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Selection of intervention components in an internet stop smoking participant preference trial: Beyond randomized controlled trials

Stephen M. Schueller [a,b], Yan Leykin [a], Eliseo J. Pérez-Stable [a], Ricardo F. Muñoz [a,b,*]

[a] Department of Psychiatry, University of California, San Francisco, CA, USA
[b] Department of Psychiatry, San Francisco General Hospital, San Francisco, CA, USA

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ABSTRACT

To address health problems that have a major impact on global health requires research designs that go beyond randomized controlled trials. One such design, the participant preference trial, provides additional information in an ecologically valid manner, once intervention efficacy has been demonstrated. The current study presents illustrative data from a participant preference trial of an internet-based smoking cessation intervention. Participants (N=7763) from 124 countries accessed the intervention and were allowed to choose from nine different site components to aid their quit attempt. Of consenting participants, 36.7% completed at least one follow-up assessment. Individuals with depression were more likely to choose a mood management module and participants who smoked a higher number of cigarettes were more likely to choose a cigarette counter and a nicotine replacement therapy guide. Furthermore, depressed participants selecting the mood management component were more likely to report at least one successful 7 day quit (37.2% vs. 22.2%) in the 12 months following the intervention. Thus, participants with depressive symptoms appear to make choices on the basis of their needs and to benefit from these decisions. This suggests that providing the ability to customize previously validated resources may be a successful way to widely disseminate interventions.

1. Introduction

The internet enables individuals to access up-to-date health information and resources comfortably and discretely from their own homes or mobile devices. In 2010, 80% of internet users indicated searching for health care information online (Fox, 2011). But the internet can go beyond providing health information. Full-scale internet-based health interventions for various concerns have been evaluated and found successful, including those for anxiety (Carlbring et al., 2011), depression (Christensen et al., 2004), and smoking cessation (Muñoz et al., 2006, 2009). Internet interventions can complement face-to-face practices and act as stand alone, fully automated self-help interventions. Guided, therapist-assisted, internet interventions can be as effective as face-to-face interventions at a lower cost (Kiropoulos et al., 2008). These interventions, however, still require the investment of professionals' time. Fully automated interventions may be less effective for each user but still valuable from a societal perspective as they can provide a basic level of care for people around the world who lack access to other resources and are scalable at a level unmatched by guided techniques (Muñoz, 2010; but see also Rabius et al. (2008) and Graham et al. (2011)).

Beyond expanding access to resources for consumers, internet interventions allow investigators to address questions that might be more difficult to study with face-to-face trials. Thus far, trials of internet interventions have largely adopted traditional research designs to determine efficacy (e.g., randomized controlled trials, RCTs). Ritterband et al. (2003) argued that randomized controlled trials are the final step in the process of developing internet interventions. However, other types of studies can provide additional information and delve deeper into questions of effectiveness and wide-scale implementation. This is especially relevant for internet interventions, the fluidity of which permits rapid modifications of trial designs (Muñoz et al., 2012).

The current study draws data from a participant preference trial of an internet-based smoking cessation intervention, previously tested in traditional RCTs (Muñoz et al., 2006, 2009). In this trial, users selected from nine possible intervention components validated in the previous RCTs. We examined whether participants chose components most relevant to their needs and whether such choices yielded higher quit rates.

Although participant choice models real world application, it poses an important question: can participants pick practices that meet their needs? Despite some evidence demonstrating that participants benefit more when receiving a preferred treatment

* Corresponding author at: UCSF Psychiatry, San Francisco General Hospital, 1001 Potrero Avenue, Suite 7M, San Francisco, CA 94110, USA. Tel.: +1 415 206 5214; fax: +1 415 206 8942.
E-mail address: ricardo.munoz@ucsf.edu (R.F. Muñoz).

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(Swift and Callahan, 2009), it migh be that people would be better off following expert opinion or empirically determined recommendations.

An open trial of an internet-delivered cognitive-behavioral intervention for anxiety disorders found that when participants chose which modules they received, rather than being assigned to them, they still experienced significant reduction in anxiety symptoms (Andersson et al., 2011). Some modules provided general techniques (e.g., cognitive restructuring, relaxation) whereas others targeted specific diagnoses (e.g., panic, agoraphobia). Although the general techniques were selected more often than the specific modules, the researchers did not examine whether choices of the specialized modules were related to specific diagnoses. More research needs to examine individual characteristics that influence choices and how these selections might relate to comparative efficacy of techniques.

The current study investigated the selection patterns of intervention components among participants visiting the "San Francisco Stop Smoking Site," an internet-based smoking cessation resource. Participants could select and access nine different intervention components from an online web portal. We report the choices that participants made and whether people selected components that addressed their specific needs. Further, we examine whether participants who chose the component that addressed a need had better quit rates than those who did not. We had two hypotheses.

1. People's choices will be related to their needs. Specifically, participants with higher levels of depressive symptoms and those who screened positive for a current depressive episode would be more likely to select the mood management component; participants smoking a greater number of cigarettes would be more likely to select a cigarette counter and a nicotine replacement therapy (NRT) guide. We predicted these components would be selected by those smoking a greater number of cigarettes because nicotine replacement is especially beneficial for those with moderate to high nicotine dependence (Fiore et al., 2008) and self-monitoring, an effective element of self-help smoking cessation programs (Foxx and Axelroth, 1983; Míguez and Becoña, 2007), has some evidence suggesting it may have a larger impact on those smoking a greater number of cigarettes (Shiffman, 2009).
2. Those who make choices that are consistent with their needs will report increased quit rates. That is, participants who are depressed will be more likely to quit if they select the mood management component; participants smoking a greater number of cigarettes will be more likely to quit if they select the cigarette counter or the NRT guide.

2. Method

The data we present are from an open participant preference trial of an internet-based automated self-help smoking cessation. Details of the intervention and quit rates are described elsewhere (Muñoz et al., 2012). Here, we present aspects of the procedure relevant to the selection of differential intervention components.

2.1. Participant recruitment

Google Adwords campaigns were the primary source of recruitment. Searching for smoking-related terms (e.g. "stop smoking" "how to quit smoking") via the Google search engine triggered a "sponsored link" (an advertisement in a column to the right of the search result). Clicking on this link forwarded the user to the website. Other participants came to the sites via organic searches (regular search result), links from other websites, media stories, or word of mouth.

2.2. Procedure

The landing page informed visitors that the smoking cessation study was open to anyone 18 years of age or older, was designed to take about 8 weeks to finish, and that follow-up surveys would be sent out to participants at 1, 3, 6, and 12 months after enrollment. Interested participants clicking on the enrollment link were asked to complete a brief questionnaire containing basic demographic information. Eligible participants (those 18 years of age or older) were asked to provide their e-mail address. Email addresses were used to send consented participants their personalized password to enter the site, the invitations to complete the follow-up questionnaires, and Individually Timed Educational Messages (Lenert et al. (2004), described below), if the participant chose this component.

After electronically signing the consent document, participants were presented a baseline questionnaire battery, which contained an extended demographics questionnaire, smoking patterns and history questionnaire, and depression measures. Participants could skip individual items but were provided a warning prior to moving on to the next page if any item was left blank. Participants were presented a list of nine components (described below) that they could select for their personalized website home page. The list, offered in a fixed order to all participants contained a brief description of each component. Selecting a component required clicking on a checkbox next to a descriptive title of each component. Upon completing their selection, participants were forwarded to their personalized home page. The personalized home page contained a navigation bar providing access to the selected components. Consenting participants were automatically e-mailed invitations to complete online follow-up assessments at 1, 3, 6, and 12 months after the date of consent.

2.2.1. Intervention components

Participants could choose from among the following nine components:

The Stop Smoking Guide (*Guía para dejar de fumar;* henceforth—"*Guía*") is an evidence-based intervention approved by the National Cancer Institute (2002). Originally developed for Spanish-speaking smokers, the *Guía* provides information about the effects of smoking and empirically validated methods for cessation.

The Nicotine Replacement Therapy (*NRT*) *Guide* offered information regarding three options for nicotine substitutes (nicotine patch, nicotine gum, and nicotine inhaler) and antidepressant medication as quit aids and guidance regarding the appropriate times to consider such interventions.

The Cigarette Counter is a tool for participants to indicate the number of cigarettes smoked during the previous day. It has a graphic interface, and the results from previous entries are displayed as a graph.

The Pre-Quit Checklist listed 10 suggestions to prepare for the quit attempt, e.g., removing smoking-related cues from one's environment, identifying situations that might lead to relapses, and dealing with those situations.

"Taking Control of Your Life" (*Tomando Control de su Vida;* henceforth—*"Tomando Control"*) is a downloadable document containing information useful for the quit attempt (e.g., keeping a daily log with activities, mood, and number of cigarettes smoked). This document had been found to significantly increase quit rates when administered via surface mail (Muñoz et al., 1997).

Mood Management is a brief cognitive-behavioral course to help participants improve their mood. It has been found effective at reducing symptoms of depression and increasing rates of quitting (Bränström et al., 2010). It contains eight lessons that highlight the link between thoughts, behaviors, and moods and how learning to gain more control over one's mood without the use of cigarettes can promote quitting.

Individually Timed Educational Messages (*ITEMs*) contain tips and encouragement to stop smoking. The emails are timed to the selected quit date and contained the link to the site; they have been shown to increase the likelihood of quitting successfully compared to a static online intervention that did not encourage participants to return (Lenert et al., 2004).

The Journal allows participants to enter notes regarding their progress (or anything else); previous entries are available for participants to review. Participants could also choose to post their journal entries on the virtual group bulletin board.

The Virtual Group is an asynchronous bulletin board where participants can post messages and respond to other user's posts. It is intended to allow participants to obtain support and information from other individuals trying to quit smoking.

2.3. Measures

Demographic questionnaire—participants were asked about their age, gender, race/ethnicity, education, and country of residence.

The *MDE Screener* (Muñoz, 1998) is an instrument designed to screen for the presence of current and past major depressive episodes (MDEs). The MDE Screener assesses the presence of the nine DSM-IV symptoms of depression during a 2-week period, as well as for Criterion C (significant impairment in functioning). This instrument has been shown to have good agreement with structured (Muñoz et al., 1999) and clinician-administered interviews (Vázquez et al., 2008).