged 16 to 24 (χ^2_{10} = 49.6, P < .001, n = 964).

Respondents without higher education valued support groups most, and those completing an undergraduate degree valued support groups least in comparison with other education groups (χ^2_{16} = 27.1, P = .04, n = 708). Access to therapist-assisted online treatment programs was also influenced by the respondents higher education level (χ^2_{16} = 27.9, P = .03, n = 713), with those holding a diploma as their highest tertiary educational qualification valuing therapist-assisted online treatment programs most highly and those undertaking a degree valuing them least. Finally, respondents with a diploma, an apprenticeship, or no higher education valued the presentation of website content in another language the most, and those currently completing an undergraduate degree valued this the least (χ^2_{16} = 27.7, P = .03, n = 714).

Preferred Support Mode for Alcohol and Drug Problems

Respondents were asked to consider what type of online service they would prefer if they had an alcohol or drug problem. As

shown in Table 6, the most highly preferred service mode for either problem was a website with email support from a therapist, and the least preferred was a website with no support or with telephone support from a therapist. No significant differences were found between the alcohol and drug website user groups on preferred support options (Drug problem: χ^2_4 = 5.2, P = .26, n = 994; Alcohol problem: χ^2_4 = 1.5, P = .82, n = 994).

Table 6. Most preferred support mode if the respondent had a drug or alcohol problem (n = 994)

Type of Treatment Support	Treatment for Drug Problem		Treatment for Alcohol Problem	
	Drugs (n = 629) % (n)	Alcohol (n = 365) % (n)	Drugs (n = 629) % (n)	Alcohol (n = 365) % (n)
Website with email support from a therapist	34.0% (214)	33.4% (122)	34.8% (219)	36.2% (132)
Website with face-to-face support from a therapist	23.7% (149)	29.0% (106)	21.0% (132)	21.9% (80)
A self-help website with no therapist support	18.9% (119)	15.3% (56)	20.3% (128)	17.8% (65)
Website with telephone support from a therapist	17.8% (112)	18.1% (66)	18.0% (113)	19.2% (70)
Other (Please specify)	5.6% (35)	4.1% (15)	5.9% (37)	4.9% (18)

Respondents were again able to specify other preferred support options and 55 respondents did so. The most common responses were “all the above,” only wanting to see a healthcare practitioner on a face-to-face basis without a treatment website, an alcoholics/narcotics anonymous online group, synchronous online one-to-one counselling, and an Internet site with chat room support.

No demographic variables were found to impact upon preferences for online treatment and supports.

Discussion

This study was the first to capture information on the content and functionality preferences of AOD and health-related websites users in Australia. Consistent with previous research on health-related websites, such as the study by Brouwer et al [18], fundamental website features relating to design and navigation were highly valued. The most common reason for using an AOD website was to obtain information about alcohol and other drugs, and approximately half of the respondents found information they wanted in 5 to 15 minutes. It is unclear whether this result was because website writers paid insufficient attention to the provision of information that users want; was due to deficiencies in website design, navigation, and search functions; or reflected problems with the written expression, structure, or layout of the material. However, consistent with an informational focus, open access, the right amount of information, easily understood language, no need for additional software, and an ability to download or print material were accordingly seen as particularly important.

Presentation was also important: approximately half the sample highly valued interesting Web pages, pictures and graphics, and external links, although video, audio, and flash or animations were far less preferred. Being able to ask a question was also valued by more than half of respondents, but other interactive features such as quizzes and online games were highly valued by less than 20% of the sample. This clearly raises important questions for website developers with respect to the prioritization of elements and features to be incorporated, particularly given the high cost of games, videos, and animations.

Respondents were more likely to reply that website trustworthiness was primarily indicated by evidence, cited sources, expertness of its writers, and documented currency, rather than by recommendations or seals of approval. These results suggest that this sample of users was relatively sophisticated in its ability to judge the quality of websites for themselves.

Alcohol website users were more likely than respondents who had accessed sites on other drugs to highly value online screening tools, prevention and self-help treatment programs, tracking functions, and fact sheets for family and friends. It is unclear why this result was found, and in particular, whether it reflected a greater willingness in this sample to consider addressing problems with alcohol than addressing problems with other drugs. Replication of the result and further investigation of its implications for website marketing and design are needed. In other respects, the alcohol and other drug samples provided very similar responses.

Gender did not affect any survey responses. However, there were several differences across age and education groups. Notably, younger people were more likely to value interactive and social networking features (being able to ask a question, the consumer hub, chat room access, ability to set up an online support group, games, and the option to blog). This result may reflect the greater likelihood among younger website users to turn to peers when seeking information or support. In contrast, older respondents valued the site map, the Web portal and the ability to download information or fact sheets for family and friends more highly. The value placed on the ability to access information may reflect a greater likelihood among this group that they were caring for someone with a drug or alcohol problem, and, therefore, valued high-quality information with which to assist these people. It may also reflect a greater reliance among older respondents on expert information about alcohol and other drugs in preference to obtaining this information from peers. Interestingly, respondents without higher education valued having a support group most, and those undertaking a degree

valued online treatment least. It is not clear whether less educated respondents were more likely to see their existing support system as inadequate or whether they felt less able to address alcohol or other drug issues on their own. Respondents undertaking a degree also valued multilingual options least (presumably because higher education in Australia is typically conducted in English).

Overall, these demographic differences suggest that website developers should consider the characteristics of the intended target group when designing a website. Greater understanding of each of the results is needed to know how best to address the differences in perceived needs.

Lastly, we were interested in knowing what type of online support was most preferred by the survey respondents if they were to require treatment for either a drug or alcohol problem. An Internet site with email support from a therapist was the most preferred option by both AOD website user groups, although this was selected by less than a third of respondents, with other selections being almost evenly spread across the other options. This survey did not directly compare Internet options with face-to-face treatment alone. However, as very few AOD groups endorsed the "other" option for support and only a subset of these identified standard face-to-face therapy as their preferred type of support, this suggests that standard therapy was not salient and that respondents to an online survey may be willing (and may even prefer) to use online treatment modalities should they require treatment. It is particularly noteworthy that neither the type of website accessed nor respondent demographics impacted upon the preferred type of online support. It seems that an important component of an online "treatment" program could potentially be the provision of some therapist support, especially via email.

Limitations

Survey respondents were primarily a young, educated, English speaking, and employed Australian sample who used the Internet on a daily basis. Relative to the Australian population at the time of the survey, our sample had more women (66% vs 51%), was younger (median age 22.0 years vs median of 36.9 years), had higher participation rates in employment (75% vs 65.2% of 15-74 year olds), and had higher rates of post school qualifications (7% vs 31% with no tertiary qualifications) [20]. However, the percentage of respondents for whom English was a second language (14%) was identical to the percentage in the Australian general population.

The interaction between these sociodemographic variables and health seeking/health literacy is well documented. For example, education can increase the likelihood of employment, thereby affecting the means by which people can improve their health and well-being as well as their ability to understand and choose pathways to better health [21]. Higher rates of health literacy are also found among people with higher levels of education and who are employed versus unemployed [21].The representativeness of the sample may have been further compromised by the online nature of the survey (ie, self selecting bias) and where it was marketed (eg, Facebook). The implications of these differences in terms of generalizability may also be similar to those encountered when conducting other Internet-based research. For example, in Australia, Internet access is highest amongst people with higher incomes, higher levels of educational attainment, and in households with children over the age of 15 years, with younger age groups reporting higher levels of Internet usage compared with those aged 55 years and over [22]. Thus, our survey respondents may more closely resemble Australian Internet users than the wider population. Furthermore, our recruitment methods may have attracted a sample of respondents with greater experience and knowledge of AOD websites than the general population of Internet users. These features can be seen as both a limitation (results may not be generalized to the whole Australian population) and a strength (they may more closely match Internet users, especially those who access AOD sites). An additional, related limitation is that the sample was entirely Australian, and results may not be fully generalizable to AOD respondents from other countries.

Respondents answered the questions based on websites they had visited before. There was no control for variability in website exposure (eg, type, frequency, or recency of previous website visits). Nor were motivations for seeking information standardized. So, respondents may have been seeking information about their own substance use, about family members or friends, or may have been seeking information for study programs or for entertainment. Differing features may have been seen as important or satisfactory based on these differing agendas. Perhaps more importantly, we do not know whether any of the respondents had an AOD use problem (either in the past or currently) and accordingly, we do not know how these results may relate to an AOD treatment-seeking population.

Future Research

Future researchers might consider conducting a comparison of similarly motivated individuals seeking websites on AOD issues. Developing and evaluating AOD websites based upon the specifications identified as highly important by this sample could lead to higher rates of engagement and usage of AOD websites. In addition, exploration of some of the functional design issues, such as determining what amount of information is considered the "right" amount could assist in the design of a more user-friendly AOD website. Targeting people with AOD use problems would also provide more specific information regarding the wants and needs of this group in accessing online AOD websites. Tailoring AOD websites based on age and education level appears to be an important line of research investigation, and whether gender is indeed an irrelevant factor when developing AOD websites will be an important finding to replicate.

Implications and Conclusion

Engagement of people with AOD problems in behavior change remains a difficult challenge. The Internet offers opportunities both for increased community understanding of AOD issues, and potentially, for engagement of affected individuals at an earlier stage than traditional treatment services, with lower stigma, and at less cost. However, community-wide Internet sites have not engaged young people at the rates one might have wished, with alcohol-related website users often having mean

or median ages in the mid 40s, as in the study of Kramer et al, for example [23]. The results of the current study suggest some partial solutions. For example, the results suggest that both younger and older website users may be attracted to sites that offer easily understood information, particularly if it can be easily accessed, as well as sites where there is no need to log in or download additional software and there are opportunities to ask questions. While websites should be attractive and easy to use, high cost features such as games, animations, or videos are not required by the majority. Users may at first be tempted to look at screening tools or tips, although once engaged, we found that users showed a preference for therapist assistance over stand-alone websites (a preference that may limit the ability of the websites to fully realize their potential for reaching the community at low cost). The results of the study also suggests that the challenge of eliciting a transition from information seeking to screening and treatment-seeking may be greater for other drug website users than for alcohol website users, although that apparent effect requires replication and clarification.

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Conflicts of Interest

None declared

Multimedia Appendix 1

Online alcohol and drug websites: What do you think?

[PDF file (Adobe PDF File), 49 KB - jmir_v12i5e51_app1.pdf]

Multimedia Appendix 2

Alcohol and drug websites

[PDF file (Adobe PDF File), 37 KB - jmir_v12i5e51_app2.pdf]

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Abbreviations

AOD: alcohol and other drugs
IP: Internet protocol
SMS: short message service

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Original Paper

A Comparison of Psychometric Properties Between Internet and Paper Versions of Two Depression Instruments (BDI-II and MADRS-S) Administered to Clinic Patients

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Abstract

Background: Self-report measures can guide clinical decisions and are useful when evaluating treatment outcomes. However, many clinicians do not use self-report measures systematically in their clinical practice. Internet-based questionnaires could facilitate administration, but the psychometric properties of the online version of an instrument should be explored before implementation. The recommendation from the International Test Commission is to test the psychometric properties of each questionnaire separately.

Objective: Our objective was to compare the psychometric properties of paper-and-pencil versions and Internet versions of two questionnaires measuring depressive symptoms.

Methods: The 87 participating patients were recruited from primary care and psychiatric care within the public health care system in Sweden. Participants completed the Beck Depression Inventory (BDI-II) and the Montgomery-Åsberg Depression Rating Scale—Self-rated (MADRS-S), both on paper and on the Internet. The order was randomized to control for order effects. Symptom severity in the sample ranged from mild to severe depressive symptoms.

Results: Psychometric properties of the two administration formats were mostly equivalent. The internal consistency was similar for the Internet and paper versions, and significant correlations were found between the formats for both MADRS-S (r = .84) and the BDI-II (r = .89). Differences between paper and Internet total scores were not statistically significant for either questionnaire nor for the MADRS-S question dealing with suicidality (item 9) when analyzed separately. The score on the BDI-II question about suicidality (item 9) was significantly lower when administered via the Internet compared with the paper score, but the difference was small (effect size, Cohen's [d] = 0.14). There were significant main effects for order of administration on both questionnaires and significant interaction effects between format and order. This should not, however, pose a problem in clinical use as long as the administration format is not changed when repeated measurements are made.

Conclusions: The MADRS-S can be transferred to online use without affecting the psychometric properties in a clinically meaningful way. The full BDI-II also seems to retain its properties when transferred; however, the item measuring suicidality in the Internet version needs further investigation since it was associated with a lower score in this study. The use of online questionnaires offers clinicians a more practical way of measuring depressive symptoms and has the potential to save resources.

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KEYWORDS

Questionnaires; psychometrics; Internet; depression

Introduction

Routine use of self-report measures (of depressive symptoms, for example) can be useful in clinical settings. A recent study found that clinicians in psychiatric practice rated a self-report measure as helpful for making treatment decisions in 93% of patient visits [1]. In the same study, all the psychiatrists rated the feedback from such rating scales as helpful for monitoring treatment response, and 94% regarded them as helpful for measuring severity of illness. Frequent feedback to clinicians on symptoms from self-report questionnaires has been found to reduce in-patient days and hence the costs of psychiatric care without influencing treatment outcome [2]. According to these results, self-report instruments can be useful tools in mental health care. However, the use of such scales is not the rule in all psychiatric settings. In a survey among UK psychiatrists, only 10.5% reported using self-report scales on a routine basis to measure depression and/or anxiety. Over 55% of psychiatrists answered that they never used self-report scales to measure these symptoms in their patients. One of the most common reasons given for not using self-report was a perceived lack of a robust infrastructure to support the process. In particular, many saw a need for information technology solutions to make such self-report scales more practically useful [3].

One medium that has the potential to make self-report questionnaires easier to use is the Internet. Traditional paper-and-pencil questionnaires are now being complemented by Internet-based questionnaires that can be completed anywhere, reach their destination instantly, automatically calculate scores correctly, and be stored in a practical way. By employing Internet-based questionnaires, clinicians could easily access information about symptom levels and use this information to inform their decisions about treatment. Using the Internet to facilitate this kind of “reflective practice” has been suggested previously [4], and in several treatment studies on Internet-based self-help, patients have used online questionnaires to rate their symptoms [5,6]. Additional possible advantages of Internet-based questionnaires include lower costs, less environmental load, and the ability to rapidly update questionnaires to later versions. More detailed discussions of Internet-based psychological assessments are available [7,8].

There is also an indication that patients may prefer Internet-based questionnaires. One study found that more people reported a preference for responding to mental health questionnaires on a computer compared with answering on paper [9]. Moreover, in a controlled investigation, Internet-based versions of questionnaires yielded higher response rates and fewer missed items compared with the paper versions [10].

Since the spread of the Internet, researchers and test developers have adapted several tests for Internet administration by simply moving the items from established paper questionnaires to websites. However, it has been argued that we cannot assume that the psychometric properties remain the same after such adaptation [11]. The new setting in which the items are presented could render earlier reports on psychometric properties invalid. Internet administration of self-report measures could yield different answers than paper-and-pencil administration. For example, people may tend to answer in a less socially desirable way on the Internet compared with when they answer the same questions on paper [12]. Another reason why Internet administration could differ is computer anxiety, meaning that the use of the computer per se could create some of the very feelings that are rated in questionnaires. One indication of this is a significant correlation between computer anxiety and the score on a scale measuring negative mood that was found when the assessment was made on computer but not when it was done on paper [13]. If scores from Internet versions of self-report measures differ from the established paper versions, it could have serious consequences if decisions about treatment are based on them. This is especially true when it comes to questions about suicidality (item 9 in both the Beck Depression Inventory—second edition (BDI-II) and the Montgomery-Åsberg Depression Rating Scale—Self-rated (MADRS-S) since a score that underestimates the risk might reduce the inclination to ask further questions about suicidal ideation. In Internet-based self-help, possibly underestimating suicide risk becomes even more important since the clinician typically does not meet the patient face-to-face.

The International Test Commission (ITC) guidelines on good practice in Internet-based testing contain recommendations about the process of adapting an established paper-and-pencil questionnaire for online use. The equivalence of the psychometric properties of the two versions is a central issue, and the ITC recommends presenting evidence that the two versions produce scores with comparable means and standard deviations, comparable reliabilities, and a correlation at the expected level from the reliability estimates. It was also stated that there should be the same level of test taker control (for instance the possibility to review or skip items in a similar fashion) [14].

In two previous randomized studies [15,16] that compared Internet and paper versions of the MADRS-S [17], the results indicated similar psychometric properties of the two versions. In spite of these consistent results, there was a need for further investigation mainly because both previous studies used samples with mild depressive symptoms, recruiting only from a university campus in one case [15], and the generalizability of the results is therefore limited. The established paper version of the BDI-II [18] was also compared with Internet versions in the reports of these studies [15,16] as well as with a computerized version in an earlier study with a student sample [19]. There were no differences in the psychometric properties between the two versions in the two studies with samples showing minimal symptoms of depression [15,19], but a significantly higher mean score was generated from the Internet version of the BDI-II compared with its paper version in the study with a sample showing mild depressive symptoms [16]. However, the difference was small.

Previous research on these questionnaires indicates equivalence between Internet and paper versions. Participants in those trials, however, are probably not representative of patients seeking help at psychiatric or primary care clinics, making the results less relevant to this context. From a health care perspective, a study of clinic patients could increase the external validity of a psychometric study, not only because such a study population would consist of persons exhibiting higher levels of depressive symptoms, but also because it is reasonable to assume that clinic patients would have less experience with computers compared with study populations composed of students. Having higher levels of depressive symptoms, individuals in a clinical sample may have some concentration difficulties and therefore might also be more negatively affected by new technology.

The aim of this study was to compare the psychometric properties of two administration formats for the BDI-II and the MADRS-S using a sample of clinic patients. We contrasted paper-and-pencil versus Internet administration of the two questionnaires.

Method

Participants

Participants completed the paper and Internet-based questionnaires as part of their registration for a clinical trial of Internet-based treatment for depression. Participants were recruited within public health care in Örebro County Council and Värmland County Council in Sweden. Patients and staff in primary care and psychiatric care were informed about the trial at staff meetings and via posters in waiting rooms. Both referrals and self-referrals were accepted. Participants were required to be at least 18 years of age, have access to a computer with an Internet connection, be fluent in the Swedish language, and be willing to attend two interviews with a psychologist.

Procedure

All patients who expressed interest in the clinical trial received a letter with an informed consent form. When written consent was received from the patient, the patient was randomized to complete the questionnaires on paper or Internet first to control for order effects. A block randomization sequence was created by a statistician and concealed from study personnel by the use of sealed envelopes. After randomization, a letter was sent to the patient's home that contained instructions on how to proceed. Patients randomized to completing the paper version first received the questionnaires together with the instructions and a return envelope. Patients randomized to completing the Internet version first received a letter with instructions on how to fill out the Internet version as well as a user name and password. As soon as the trial staff received the responses from the first administration of the questionnaires, a new letter was sent out that contained instructions for the opposite administration format. MADRS-S was completed first and BDI-II second both on the Internet and on paper. Group 1 (n = 43) completed the paper version first and then the Internet version. Group 2 (n = 44) answered the questionnaires in the opposite order. Ethical approval was obtained from the Regional Ethics Committee in Uppsala, Sweden.

Material

A website was constructed for the study, and all Internet-based measurements were carried out by patients logging in and completing the questionnaires under their user name. All items had to be answered one-by-one, and only one item at a time appeared on the screen. After the answer to an item had been provided, the next item appeared on the screen. It was possible to change the answers of previous items until the last item was completed for each test (BDI-II and MADRS-S).

The Montgomery-Åsberg Depression Rating Scale—Self-rated (MADRS-S) is a 9-item self-report scale that measures depressive symptoms. The patients are asked to rate their symptom severity on a scale ranging from 0 to 6, resulting in a total score ranging from 0 to 54. A higher score indicates a higher level of depressive symptoms. Satisfactory internal consistency was found in a recent study, in which a Cronbach alpha of .84 was reported [20]. The MADRS-S is a self-rated version of the original clinician-rated MADRS, which was especially designed to be sensitive to change in symptom levels [21]. MADRS-S was used in our study because of its briefness, its good psychometric properties, and the fact that it is freely available.

The Beck Depression Inventory—second edition (BDI-II) is a 21-item self-report scale of depressive symptoms. Each item yields a score ranging from 0 to 3 resulting in a total score ranging from 0 to 63, and a higher score indicates a higher level of depressive symptoms. The internal consistency of the BDI-II has been reported to be good in several studies, for example, a Cronbach alpha of .90 has been reported [22]. The BDI-II is a revised version of the original BDI [23]. BDI-II was used in our study because it is one of the most widely used self-report scales for depressive symptoms and is, therefore, of interest to many clinicians.

Analyses

Cronbach alpha coefficients were used to estimate internal consistency, and Pearson correlations were calculated between the different administration formats. To test differences between the two orders of administration (paper first or Internet first), and formats (paper or Internet) two-way Analyses of Variance (ANOVA) were calculated. Significant interactions were post tested with *t* tests with Bonferroni adjusted alpha levels ($P < 0.0125$). Effect sizes (Cohen's *d*) were calculated by dividing the difference between scores by the pooled standard deviation.

Results

Out of 119 patients that showed interest in a clinical trial, 112 gave written consent and were asked to fill out the questionnaires on both Internet and paper. The response rate was 77.7%, that is, 25 patients did not complete the task (4 filled out questionnaires only on the Internet, 8 filled out questionnaires only on paper and 13 didn't fill out any). A total of 87 patients filled out both questionnaires on paper and on the Internet and are included in the analyses. On average, 9.79 days (SD 9.83) passed between the first and second assessment. Of the 87 study participants, 57 (65.5%) were women, and 30 (34.5%) were men; the mean age was 41.1 years (SD 13.0),

ranging from 20 to 72 years of age. The degree of depressive symptoms ranged from minimal to severe, with a range from 7 to 57 on the BDI-II and 6 to 39 on the MADRS-S (paper versions). The mean scores on the paper version of the MADRS-S indicated moderate depressive symptoms, and on the paper BDI-II the mean value indicated severe depressive symptoms.

Cronbach alpha levels were similar for the Internet and paper versions of the Montgomery-Åsberg Depression Rating Scale – Self-rated (MADRS-S). The alpha levels for the different orders and formats of administration are presented in Table 1. The correlation between the MADRS-S total scores from the Internet administration and the paper administration was high $r = .84$ ($P < .001$). Correlations between scores from Internet and paper in the different groups are shown in Table 2. The correlations between the Internet and paper versions of all MADRS-S items were significant. Correlations for each item separately are shown in Table 3.

Table 1. Internal consistency (Cronbach alpha) for the two groups and administration formats

	Paper-First Group on Paper Alpha	Internet-First Group on Internet Alpha	Paper-First Group on Internet Alpha	Internet-First Group on Paper Alpha
MADRS-S	.81	.73	.81	.81
BDI-II	.90	.87	.89	.89

Table 2. Pearson Correlations between scores from paper and the Internet

	Paper First r^a	Internet First r^a	Both Groups Together r^a
MADRS-S	.86	.80	.84
MADRS-S item 9	.88	.64	.79
BDI-II	.91	.85	.89
BDI-II item 9	.84	.73	.80

[a]All correlations are significant at the $P < .001$ level.

Table 3. MADRS-S item, mean score on paper and Internet and the correlation (Pearson) between them

Item	Paper Format Mean (SD)	Internet Format Mean (SD)	Correlation[a]
1 Mood	2.38 (1.73)	2.43 (1.34)	.57
2 Anxiety	3.53 (1.36)	3.55 (1.02)	.58
3 Sleep	2.32 (1.45)	2.32 (1.52)	.66
4 Appetite	1.36 (1.36)	1.48 (1.26)	.65
5 Ability to concentrate	2.83 (1.38)	2.90 (1.32)	.71
6 Initiative	3.18 (1.48)	3.22 (1.43)	.74
7 Emotional involvement	2.66 (1.28)	2.63 (1.21)	.65
8 Pessimism	3.20 (1.38)	3.48 (1.21)	.63
9 Zest for life	2.34 (1.26)	2.41 (1.10)	.79
Total	24.43 (6.97)	23.79 (7.98)	.84

[a]All correlations are significant at the $P < .01$ level.

For the MADRS-S there was no significant main effect for administration format (paper or Internet). There was, however, a significant main effect of administration order, indicating higher scores for the group that answered the questionnaire on paper first compared with the Internet-first group (means 26.2 vs 22.08), and the effect size was moderate (Cohen's $d = 0.57$). There was also a significant interaction between order of administration and administration format. Subsequent t tests with Bonferroni adjusted alpha levels showed no significant difference between scores from paper and Internet for the paper-first group ($t_{42} = 0.53$, $P = .60$), and no significant difference between scores from paper and Internet for the Internet-first group ($t_{43} = -2.37$, $P = .02$). The paper-first group, however, scored significantly higher on the paper-MADRS-S than the Internet-first group ($t_{85} = 3.1$, $P = .003$). No significant difference was found between the Internet scores from the two groups ($t_{85} = 2.16$, $P = .03$).

For MADRS-S item 9 (suicidality) there was no significant main effect for format or order of administration. There was, however, a significant interaction effect between format and order of administration. The subsequent *t* tests showed no significant difference between paper scores and Internet scores in the paper-first group (t_{42} = 1.15, *P* = .26), and no significant difference between paper scores and Internet scores in the Internet-first group (t_{43} = -1.98, *P* = .05). No significant difference was found between the paper scores from the paper-first and the Internet-first group (t_{85} = 2.47, *P* = .02), nor was a significant difference found between the Internet scores from the two groups (t_{85} = 1.22, *P* = .23). Means and standard deviations from MADRS-S and BDI-II are shown together with *F* and *P* values for the two groups and administration formats in Table 4.

Table 4. Means (SD), main effects, and interaction effect

	Group	Paper Format	Internet Format	Main Effect		Interaction
		Mean (SD)	Mean (SD)	Format	Order	
				F, *P* Value	F, *P* Value	F, *P* Value
MADRS-S	Paper first	26.35 (7.93)	26.02 (7.32)			
	Internet first	21.30 (7.28)	22.86 (6.31)	1.88, *P* = .18	7.68, *P* = .007	4.36, *P* = .04
MADRS-S item 9	Paper first	2.67 (1.39)	2.56 (1.24)			
	Internet first	2.02 (1.05)	2.27 (0.92)	0.68, *P* = .41	3.95, *P* = .05	5.1, *P* = .03
BDI-II	Paper first	34.21 (10.9)	31.93 (10.54)			
	Internet first	26.98 (9.34)	27.48 (9.2)	2.97, *P* = .09	7.86, *P* = .006	7.26, *P* = .009
BDI-II item 9	Paper first	0.88 (0.66)	0.72 (0.66)			
	Internet first	0.52 (0.66)	0.5 (0.55)	4.28, *P* = .04	5.08, *P* = .03	2.44, *P* = .12

Table 5. BDI-II item, mean score on paper and Internet, and the correlation between them

Item	Paper Format Mean (SD)	Internet Format Mean (SD)	Correlation[a]
(1) Sadness	1.26 (.58)	1.29 (.61)	.70
(2) Pessimism	1.38 (.72)	1.39 (.62)	.66
(3) Feelings of failure	1.55 (.92)	1.53 (.86)	.68
(4) Loss of pleasure	1.72 (.77)	1.59 (.77)	.70
(5) Guilty feelings	1.53 (1.0)	1.53 (.94)	.69
(6) Punishment feelings	0.68 (.97)	0.80 (1.03)	.74
(7) Self-dislike	1.72 (.98)	1.78 (1.02)	.59
(8) Self-criticism	1.43 (.90)	1.43 (.86)	.59
(9) Suicidal thoughts or wishes	0.70 (.68)	0.61 (.62)	.80
(10) Crying	1.68 (1.21)	1.69 (1.19)	.80
(11) Agitation	1.25 (.81)	1.05 (.70)	.66
(12) Loss of interest	1.49 (.83)	1.48 (.85)	.63
(13) Indecisiveness	1.53 (.91)	1.53 (.91)	.71
(14) Worthlessness	1.43 (.90)	1.38 (.90)	.79
(15) Loss of energy	1.84 (.64)	1.68 (.69)	.61
(16) Change in sleeping patterns	1.64 (.85)	1.59 (.87)	.66
(17) Irritability	1.47 (.89)	1.40 (.90)	.68
(18) Changes in appetite	1.39 (.98)	1.22 (.99)	.64
(19) Concentration difficulty	1.52 (.66)	1.44 (.68)	.63
(20) Tiredness or fatigue	1.85 (.77)	1.79 (.88)	.71
(21) Loss of interest in sex	1.48 (1.06)	1.49 (1.04)	.88
Total	30.55 (10.72)	29.68 (10.07)	.89

[a]All correlations are significant at the $P < .01$ level

For the BDI-II Cronbach alpha levels were similar in the Internet and paper versions. The alpha levels for the different orders and formats of administration are presented in Table 1. The correlation between the BDI-II total scores from the Internet administration and the paper administration was high, $r = .89$ ($P < .001$). Correlations between scores from Internet and paper in the different groups are shown in Table 2. The correlations between the Internet and paper versions of all BDI-II items were significant. Correlations for each item are shown in Table 5.

For the Beck Depression Inventory (BDI-II), there was no significant main effect for administration format (paper or Internet). There was, however, a significant main effect for administration order, indicating higher scores for the paper first group compared with the Internet-first group (means 33.07 vs 27.23), and the effect size was moderate ($d = 0.58$). There was also a significant interaction between order and administration format. Subsequent *t* tests with Bonferroni adjusted alpha levels showed that the paper-first group scored significantly higher on the paper BDI than on the Internet BDI ($t_{42} = 3.36$, $P = .002$). No significant difference was found between the paper score and the Internet score for the Internet-first group ($t_{43} = -0.65$, $P = .52$). The paper-first group scored significantly higher than the Internet-first group on the paper BDI ($t_{85} = 3.33$, $P = .001$), but not on the Internet BDI ($t_{85} = 2.1$, $P = .04$).

For BDI item 9 (suicidality), there were significant main effects of format and order of administration, but no significant interaction between them. The mean score for the paper BDI item 9 (both groups) was higher than the Internet BDI item 9 (means 0.7 vs 0.61) and the effect size was small (Cohen's $d = 0.14$). The paper-first group scored higher (both formats) than the Internet first group (means 0.80 vs 0.51) and the effect size was small (Cohen's $d = 0.46$).

Discussion

The internal consistency of both questionnaires was similar across administration formats, and medium to high correlations were found between paper and Internet total scores, and for each individual item. No significant main effect separated the paper total scores from the Internet total scores, but interaction effects were found as well as main effects for order of administration. Participants rated their suicidality on the same level on paper and Internet-based MADRS-S, but rated lower suicidality levels on the Internet BDI-II compared with the paper version.

These results do not indicate any clinically relevant differences between the total scores from paper and Internet versions of the BDI-II and MADRS-S, but rather that people suffering from depression rate their overall depressive symptoms on the same level with both administration formats. An important clinical implication is that it is probable that the questionnaires tested in this study can be used online with the same cutoff points and without changed internal consistency. Online versions should make it easier for clinicians to administer these questionnaires, hopefully making them more common in everyday practice.

If people tend to rate their suicidality lower on the Internet, this has to be taken into account in clinical use. In a previous study [15], however, we did not find a significant difference between suicidality ratings on paper and Internet BDI-II (item 9), and although the difference in the current study was significant, the effect size was small. When it comes to the overall scores, previous research has indicated similar psychometric properties, but in samples with minimal and mild symptoms. Although encouraging, this was of limited clinical relevance since these levels of symptoms are rarely seen in clinical practice. In the current study, the psychometric properties of paper and Internet versions of BDI-II and MADRS-S were compared using a sample of clinic patients recruited within public health care. The sample had mean scores indicating moderate to severe depressive symptoms.

In an earlier study [16] with a sample size of 350, the subjects scored significantly higher on the Internet version than on the paper version of the full BDI-II. In contrast, the current study showed no significant main effect for administration format. The actual difference found by Carlbring et al was small (0.49 points) [16], and thus both studies indicate no clinically meaningful differences between the two administration formats. The difference between the results in the two studies mainly seems to be a difference in statistical power. The significant correlations between scores from Internet and paper versions of each item needs replication since the authors found no previous studies that presented separate results for each item.

A case could be made for a possible difference between the two administration formats, mainly concerning computer anxiety and social disinhibition on the Internet, although this was not directly investigated in the current study. Since no clinically relevant differences were found, these arguments are probably less important in our study. In the case of computer anxiety, a recently published study [24] found that experience with computers reduced the problem, indicating that it is a temporary problem that mainly occurs when new technology is introduced. It is therefore possible that computer anxiety is higher in countries, or subgroups, with low levels of computer experience. In such populations, paper and Internet versions of the same questionnaires may not be equivalent. The design of the current study does not allow any analysis to investigate this.

The significant main effects for order of administration mean that the paper-first group had higher scores regardless of administration format. It is difficult to interpret these results, but one possible explanation is a small difference surrounding the administration of the paper and Internet versions. Before completing the Internet versions, patients had to identify themselves by means of a personal username and password, after which they were asked some questions about sociodemographic characteristics. It is unclear whether this could affect results of both administration formats. Another possible contributing factor could be an actual difference in depressive symptoms between the two groups. The interaction effects found in this study indicate that the order of administration affects the difference between the first and the second measurement if different administration formats are used. In a clinical context it is therefore important to use the same administration format for all measurements made by the same individual.

Since all patients in this study showed an interest in an Internet-based treatment trial, it is possible that they are relatively positive toward using the Internet, which could limit the generalizability of the results. Another limitation of this study is that although the MADRS-S has a maximum score of 54, no subjects in the sample had a score higher than 39 (on the paper version). The full range of the scale was not used and thus the results should not be generalized outside the score range of the sample in the study. A third limitation is that the design did not address the question of test–retest reliability of the Internet versions of the tests. Future studies should address this question by using repeated measures with Internet-based tests. A fourth limitation is that computer anxiety and social disinhibition were not measured. A fifth possible limitation is that the items were presented one at a time on the Internet, which differs from the paper versions. However, earlier research shows that the two methods are psychometrically equivalent [25]. The most apparent strength of the current study is the use of a sample of clinic patients with moderate to severe depressive symptoms.

The results in this study, and in previous studies, suggest that the Internet-based BDI-II generates a total score that does not differ in a clinically meaningful way from the total score generated from the paper version. The suicidality rating in the BDI-II, however, needs further investigation since we found a small but significant difference in this study, but no difference was found in a previous study. Future research on this is needed and should be made with samples with higher levels of suicidality compared with the levels found in this study.

The psychometric properties of MADRS-S were not affected when the scale was transferred for use on the Internet in this study. Since this finding is consistent with two previous studies, it seems safe to transfer the MADRS-S to online use without affecting the psychometric properties in any clinically relevant way. Internet-based MADRS-S is, therefore, a clear candidate to complement traditional self-report measures in clinical work.

Besides the psychometric properties, however, there might also be other problems that have to be addressed before clinical implementation of Internet-based self-report measures, one of which is the security of information technology solutions. Another challenge may be test taker preferences. If patients, or subgroups of patients, find Internet-based questionnaires less attractive than traditional administration formats, it could lower response rates. Future research should investigate the possibilities and challenges associated with implementing online questionnaires in clinical practice. Patient acceptability,

information security, and cost effectiveness are some important aspects.

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Conflicts of Interest

None declared

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Abbreviations

BDI-II: Beck Depression Inventory—Second Edition
ITC: International Test Commission
MADRS-S: Montgomery-Åsberg Depression Rating Scale—Self-rated

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Original Paper

The Ins and Outs of an Online Bipolar Education Program: A Study of Program Attrition

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Abstract

Background: The science of eHealth interventions is rapidly evolving. However, despite positive outcomes, evaluations of eHealth applications have thus far failed to explain the high attrition rates that are associated with some eHealth programs. Patient adherence remains an issue, and the science of attrition is still in its infancy. To our knowledge, there has been no in-depth qualitative study aimed at identifying the reasons for nonadherence to—and attrition from— online interventions.

Objective: This paper explores the predictors of attrition and participant-reported reasons for nonadherence to an online psycho-education program for people newly diagnosed with a bipolar disorder.

Methods: As part of an ongoing randomized controlled trial (RCT) evaluating an online psycho-education program for people newly diagnosed with a bipolar disorder, we undertook an in-depth qualitative study to identify participants' reasons for nonadherence to, and attrition from, the online intervention as well as a quantitative study investigating predictors of attrition. Within the RCT, 370 participants were randomly allocated to 1 of 2 active interventions or an attention control condition. Descriptive analyses and chi-square tests were used to explore the completion rates of 358 participants, and standard regression analysis was used to identify predictors of attrition. The data from interviews with a subsample of 39 participants who did not complete the online program were analyzed using "thematic analysis" to identify patterns in reported reasons for attrition.

Results: Overall, 26.5% of the sample did not complete their assigned intervention. Standard multiple regression analysis revealed that young age (P= .004), male gender (P= .001), and clinical recruitment setting (P= .001) were significant predictors of attrition ($F_{7,330}$= 8.08, P< .001). Thematic analysis of interview data from the noncompleter subsample revealed that difficulties associated with the acute phases of bipolar disorder, not wanting to think about one's illness, and program factors such as the information being too general and not personally tailored were the major reasons for nonadherence.

Conclusions: The dropout rate was equivalent to other Internet interventions and to face-to-face therapy. Findings from our qualitative study provide participant-reported reasons for discontinuing the online intervention, which, in conjunction with the quantitative investigations about predictors, add to understanding about Internet interventions. However, further research is needed to determine whether there are systematic differences between those who complete and those who do not complete eHealth interventions. Ultimately, this may lead to the identification of population subgroups that most benefit from eHealth interventions and to informing the development of strategies to improve adherence.

Trial Registration: ACTRN12608000411347; http://www.anzctr.org.au/ACTRN12608000411347.aspx (Archived by WebCite at http://www.webcitation.org/5uX4uYwVN)

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KEYWORDS

Non-adherence; Nonadherence; attrition; eHealth; online psycho-education program; bipolar disorder; Internet intervention

Introduction

The science of eHealth interventions is evolving [1,2]. Drawing on quality standards for the field [3], new programs and platforms have been developed, clinical trials utilizing gold standard methodologies have been conducted, and clinical efficacy and cost effectiveness have been demonstrated [4,5]. However, participant adherence to the interventions remains an issue. A recent systematic review of 19 Internet-based psychological treatment programs found that attrition during treatment ranged from 2% to 83% with a median of 19% and a weighted average of 31% [6]. High eHealth attrition rates may be a natural and typical feature [7], but the reasons are not well known, and the phenomenon creates methodological challenges in studies evaluating eHealth applications. In this particular area, the science of eHealth interventions is still in its infancy.

Dropout rates from online programs do not differ greatly from psychotherapy delivered face-to-face. A mean rate of premature termination of 46.86% (SD 22.25) was found in a meta-analysis of 125 studies of face-to-face therapy [8], while more recent studies of attrition in face-to-face psychotherapy have reported rates of 24% in a clinical psychology service setting [9] and 33% in primary care settings [10]. However, the vast methodological differences between traditional and eHealth interventions necessitate the investigation of attrition from online interventions in their own right. Appropriate frameworks and models of eHealth attrition are needed to fully understand and assess the reasons behind dropout in order to maximize the impact of interventions. Eysenbach [7] has posited that, among other factors, "losing interest" is one common factor to both dropout to follow-up and nonusage of the application, but this has yet to be tested. Other hypothesized reasons for attrition include characteristics of the intervention such as its ease of use [7], clarity of expectations [7], and adjunctive personal contact, which can influence usage [7, 11]. User characteristics such as education level, severity of the mental health problem, need for anonymity, availability of alternative resources, and preference for treatment modalities have also been suggested [12].

Until recently, very little research has investigated nonadherence to and attrition from Internet interventions [7, 13]. A recent review of Internet interventions for anxiety and depression by Christensen et al [14] noted that many studies failed to report adherence to the content of the intervention, detailing only dropout from trial assessments. Even fewer studies have assessed the predictors of adherence, while only one [15] has formally examined participant-reported reasons for nonadherence and dropout. Although an important addition to the field, the data from that study were collected by questionnaire, which by necessity imposes restrictions on their possible richness and depth.

The paucity of research into attrition represents a significant gap in the science of eHealth interventions [7]. The necessity for such studies is emphasized by the tendency to base judgments of the utility of interventions on dropout rates. However, Proudfoot et al's [16] survey of noncompleters of their "Beating the Blues" computer-based cognitive behavioural therapy (CCBT) for depression and anxiety found that only half the noncompleters (53%) cited negative reasons for abandoning the program. Therefore, the assertion that nonadherence and dropout are negative reflections on interventions may not always be correct in eHealth, and more investigation is required to better understand the intricacies of attrition.

As eHealth interventions have the potential to significantly enhance access to high quality cost-effective care throughout the world, reasons behind participant nonadherence, and an examination of who continues with the intervention and why is of scientific interest and crucial for the future utility of online mental health delivery.

The current study was designed to investigate patterns of adherence to an online psycho-education program for people with bipolar disorder. Bipolar disorder is a chronic illness that is characterized by periods of mania/hypomania and depression. It was earlier reported that 1.3% of the population will suffer from bipolar disorder across their lifetime; however, more recent evidence suggests a lifetime risk of 5% [17,18]. Bipolar disorder has been ranked the sixth leading cause of disability in the world, with approximately 40% of people with bipolar disorder relapsing in the first year, 60% over two years, and 75% over three years [19]. Moreover, bipolar disorder bears the highest suicide rate of all psychiatric disorders, with approximately 25% of patients attempting suicide, and 10% to 20% completing suicide [20]. Psycho-education has been shown to increase patients' and their supporters' knowledge of the disorder and of treatment options, improve treatment adherence, and decrease relapses and hospitalizations [21].

Our study aimed to identify participant, program, and setting factors related to nonadherence in an online psycho-education program and to fill a gap in the literature by undertaking in-depth qualitative interviews with a cross section of non-completers to understand their reasons for discontinuation. Based on previous research [13-15] we predicted that gender, age, and illness severity would influence program adherence.

Methods

Participants

This study is part of an ongoing randomized clinical trial (RCT) aimed at evaluating the effectiveness of an online psycho-education program in helping people newly diagnosed with bipolar disorder to adjust to their diagnosis and to gain control of their illness. Details of the randomized controlled trial have been outlined in Proudfoot et al [22]. Participants were recruited through the Black Dog Institute Mood Disorders clinic, the Black Dog Institute website [23], community mental health organizations, general practitioners and psychiatrists, and the print media. Information and flyers were placed in the clinic and on the website and were distributed to community organizations, general practitioners and psychiatrists, and their

professional and support organizations. In addition, brief text advertisements were placed in 3 newspapers, 1 Australia-wide and 2 Sydney-based (see Multimedia Appendix 1). To be eligible for the study, participants had to be 18 or more years of age, had to have been diagnosed with bipolar disorder by a general practitioner or psychiatrist within the past 12 months, had to be currently seeing a health professional for the treatment of their bipolar disorder, had to be without suicidal ideation, had to have access to the Internet, had to be computer literate, had to be living in Australia, had to be able to read and write English, and had to be prepared to take part in the 6-month study. To confirm their diagnosis of bipolar disorder, participants completed the Mood Swings Questionnaire [24], and those who scored at or above the cutoff of 22 were invited to take part in the study. Power calculations based on the outcome measures showed that to detect an effect size of 0.5 between the online psycho-education program and the control group, and 0.4 between the two online programs, with a power of 80% (alpha = .05), a sample of 100 participants per group was required. To allow for attrition, we set a sample size of 140 in each of the 3 groups (ie, a sample size of 420). From January 2007 to August 2009, 370 participants were enrolled in the program and their pattern of adherence was studied as a substudy within the RCT. The results of the RCT will be reported separately when the full sample has been recruited and follow-up data have been collected.

Interventions

Using a computer-generated randomization list, an independent researcher randomly allocated consenting participants to 1 of 3 conditions: 2 active interventions and 1 attention control condition. Those allocated to the 2 active intervention groups received an online psycho-education program for bipolar disorder either alone (Bipolar Education Program [BEP], see below) or with email support from informed supporters (BEP + IS). The allocation sequence was concealed from the researcher (author JN) who enrolled and assessed participants.

Informed supporters were expert patients with bipolar disorder who were effectively managing their condition and trained to provide email support to participants under the supervision of the research team. Informed supporters were evaluated for suitability for the study on advice from their managing psychiatrist and the judgement of study chief investigator (author JP) of their performance during the training program. Informed supporters attended an 8-hour manual-based training course developed specifically for the program, which was administered over 2 sessions by the study team. Session 1 provided an overview of the research study, including study protocol and ethical requirements and the psycho-education program. Session 2 concentrated on the role of informed supporters and included how to offer practical advice and coping strategies, particularly on issues associated with the module content, how to write sensitive and supportive emails, and how to stay within the boundaries of the role. Informed supporters attended monthly supervision sessions with the research team and were paid on an hourly basis for the supervision sessions and for the time they spent carrying out their role. All informed supporter emails to and from participants were copied to the research team for quality control and safety checking throughout the study.

The online psycho-education program consisted of 8 modules, each with associated workbooks, delivered 1 per week. It was estimated that viewing the module content and completing the workbook would take participants 30 minutes each week. The content of modules was presented as an audio-visual lecture-style slide presentation with voice narration, and topics included the causes of bipolar disorder, medications, psychological treatments, and “stay-well plans” (see Table 1). Workbooks consisted of exercises and activities designed to help participants to apply the psycho-education material to their individual situation. Specifically, the workbook activities were designed to assist participants to develop and implement their own “stay well plan.” For example, one workbook activity focussed on helping participants to identify their triggers to a depressive or manic episode. Another required them to devise a map of their support network, deciding on whom they would allow to assume what roles if they became ill.

The attention control condition consisted of online information about bipolar disorder presented in text as bullet points, of no more than 2 pages in length. It was matched on duration (8 weeks) and structure (1 module per week) to the intervention conditions and contained a “workbook” containing a brief quiz (4 questions) relating to the content of the module and a mood chart, similar to the active conditions. All participant workbook responses and mood charts were monitored by the research team for any reports of suicidal ideation or extremes in mood. Participants reporting these states were contacted by the research team via email and advised to consult their health professional. In extreme cases, the clinical psychologist on the research team contacted the participant’s doctor.

Table 1. Content of the Online Bipolar Education Program

Module	Topic	Content
1	Diagnosing bipolar disorder:	The importance of detection, diagnosis, and management of the bipolar disorders and distinguishing them from other conditions such as attention deficit/hyperactivity disorder, anxiety states, personality styles, and, in particular, schizophrenia
2	The causes of bipolar disorder	Genes, neurochemistry, hormones, environmental factors, stress, and personal and family background
3	Medications for bipolar disorder	Mood stabilizers, antidepressants, antipsychotics
4	Psychological treatments	Cognitive behaviour therapy; narrative therapy; solution-focussed therapy; pinpointing "early warning signs," the signals that an episode of depression or mania may be on the horizon
5	Stay-well plans	How to reduce stress, minimize risks and maximize the chances of staying well; identifying personal triggers to illness episodes
6	Carers and support networks	Developing a contingency plan about what to do if they become unwell; considerations: extra medication, finances, work, additional treatment(s), and who to allow to help them make those decisions
7	Lifestyle changes	The benefits of establishing routines for regular sleep times and relaxation, taking medication, exercising, eating healthy foods, drinking less alcohol and caffeine, avoiding stress
8	Person first, illness last, and conclusion	People with bipolar disorder have an illness, but they themselves are not the illness; steps for setting up and implementing an action plan to stay well with bipolar disorder

Procedure

Participant adherence was monitored throughout the study to identify noncompleters. Adherence was defined as active use (completion and return of workbooks) and sufficient dose (completion of 4 or more sessions) of the program. Participants who returned 3 or fewer completed workbooks were considered "noncompleters." In total, 370 participants took part in the quantitative study to identify predictors of attrition.

In addition, those who met criteria for noncompletion were contacted at the 6-month follow-up point and invited to participate in a semistructured telephone interview about their impressions of the program and their reasons for discontinuation. To encourage nonresponders to participate, the interviews were not audio taped but participants' responses were transcribed in real time. We employed the standard qualitative sampling technique of "sampling to saturation" which rests not on generalizability nor on representativeness, but on notions of "saturation," that is, sampling is continued until the point is reached at which no new information or insights are obtained [25]. All recruited participants had completed the intervention phase of the randomized controlled trial and, consistent with best-practice qualitative method, we continued sampling as participants reached the 6-month follow-up point until no new insights were gained from the interviews. We contacted participants prior to the actual interview to allow them to choose a time that would suit them for the interview. We also asked interviewees general questions about their health at the beginning of the interview to get an indication of their current state. Participants were sent a double cinema pass for taking part in the interview. The study was approved by Human Research Ethics Committee of the University of New South Wales.

Measures

Participants completed baseline questionnaires before taking part in the online program. These included the Goldberg Anxiety and Depression Questionnaire [26] consisting of 2 subscales, each of 9 items rated with a yes/no response. "Yes" responses were summed, producing a possible range of scores from 0 to 9, with higher scores representing more severe anxiety/depression. Details of the age that participants experienced their first symptoms of mania and depression and their current self-rated mood state (normal, depressed, high, or mixed) were also collected, as well as a range of demographic information including age category, gender, marital status, education level, and current employment status. Age category, rather than exact age, was collected as our pilot testing showed that it was more acceptable to potential participants and, therefore, they were more likely to supply it. As participants were sent modules weekly—regardless of whether they had completed the previous week's workbook—we measured attrition by the number of participants "forever lost" from the program and their last completed workbook, as well as the total number of workbooks completed.

A specially designed semistructured interview schedule was used to gather noncompleters' perceptions of the online bipolar psycho-education program, their health status, and their reasons for discontinuation. The health assessment portion of the interview consisted of questions measuring perceived self-control and understanding of bipolar disorder. Participants were also asked to rate their mental health at the time of discontinuation and whether they felt that depression or mania compromised their ability to do the program. The second part of the interview assessed participants' perceptions of the online program and reasons for discontinuation. Questions related to motivations for and expectations upon joining the study, as well as their comments about the main program elements, the module information, the workbooks, their overall thoughts of, and what they would change about, the online program as a whole, how often they accessed the information, and their reasons for discontinuation. Whether participants' expectations of the study were met and their thoughts on the online format were also explored.

Analysis

Exploratory descriptive analyses and chi-square tests were conducted to compare the completion rates of the groups of participants. Because the majority of people with bipolar disorder are diagnosed in their twenties and an inclusion criterion for the study was that participants had to have been diagnosed within the last 12 months, we dichotomized the age categories into 18 to 29 years and over 30 years for analysis. Standard multiple linear regression was used to explore predictors of attrition; the number of workbooks completed was the studied outcome.

Noncompleter interviews were analyzed using "thematic analysis" [27] to identify patterns in reported reasons for attrition. This method entails allowing the data to inform major themes derived from the participants' responses to the questions and issues raised at interview. It involves organizing and describing the data in rich detail within a theoretical framework. In contrast to other forms of qualitative analysis, thematic analysis is not wedded to any preexisting theoretical framework, although the theoretical position used in the analysis is made clear [27]. In our analysis, we used an essentialist or realist theoretical approach, in which participants' experiences, meanings, and reality are examined in an inductive way, in contrast to other frameworks which focus on, for example, the manner in which participants' meanings are "constructed' within the broader context of society. Participants' interviews were analyzed by two members of the research team (authors JN and RB). Recurrent themes were identified and coded, and discrepancies in theme identification were resolved by discussion. Consistent with thematic analysis procedures, themes rather than numbers were analyzed and reported.

Results

Originally, 370 participants took part in this study; however, the data from 12 participants were excluded from analysis as these participants subsequently withdrew. Participant flow for the attrition substudy within the RCT is reported in Figure 1.

Of the sample of 358 participants, 69.8% (250) were female, 28.8% (103) were under 30 years of age, 45.5% (163) were married, 70.7% (253) were tertiary educated, and 57.5% (206) were in full-time employment. The mean anxiety score at baseline was 6.97 (SD 2.16), while the mean depression score at baseline was 6.47 (SD 2.11). Further details of the sample are shown in Table 2.

Figure 1. Flow diagram

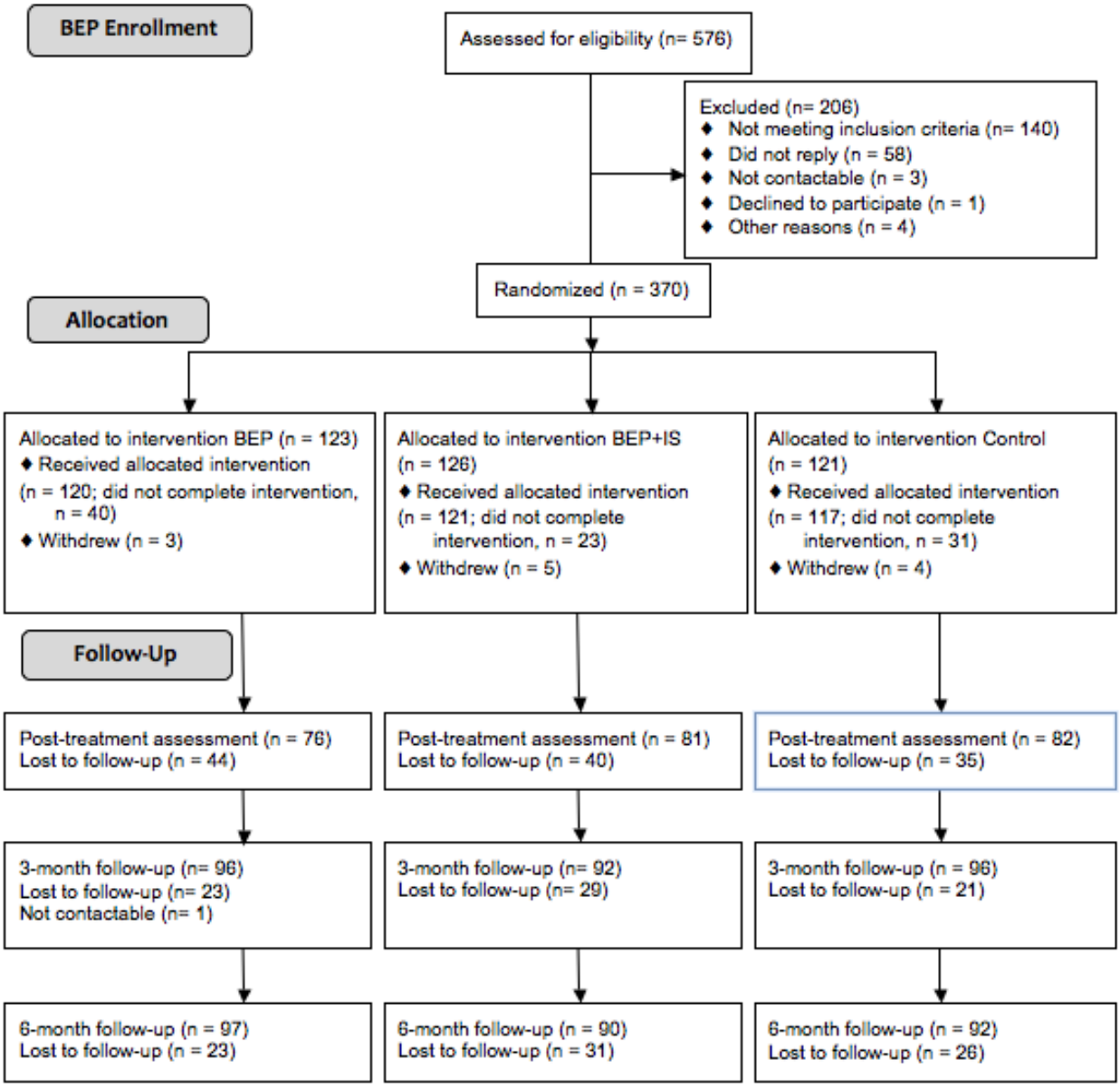


Table 2. Participant demographic characteristics

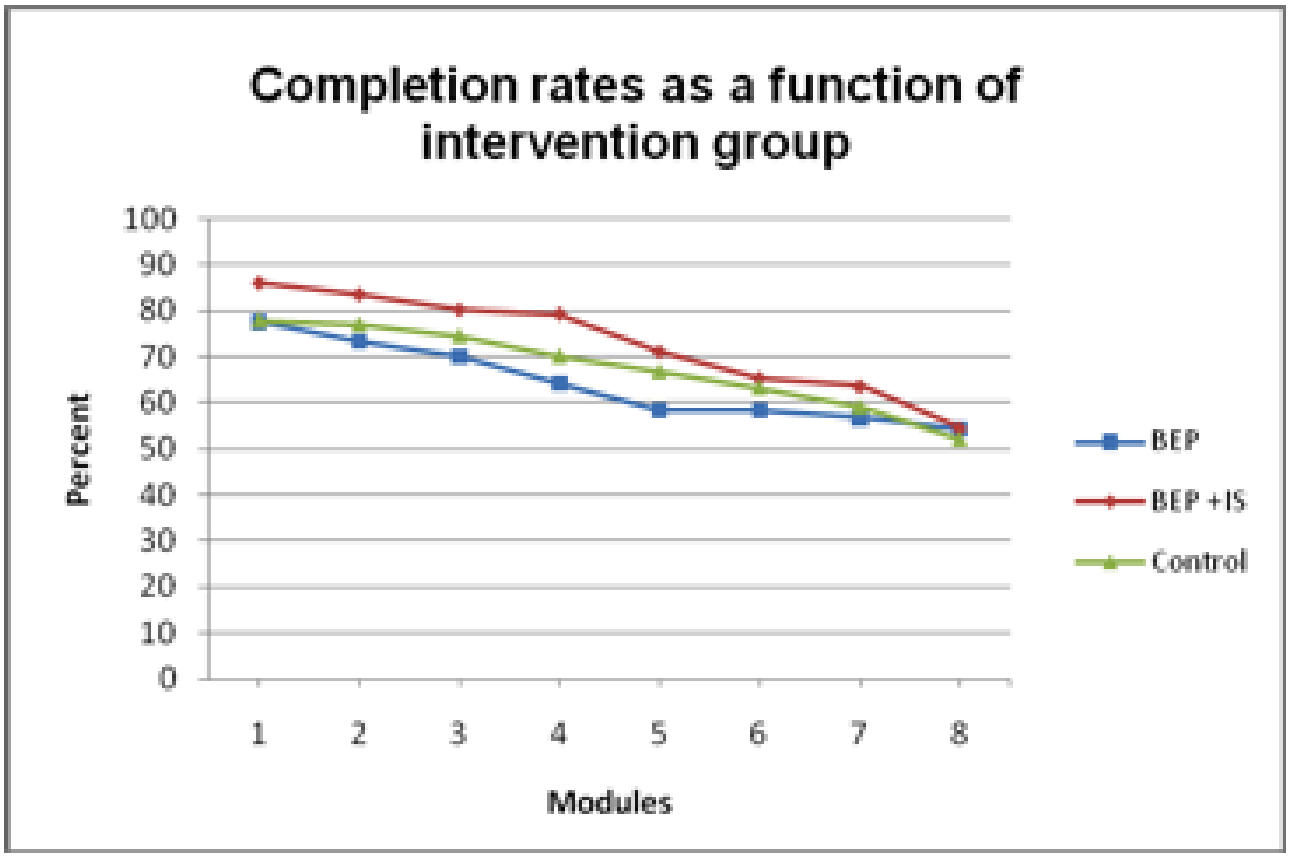
	BEP	BEP + IS	Control
	n = 120	n = 121	n = 117
	n (%)	n (%)	n (%)
Gender			
Male	38 (31.7%)	32 (26.4%)	38 (32.5%)
Female	82 (68.3%)	89 (73.6%)	79 (67.5%)
Age			
18-29	40 (33.3%)	34 (28.1%)	29 (24.8%)
30-39	43 (35.8%)	39 (32.2%)	45 (38.5%)
40-49	21 (17.5%)	35 (28.9%)	30 (25.6%)
50-59	12 (10.0%)	12 (9.9%)	11 (9.4%)
60+	4 (3.3%)	1 (0.8%)	2 (1.8%)
Marital status			
Never married	40 (33.3%)	41 (33.9%)	35 (29.9%)
Married	53 (44.2%)	54 (44.6%)	56 (47.9%)
Separated or divorced	18 (15.0%)	21 (17.4%)	21 (17.9%)
Other	9 (7.5%)	5 (4.0%)	5 (4.3%)
Highest education level			
Primary school	1 (0.8%)	0 (0%)	2 (1.7%)
Secondary school	33 (27.5%)	35 (28.9%)	34 (29.1%)
Tertiary education	86 (71.7%)	86 (71.1%)	81 (69.2%)
Employment			
Employed (full- or part-time)	66 (55.0%)	71 (58.7%)	69 (59.0%)
Unemployed	7 (5.8%)	7 (5.8%)	11 (9.4%)
Full-time education	10 (8.3%)	12 (9.9%)	3 (2.6%)
Unable to work due to sickness	16 (13.3%)	8 (6.6%)	14 (12.0%)
Looking after home/family	11 (9.2%)	8 (6.6%)	7 (6.0%)
Retired	2 (1.7%)	1 (0.8%)	5 (4.3%)
Other	8 (6.6%)	14 (11.6%)	8 (6.8%)

Of the noncompleting participants, 44 were invited to be interviewed regarding their impressions of the program and their reasons for nonadherence, of whom 39 agreed. A further 26 noncompleting participants were eligible, but we were unable to contact them. Participants from all 3 study groups were interviewed, 16 from the unsupported intervention group (BEP), 9 from the supported BEP intervention group (BEP + IS), and 14 from the minimal information control group. Of these 39 noncompleting participants, 22 (56%) were female, 20 (51%) were aged less than 30 years of age, 14 (36%) were married, 29 (74%) were tertiary educated, and 24 (62%) were in full-time employment.

Attrition Patterns

The attrition patterns of the three 8-module interventions are presented in Figure 2.

Figure 2. Completion rates for each of the 8 modules by intervention group: Bipolar Education Program (BEP); Bipolar Education Program with email support from informed supporters (BEP + IS); and minimal information about bipolar disorder (control)



Across the 3 interventions, there was a 73.5% (263/358) completion rate throughout the 8-week intervention, with the remaining 26.5% (95/358) of participants returning 3 or fewer module workbooks. Furthermore, 44.7% (160/358) of participants returned all 8 module workbooks, whereas 15.4% (55/358) did not return any module workbooks. Adherence was significantly higher in the supported intervention (98/121, 81.0%) compared with the unsupported (80/120, 66.7%) intervention ($\chi^2_{1,241} = 6.4$, $P = .01$).

Predictors of Attrition

The results of the standard multiple regression analyses are presented in Table 3.

Significant predictors of attrition were male gender, young age, and recruitment via the Black Dog Institute clinic rather than the other recruitment avenues. Males were estimated to complete an average of 0.98 fewer workbooks than females, holding all other variables constant. Participants over 30 years of age were estimated to complete an average of 1.04 more workbooks than those under 30 years of age, and those recruited from other avenues, on average, completed 1.77 more workbooks than those recruited from the clinic, holding all other variables constant for each. Level of symptomatology, highest level of educational attainment, and baseline depression and anxiety scores did not significantly contribute to the overall model. The total variance explained by the model was 14.6% ($F_{7,330} = 8.08$, $P < .001$).

Table 3. Predictors of attrition

Variable	Coefficient	Standard Error	*P*
Gender (female vs male)	-.98	.36	.001
Symptomatic at recruitment	.24	.33	.46
Age (old vs young)	1.04	.36	.004
Anxiety preintervention score	-.02	.08	.83
Depression preintervention score	-.13	.08	.66
Method of recruitment (other vs clinic)	1.77	.34	.001
Highest level of education achieved	-.11	.34	.75

Participant-Reported Reasons for Nonadherence

There were no statistically significant differences in baseline measures between interviewed participants and program completers or noncompleters who we were unable to contact or who declined to be interviewed.

A qualitative analysis of the interview transcripts elicited a number of key themes regarding reasons for noncompletion of the intervention. They related to participants' health, characteristics of the online interventions, and practical issues, as detailed below. Participant ratings of their mental health on 10-point scales at the point of discontinuation yielded the following: mean reported "general mental well-being" was 6.18 (SD 2.5) (where 0 = "normal" and 10 = "worst"); mean reported "control over their bipolar disorder" was 6.94 (SD 2.18) (where 0 = "no control" and 10 = "extreme control"); and mean reported "understanding of their bipolar disorder" was 7.17 (SD 2.12) (where 0 = "no understanding" and 10 = "understand very clearly").

Key Themes of Qualitative Analysis

Discontinuation Due to the Illness Itself

Many interviewees reported that, while they were able to complete the modules and workbooks when well, being in an acute phase of the illness interfered with their ability to participate in the program. Those in a depressive phase of the illness found the lack of energy and motivation common to depression a significant hurdle to completing the program.

> *The biggest problem I have with my bipolar disorder is consistency; when I'm down I can't even brush my teeth or get up in the morning. So doing an education program with workbooks was beyond me.* [Female, 18-29 years, BEP group]

> *A very short while after doing the program I fell into another episode, a depressive episode, and pretty much stopped doing everything, the program included.* [Male, 18-29 years, BEP+IS group]

Participants who experienced episodes of mania during the study discussed how they became distracted by their manic symptoms and were unable to complete the online modules.

> *My highs interrupt my ability to see things through, and I get caught up in my highs.* [Female, 30-39 years, Control group]

> *I often go walking when having highs because I have to keep moving, so I didn't want to sit at a computer.* [Male, 40-49 years, BEP+IS group]

Thus, the nature of the illness itself made it difficult for some participants to continue their involvement in the program. This was the most common theme in terms of reasons for discontinuation.

Did Not Want to Think About Illness

Several participants reported that they found receiving weekly information about their disorder confronting or overwhelming. Many said they did not want to think about their illness and instead wanted to put it out of their minds.

> *I found it quite confronting, and reading the information made me feel uncomfortable, thinking that these issues related to me—I preferred the ostrich approach.* [Male, 40-49 years, BEP group]

> *[I] found it difficult to sit down and do those things. I got into an anxiety and went off to do other things. I didn't really want to sit down and think about it.* [Female, 50-59 years, BEP+IS group]

Some participants reported that they were not ready to accept their diagnosis of bipolar disorder and so didn't relate to the program's information and practical advice. As the wider study was investigating the utility of the program in those newly diagnosed, some expressed the opinion that they may have enrolled in the program too soon after their diagnosis.

> *I wasn't ready to accept the illness. At that stage after diagnosis I wasn't willing to change my life according to the program.* [Male, 18-29 years, control group]

The Online Program

The online bipolar psycho-education program itself was identified as a reason for discontinuation by a few of the participants who received that intervention. Most commonly, the information was regarded as too basic or simplistic, and those participants reported that they were already aware of a lot of the content before commencing the program.

> *The information in the modules was too general and too limited.* [Male, 18-29 years, BEP group]

Other participants said they were dissatisfied with the program because they expected personally tailored information or feedback, which was beyond the scope of the current program.

> *I wanted something more about me specifically, as opposed to talking about general issues.* [Male, 40-49 years, BEP group]

There were also comments around the layout of the programs and the amount of personal information participants were required to disclose, but these were raised by single participants and, therefore, represented a minority opinion.

Feeling Well

Some participants reported ceasing to utilize the program after they gained what they wanted from it or once their mood had stabilized. Other participants indicated that they worked through the modules but did not complete the associated workbooks.

> *I was so self-absorbed at the time that I was only interested in the information [rather than in returning workbooks].* [Male, 50-59 years, BEP+IS group]

It was also reported by some participants that they no longer felt the need to participate in the program once their mood had stabilized and they were feeling well. This response was associated with another issue raised in the interviews, whereby a number of participants stated that they would reaccess the programs' information after the study was completed if/when they were feeling depressed.

> *Things really improved for me…I just felt really good and didn't really feel like I had that much to offer in*

regard to finding out more about it. [Female, 30-39 years, control group]

Time Pressures and Competing Demands

Time-related factors such as being too busy or life being too hectic were also given as reasons for discontinuation. Such reasons included being busy at work, moving house after signing up for the program, and having more important focuses.

I didn't have the time, and with everything else, it wasn't a priority. [Female, 18-29 years, control group]

However, lack of motivation was also a commonly mentioned reason, such as being forgetful or lazy about completing the program.

I have issues with procrastination. I suppose laziness is the only reason. [Female, 18-29 years, control group]

In these cases, the motivational problems were cited as personality characteristics, as distinct from symptoms of the bipolar disorder.

Discussion

A comparison of adherence rates from the 3 participant groups within the large sample showed significant differences between the groups. Participants who were supported by an expert patient "informed supporter" were significantly more likely to adhere to the program compared with those who worked through the intervention modules and workbooks alone. This is consistent with previous research, which has found that guided interventions are associated with better adherence than fully automated interventions [4]. Interestingly, adherence was poorer in the unguided intervention group than in the control condition, although the difference did not reach statistical significance. Overall, our attrition rate of 26.5% is comparable to the 31% weighted average from the systematic review of 19 Internet-based psychological treatment programs [6]. It is also comparable to the attrition rate of 21% from the meta-analysis of Web-based and non-Web-based self-care interventions for chronic illness conducted by Wantland et al [28], but it is lower than the 47% dropout rate found in the older meta-analysis of psychotherapy programs delivered face-to-face [8].

Participants recruited through the Black Dog Institute Mood Disorders Clinic were significantly less likely to adhere to the program than those recruited through the other avenues. The reason for this is unclear but may have been due to clinic-recruited participants on the whole having been very recently diagnosed (often the same day as recruitment to the study) and, while they opted to take part in the study, perhaps they needed more time to come to terms with the diagnosis in order to gain more from the online psycho-education program. It is unknown whether completing the program in the clinic setting rather than at home might have enhanced adherence for this subgroup of participants. Certainly other e-mental health programs that have been delivered in clinic settings have had good rates of adherence [29].

Our finding that young age and male gender predicted nonadherence supports that of previous e-mental health findings [15] but is in contrast to research involving face-to-face treatments, such as the study by Strom et al [30], which reported that such demographic variables did not predict patient adherence across health conditions. While the relationship between gender and attrition may be mediated by other variables in the online environment [6], reaching younger males and keeping them engaged represent two distinct challenges in e-mental health research.

Similar to studies by Lange et al [15] and Strom et al [30], we did not find a significant association between education level and attrition. This is in contrast to research involving face-to-face therapies that found that clients who were from minority ethnic backgrounds, lower income groups, or were less educated were more likely to terminate therapy prematurely [8]. Although our finding does not shed any light on the commonly held belief that more highly educated users of online interventions preferentially gain greater benefit, it does point to the need for further research to tease out the relationship (if any) between benefit from online interventions and attrition.

Among people with depression, higher symptom severity has been shown to be a predictor of decreased adherence, whereas lower generalized anxiety symptom levels has predicted better adherence [14]. However, in our study, neither being symptomatic at the time of recruitment nor the severity of baseline depression or anxiety symptoms were predictors of adherence. Participant-reported reasons for nonadherence from the interviews indicated that difficulties associated with the acute phases of the illness were common reasons for nonadherence. Yet, wellness also influenced participation. The latter finding supports the hypothesis proposed by other eHealth researchers [12] that a positive factor "e-attainment" may be the root cause of some nonadherence, that is, eHealth users cease using the intervention because they feel they have achieved as much as they wish from it. This phenomenon is particular to eHealth, probably because of the relative ease with which users can disconnect, and it warrants further research.

Not wanting to think about their illness was another reason for discontinuation mentioned by participants, and this can be interpreted in a number of ways. It may be a form of denial about the diagnosis or a need to first understand some of the more existential questions associated with the diagnosis, such as what it means about the participant as a person, that is, "who am I?" Both explanations have been documented in other studies [31]. Program factors such as the information being too general and not personally tailored were the major dissatisfactions cited by some participants in the 2 intervention arms of the study.

In summary, the key reasons for nonadherence were, in the main, participant-related, and while some of the reasons given in the qualitative interviews concerned the intervention, we were unable to explore program factors to the same extent in our quantitative study. It was interesting to note that none of the reasons for attrition related to the online setting for the intervention and the study. Our findings are consistent with studies of face-to-face treatments, in which very few variables have emerged as significant predictors of premature termination from face-to-face therapy when attrition studies have been aggregated, despite the multitude of variables that have been

examined in that context including client, therapist, and program-related factors. While the only consistent findings in face-to-face settings have related to socioeconomic variables [9], further research is needed to confirm whether the same set of variables exists across an aggregation of online studies.

Weaknesses of this study include the fact that workbook returns were used as the indicator of active participation and adherence. Other metrics may have been more precise, such as logs of page views or time spent on the website. Second, the sample of interviewees was not representative, as it was a nonprobabilistic sample, purposively selected. There is also a potential for recall bias in the interviews, as participants' current mood state was not recorded at the time of interview. Additionally, the nature of the sample (people with severe mental illness) and the type of online intervention (psycho-education rather than treatment) limits the generalizability of results from the quantitative study to other online interventions for high prevalence conditions.

Nevertheless, the study highlights a number of issues surrounding attrition that are of relevance to eHealth researchers. Further research is needed to methodologically investigate nonadherence and attrition using comprehensive interviews and prediction models to assess whether any systematic differences exist between those who complete interventions and those who do not and between those who drop out early in an intervention versus those who drop out later. Ultimately this will allow the identification of population subgroups who most benefit from eHealth interventions and will inform the development of strategies to improve adherence. The study of attrition is essential for the future efficacy and utility of online interventions.

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Conflicts of Interest

The Online Bipolar Education Program was developed at the Black Dog Institute by Gordon Parker, Vijaya Manicavasagar, Meg Smith, and colleagues with funding from New South Wales Health.

Multimedia Appendix

Advertisement for bipolar education study

[PDF file (Adobe PDF), 56 KB - jmir_v12i5e57_app1.pdf]

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Abbreviations

BEP: Bipolar Education Program
CCBT: computer-based cognitive behavioural therapy
IS: Informed Supporters
RCT: randomized controlled trial

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