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Full length article

## Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy

Jonathan B. Bricker<sup>a,b,\*</sup>, Kristin E. Mull<sup>a</sup>, Julie A. Kientz<sup>c</sup>, Roger Vilardaga<sup>a,d</sup>,  
Laina D. Mercer<sup>a</sup>, Katrina J. Akioka<sup>a</sup>, Jaimee L. Heffner<sup>a</sup>

<sup>a</sup> Fred Hutchinson Cancer Research Center, Division of Public Health Sciences, 1100 Fairview Avenue N., Seattle, WA 98109, USA

<sup>b</sup> University of Washington, Department of Psychology, Box 351525, Seattle, WA 98195, USA

<sup>c</sup> University of Washington, Department of Human Centered Design and Engineering, Box 352315, Seattle, WA 98195, USA

<sup>d</sup> University of Washington, Department of Psychiatry and Behavioral Sciences, Box 356560, Seattle, WA 98195, USA

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### ABSTRACT

**Background:** There is a dual need for (1) innovative theory-based smartphone applications for smoking cessation and (2) controlled trials to evaluate their efficacy. Accordingly, this study tested the feasibility, acceptability, preliminary efficacy, and mechanism of behavioral change of an innovative smartphone-delivered acceptance and commitment therapy (ACT) application for smoking cessation vs. an application following US Clinical Practice Guidelines.

**Method:** Adult participants were recruited nationally into the double-blind randomized controlled pilot trial ( $n = 196$ ) that compared smartphone-delivered ACT for smoking cessation application (SmartQuit) with the National Cancer Institute's application for smoking cessation (QuitGuide).

**Results:** We recruited 196 participants in two months. SmartQuit participants opened their application an average of 37.2 times, as compared to 15.2 times for QuitGuide participants ( $p < 0.001$ ). The overall quit rates were 13% in SmartQuit vs. 8% in QuitGuide (OR = 2.7; 95% CI = 0.8–10.3). Consistent with ACT's theory of change, among those scoring low (below the median) on acceptance of cravings at baseline ( $n = 88$ ), the quit rates were 15% in SmartQuit vs. 8% in QuitGuide (OR = 2.9; 95% CI = 0.6–20.7).

**Conclusions:** ACT is feasible to deliver by smartphone application and shows higher engagement and promising quit rates compared to an application that follows US Clinical Practice Guidelines. As results were limited by the pilot design (e.g., small sample), a full-scale efficacy trial is now needed.

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### 1. Introduction

On the fiftieth anniversary of the landmark 1964 US Surgeon General's Report on Smoking and Health (US Department of Health E., and Welfare, 1964), the 2014 Surgeon General's report concludes that, while all forms of tobacco use are unsafe, 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) leads to \$289 billion in healthcare and lost productivity costs annually in the US alone (CDC, 2014). The decline in the smoking prevalence has slowed in recent years, with 42 million Americans still smoking.

States' funding for population-level smoking cessation programs (e.g., quitlines) remains far below CDC-recommended levels. Consequently, there is a tremendous need for interventions with strong potential population-level impact at the lowest possible cost (CDC, 2014).

#### 1.1. New technology: Smoking cessation apps

That potential can be found in the newest technological innovation in quit smoking interventions: smartphone-based smoking cessation software applications ("apps"; Abroms et al., 2011, 2013; Buller et al., 2013). Smartphones apps have all of the beneficial features of websites and text messaging interventions, but without their limitations (Abroms et al., 2013; Buller et al., 2013; Chen et al., 2012). Specifically, smartphone apps can have these important features: (1) available at arm's reach, (2) visually-engaging design, (3) video and audio capabilities, (4) unrestricted text capabilities, (5) access without cellular or internet connection, (6) immediate

\* Corresponding author at: Fred Hutchinson Cancer Research Center, Division of Public Health Sciences, 1100 Fairview Avenue North, PO Box 19024, M3-B232, Seattle, WA 98109, USA. Tel.: +1 206 667 5074.  
E-mail address: [jbricker@fhcrc.org](mailto:jbricker@fhcrc.org) (J.B. Bricker).

access to intervention content, (7) optimized to smartphone screen size, (8) content sharable via social media, and (9) tracking progress anywhere and anytime. Indeed, apps are an important technological advance over web sites and text messaging programs because of their high potential to boost user engagement—a consistently strong predictor of smoking cessation (Civljak et al., 2010; Shahab and McEwen, 2009; Webb, 2009; Whittaker et al., 2012).

### 1.2. Apps' reach and effectiveness

Smoking interventions' population-level impact is driven by the number of smokers they reach and their effectiveness. Smartphone apps for smoking cessation now have enormous reach. In 2013, there were over 400 smoking cessation apps (Abroms et al., 2013). In March 2014, using the xyo.net app search engine, we found a total of 546 English language smoking cessation apps in the Apple Store and Google Play that were downloaded to smartphones an estimated 3.2 million times in the United States and 20 million times worldwide. By contrast, during 2012–2013, there were an estimated 1 million enrollments to US tobacco quitlines (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 (58%) of US adults now own smartphones (Smith, 2013), and ownership is projected to reach at least 90% by 2020 (Dediu, 2013; Statista, 2014). Importantly, minority ownership is strong, with 64% of African Americans and 60% of Hispanics now owning smartphones, as compared to 53% for Caucasians (Smith, 2013). The greatest ownership growth rate is among those with low incomes (Nielsen, 2013; Smith, 2013). The current and projected demographics of smartphone ownership suggest that this treatment modality could address known tobacco-related health disparities associated with race/ethnicity and socioeconomic status (Fagan et al., 2004).

The effectiveness of smartphone apps for smoking cessation is largely unknown. Except for a pilot trial of young adults (Buller et al., 2013), no randomized trials of their effectiveness for general adult cessation have been published. The contrast between smoking cessation apps' high usage and their lack of effectiveness data is a serious scientific gap that could stifle their population-level impact.

The current standard in smoking cessation interventions is the US Clinical Practice Guidelines (USCPG). The USCPG have the following essential content: tracking smoking status, offering quit planning, advice on pharmacotherapy, tools to enhance motivation, and social support for quitting (Fiore et al., 2008). Of the apps now available, a small minority follow the USCPG (Abroms et al., 2011, 2013). However, just following the USCPG is likely insufficient. For example, multiple recent meta-analyses of websites and of text messaging interventions that follow USCPG report that their average intent-to-treat 30-day point prevalence quit rates at 12 months post-randomization are remarkably similar, ranging from 7% to 10% (Civljak et al., 2010; Hutton et al., 2011; Shahab and McEwen, 2009; Whittaker et al., 2012). Consequently, an app that goes a key step beyond the USCPG through innovative theory-based intervention content has promise to produce higher quit rates.

### 1.3. ACT: An emerging theory-based intervention

To start a smartphone research paradigm focusing on innovative intervention content, the current study will compare an app that follows USCPG with one that adds novel content based on a behavior change model called acceptance and commitment

therapy (ACT; Hayes et al., 2006). ACT focuses on increasing willingness to experience physical cravings, emotions, and thoughts while making values-guided committed behavior changes. In ACT, acceptance means making room for intense physical cravings (e.g., urges to smoke), emotions (e.g., sadness that triggers smoking), and thoughts (e.g., thoughts that trigger smoking) while allowing them to come and go. Commitment in ACT means articulating what is deeply meaningful to individuals – i.e., their values – to motivate and guide specific plans of action (e.g., stopping smoking). Numerous studies have supported the effectiveness of ACT for a wide variety of problems including depression and drug addiction (Hayes et al., 2006, 2013).

### 1.4. This study

This study addressed the dual needs for (1) innovative theory-based intervention content and (2) controlled trials to evaluate the efficacy of apps for smoking cessation. Accordingly, we developed the first smartphone app-delivered ACT intervention for smoking cessation, called "SmartQuit." We then conducted a nationally-recruited randomized, controlled pilot trial comparing SmartQuit with the National Cancer Institute's QuitGuide app. The aims were to determine (1) trial design feasibility, (2) participant receptivity and satisfaction, (3) preliminary cessation outcomes overall and for two key subgroups (those reporting: (a) heavy smoking; (b) low acceptance of cravings), and (4) potential impact on acceptance of cravings to smoke—ACT's theory-based process of change.

## 2. Methods

### 2.1. Participants

Eligibility criteria: (1) age 18 or older; (2) smokes at least five cigarettes daily for at least past 12 months, as consistent with cessation trials (Civljak et al., 2010); (3) wants to quit in the next 30 days; (4) interested in learning skills to quit smoking; (5) willing to be randomly assigned to either smartphone application; (6) resides in US; (7) knows how to download a smartphone application from Apple's App Store; (8) willing and able to read English; (9) not using other smoking cessation interventions (including apps and our other intervention studies); and (10) has at least daily access to their own Apple iPhone 4, 4s, or 5. The iPhone was chosen as the singular smartphone platform for the study because it provided the technical simplicity of only one type of hardware to run the app, and thereby freed up limited resources for programming. Participants not eligible for or interested in randomization were given information on alternative treatment to help them quit.

### 2.2. Procedures

All study procedures were reviewed and approved by the Fred Hutchinson Cancer Research Center Institutional Review Board.

### 2.3. Sample size

As Aim 1's focus was on feasibility, the study's sample size was powered to show differences in engagement, operationalized as the number of times participants opened their assigned app. Extrapolating from our web-delivered intervention trial results on ACT vs. Smokefree.gov for smoking cessation (Bricker et al., 2013), we estimated that the mean number of times participants opened SmartQuit would be 9.02 for ACT and 5.46 for QuitGuide. Based on these estimates, there was 80% power to detect a significant difference in number of app openings with a sample size of 196.

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