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Results from a trial of an unsupported internet intervention for depressive symptoms



Yan Leykin ^{a,*}, Ricardo F. Muñoz ^{a,b}, Omar Contreras ^a, Melissa D. Latham ^a

- ^a University of California, San Francisco, United States
- ^b Palo Alto University, United States

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ABSTRACT

Internet interventions provide an option for those who either cannot or choose not to engage with traditional treatments. Most research on internet interventions involves guided or supported interventions. However, unsupported interventions offer considerably more scalability and cost-effectiveness, which makes them attractive for large-scale implementation. In this study, 309 participants recruited via Google AdWords entered an unsupported cognitive-behavioral internet intervention for depressive symptoms. To maximize the ecological validity of the study, participants received no incentives or live contact with study personnel. Furthermore, the study was open to individuals at any level of depressive symptoms, and all participants received the active intervention. The main outcome measures were depressive symptom level and self-efficacy in managing depressive symptoms. At follow-up, depression scores were significantly lower than baseline scores at each follow-up point (1, 2, 4, and 7 months), with pre-post effect sizes ranging from medium to large. Follow-up depression self-efficacy scores were significantly higher than baseline scores at each follow-up point, with pre-post effect sizes in the medium range. The results remained significant when analyzing only participants with depression scores indicative of a presence of a major depressive episode; results likewise remained significant when employing the conservative last observation carried forward convention, even in the presence of high attrition observed in this study. The results illustrate the potential of unsupported internet intervention to address the health needs of the global community.

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1. Introduction

Most individuals experiencing symptoms of depression lack access to effective interventions (World Health Organization, 2010). Many of them access the internet both to understand their symptoms and to look for resources that could address them. We have previously reported that, in a large worldwide sample of users visiting a depression screening website (Leykin et al., 2012b), 67% of participants screened positive for a current major depressive episode, yet only 25% of those screening positive for depression reported currently receiving depression treatment. These data suggest that innovative depression treatments must be developed and disseminated to individuals whom traditional therapies fail to reach. Given that the internet already attracts individuals seeking alternative resources, developing and distributing such resources on the internet is a good strategy.

The key advantages of internet interventions, including unparalleled breadth of reach, scalability, and cost-effectiveness, can primarily be

E-mail address: Yan.Leykin@ucsf.edu (Y. Leykin).

realized with interventions that are unsupported, that is, fully automated self-help interventions that do not rely on a provider, on a coach, or on any other human contact for provision of services or for intervention effectiveness. Though human contact may improve engagement and outcomes of internet interventions (Fridrici et al., 2009; Levkin et al., 2012a: Muñoz et al., 2009), it also introduces considerable costs. which can substantially reduce or even negate the aforementioned benefits of internet interventions. In contrast, fully-automated unsupported interventions can be scaled reliably without increasing costs and without the need to engage the complex network of local health systems. Indeed, the largest trials of internet interventions for depression were unsupported, both in terms of the interventions themselves as well as in terms of trial administration (Christensen et al., 2002, 2004b). The scalability and cost-effectiveness of unsupported interventions allow them to be both evaluated in and distributed to populations that do not usually participate in randomized trials, such as individuals with sub-syndromal symptoms (Powell et al., 2013). Thus, although interventions that are supported/guided by a clinician or a coach may yield somewhat greater improvement as compared to unguided interventions (Andersson and Cuijpers, 2009; Johansson and Andersson, 2012; Newman et al., 2011), these additional benefits are limited in scope given logistical challenges and costs of scaling such guidance to a larger

^{*} Corresponding author at: University of California, San Francisco, Department of Psychiatry, 3333 California St., Suite 465, San Francisco, CA 94143-0848, United States. Tel.: $+1\,415\,476\,8799$; fax: $+1\,415\,476\,7744$.

population (Johansson and Andersson, 2012). To tackle the enormous challenge of reducing the global disease burden of depression (World Health Organization, 2010), systematic efforts should be undertaken to study and enhance the unsupported delivery model.

The significant benefit of internet interventions is the ability to disseminate them exactly as they were evaluated. This is in sharp contrast to traditional face-to-face treatment, which must be disseminated by training individual providers, each of whom can introduce "drift", that is, administering their own versions of the intervention, rather than the one that was manualized and tested (Shafran et al., 2009; Waller, 2009). An internet intervention, once tested and found successful, can be offered to the public without any changes and alterations, greatly increasing the likelihood that its effectiveness in the community will be very similar to the one observed during the trial, even if it is offered worldwide to thousands of users (which is possible with unsupported interventions). However, this consistency also strongly suggests the need to evaluate an intervention in the same way as it is intended to be disseminated. Thus, common methods used by clinical trials to improve participant retention and engagement may compromise the generalizability of the original trials to their intended dissemination inasmuch as they introduce differences from the manner in which interventions will eventually be offered. For instance, financial incentives and phone-based follow-ups can improve retention in internet intervention trials (Fridrici et al., 2009; Leykin et al., 2012a; Muñoz et al., 2009). However, paying participants to visit the site or contacting them by phone to provide data exposes them to motivators that will not be present when the intervention is widely deployed. Thus, with financial incentives the ecological validity is reduced and engagement (and effectiveness) of an un-incentivized intervention remains unknown. Similarly, phone follow-ups introduce variables that will not be present beyond the trial.

Though avoiding trial components that depart from ecological validity likely increases the generalizability of its findings, doing so also introduces problems with a traditionally important component of trials — the control group. Without financial incentives, participants allocated to a control condition in an internet-based trial would have few reasons to return to the site to provide follow-up data; those who would remain in the trial will likely be unrepresentative of all randomized to this arm. The promise of future participation (waitlist) is also unlikely to improve the follow-up rate, given the expectation of immediacy on the internet and likely availability of other internet resources. A possible solution is to conduct a trial as a single-condition study, without employing the control condition. Though a randomized controlled design may be preferable for understanding efficacy, such designs may also systematically exclude individuals who may be reluctant to participate in a study where they do not have control over treatment assignment or may risk being assigned to a non-treatment group; removing randomization and the associated control group may actually increase the ecological validity of the intervention and the representativeness of trial participants.

A number of studies and meta-analyses of these studies have confirmed the efficacy and the usefulness of internet interventions (Andersson and Cuijpers, 2009; Andrews et al., 2010; Griffiths et al., 2010; Van't Hof et al., 2009), yet few ecologically valid studies, conducted in a manner closely resembling eventual dissemination, exist. Indeed, studies that are described as self-help or unguided have used financial incentives (Clarke et al., 2002, 2005) or phone interviews (Berger et al., 2011; Christensen et al., 2004a; Spek et al., 2007; Vernmark et al., 2010), or were administered in a structured setting such as a school (O'Kearney et al., 2006, 2009). The few truly unsupported studies (Christensen et al., 2002, 2004b; Donker et al., 2013; Meyer et al., 2009) used randomization, which may have turned away participants who were reluctant to receive a control condition or their nonpreferred condition. Thus, the goal of this study was to understand the efficacy of an ecologically valid fully-automated, unsupported intervention for the reduction of depressive symptoms. As subthreshold depression carries considerable burden (Judd et al., 1994), individuals at any level of depressive symptoms were allowed to take part in the trial. To understand the effectiveness of the intervention as the user would experience it, and not under more idealized conditions that could produce unreplicable results, our "pragmatic" trial used the same methods that would be available once this intervention is deployed outside of the research context. Thus, we offered no financial incentives or human support, and we employed a single-condition, unrandomized design.

2. Methods

2.1. Participants

A convenience sample of participants was recruited worldwide primarily via Google AdWords — the placement of ads to the right of the search results in the Google search engine. The ads appeared when users searched for depression, depression treatment, and related keywords. Eligible participants were 18 years of age or older, proficient in the English language, and with regular access to the internet and email (at least 3 times per week). No exclusion was made on the basis of depressive symptom scores or geographical location. Of the 1116 participants who provided enough data to evaluate eligibility, 521 (46.7%) signed the consent to participate in the study. Of these, 309 (59.3%) accessed the course. The rest (n = 212) did not access the course, either because they failed to proceed to the end of the baseline assessment (access was granted at the end of baseline assessment; n = 109), or because they did not enter the course even after completing baseline for undetermined reasons (n = 103).

2.2. Measures

Demographics questionnaire asked general demographic information, i.e., age, gender, race, ethnicity, English language proficiency, as well as frequency of access to the internet and email.

Quick Inventory of Depressive Symptomatology — Self-Seport (QIDS) (Rush et al., 2003) is a widely used 16-item self-report questionnaire measuring the severity of depressive symptoms. It assesses the presence and the severity of the nine symptoms that identify the presence of a major depressive episode according to the DSM-IV (APA, 2000). It has achieved good to excellent validity and reliability across numerous studies.

Depression Self-Efficacy Questionnaire (DSEQ), the Self-Efficacy Questionnaire for Depression in Adolescents (Tonge et al., 2005), was adapted for adult use, and modified to conform to Bandura's (2006) guidelines for creating efficacy questionnaires.

2.3. Procedures

Participants clicking on the Google AdWords ads arrived at the landing page that contained information about the study. Participants then completed the demographics questionnaire, to determine eligibility. Participants who were ineligible were informed of their ineligibility, and were provided links to other depression resources (i.e., NIH and WHO depression sites). Participants interested in joining the study electronically signed the consent document; they were then asked to verify their understanding of the key points of the consent form by correctly answering a follow-up question about the nature of the study (not a replacement for a mental health professional; responses are not reviewed in real time by a clinician). Those refusing consent were asked to list reasons for their refusal, and provided links to other online depression resources. Consenting participants were asked to provide their phone number (this step could be skipped), though no participant has actually been contacted via phone. Participants then completed several baseline measures, including the QIDS and the DSEQ and were presented detailed feedback on their responses summarized on a single page. Those indicating acute suicidality were shown a statement indicating our concern and were provided a link to Befrienders.org — an

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