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Single-Arm Trial of the Second Version of an Acceptance & Commitment Therapy Smartphone Application for Smoking Cessation

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Abstract

Background—The first randomized trial of a smartphone application (app) for adult smoking cessation (SmartQuit 1.0) revealed key features that predict cessation. These findings guided the revision of this Acceptance & Commitment Therapy (ACT)-based application (SmartQuit 2.0), which was primarily tested to examine participant receptivity, short-term cessation and reduction, and the relationship between program completion, smoking cessation and reduction. Secondly, outcomes were descriptively compared with the SmartQuit1.0 trial.

Method—Adult participants (78% female, 25% with high school or less education, 30% unemployed) were recruited into the single-arm pilot trial ($N=99$) of SmartQuit 2.0 with a two-month follow-up (85% retention).

Results—Regarding receptivity, 84% of participants were satisfied with SmartQuit 2.0 (vs. 59% for SmartQuit1.0), 73% would recommend it to a friend (vs. 48% for SmartQuit1.0), 81% found the ACT exercises useful for quitting (vs. 44% for SmartQuit1.0). At the 2-month follow-up, the quit rates were 21% for 7-day point prevalence (vs. 23% for SmartQuit1.0), 11% for 30-day point prevalence (vs. 13% for SmartQuit1.0), and 75% of participants reduced their smoking frequency (vs. 57% for SmartQuit1.0). Among program completers (24% of total sample), the quit rates were

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Contributors. Jonathan Bricker conceptualized and designed the study, oversaw the trial conduct, participated in the analysis, interpreted the results, and wrote the manuscript. Wade Copeland conducted the analysis and participated in the interpretation, Kristin Mull led the conduct of the propensity score matching analysis, wrote the statistical analysis section, and participated in the interpretation, Emily Zeng, Noreen Watson, and Jaimee Heffner participated in the interpretation of the study results, Noreen Watson participated in analysis planning, interpretation of the study results, and editing of the manuscript. All authors have approved the final article.

Conflicts of Interests. In July 2016, Jonathan Bricker was a consultant to GlaxoSmithKline, the manufacturer of nicotine replacement therapies. Fred Hutchinson Cancer Research Center holds a patent on the ACT app for smoking cessation, and 2Morrow® holds an exclusive license to distribute the app.

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33% for 7-day point prevalence, 28% for 30-day point prevalence, and 88% of participants reduced their smoking frequency.

Conclusions—The revised app had high user receptivity, modest quit rates, and high smoking reduction rates. Program completion may be key to boosting the app’s effectiveness.

Keywords

smoking cessation; nicotine dependence; mHealth; smartphone; acceptance; mindfulness

1. INTRODUCTION

Each year in the United States (US) alone, cigarette smoking: (1) accounts for 480,000 deaths; (2) remains the number one preventable cause of premature death; (3) causes diabetes and multiple cancers including colorectal and liver cancers; and (4) costs \$289 billion in healthcare and lost productivity (CDC, 2014). Funding in the US for population-level smoking cessation programs (e.g., telephone quitlines) remains far below CDC-recommended levels. Consequently, there is a tremendous need for smoking interventions with strong potential population-level impact at the lowest possible cost (CDC, 2014).

Technology innovations such as smartphone-based smoking cessation applications (“apps”) may offer that potential (Abroms et al., 2014; Buller et al., 2013). Highlighting this potential, using the xyo.net app search engine, we found 546 English language smoking cessation apps in the Apple Store and Google Play that were downloaded an estimated 3.2 million times in the United States and 20 million times worldwide. By contrast, from 2012 to 2013, there were an estimated 1 million enrollments to US tobacco quitlines (North American Quitline Consortium, 2013; Leischow et al., 2012) and an estimated 140,000 total subscriptions to US text messaging programs (L. Abroms, personal communication, March 4, 2014; E. Augustson, personal communication, March 4, 2014).

The reach of smoking cessation apps is climbing rapidly, greatly aided by the growing ownership of smartphones. The majority (64%) of US adults now own smartphones (Smith, 2015), and ownership is projected to reach at least 90% by 2020 (Dediu, 2013; Statista, 2014). The greatest ownership growth rate is among those with lower socioeconomic status (Nielsen, 2013; Smith, 2013). The current and projected demographics of smartphone ownership suggest that this treatment modality (apps) could reach a greater proportion of smokers and address known tobacco-related health disparities associated with socioeconomic status (Fagan et al., 2004).

We recently published the first randomized trial of a quit smoking app (SmartQuit1.0) for general adult cessation (Bricker et al., 2014). The app followed a behavior change model called Acceptance & Commitment Therapy (ACT; Hayes et al., 2006). ACT focuses on increasing willingness to experience physical cravings, emotions, and thoughts while committing to values-guided behavior changes. In the context of ACT, acceptance refers to making room for intense physical sensations (e.g., urges), emotions (e.g., sadness), and thoughts (e.g., “I really need a cigarette right now.”) that trigger smoking while allowing them to come and go. Commitment in ACT refers to articulating what is deeply meaningful

to individuals—their values—to motivate and guide specific plans of action (e.g., stopping smoking). In our first study, participants were recruited nationally into the double-blind randomized controlled pilot trial ($N=196$) that compared the SmartQuit 1.0 app with the National Cancer Institute's app for smoking cessation (QuitGuide). Demonstrating promise for the modality of treatment, the overall quit rates at two months were 13% in SmartQuit 1.0 vs. 8% in QuitGuide (OR=2.7; 95% CI=0.8–10.3) (Bricker et al., 2014).

To potentially improve upon SmartQuit 1.0 (SQ1.0), we examined which app features were prospectively associated with quitting smoking. These features included: tracking ACT skills practice (OR = 16.4; $p=.01$), tracking practice of letting urges pass without smoking (OR = 10.5; $p=.03$), and viewing a variety of ACT-specific skills exercises (Heffner et al., 2015). Guided by these results, we revised the app as SmartQuit 2.0 (SQ2.0).

The primary aim of this study was to employ a single-arm trial of SQ2.0 in order to determine participant receptivity, short-term smoking cessation and reduction, and the impact of program completion on smoking cessation and reduction. The secondary aim of this paper was to explore whether SQ2.0 is an improvement over SQ1.0 by descriptively comparing the outcomes of the current SQ2.0 trial to the outcomes of the SQ1.0 randomized trial (Bricker et al., 2014).

2. METHODS

2.1. Participants

All study procedures were reviewed and approved by the Fred Hutchinson Cancer Research Center Institutional Review Board. To be eligible, participants had to: (1) be age 18 or older, (2) smoke at least five cigarettes daily for at least one year, (3) want to quit smoking in the next 30 days, (4) have daily access to a smartphone, which was either an iPhone IOS Version 6 or higher or Android Version 4.1 or higher and (5) not be participating in any other cessation interventions.

2.2. Recruitment

From March to May, 2015, potential participants were recruited through their employers ($n=150$) or Facebook advertisements ($n=293$) and were emailed a link to the recruitment website to fill out a screening form. Participants who screened eligible ($n=347$) completed consent ($n=221$), filled out baseline measures that included confirmation of eligibility criteria ($n=201$), and provided their email address twice for confirmation ($n=161$), were emailed a secured link and passcode to download the app ($n=99$ downloaded). The proportions of self- and criterion-driven exclusions from initial screening through enrollment, especially in the large drop between consent and downloading the app, were very similar to our first app-delivered (Bricker et al., 2014) and web-delivered intervention trials (Bricker et al., 2013), and a large web-based smoking cessation trial that used recruitment methods similar to the current study (Muñoz et al., 2006).

2.3. Data Collection

Participants who completed the consent form completed an online baseline survey that assessed demographic and smoking characteristics (baseline characteristics are shown in Table 1). We administered a follow-up survey two months post enrollment. To maximize retention, we sequentially timed the administration of separate survey modalities until the surveys were completed: first via the web, followed by telephone, and then by mail. Participants were compensated with a \$25 online gift certificate to Amazon, Inc. for completing the survey. The retention rate of 85% (84/99) was much higher than the 54% typically obtained in web-based cessation trials (Civljak et al., 2010; Shahab and McEwen, 2009) and nearly identical to the 84% attained in the Bricker et al. trial (Bricker et al., 2014).

2.4. App Description

SQ2.0 prominently presented, via the menu, the features which SQ1.0 trial data predicted smoking cessation (Heffner et al., 2015); (See Figure 2 for a SQ2.0 main menu screen shot). Specifically, upon initially opening the app, users were prompted to complete a quit plan, including picking a quit date. Afterwards, users were directed to the main menu which on the top half allowed users to view the eight core ACT exercises and on the bottom half allowed users to track urges they let pass without smoking. Regarding the eight core exercises, as the practice of these ACT skills predicted cessation (Heffner et al., 2015) users were tunneled, via sequentially unlocking each skill 24 hours after viewing the previous exercise. The intent was to directly guide users to practice each exercise daily, with each skill building on the previous skill. (By contrast, in SQ1.0 these exercises and many others were presented in an unstructured, unlocked, and non-successive format throughout a variety of program menus, with all exercises accessible at any time). Since practicing letting urges pass strongly predicted cessation, and acceptance is a core process underlying the ACT model, we created an “urge pass” tracker on the bottom of the main menu that allowed a user to track each time he/she let an urge pass and receive progress badges at an interval of every ten urges passed. By contrast, in SQ1.0 urge pass tracking was part of a separate “Track Your Progress” menu that asked users to track a variety of progress indicators. In addition to the main menu, users had immediate access to the “Anytime Coaching” section, which included other ACT-based exercises to support quitting, and with additional exercises unlocked after the eight core exercises are viewed to reinforce content presented in the core exercises. Users were informed that “program completion” would mean meeting the following requirements: (1) creating a quit plan, (2) completing the initial eight ACT modules, (3) tracking letting at least 10 urges passing, and (4) visiting the “Anytime Coaching” section at least once. The app displayed a “certificate of completion” for completing the program. By contrast, SQ1.0 did not have a defined program completion as it was unstructured and content was presented in a non-successive format.

2.5 Measurements

2.5.1 Receptivity—App receptivity at the two-month follow-up was measured with a three-item survey that included questions such as: “*How useful were your program's skills exercises for quitting smoking?*” Response choices ranged from “*Not at all*” (1) to “*Very much*” (5).

2.5.2 Smoking Cessation—To detect a potential signal in this short-term trial, the two-month post-enrollment follow-up survey assessed 7-day and 30-day point prevalence abstinence (Brunette et al., 2015; Courtney et al., 2016; Salepci et al., 2016). Due to cost and low demand characteristics for false reporting, the SRNT Subcommittee on Biochemical Verification recommends biochemical confirmation is unnecessary in population-based studies with limited face-to-face contact and studies where the optimal data collection methods are through the mail or telephone (Benowitz et al., 2002). Therefore, self-reported smoking is a standard method for assessing the efficacy of low-intensity interventions (Hutton et al., 2011; Stead et al., 2013), and was used in the current study.

2.5.3 Smoking Reduction—On the baseline and follow-up surveys, participants were asked how many cigarettes they smoked per day at that time. Because people who reduce their smoking are more likely to quit smoking (Hughes and Carpenter, 2006), we operationalized smoking reduction as the fraction of participants who reduced their smoking rate from baseline to the two-month follow-up.

2.6 Data Analysis

For the primary aim, descriptive statistics were used to estimate receptivity to the app, smoking cessation and reduction, and impact of program completion. Consistent with complete case analytic methods, only those who responded to questions about their smoking status in the outcome survey ($n = 84$; 85% retention) were included in these analyses. We did not use the worst-case scenario assumption that non-respondents were still smoking (i.e., missing = smoking) because such imputation has been shown to result in biases in effect size estimates, and may lead either to (1) reduced statistical power and increased type II error, or (2) underestimation of variance and increased type I error, depending on the smoking cessation rate of respondents (Hallgren and Witkiewitz, 2013; Nelson et al., 2009).

For the secondary aim, the main method of analysis was to descriptively compare the current single arm trial's SQ2.0 participant receptivity, cessation, and reduction with those of the prior SQ1.0 randomized trial (Bricker et al., 2014). In comparison with the SQ1.0 trial, participants in SQ2.0 had a difference (p value under .10) in the following baseline factors that predicted lower odds of cessation in either the SQ1.0 or 2.0 trial data: *age* (Mean = 38.4 vs. 41.5, p value for baseline difference = .042; p value for predicting cessation = .020 in both SQ1.0 and SQ2.0), *proportion of women* (78% vs. 53%, p value for baseline difference = .001; p value for predicting cessation = .001 for SQ1.0 and .27 for SQ2.0), *severity of nicotine dependence* (Mean = 5.5 vs. 4.9, p value for baseline difference = .062; p value for predicting cessation = .054 for SQ1.0 and .42 for SQ2.0) and *smokes more than half pack per day* (83% vs. 70%, p value for baseline difference = .059; p value for predicting cessation = .718 for SQ1.0 and .016 for SQ2.0). Given these differences, we also conducted an emerging method of analysis, called propensity score matching (PSM; Boccio et al.; Stuart, 2010), to adjust for these four, above-named covariates that (1) differed at baseline and (2) predicted the smoking cessation outcomes in either SQ1.0 or SQ2.0. The reason for this latter criterion is that variables which do not predict outcome have been shown to decrease precision of the resulting propensity score estimators and violate positivity of the model (Westreich et al., 2011; Wyss et al., 2013). Using the inverse probability of treatment

weighted method (IPTW; Boccio et al., 2015) of PSM, the SQ1.0 and SQ2.0 datasets were balanced, and a standardized difference of less than 0.10 was considered to be acceptable. The datasets were compared by conducting logistic regression analysis weighted by propensity scores. All statistical tests were two-sided, with $\alpha = 0.05$.

3. RESULTS

3.1. Participant receptivity

As shown in Table 2, user receptivity to SQ2.0 was generally high: 84% were satisfied with the app (vs. 59% for SQ1.0), 73% would recommend it to a friend (vs. 48% for SQ1.0), 81% found the ACT exercises useful (vs. 44% for SQ1.0), and 93% reported the app was easy to use (question not asked in Bricker et al. 2014 study of SQ1.0). The mean number of logins for SQ2.0 was 18.2 (SD = 21.2) vs. 34.1 (SD = 78.8) for SQ1.0. PSM results comparing SQ2.0 with SQ1.0 were similar to those of these descriptive results: satisfaction (84% vs. 57%; $p=.003$), recommend to friend (73% vs. 47%; $p=.012$), and ACT exercises useful (80% vs. 43%; $p=.0002$), and logins (18.3 vs. 31.4; $p=.073$).

3.2. Smoking cessation and reduction

Overall, the quit rates for SQ2.0 were 21% for 7-day point prevalence (vs. 23% for SQ1.0), 11% for 30-day point prevalence (vs. 13% for SQ1.0), and the smoking reduction rate was 75% (vs. 57% for SQ1.0). PSM results comparing SQ2.0 with SQ1.0 were similar to those of the main descriptive results: 7-day point prevalence (19% vs. 20%; $p=.976$), 30-day point prevalence (10% vs. 10%; $p=.827$), and smoking reduction rate (73% vs. 56%; $p=.127$).

Among participants who completed the program (24% of all participants), the quit rates were 33% for 7-day point prevalence, 28% for 30-day point prevalence, and 88% of participants reduced their smoking rate. As there is not a comparable definition of “treatment completion” for SQ1.0, this comparison was not made between the two versions.

4. DISCUSSION

4.1. Summary of Results

The primary aim of this paper was to determine participant receptivity, smoking cessation and reduction, and the impact of program completion on cessation and reduction from a single-arm trial of SQ2.0. The results showed that SQ2.0 (1) has high user receptivity, (2) yields modest quit rates, and (3) yields high rates of smoking reduction. Smoking cessation and reduction rates were higher among those who completed the program. The secondary aim of this paper was to explore whether SQ2.0 improved on SQ1.0. Although SQ2.0 had a lower number of app openings than SQ1.0, the results showed that SQ2.0 had descriptively higher user satisfaction, similar quit rates, and descriptively higher reductions in smoking. The propensity score matching analysis provided similar results.

4.2. Implications

The results suggest several implications for the app’s design and intervention features. Regarding design improvements over SQ1.0, the results suggest that SQ2.0 was easier to

navigate and it was clearer to the user what he/she needed to do to make use of the program. We think the main menu, split between the eight core ACT exercises and the urge pass button, helped create that clarity, and this was reflected in high user receptivity results. On the other hand, the lower number of app openings in SQ2.0 might have been due to the fact that users were required to return at least 24 hours later to unlock the next core ACT exercise. While the 24 hour lock was designed to encourage practicing a given core ACT skill, it might have had the opposite effect of discouraging engagement with the app by requiring users to wait a day to see the next exercise.

Regarding intervention features, the clear limitation of both SQ2.0 and SQ1.0 was the very modest quit rates that were similar in both trials. This might be because, like most software interventions (Richardson et al., 2013; Strecher et al., 2008), user engagement was modest. However, if users completed the SQ2.0 program, the quit rate was substantially higher. Indeed, we recently reported that in SQ2.0, program completion predicts a 4.45 times higher odds of quitting smoking ($p = .032$) and in that report we also present the predictors of program completion (Zeng et al., 2016). This result suggests that the SQ2.0 program, if utilized, might be more effective for quitting smoking.

The data suggest that SQ2.0 was more effective than SQ1.0 at helping users reduce their smoking rate. This is encouraging because reduction can lead to a greater likelihood of eventual cessation (Hughes and Carpenter, 2006). The higher reduction rate might be because the SQ2.0 focused on the eight core ACT exercises that teach users how to let urges pass—the theoretical process of accepting cravings without having a cigarette. So, it might be that SQ2.0 was more useful at the urge level, which in turn, helped users not smoke in a given moment. This focus on the process of letting urges pass might have helped users to cut back their overall smoking rate. What might be needed next is a greater emphasis in the program on achieving the outcomes of quitting (e.g., skills to practice on the quit day) and staying quit (e.g., skills to practice each day following the quit day).

4.3. Future Direction: Increase Engagement

The results generally suggest that a key to making SmartQuit more effective for smoking cessation is to increase program completion—as quit rates were much higher among completers. Future research might be to apply gaming elements that reinforce skills comprehension (e.g., quizzes) and progress (e.g., money saved by not smoking). Gaming elements might include different levels of “expertise” to reach based on ACT skills practice, progress in letting urges pass, and smoke-free days. ACT skills training tailored to the user’s specific needs and challenges in a given moment (e.g., feeling stress) may also provide the user a higher level of interactivity, and thereby higher engagement. Future experimental research on methods for locking content (e.g., by time vs. by progress) might also identify design features that increase engagement in specific components of the program.

4.4. Limitations

The study has important limitations. The small sample size limited precision of the estimate of main outcomes. The one-arm trial design did not make it possible to compare SQ2.0 to SQ1.0 with strong inferences. The follow-up period was short; substantial relapse naturally

occurs after a two-month follow-up (Hollis et al., 2007; Stead et al., 2013), therefore a longer term follow-up (e.g., 12 months) is recommended in future trials. Finally, we relied exclusively on self-reported abstinence in our estimate of 30-day point prevalence abstinence. However, expert consensus suggests that biochemical verification of abstinence is impractical and unnecessary in studies similar to the current one (Benowitz et al., 2002).

4.5. Conclusion

SmartQuit 2.0 has (1) high user receptivity, (2) modest quit rates, and (3) high reduction in smoking. While the reduction rate (75%) was encouraging, increasing program engagement might be important for increasing quit rates.

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Highlights

- Participants were receptive (73%-84%) to the SmartQuit 2.0 smoking cessation app.
- The app's quit rate was 21% (7D PP) and smoking reduction rate was high (75%).
- Program completers had high quit (33% 7D PP) and reduction rates (88%).
- SmartQuit 2.0 had higher receptivity and reduction rates than SmartQuit 1.0.

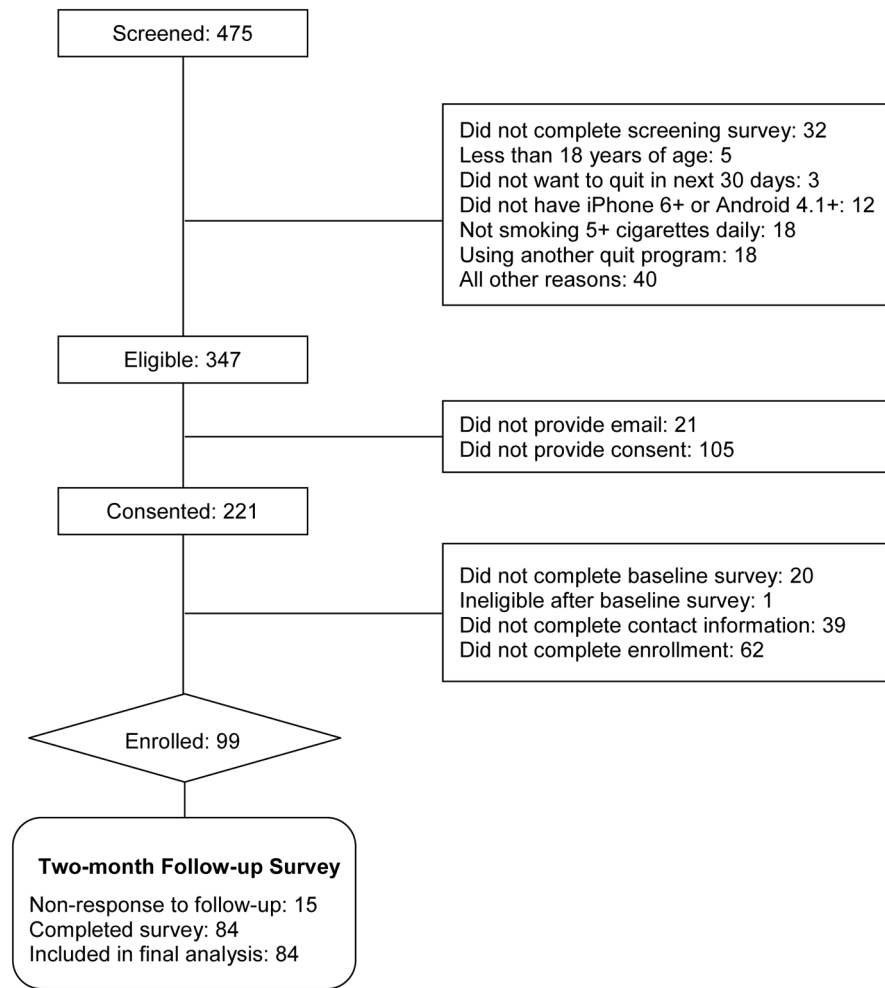


Figure 1.
Participant Flow Diagram

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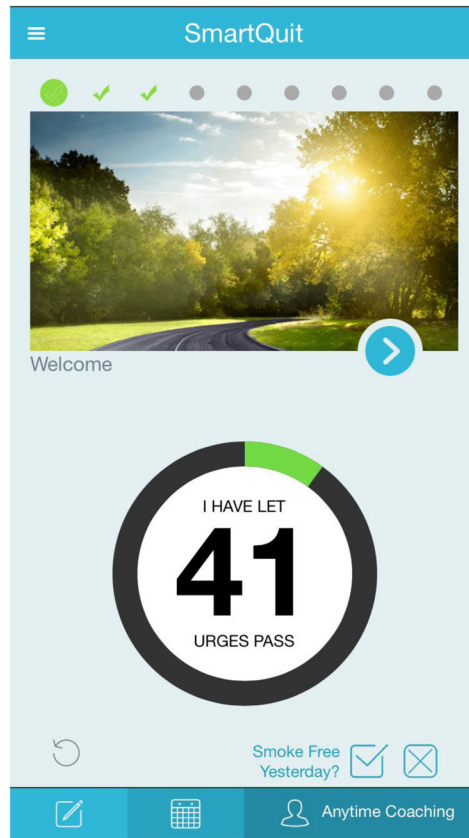


Figure 2.
SmartQuit 2.0 Main Menu

Table 1

Baseline characteristics of the SmartQuit 2.0 study participants and comparison with the SmartQuit 1.0 (Bricker et al., 2014) study participants.

	SmartQuit 2.0 (n=99)	SmartQuit 1.0 (n=98)
<i>Demographics</i>		
Age, mean (SD)	38.4 (8.9)	41.5 (12.0)
Female	78%	53%
Caucasian	97%	85%
Hispanic	6%	4%
Married	40%	37%
Working	70%	58%
HS or less education	25%	14%
<i>Smoking Behavior</i>		
Nicotine Dependence, mean (SD)	5.5 (2.1)	4.9 (2.5)
Smokes at least a pack per day	32%	28%
Smoked for 10 or more years	81%	72%
First cigarette within 5 minutes of waking	47%	30%
Quit attempts in past year, mean (SD)	1.1 (3.2)	1.7 (4.1)
Living with partner who smokes	24%	24%
<i>ACT Theory-Based Measure, mean (SD)</i>		
Acceptance of cravings score ^I	2.84 (0.49)	2.87 (0.36)

^IResponse choices for each item ranged from “Not at all” (1) to “Very willing” (5).

Scores were derived by averaging the items.

Table 2

Receptivity, engagement, cessation, and reduction rates of SmartQuit 2.0 study participants and comparison with SmartQuit 1.0 (Bricker et al., 2014) study participants.

	SmartQuit 2.0		SmartQuit 1.0	
	n	Summary	n	Summary
<i>Satisfaction with assigned application, % (n)</i>				
Satisfied overall ^I	70	84% (59)	75	59% (44)
Recommend to friend	70	73% (51)	79	48% (38)
ACT exercises were useful ^I	69	81% (56)	75	44% (33)
<i>Engagement</i>				
Times application was opened	99	16.6 (20.5)	98	34.1 (78.8)
<i>Cessation and reduction rate, % (n)</i>				
7-day point prevalence abstinence	82	21% (17)	80	23% (18)
30-day point prevalence abstinence	82	11% (9)	80	13% (10)
Smoking reduction	72	75% (54)	79	57% (45)

^I Responses dichotomized as “Somewhat”, “Mostly”, or “Very Much” vs. “Not at all” or “A little”