ORIGINAL INVESTIGATION

Pilot Randomized Controlled Trial of Web-Based Acceptance and Commitment Therapy for Smoking Cessation

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ABSTRACT

Objective: Web-based smoking cessation interventions have high reach, but low effectiveness. To address this problem, we conducted a pilot randomized controlled trial of the first web-based acceptance and commitment therapy (ACT) intervention for smoking cessation. The aims were to determine design feasibility, user receptivity, effect on 30-day point prevalence quit rate at 3 months post-randomization, and mediation by ACT theory-based processes of acceptance.

Methods: Adult participants were recruited nationally into the double-blind randomized controlled pilot trial ($N = 222$), which compared web-based ACT for smoking cessation (WebQuit.org) with the National Cancer Institute's Smokefree.gov—the U.S. national standard for web-based smoking cessation interventions.

Results: We recruited 222 participants in 10 weeks. Participants spent significantly longer on the ACT WebQuit.org site per login (18.98 vs. 10.72 min; $p = .001$) and were more satisfied with the site (74% vs. 42%; $p = .002$). Using available follow-up data, more than double the fraction of participants in the ACT WebQuit.org arm had quit smoking at the 3-month follow-up (23% vs. 10%; *OR* = 3.05; 95% CI = 1.01–9.32; $p = .050$). Eighty percent of this effect was mediated by ACT theory-based increases in total acceptance of physical, cognitive, and emotional cues to smoke ($p < .001$).

Conclusions: The trial design was feasible. Compared with Smokefree.gov, ACT had higher user receptivity and short-term cessation, and strong evidence of theory-based mechanisms of change. While results were promising, they were limited by the pilot design (e.g., limited follow-up), and thus a full-scale efficacy trial is now being conducted.

INTRODUCTION

Access to effective smoking cessation treatments is critical for reducing smoking-related morbidity and mortality, which includes approximately 5 million deaths per year worldwide (Mathers & Loncar, 2006). Access barriers include inadequate training and reimbursement of treatment providers and low consumer demand for traditional treatments (Husten, 2010; Krist et al., 2010). Behavioral treatments reach fewer than 5% of smokers who try to quit (Shiffman, Brockwell, Pillitteri, & Gitchell, 2008). Fortunately, web-based interventions are an innovative behavioral treatment modality delivered at low cost and with potentially high population-level reach (Berg, 2011; Civljak, Sheikh, Stead, & Car, 2010; Hutton et al., 2011). Indeed, approximately 10% of Internet users in the United States access information about how to quit smoking on the web (Fox, 2005).

However, web-based interventions have low cessation rates of about 10%, which thereby limits their overall population-level impact (Civljak et al., 2010). While personal tailoring or adjunctive treatments such as pharmacotherapy or telephone counseling may boost effectiveness (Civljak et al., 2010; Graham et al., 2011; Hutton et al., 2011), these components limit reach because they require additional resources to develop and maintain and can increase costs as much as 5- to 10-fold (An et al., 2010). Thus, there is a need to develop more effective standalone web-based interventions that have the potential for high population-level impact.

Acceptance and commitment therapy (ACT; Hayes, Strosahl, & Wilson, 2011) is an emerging theory-based treatment that has demonstrated preliminary feasibility and efficacy for smoking cessation in several studies when delivered as face-to-face individual, group, or telephone counseling (Bricker, 2010; Bricker, Mann, Marek, Liu, & Peterson, 2010; Bricker & Wyszynski, 2012; Gifford et al., 2004, 2011; Hernandez-Lopez, Luciano, Bricker, Roales-Nieto, & Montesinos, 2009). ACT compared favorably with standard cognitive behavioral therapy for smoking cessation (30% vs. 13% quit rate at 1 year; *OR* = 5.16, $p = .02$; Hernandez-Lopez et al., 2009).

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In ACT, acceptance means allowing intense physical sensations, cognitions, and emotions that cue smoking to come and go without trying to control them. Commitment in ACT means articulating what is deeply meaningful to individuals—that is, their values—in order to guide specific plans of action (e.g., stopping smoking). Regarding values, a recent survey supports the role of values in smoking cessation (Busch & Borrelli, 2012), and, like ACT, other treatments for smoking cessation include values-focused work. For example, ACT and motivational interviewing (Miller & Rollnick, 1991) both view values as a core motivator to change, while behavioral activation for smoking cessation (MacPherson et al., 2010) focuses on identifying valued activities primarily for mood management purposes (for a comparison of these approaches, see Bricker and Tollison, 2011; Kanter & Baruch, 2006).

ACT is an outgrowth of the current standard counseling approach to smoking cessation: traditional cognitive behavioral therapy. Specifically, ACT focuses on identifying thoughts, feelings, and physical sensations that trigger smoking. Unlike traditional cognitive behavioral therapy, however, ACT does not teach methods to avoid or control these triggers (Fiore et al., 2008; Perkins, Conklin, & Levine, 2008). Rather, it focuses on changing one's relationship with them by allowing them to be present without acting on them (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). ACT focuses on increasing a person's willingness to experience urges to smoke or to be mindful of them (Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009). The efficacy of ACT for a variety of outcomes (e.g., anxiety) was mediated by increases in acceptance of internal triggers (Bond & Bunce, 2000; Forman, Herbert, Moitra, Yeomans, & Geller, 2007; Lappalainen et al., 2007), present awareness (Forman et al., 2007), and noticing thoughts as thoughts (Hayes, Strosahl, & Wilson, 1999; Zettle, Rains, & Hayes, 2011).

We developed the first web-based adaptation of ACT for smoking cessation (WebQuit.org). This study reports on a pilot randomized controlled trial of this ACT intervention (NCT#01166334). As a comparison intervention, we chose the most accessed current standard intervention for smoking cessation, the U.S. Government's Smokefree.gov—which reaches more than 1.2 million individual smokers each year (Dr. Erik Auguston, personal communication, April 18, 2011). The study aims were to: (a) show that the design was feasible—successful participant recruitment (i.e., ability to overcome recruitment challenges demonstrated in previous trials; Danaher & Seeley, 2009), and at least 50% data retention (benchmark consistent with web-based cessation trials; Civljak et al., 2010) using limited resources follow-up effort; (b) show receptivity to the ACT intervention—higher participant utilization and satisfaction in comparison with Smokefree.gov; (c) preliminarily assess ACT's 30-day point prevalence quit rate compared with Smokefree.gov at the 3-month follow-up; and (d) determine the extent to which ACT's effects are mediated by the theory-based mechanism of acceptance.

METHODS

Participants

Participants ($N = 222$) were recruited nationally via traditional media (radio and television public service announcements), web-based media (e.g., links on WebMD), social networking sites (Facebook page and Twitter messages), paid Internet advertisements (Google AdWords), and E-mails to relevant professional organizations and employers. To prevent potentially biasing participants in favor of one intervention over another, the media materials, enrollment Web site, and consent form presented the study as a comparison of "two web-based smoking cessation programs." There were no references to ACT or to Smokefree.gov in the study recruitment materials. The eligibility criteria were as follows: (a) age 18 or older, (b) smokes at least five cigarettes daily for at least the past 12 months, (c) wants to quit in next 30 days, (d) willing to be randomly assigned, (e) resides in United States, (f) has at least weekly access to a high speed Internet connection, (g) willing and able to read in English, (h) not participating in other smoking cessation interventions (including our other ongoing interventions), and (i) has never used the Smokefree.gov Web site.

Procedure

Sample Size

Consistent with the aims of this pilot study, the sample size was determined using a precision-based approach (Julious, 2010) with an assumed data retention rate of 50% ($n = 111$ treatment completers). We estimated web-based efficacy of ACT by assuming that its quit rate would be one-third lower than its in-person quit rate. This assumption was based on prior web cessation studies (of other treatment approaches) having an average one-third lower cessation fractions than their in-person delivery modalities (Berg, 2011; Civljak et al., 2010; Hutton et al., 2011). To be conservative, we used 6- and 12-month outcome data to estimate in-person ACT's quit rate at 30% (Gifford et al., 2004, 2011; Hayes et al., 2006; Hernandez-Lopez et al., 2009; Luoma et al., 2007). Therefore, we estimated that the web-based ACT's quit rate would be 20%. Assuming a 20% ACT quit rate and a 50% follow-up data retention at 3 months, 111 participants randomized to each arm ($N = 222$) would obtain 95% confidence interval (CI) width estimate of +/−10% for the ACT quit rate. The 10%–30% ACT quit rate CI was designed to provide precision toward estimating the ACT web-based quit rate for a Phase III trial.

Recruitment

Participants were recruited over a 10-week period starting June 15, 2010. Participants were directed to the study's recruitment webpage by either directly entering the URL into their web browser or by being redirected to the recruitment page by a referring link. Repeat logins from the same IP address were recorded and excluded. Participants choosing to screen for the study completed a screening survey ($n = 965$), and were notified of their eligibility via an E-mail. This E-mail was designed to indicate if the eligible participants had valid E-mail accounts. After a 24-hr run in period, all eligible participants ($n = 621$) were invited to return to the enrollment Web site. Participants who returned to the study Web site were asked to provide consent ($n = 295$), complete a baseline survey ($n = 248$), complete a follow-up contact form ($n = 242$), and click to activate the automated randomization algorithm ($n = 222$). All 222 trial participants were randomized into either the Smokefree.gov comparison group or the ACT experimental group (WebQuit.org). The proportions of self- and criterion-driven exclusions from initial screening through randomization (see Figure 1) were very similar to a large web-based smoking

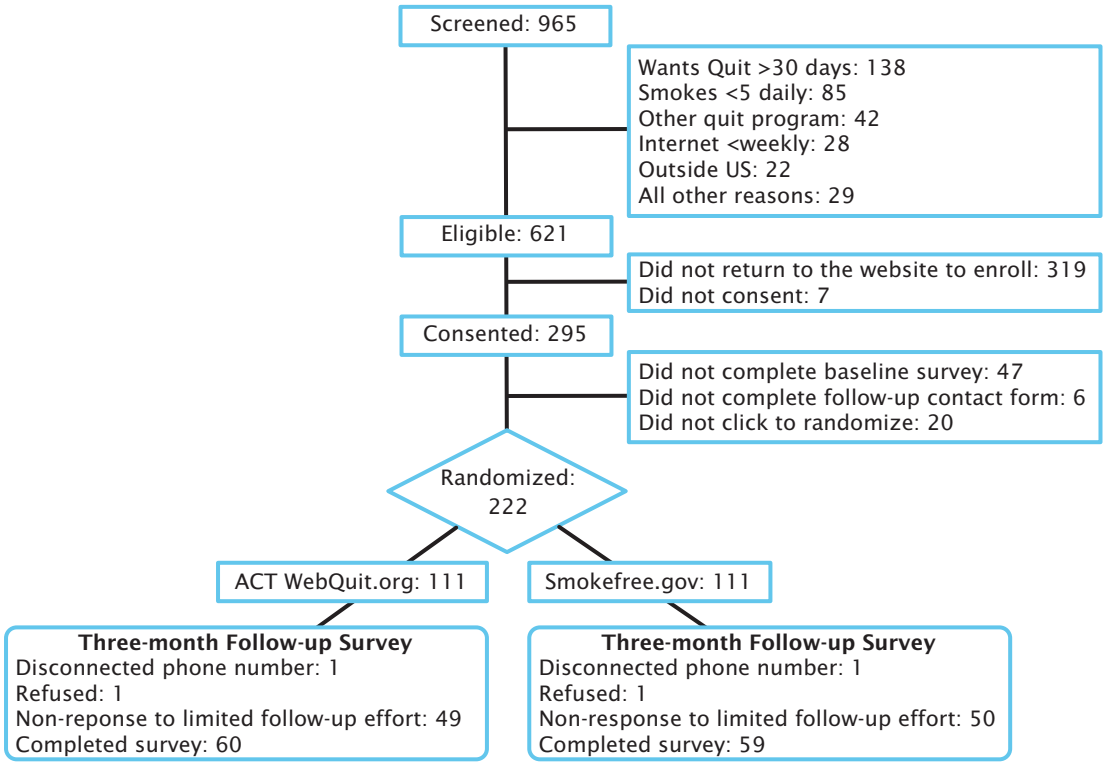

Figure 1. Participant flow diagram.

cessation trial that used recruitment methods similar to this study (Muñoz et al., 2006).

Stratified Block Randomization

We used stratified blocked randomization (with random block sizes), stratifying on two key variables known to predict smoking cessation (Borrelli, Spring, Niaura, Hitsman, & Papandonatos, 2001; Hellman, Cummings, Haughey, Zielezny, & O'Shea, 1991; Hughes & Kalman, 2006; MacKenzie, Pereira, & Mehler, 2004; Perkins et al., 2008; Shiffman et al., 1997; Ward, Klesges, Zbikowski, Bliss, & Garvey, 1997). These two variables were gender and current depression (Yes/No answer to the question "In the past 3 months, did you have a period of one week when you lost interest in most things like work, hobbies and other things you usually enjoyed?" from Means-Christensen, Sherbourne, Roy-Byrne, Craske, & Stein, 2006). Randomized study arm assignments were computer generated and concealed from participants after study eligibility was determined and consent for participation was obtained. Neither research staff nor study participants had access to upcoming randomized study arm assignments.

Experimental Intervention

The ACT experimental arm of the study was adapted from the telephone-based and group ACT intervention protocols (Bricker et al., 2010; Hernandez-Lopez et al., 2009) and developed into an eight-part, self-paced program called "WebQuit.org." The program centered on the metaphor of a car journey: the participant is the "driver" heading in the directions that matter to him or her (i.e., life values guiding quitting), the program is helping to "navigate" the way, and in the backseat are "passengers" (i.e., urges, emotions, and thoughts about quitting) carried along for the ride. The goal of the program is to make room for these "passengers" while staying focused on the road ahead—quitting smoking. Part 1 targeted ACT's core process of values guiding quitting and contained videos of former smokers describing how quitting smoking changed their lives in fundamental ways. Part 2 targeted ACT's core process of committed action by having users apply their core values guiding quitting toward a personalized quit plan (e.g., setting a quit date and smoking only during specific times). Users were invited to update this plan as necessary during their journey of quitting smoking. Parts 3–7 targeted ACT's core processes of acceptance (willingness to experience feelings or sensations), being present (staying connected with the here-and-now), cognitive defusion (watching the process of thinking), and self-as-context (awareness of the difference between one's self and one's thoughts) through a series of videos in which former smokers modeled each experiential exercise and metaphor. During Parts 3–7, participants were invited to use these skills when they had urges, withdrawal, and lapses. Part 8 invited users to review their progress in the development of new skills for quitting smoking.

Comparison Intervention

Smokefree.gov was chosen as the comparison intervention because it: (a) is the most widely accessed Web site for smoking cessation, reaching more than 1.2 million smokers each year (Dr. Erik Auguston, personal communication, April 18, 2011), (b) follows clinical practice guidelines developed by an expert panel (Fiore et al., 2008), (c) reports the highest user satisfaction rates among nonprofit smoking cessation Web sites

(Etter, 2006), and (d) has benchmark quit rates of 7%–10%, which are consistent with other smoking cessation Web sites (Berg, 2011; Civljak et al., 2010; Graham et al., 2011). Specific components of the Smokefree.gov intervention included quit planning, skills training, advice on pharmacotherapy, and social support for quitting (Fiore et al., 2008).

Follow-up Data Collection

Throughout the 3 months of active Web site use, the study's server recorded utilization data (e.g., number of logins) for each participant's assigned Web site. Three months post-randomization, participants self-reported their satisfaction with the Web site, ACT theory-based processes, and their smoking behaviors via Web survey (with limited effort phone and US mail follow-up for nonresponders). Participants received $10 in compensation for completing study assessments at 3-month follow-up. From randomization through completion of follow-up data collection, all research team members remained blind to intervention group assignment. The Fred Hutchinson Cancer Research Center Institutional Review Board approved all study procedures.

Measures

Participant Demographics and Smoking Behaviors at Baseline

Participants self-reported a variety of demographics at baseline including age, gender, ethnicity, marital status, work status, and education level. The survey also included several questions designed to assess current and past smoking behaviors. Nicotine dependence was measured with the two-item Heaviness Smoking Index from the Fagerström Test for Nicotine Dependence (cutoff score: 4 or more; Heatherton, Kozlowski, Frecker, & Fagerström, 1991).

Satisfaction

Treatment satisfaction was measured with a brief survey. A sample item was "Overall, how satisfied were you with your assigned website?" Response choices ranged from (1) *Not at all* to (5) *Very much*.

ACT Theory-Based Acceptance Processes

Acceptance processes were measured at baseline and 3-month follow-up using a 27-item adaptation of the Avoidance and Inflexibility Scale (AIS-27; adapted from Gifford et al., 2004). The AIS-27 assesses one's willingness to experience physical sensations (9 items), cognitions (9 items), and emotions (9 items) that historically cue smoking. Response choices for each item ranged from (1) *Not at all* to (5) *Very willing*. Scores for each of the three subscales, as well as a total score combining all three subscales (Cronbach's $\alpha = 0.87$ at baseline and 0.97 at follow-up), were derived by averaging their respective items.

To examine the psychometric properties of the AIS-27, we first conducted principal axis factor extraction from the baseline data ($N = 222$). This analysis produced a three-factor solution that explained a large proportion (78.7%) of the variance. The three factors were consistent with the constructs of willingness to experience: (a) physical sensations, (b) cognitions, and (c) emotions that cue smoking (9 items each). Second, using these scales, we calculated each of their Cronbach's alpha, which were .79, .67, and .72, for physical sensations, cognitions, and emotions, respectively. Third, we examined the correlations among the three factors. The physical sensations scale's correlations with the cognitions and emotions scales were .33 ($p < .001$) and .58 ($p < .001$), respectively. The emotions scale was correlated .47 ($p < .001$) with the cognitions scale. These moderate relationships among the three factors provided evidence that they each reflect related yet distinct constructs. Finally, we examined the empirical relationships of AIS-27 with related constructs and behaviors. In general, higher scores were associated with higher commitment to quitting ($r = .17$, $p < .05$ for sensations; $r = .10$, $p = .12$ for cognitions; $r = .14$, $p < .05$ for emotions), lower levels of nicotine dependence ($r = -.16$, $p < .05$ for sensations; $r = -.16$, $p < .05$ for cognitions; $r = -.11$, $p = .09$ for emotions), and fewer number of cigarettes smoked per day ($r = -.13$, $p < .05$ for sensations; $r = -.17$, $p < .01$ for cognitions; $r = -.17$, $p < .01$ for emotions).

Thirty-Day Point Prevalence Cessation Outcome

Thirty-day point prevalence abstinence was measured via consistent responses to the following two items: (a) "When was the last time you smoked, or even tried, a cigarette?" Response choices ranged from "Earlier today" to "more than 31 days ago"; (b) "Have you smoked cigarettes at all, even a puff, in the last 30 days?" Response choices were "Yes" or "No."

Statistical Analysis

Demographic characteristics, baseline smoking habits, and baseline process measures were assessed for balance between study groups using two-sample t tests for continuous variables and Fisher exact test for categorical variables. We used univariate logistic regression models to examine whether any of these same factors were predictive of 3-month retention or missingness. We considered imputing missing data (e.g., missing = smoking) but elected not to because of the potential biases in effect size estimates that can be more liberal than non-imputed results (e.g., Barnes, Larsen, Schroeder, Hanson, & Decker, 2010; Hedeker, Mermelstein, & Demirtas, 2007; Nelson, Partin, Fu, Joseph, & An, 2009). Moreover, we did not find that any baseline factors were associated with retention at 3 months and retention did not differ by treatment group (Table 1). Therefore, all subsequent analyses were restricted to the evaluable study population that completed the 3-month follow-up assessment.

Participants were analyzed in the study arm to which they were randomized regardless of exposure to or utilization of the assigned study Web site. Our primary efficacy evaluation of the two study Web sites was a logistic regression comparing of 30-day quit rates at 3-month follow-up, using analysis of the $n = 119$ participants who provided outcome data. A similar model was used to compare satisfaction between the two assigned study Web sites. We considered, as covariates, any variables that either differed between the treatment groups or were predictive of smoking cessation outcome. Participation in other treatment was the only variable that met either of these criteria, as it was predictive of outcome.

To test the extent to which 30-day quit rate differences between the two treatment arms were mediated by acceptance of physical, cognitive, and emotional cues, mediation analyses consisting of a series of three regression models for each mediator was conducted (MacKinnon, 2008). The first two regression models measured the impact of the treatment assignment (X)

Table 1. Baseline Characteristics and Their Prediction of Outcome Data Retention of Trial Participants Randomized to Each Arm

	WebQuit.org (n = 111)	Smokefree.gov (n = 111)	p value* (baseline)	p value** (retention)
Demographics				
Age, mean (*SD*)	44.8 (13.6)	45.3 (13.1)	0.76	0.84
Male	41%	35%	0.36	0.15
Caucasian	95%	90%	0.20	0.32
Hispanic	6%	3%	0.20	0.53
Married	45%	42%	0.95	0.14
Working	62%	60%	0.78	0.67
HS or less education	19%	24%	0.15	0.56
Current depressive Symptoms	42%	42%	0.99	0.32
Smoking behavior				
Nicotine dependence	46%	49%	0.35	0.69
Smokes more than half pack per day	76%	80%	0.63	0.30
Smoked for 10 or more years	81%	79%	0.45	0.20
Quit attempts in past 12 months, mean (*SD*)	1.5 (2.6)	1.4 (2.1)	0.61	0.36
Commitment to quitting	4.1 (0.8)	4.2 (0.7)	0.30	0.37
Friend and partner smoking				
Close friends who smoke, mean (SD)	1.7 (1.5)	1.6 (1.6)	0.84	0.44
Living with partner who smokes	22%	26%	0.53	0.33
ACT theory-based acceptance, mean (*SD*)				
Acceptance of physical triggers	2.85 (0.83)	2.77 (0.79)	0.45	0.76
Acceptance of emotional triggers	2.51 (0.59)	2.50 (0.54)	0.85	0.98
Acceptance of cognitive triggers	2.19 (0.68)	2.12 (0.67)	0.44	0.66
Acceptance total score	2.52 (0.57)	2.46 (0.52)	0.41	0.74

*p values compare baseline variables between the WebQuit.org (ACT) and Smokefree.gov arms. The p values were generated from two-sample t tests for continuous variables and Fisher exact test for categorical variables.
**p values assess whether baseline characteristics were predictive of 3-month retention. The p values were generated for each variable using univariate logistic regression models predicting an indicator of 3-month retention.

on: (a) the 3-month follow-up 30-day quit rate (Y) and (b) each mediator (M; change from baseline to 3-month follow-up in the acceptance variable). The third model measured the simultaneous impact of treatment assignment (X) and mediators (M) on the 3-month follow-up 30-day quit rate. All reported p values are two sided. Mediation analyses and calculation of the amount of variance explained by the mediators were conducted using the INDIRECT macro (Preacher & Hayes, 2008) for SPSS (v. 19;SPSS, Inc.: Chicago, IL). All other analyses were performed using Stata (Stata version 10.1 for Mac, College Station, TX).

RESULTS

Study Design Feasibility: Recruitment and Retention

We recruited the target sample size of 222 in 10 weeks—approximately 98 participants per month. As seen in Table 1, participant characteristics were balanced at baseline across the two treatment arms on all demographic and smoking behavior measures (all $p > .05$). One hundred nineteen participants (54%) completed the 3-month follow-up assessment. None of the baseline characteristics predicted follow-up data retention status (all $p > .05$).

Participant Receptivity: Utilization and Satisfaction

Table 2 compares participant utilization and satisfaction scores of WebQuit.org to those of Smokefree.gov. As shown in the table, WebQuit.org participants remained on the site for a significantly greater number of minutes per login than the Smokefree.gov participants. Compared with Smokefree.gov, WebQuit.org participants reported greater satisfaction with their assigned Web site, greater agreement that their assigned program was a good fit, and were more likely to report that their program's quit plan was useful.

Smoking Cessation at 3-Month Follow-up: 30-Day Point Prevalence Quit Rates

As shown in Table 2, using the available follow-up data, the 23% quit rate for the WebQuit.org group was significantly higher than the 10% quit rate for the Smokefree.gov group (OR = 3.05; 95% CI = 1.01–9.32; p = .050). In a supplementary analysis restricted to participants in either group who logged in for the recommended eight (or more) times to their assigned Web site, the quit rate in the WebQuit.org group was 41% (7 out of the 17 logging in at least eight times) compared with 0% (0 out of the 11 logging in at least eight times) of Smokefree.gov (p = .023).

Acceptance Processes as Mediators of WebQuit.org's Effects on Smoking

At the 3-month follow-up, WebQuit.org participants, compared with Smokefree.gov participants, reported greater acceptance of physical urges (p = .001), cognitions (p = .083), and emotions (p = .022) that cue smoking, as well as greater total scores

Table 2. Comparison of WebQuit.org and Smokefree.gov on Receptivity to Assigned Web site and 30-Day Quit Rate

	WebQuit.org		Smokefree.gov		
Receptivity measures	*n*	Summary	*n*	Summary	*p* value[a]
Utilization of assigned website, mean (*SD*)					
Length of each login (min)	54	18.98 (14.00)	46	10.72 (9.24)	0.001
Times logged in	52	9.02 (13.53)	48	5.46 (5.94)	0.072
Satisfaction with assigned website, *n* (%)					
Satisfied overall[b]	53	39 (74%)	52	22 (42%)	0.002
Recommend to friend	58	40 (69%)	53	29 (54%)	0.139
Overall approach for quitting a good fit[b]	56	29 (52%)	53	15 (28%)	0.014
Utility of program's quit plan[b]	57	30 (53%)	53	11 (21%)	0.001
Cessation outcome					
Thirty-day quit rate, *n* / *N* (%)	57	13 / 57 (23%)	58	6 / 58 (10%)	0.050

[a]Two-sided *p* values calculated from logistic regression models adjusted for participation in other quit programs ($n = 8$ in Smokefree.gov and $n = 7$ in WebQuit.org [ACT]). Participants in other quit programs had six times higher odds ($OR = 6.08$, $p = .006$) of not smoking in the last 30 days. Unadjusted two-sided *p* values were very similar.
[b]Responses dichotomized as "Somewhat" or "Very Much" versus "Not at all" or "A little."

for acceptance ($p = .003$). The mediation models showed that baseline to 3-month follow-up changes in each of the three acceptance processes explained a very large amount of the effect of the WebQuit.org treatment on the 3-month follow-up 30-day quit rate: 76% for acceptance of physical sensations ($p < .001$), 69% for acceptance of cognitions ($p < .001$), and 73% for acceptance of emotions ($p < .001$). Changes in the total score for acceptance accounted for 80% ($p < .001$) of the effect of WebQuit.org on the 30-day quit rate and rendered its treatment effect nonsignificant ($OR = 1.26$; 95% CI = 0.21–7.41; $p = .798$). As an exploratory analysis, we examined whether quitters in the WebQuit.org condition were more accepting at follow-up than quitters in Smokefree.gov. Results showed a nonsignificant trend of greater acceptance in WebQuit.org quitters than in the Smokefree.gov quitters (results not shown).

DISCUSSION

This pilot study of web-based ACT for smoking cessation was conducted to determine design feasibility, user receptivity to the intervention, short-term treatment efficacy, and ACT's theory-based mechanisms of change. We found that the study design was feasible. We recruited the target sample size in a relatively short timeframe (i.e., 10 weeks) and had follow-up data retention consistent with published trials of web-based cessation interventions (Berg, 2011; Civljak et al., 2010; Hutton et al., 2011). In preparation for the Phase III trial, which we now have funding to conduct, we aim to improve on recruitment efficiency by developing methods to increase the likelihood that eligible participants continue the enrollment process. Such methods include removing the 24-hr run-in period and making it possible to remain on the enrollment Web site to continue the enrollment process once a participant's E-mail address is confirmed.

We also demonstrated that user receptivity to the ACT WebQuit.org intervention was high and exceeded that of the Smokefree.gov site. Compared with Smofree.gov participants, WebQuit.org participants spent almost twice the amount of time on the site per login, and over three times as much when considering average treatment dosage as the average number of logins multiplied by the average number of minutes per login. Webquit.org participants also reported significantly greater satisfaction with the intervention.

Notably, using the available follow-up data, the WebQuit.org 30-day point prevalence quit rate was over double that of the Smokefree.gov quit rate (23% vs. 10%). These differences were even more powerful among those who completed the recommended number of Web site logins (41% vs. 0%). Participants who frequently logged in may have been highly motivated to seek help to quit smoking. Those who were assigned to ACT may have found the help they were looking for, whereas those assigned to Smokefree.gov may have been discouraged. We plan to empirically test this interpretation in our Phase III trial.

Our preliminary estimate of the efficacy of WebQuit.org is significant because it was obtained without the offer of pharmacotherapy and provides rare evidence suggesting that an intervention Web site was more effective than an active treatment comparison Web site (Berg, 2011; Civljak et al., 2010; Graham et al., 2011; Hutton et al., 2011; Shahab & McEwen, 2009; Webb, 2009). Indeed, the results suggest that the ACT WebQuit.org Web site has the potential to improve on the most accessed cessation Web site in the world and arguably the current standard of care for web-based interventions. Given the high reach of web-delivered interventions, the population-level impact of WebQuit.org's quit rate could be significant if validated in a Phase III trial with longer term follow-up. And while these results were promising, they should be interpreted with caution given limitations of the pilot design (e.g., limited follow-up).

Finally, the mediational analysis showed that the difference between ACT's quit rate and Smokefree.gov's quit rate could be largely explained by the ACT arm's greater increases in noticing and not acting on urges to smoke (i.e., acceptance). While a stronger design would be to measure longitudinal changes in acceptance well before the quit smoking outcome (MacKinnon, 2008), these results are significant for three reasons. First, they suggest that the differences in quit rates are largely due to the two Web sites' differences in intervention content. Second, they suggest that interventions increasing one's willingness to notice and not act on a smoking urge may

boost the success rates of web-based smoking cessation interventions. Finally, the results comport with the ACT theoretical model of behavior change and are consistent with prior mediational results for when ACT was delivered as a face-to-face intervention for quitting smoking (Gifford et al., 2004, 2011).

The study has key limitations. First, rates of follow-up data retention in the study were modest overall at 54%. While this figure is consistent with other published rates of retention in web-based treatment studies (Berg, 2011; Civljak et al., 2010; Hutton et al., 2011), with far less than 100% retention it is difficult to know the actual quit rates in each arm. Accordingly, our Phase III trial will focus on maximizing outcome data retention through methods such as higher participant incentives and multimodal surveys, thereby reducing potential biases in the outcome data comparisons. Second, we relied exclusively on self-reported abstinence in our estimate of 30-day point prevalence abstinence. However, expert consensus (SRNT Subcommittee on Biochemical Verification, 2002) suggests that biochemical verification of abstinence is impractical and unnecessary in population-based studies that do not involve in-person contact. Moreover, there is no reason to believe that the validity of self-reported abstinence would differ by treatment group. Finally, men and racial/ethnic minorities were underrepresented in this study, possibly due to women's greater predilection for using the Internet to seek health information (Fallows, 2005) as well as current disparities in Internet access among racial/ethnic minorities (U.S. Department of Commerce, 2011). Consequently, the generalizability of our findings to these groups is not known. Overall, however, participant demographics (e.g., race/ethnicity and education) and smoking behaviors were consistent with those in other nationally recruited randomized trials of web-based smoking cessation interventions (Civljak et al., 2010; Hutton et al., 2011; Shahab & McEwen, 2009). Taking these limitations into account, the results should be interpreted with caution.

This is the first trial of web-based ACT for smoking cessation. Moreover, we are aware of only one other study of web-based ACT for any condition (tinnitus). However, in that study the intervention was supplemented with online support from a therapist, making it difficult to disentangle the effects of the self-guided web program from the effects of therapist support (Hesser et al., 2012). Thus, our pilot data not only support the feasibility and efficacy of web-based ACT as a standalone intervention for smoking cessation but they also build on successful prior studies demonstrating feasibility of ACT and preliminary efficacy for smoking cessation when delivered in face-to-face individual, group, and telephone counseling formats (Bricker et al., 2010; Gifford et al., 2004, 2011; Hernandez-Lopez et al., 2009). Web delivery of ACT for smoking cessation, if confirmed effective in a Phase III trial, would allow the intervention to be disseminated broadly and delivered in a consistent and cost-effective manner.

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DECLARATION OF INTERESTS

Dr. Heffner has in the past served as a consultant for Pfizer. None of the other authors have competing interests to disclose.

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