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Efficacy of Smartphone Applications for Smoking Cessation
A Randomized Clinical Trial

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IMPORTANCE Smoking is a leading cause of premature death globally. Smartphone applications for smoking cessation are ubiquitous and address barriers to accessing traditional treatments, yet there is limited evidence for their efficacy.

OBJECTIVE To determine the efficacy of a smartphone application for smoking cessation based on acceptance and commitment therapy (ACT) vs a National Cancer Institute smoking cessation application based on US clinical practice guidelines (USCPG).

DESIGN, SETTING, AND PARTICIPANTS A 2-group, stratified, double-blind, individually randomized clinical trial was conducted from May 27, 2017, to September 28, 2018, among 2415 adult cigarette smokers (n = 1214 for the ACT-based smoking cessation application group and n = 1201 for the USCPG-based smoking cessation application group) with 3-, 6-, and 12-month postrandomization follow-up. The study was prespecified in the trial protocol. Follow-up data collection started on August 26, 2017, and ended at the last randomized participant's 12-month follow-up survey on December 23, 2019. Data were analyzed from February 25 to April 3, 2020. The primary analysis was performed on a complete-case basis, with intent-to-treat missing as smoking and multiple imputation sensitivity analyses.

INTERVENTIONS iCanQuit, an ACT-based smoking cessation application, which taught acceptance of smoking triggers, and the National Cancer Institute QuitGuide, a USCPG-based smoking cessation application, which taught avoidance of smoking triggers.

MAIN OUTCOMES AND MEASURES The primary outcome was self-reported 30-day point prevalence abstinence (PPA) at 12 months after randomization. Secondary outcomes were 7-day PPA at 12 months after randomization, prolonged abstinence, 30-day and 7-day PPA at 3 and 6 months after randomization, missing data imputed with multiple imputation or coded as smoking, and cessation of all tobacco products (including e-cigarettes) at 12 months after randomization.

RESULTS Participants were 2415 adult cigarette smokers (1700 women [70.4%]; 1666 White individuals [69.0%] and 868 racial/ethnic minorities [35.9%]; mean [SD] age at enrollment, 38.2 [10.9] years) from all 50 US states. The 3-month follow-up data retention rate was 86.7% (2093), the 6-month retention rate was 88.4% (2136), and the 12-month retention rate was 87.2% (2107). For the primary outcome of 30-day PPA at the 12-month follow-up, iCanQuit participants had 1.49 times higher odds of quitting smoking compared with QuitGuide participants (28.2% [293 of 1040] vs 21.1% [225 of 1067]; odds ratio [OR], 1.49; 95% CI, 1.22-1.83; $P < .001$). Effect sizes were very similar and statistically significant for 7-day PPA at the 12-month follow-up (OR, 1.35; 95% CI, 1.12-1.63; $P = .002$), prolonged abstinence at the 12-month follow-up (OR, 2.00; 95% CI, 1.45-2.76; $P < .001$), abstinence from all tobacco products (including e-cigarettes) at the 12-month follow-up (OR, 1.60; 95% CI, 1.28-1.99; $P < .001$), 30-day PPA at 3-month follow-up (OR, 2.20; 95% CI, 1.68-2.89; $P < .001$), 30-day PPA at 6-month follow-up (OR, 2.03; 95% CI, 1.63-2.54; $P < .001$), 7-day PPA at 3-month follow-up (OR, 2.04; 95% CI, 1.64-2.54; $P < .001$), and 7-day PPA at 6-month follow-up (OR, 1.73; 95% CI, 1.42-2.10; $P < .001$).

CONCLUSIONS AND RELEVANCE This trial provides evidence that, compared with a USCPG-based smartphone application, an ACT-based smartphone application was more efficacious for quitting cigarette smoking and thus can be an impactful treatment option.

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Cigarette smoking is a leading cause of early death and disability[1] and accounts for more than 1 in 10 deaths worldwide.[2] Barriers to accessing smoking cessation treatments include low reimbursement for clinicians and low demand for in-person treatment.[3] Since 2012, smartphone applications for smoking cessation have been addressing access barriers by serving as digital interventions with high population-level reach.[4] There are now approximately 490 English-language smoking cessation applications, which have been downloaded an estimated total of 33 million times, according to an April 2020 analysis by SensorTower.com of all English-language cigarette smoking cessation applications on the Google Play and Apple App stores downloaded to smartphone devices (R. Nelson, SensorTower.com, personal communication, April 15, 2020). In the United States, the reach of smoking cessation applications has been aided by the fact that, as of 2019, 81% of all adults owned smartphones—up from 35% in 2011.[5]

Despite their ubiquity, there is limited evidence for the efficacy of smartphone applications for smoking cessation, to our knowledge. A 2019 Cochrane review included only 5 randomized trials testing the efficacy of smoking cessation smartphone applications, all of which were compared with lower-intensity cessation interventions (ie, lower-intensity application or nonapplication with minimal support).[4] These applications, which were based mainly on the US Clinical Practice Guidelines (USCPG),[6] had modest abstinence rates at the 6-month follow-up (eg, self-reported rates ranged from 4% to 18%[4]). Overall, there was no evidence that smartphone applications improved the likelihood of smoking cessation (relative risk, 1.00; 95% CI, 0.66-1.52; I^2 = 59%; 3079 participants). The Cochrane review called for rigorous randomized trials of smartphone applications for smoking cessation, and we see room for substantial improvement in the abstinence rates achieved with the use of these applications.

One smoking cessation treatment model that has promise when delivered as a smartphone application is acceptance and commitment therapy (ACT).[7] Acceptance and commitment therapy teaches skills for allowing urges to smoke to pass without smoking, which is conceptually distinct from USCPG-based standard approaches that teach avoidance of urges.[6] Acceptance and commitment therapy motivates smokers to quit by appealing to their values, whereas the USCPG-based approaches motivate by using reason and logic.[6] Acceptance and commitment therapy was promising for smoking cessation across a variety of delivery modalities, including a pilot randomized trial comparing an ACT-based smartphone application with the National Cancer Institute's (NCI's) smartphone application (QuitGuide) that followed the USCPG.[8-11] Therefore, the purpose of the present study was to conduct a full-scale randomized clinical trial to determine the efficacy of a smartphone application for smoking cessation (iCanQuit) based on ACT, compared with an NCI smoking cessation application based on the USCPG (QuitGuide).

Key Points

Question Is a smartphone application based on acceptance and commitment therapy (ACT) efficacious for smoking cessation?

Findings In this 2-group stratified, double-blind, individually randomized clinical trial of 2415 adult smokers with a 12-month follow-up and high retention, participants assigned to the smartphone application based on ACT had 1.49 times higher odds of quitting smoking compared with the participants assigned to the smartphone application based on US clinical practice guidelines.

Meaning Compared with a US clinical practice guidelines–based application that teaches avoidance of smoking triggers, an ACT-based application that teaches acceptance of smoking triggers was more efficacious for quitting smoking.

Methods

Study Design

The design was a blinded, parallel, 2-group randomized clinical trial comparing iCanQuit with QuitGuide. Participants were recruited online, were randomized, and completed follow-up surveys at 3, 6, and 12 months after randomization. The 12-month primary end point accounted for the high relapse rates that commonly occur by 12 months.[12-15] On the basis of the 2-month abstinence rates observed in a pilot trial[11] and relapse rates occurring between 2 and 12 months after randomization,[12-15] the study was 80% powered for a 2-tailed significant difference between an 11.0% iCanQuit quit rate and a 7.0% QuitGuide quit rate with a sample size of 1622. However, we set the target recruitment to 2500 participants for later exploratory analyses. The study was prespecified in the trial protocol. Details on the trial protocol are available in Supplement 1. All study activities were approved by the Fred Hutchinson Cancer Research Center Institutional Review Board. Participants provided consent online by clicking an "I accept" button option on the online consent form. Results are reported according to the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.

Procedures

Participants and Enrollment

From May 27, 2017, to September 28, 2018, we recruited smokers nationally via Facebook ads (1943 of 2415 [80.5%]), a survey sampling company (336 of 2415 [13.9%]), search engine results (65 of 2415 [2.7%]), and referral from friends and family (71 of 2415 [2.9%]). Participants could have more than a single recruitment source; a few participants reported multiple sources (eg, search engine results and Facebook ads). The Facebook ad cost per click was $0.55, cost per randomized participant was $13.60, and total impressions were 5 962 400. Eligibility criteria included the following: age 18 years or older; 5 or more cigarettes smoked per day for the past year; wants to quit smoking within the next 30 days; if concurrently using any other tobacco products (eg, e-cigarettes), wants to quit using them within the next 30 days; has an interest in learning skills to quit smoking; willing to be randomly assigned to either condition; resides in the United States; has daily access to their own iPhone or Android smartphone; knows how to download smartphone applications; willing and able to read in English; has never used QuitGuide and is not currently using other smoking cessation treatment; has never participated in our prior studies; no household members already enrolled; are

Box. Major Similarities Between iCanQuit and QuitGuide

- Education and skills for preparing to quit smoking
- Education and skills for preventing relapse after quitting, including self-compassion, learning, and starting again
- Intention formation, including setting a specific, actionable plan for quitting smoking that includes setting a quit date
- Education on US Food and Drug Administration–approved medications for smoking cessation
- Skills for coping with cravings to smoke
- Education on common triggers to smoke and barriers to cessation, nicotine withdrawal reactions, and how to seek support for smoking cessation
- Presented as a step-by-step guide with content at sixth-grade or less reading level

willing to complete outcome surveys, and can provide contact information for themselves and 2 relatives. Some advertisements were targeted to racial/ethnic minorities and men, and enrollment was limited to no more than 70% White participants and no more than 70% women, to ensure racial/ethnic minority and male representation.

Participants completed an encrypted, web-based screening survey and were notified of their eligibility via email. They then clicked on a secured emailed link to the study website, where they provided consent and completed the baseline survey. At each enrollment step, the study was presented as a comparison of 2 smartphone applications for smoking cessation.

Because enrollment occurred online, additional actions were taken to ensure that enrollees were eligible, including CAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) authentication, review of IP (internet protocol) addresses for duplicates or non-US origin, and review of survey logs for suspicious response times (<90 seconds to complete the screening or <10 minutes to complete the baseline survey). In suspicious cases, participants were contacted by staff. If participants' information could not be confirmed (n = 68), they were not enrolled.

Randomization, Follow-up, Blinding, and Contamination

After completing the baseline survey, participants were randomly assigned in a 1:1 manner to either iCanQuit or QuitGuide using randomly permuted blocks of size 2, 4, and 6, stratified by daily smoking frequency (≤20 vs ≥21 cigarettes per day), educational level (high school or less vs some college or more), race/ethnicity (minority race/ethnicity vs non-Hispanic White), and results of depression screening (Center for Epidemiological Studies Depression Scale[16] score ≤15 vs ≥16). Random assignments were concealed from participants throughout the trial. The random allocation sequence was generated by a database manager and implemented automatically by the study website. Neither research staff nor study participants had access to upcoming randomized study group assignments. In both groups, participants could access their interventions from the moment of randomization and beyond (ie, after the end of the 12-month follow-up period). Follow-up data collection started on August 26, 2017, and ended at the last randomized participant's 12-month follow-up survey on December 23, 2019.

For blinding, each application was branded as "iCanQuit" and did not mention either ACT or QuitGuide. Contamination between applications was avoided with a unique username and password provided only to the individual user and by having an eligibility criterion of not having other household members participating in the study.

Interventions

iCanQuit

iCanQuit (version 1.2.1; released 2017[17,18]) teaches ACT skills for coping with smoking urges, staying motivated, and preventing relapse. After setting up a personalized quit plan in which users can learn about US Food and Drug Administration–approved cessation medications that they can obtain on their own, users are taken to the home screen, where they can progress through 8 levels of the intervention content, receive on-demand help in coping with smoking urges, track the daily number of cigarettes smoked, and track how many urges they let pass without smoking. The program is self-paced, and content is unlocked in a sequential manner. For the first 4 levels, exercises are unlocked immediately after the prior exercise is complete. For the last 4 levels, the next level will not unlock until users record 7 consecutive smoke-free days. If a participant lapses (eg, records having smoked a cigarette), the program encourages (but does not require) them to set a new quit date and return to the first 4 levels for preparation (eAppendix in Supplement 2). iCanQuit is a research application created for this randomized clinical trial, and its content is not yet available to the public.

QuitGuide

The iCanQuit application was compared with NCI's QuitGuide application (version 1.2.2; released 2014),[19,20] which, with the NCI's permission, we posted on the Google Play and Apple stores in a blinded format branded as "iCanQuit." We selected QuitGuide for comparison for the following reasons: (1) it follows the USCPG[6]; (2) it is a smartphone application, and thus avoids confounding treatment content with treatment delivery modality; (3) its content is based directly on the NCI's smokefree.gov website, a well-established digital intervention[21]; and (4) it is nonproprietary and freely available to the public, providing maximal transparency and replicability.

QuitGuide contained 4 sections of content. "Thinking about quitting" focuses on motivations to quit by encouraging users to think of reasons for quitting and providing information on the general health consequences of smoking and quitting. "Preparing to Quit" helps users develop a quit plan; helps users identify smoking behaviors, triggers, and reasons for being smoke-free; helps users identify social support for quitting; and provides information on US Food and Drug Administration–approved medications for quitting smoking. "Quitting" teaches skills for avoiding cravings to smoke, such as finding replacement behaviors (eg, chewing on carrot sticks) and staying busy. "Staying Quit" presents tips, motivations, and actions to stay smoke-free and skills for coping with slips via fighting cravings and trying to be positive. See the **Box** for major similarities and

Table 1. Major Differences Between iCanQuit and QuitGuide

Major difference	iCanQuit	QuitGuide
Approach to addressing motivation	1. Values: chosen life directions that guide goals and actions (eg, major life areas, such as family, that inspire you to be smoke-free) 2. Testimonials (eg, 10- to 12-short sentence audio-recorded stories from the program guide "Nancy") 3. Gamification (eg, earning visual "badges" of health progress contingent on number of smoke-free days)	1. Expectations: beliefs about what actions will produce the goal (eg, listing expected outcomes of quitting smoking) 2. Factual information processing (eg, listing ingredients of a cigarette) 3. Risk perception (eg, risks of secondhand smoke and risks for smoking during pregnancy) 4. Rewards for quitting (eg, describing health progress based on number of smoke-free days)
Approach to addressing triggers to smoke	Acceptance: openness to experience urges, emotions, and thoughts that trigger smoking (eg, on-demand tips for letting urges come and go; progress tracking; experiential exercises on letting urges pass)	Avoidance: actively trying not to experience urges, emotions, and thoughts that trigger smoking (eg, advice on avoiding triggers; advice on staying busy; recommendations for distracting yourself during an urge)
Approach to addressing relapse prevention	Acceptance: perspective taking (eg, writing a letter from your smoke-free future self); values (eg, making a smoke-free vision statement)	Avoidance: avoid high-risk situations (eg, avoid places where you used to smoke) and avoid urges (eg, advice on how to fight cravings)
Approach to presenting content	Presented in a sequenced interactive format with short paragraphs of text and some audio or visual for experiencing ACT concepts	Presented in a sequenced format with short paragraphs of text

Abbreviation: ACT, acceptance and commitment therapy.

Table 1 for differences between the 2 applications.

Measures

At baseline, participants reported on demographic characteristics, depression (Center for Epidemiological Studies Depression Scale[16]), alcohol use (Quick Drinking Screen[22]), nicotine dependence (Fagerström Test for Nicotine Dependence[23]), and smoking in their social environment (eg, number of adults at home who smoke). The primary outcome was self-reported complete-case 30-day point prevalence abstinence (PPA; ie, no smoking at all in the past 30 days) at the 12-month follow-up (eAppendix in Supplement 2). Secondary outcomes were 7-day PPA at 12 months after randomization, prolonged abstinence, 30-day and 7-day PPA at 3 and 6 months after randomization, missing data imputed with multiple imputation or coded as smokers, and cessation of all tobacco products (including e-cigarettes) at 12 months after randomization (eAppendix in Supplement 2).

Objective measures of application engagement were collected for 12 months after randomization. The number of times a participant opened their assigned application, minutes spent per session of use, and number of unique days of use were calculated from data automatically logged by Google Analytics. Treatment satisfaction outcomes were the extent to which participants were satisfied with the assigned application, the assigned application was useful for quitting, and participants would recommend assigned application to a friend (eAppendix in Supplement 2).

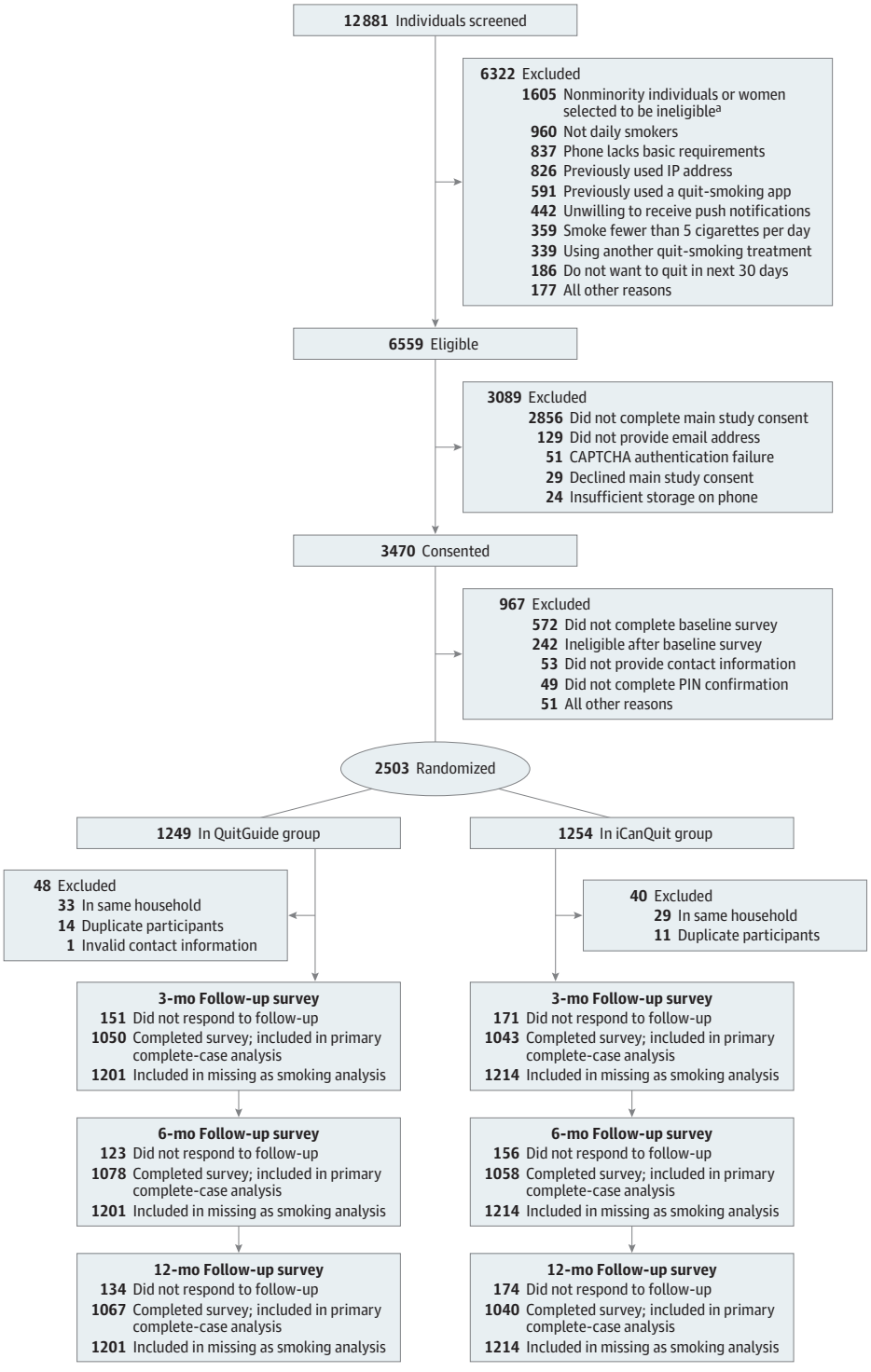
Statistical Analysis

Data were analyzed from February 25 to April 3, 2020. The primary analysis was performed on a complete-case basis, with intent-to-treat missing as smoking and multiple imputation sensitivity analyses. Primary and secondary outcomes are described above. The missing = smoking imputation was a secondary outcome because it may be biased, including a bias in favor of the group with lower attrition.[24-26] The small differential attrition at 6- and 12-month follow-up (ie, 3% difference; **Figure**) had a low risk of bias for the primary, complete-case analysis,[4] and the multiple imputation provided a further test of the sensitivity of this primary analysis (eAppendix in Supplement 2). We used logistic regression models for the cessation outcome as well as secondary binary outcomes associated with cessation and treatment satisfaction. Negative binomial models were used to assess differences between treatment groups for zero-inflated count outcomes (eg, number of application openings), whereas generalized linear models were used for continuous outcomes. We adjusted for all 4 stratification variables used in randomization to avoid losing power and obtaining incorrect 95% CIs.[27] We also adjusted for baseline number of alcoholic drinks per day to reduce the potential for confounding, as this variable was slightly different between groups ($P = .07$) and was associated with the primary cessation outcome ($P = .01$). All statistical tests were 2-sided, with results deemed statistically significant at $P < .05$, and analyses were completed using R, version 3.6.1,[28] library "MASS"[29] for negative binomial regression, and library "mice"[30] for multiple imputation.

Results

A total of 12 881 individuals were screened and 2503 participants were randomly assigned to a smoking cessation application (1254 to iCanQuit and 1249 to QuitGuide). Owing to a technical error in our automated enrollment system, 40 participants in the iCanQuit group and 48 participants in the QuitGuide group were excluded after randomization because they were determined to be ineligible (eg, same household). Thus, the full analyzable sample was 2415 (1214 in the iCanQuit group and 1201 in the QuitGuide group). The follow-up data retention rates were 86.7% (2093 of 2415) overall at 3 months (iCanQuit, 85.9% [1043 of 1214] vs QuitGuide, 87.4% [1050 of 1201]; $P = .20$), 88.4% (2136 of 2415)

Figure. CONSORT Diagram for iCanQuit Trial



IP indicates internet protocol; PIN, personal identification number.

[a] To increase enrollment of racial/ethnic minorities and men, some nonminorities and women who were otherwise eligible for study enrollment were randomly selected to be excluded.

overall at 6 months (iCanQuit, 87.1% [1058 of 1214] vs QuitGuide, 89.8% [1078 of 1201]; $P = .05$), and 87.2% (2107 of 2415) overall at 12 months (iCanQuit, 85.7% [1040 of 1214] vs QuitGuide, 88.8% [1067 of 1201]; $P = .02$]) (Figure).

Mean (SD) age at enrollment was 38.2 (10.9) years (**Table 2**). Participants included 1700 women (70.4%), 1666 White individuals (69.0%), and 868 racial/ethnic minorities (35.9%). A total of 995 participants (41.2%) had a high school education or less. Regarding smoking, 2009 participants (83.2%) had smoked for 10 years or more and 1803 (74.7%) smoked more than one-half pack (≥11 cigarettes) per day. There were no statistically significant differences between the 2 groups on

Table 2. Baseline Demographics and Smoking Behavior

Characteristic	No. (%)		
	Total (N = 2415)	QuitGuide (n = 1201)	iCanQuit (n = 1214)
Age, mean (SD), y	38.2 (10.9)	38.3 (11.0)	38.2 (10.8)
Male	715 (29.6)	358 (29.8)	357 (29.4)
Race[a]			
White	1666 (69.0)	830 (69.1)	836 (68.9)
African American	466 (19.3)	232 (19.3)	234 (19.3)
Asian	6 (0.2)	1 (0.1)	5 (0.4)
Native American or Alaska Native	58 (2.4)	30 (2.5)	28 (2.3)
Native Hawaiian or Pacific Islander	5 (0.2)	3 (0.2)	2 (0.2)
>1 Race/ethnicity	173 (7.2)	84 (7.0)	89 (7.3)
Ethnicity			
Hispanic	210 (8.7)	105 (8.7)	105 (8.6)
Married	756 (31.3)	383 (31.9)	373 (30.7)
Working	1320 (54.7)	653 (54.4)	667 (54.9)
High school or less education	995 (41.2)	495 (41.2)	500 (41.2)
LGBT	405 (16.8)	193 (16.1)	212 (17.5)
Alcohol use			
Heavy drinker, No. (%)[b]	348 (14.9)[c]	160 (13.8)[d]	188 (16.0)[e]
No. of drinks per drinking day, mean (SD)	1.9 (3.8)[f]	1.7 (3.5)[d]	2.0 (4.0)[g]
Positive depression screening results	1166 (48.5)[h]	583 (48.7)[i]	583 (48.3)[j]
Smoking behavior			
FTND score, mean (SD)	5.9 (2.1)	5.9 (2.0)	5.8 (2.1)
High nicotine dependence (FTND score ≥6)	1452 (60.1)	716 (59.6)	736 (60.6)
Smokes more than one-half pack/d	1803 (74.7)	912 (75.9)	891 (73.4)
Smokes more than 1 pack/d	488 (20.2)	239 (19.9)	249 (20.5)
First cigarette within 5 min of waking	1300 (53.8)	650 (54.1)	650 (53.5)
Smoked for ≥10 y	2009 (83.2)	999 (83.2)	1010 (83.2)
Used e-cigarettes at least once in past mo	575 (23.8)	278 (23.1)	297 (24.5)
Quit attempts in past 12 mo, mean (SD)	1.4 (5.6)[k]	1.5 (7.0)[l]	1.3 (3.8)[d]
At least 1 quit attempt in past 12 mo	891 (38.7)[k]	452 (39.5)[l]	439 (37.8)[d]
Confidence to quit smoking, mean (SD)[m]	64.3 (26.9)	64.9 (26.7)	63.8 (27.1)
Friend and partner smoking			
Close friends who smoke, mean (SD)	2.7 (1.7)	2.6 (1.7)	2.7 (1.8)
No. of adults in home who smoke, mean (SD)	1.5 (0.9)	1.5 (0.9)	1.5 (0.8)
Living with partner who smokes	858 (35.5)	427 (35.6)	431 (35.5)

Abbreviations: FTND, Fagerström Test for Nicotine Dependence, LGBT, lesbian, gay, bisexual, or transgender.

[a] 119 Participants identified as both White race and Hispanic ethnicity; thus 749 racial minority + 119 White Hispanic individuals = 868 total racial/ethnic minorities.

[b] Heavy drinking is defined as 4 or more drinks per day for females and 5 or more drinks per day for males within the past 30 days.

[c] n = 2337.

[d] n = 1162.

[e] n = 1175.

[f] n = 2336.

[g] n = 1174.

[h] n = 2405.

[i] n = 1197.

[j] n = 1208.

[k] n = 2305.

[l] n = 1143.

[m] Range, 0 to 100, where 0 indicates not at all confident and 100 indicates extremely confident.

any baseline variable. Participants were from all 50 US states (eFigure in Supplement 2).

Smoking Cessation

For the primary outcome of 30-day PPA at the 12-month follow-up, iCanQuit participants had 1.49 times higher odds of quitting smoking compared with QuitGuide participants (28.2% [293 of 1040] vs 21.1% [225 of 1067]; odds ratio [OR], 1.49; 95% CI, 1.22-1.83; $P < .001$); these results were similar when all 2503 randomized participants were included (28.5% [306 of 1074] vs 21.0% [234 of 1113]; OR, 1.50; 95% CI, 1.23-1.83; $P < .001$). Effect sizes were similar and all were statistically significant for 7-day PPA at the 12-month follow-up (OR, 1.35; 95% CI, 1.12-1.63; $P = .002$), prolonged abstinence at the 12-month follow-up (OR, 2.00; 95% CI, 1.45-2.76; $P < .001$), abstinence from all tobacco products (including e-cigarettes) at the 12-month follow-up (OR, 1.60; 95% CI, 1.28-1.99; $P < .001$), 30-day PPA at 3-month follow-up (OR, 2.20; 95% CI, 1.68-2.89; $P < .001$), 30-day PPA at 6-month follow-up (OR, 2.03; 95% CI, 1.63-2.54; $P < .001$), 7-day PPA at 3-month follow-up (OR, 2.04; 95% CI, 1.64-2.54; $P < .001$), and 7-day PPA at 6-month follow-up (OR, 1.73; 95% CI, 1.42-2.10; $P < .001$) (**Table 3**). Effect sizes were also similar and all were statistically significant when missing data were imputed with multiple imputation or coded as smokers (eTable in Supplement 2).

Use and Satisfaction

As shown in **Table 4**, compared with participants using QuitGuide, iCanQuit participants had a higher mean (SD) number of times the application was opened (37.5 [88.4] vs 9.9 [50.0]; $P < .001$), mean (SD) minutes spent per session (3.9 [5.3] vs 2.6 [2.6] minutes; $P < .001$), and mean (SD) number of unique days of use (24.3 [50.2] vs 7.1 [15.8] days; $P < .001$). Compared with

Table 3. Smoking Cessation Outcomes by Follow-up Time Point[a]

Outcome variable	No. (%) Overall (N = 2415)	QuitGuide (n = 1201)	iCanQuit (n = 1214)	Odds ratio (95% CI)[b]	*P* value
12-mo Outcomes					
30-d PPA	518/2107 (24.6)	225/1067 (21.1)	293/1040 (28.2)	1.49 (1.22-1.83)	<.001
7-d PPA	658/2107 (31.2)	302/1067 (28.3)	356/1040 (34.2)	1.35 (1.12-1.63)	.002
Prolonged abstinence	181/1710 (10.6)	65/871 (7.5)	116/839 (13.8)	2.00 (1.45-2.76)	<.001
30-d PPA of all tobacco products (including e-cigarettes)	420/2107 (19.9)	175/1068 (16.4)	245/1039 (23.6)	1.60 (1.28-1.99)	<.001
6-mo Outcomes					
30-d PPA	423/2136 (19.8)	158/1078 (14.7)	265/1058 (25.0)	2.03 (1.63-2.54)	<.001
7-d PPA	618/2136 (28.9)	259/1078 (24.0)	359/1058 (33.9)	1.73 (1.42-2.10)	<.001
3-mo Outcomes					
30-d PPA	269/2093 (12.9)	94/1050 (9.0)	175/1043 (16.8)	2.20 (1.68-2.89)	<.001
7-d PPA	453/2093 (21.6)	168/1050 (16.0)	285/1043 (27.3)	2.04 (1.64-2.54)	<.001

Abbreviation: PPA, point prevalence abstinence.

[a] Complete-case analysis (ie, exclusion of participants lost to follow-up) was specified a priori as the primary outcome.

[b] Odds ratios are adjusted for baseline number of alcoholic drinks per day and the 4 factors used in stratified randomization: daily smoking frequency, educational level, race/ethnicity, and depression screening result.

participants using QuitGuide, iCanQuit participants reported higher overall satisfaction (865 of 977 [88.5%] vs 773 of 1002 [77.1%]; $P < .001$), found it more useful for quitting (805 of 1005 [80.1%] vs 739 of 1033 [71.5%]; $P < .001$), and were more likely to recommend it to a friend (840 of 1011 [83.1%] vs 724 of 1024 [70.7%]; $P < .001$).

Discussion

The present study determined the efficacy of a smartphone application for smoking cessation (iCanQuit) based on ACT compared with an NCI smoking cessation application (QuitGuide) based on the USCPG. For the primary outcome of 30-day PPA at the 12-month follow-up, iCanQuit participants were 1.49 times more likely to quit smoking compared with QuitGuide participants (28.2% abstinent vs 21.1% abstinent). Effect sizes were similar and statistically significant for all secondary outcomes.

The current study advances the evidence base for smartphone applications for smoking cessation. Prior randomized clinical trials in a 2019 Cochrane review ranged in sample size from 49 to 1599 and had a weighted mean 55.3% final outcome data retention rate.[4] By contrast, the current trial is, to our knowledge, now the largest to date, had a substantially higher retention rate (ie, 87.2% vs 55.3%), and had twice the follow-up length (ie, 12 vs 6 months). The self-reported 6-month abstinence rates of individuals using smartphone applications included in the Cochrane review ranged from 4% to 18%,[4] which is within the range of the abstinence rates observed for the QuitGuide application. That participants using iCanQuit had substantially higher odds of quitting than those using QuitGuide suggests that iCanQuit is an advance compared with a smartphone intervention that followed the USCPG. Future mediational process research should examine theoretical processes as well as specific features listed in the Box and Table 1 to understand why iCanQuit was the more efficacious intervention.

Strengths and Limitations

This study has multiple strengths, including a large sample size and 12-month follow-up. Notably, the 87.2% 12-month outcome retention rate contributes to confidence in the study findings. Our group's methods for obtaining high retention rates are described elsewhere.[31] The broad demographic characteristics of the sample from all 50 US states increased confidence in the generalizability of the study findings and overcame a key limitation of the prior trials, which tended to include less diverse and more educated samples.[4]

This study also has some limitations. First, remote biochemical data collection for the cessation outcome data was not conducted. We elected not to do so, as there are 3 major methodological problems with remote biochemical data collection: high attrition, problems with identifying the person providing the sample, and the high cost relative to the likely low percentage of falsifying from a high reach-low intensity intervention.[32-35] Although there is evidence of high levels of agreement between self-reported and biochemically validated smoking status,[36,37] the external validity of the self-reported smoking status in this trial is not known. However, given the double-blinding of the intervention, we see no compelling reason why the false reporting rate would be higher in one intervention group vs the other group; thus, there is no strong rationale for a bias in the ORs. Owing to low demand characteristics for false reporting, the Society for Research on Nicotine and Tobacco Subcommittee on Biochemical Verification recommended that biochemical confirmation be considered unnecessary in population-based studies with no face-to-face contact and studies in which data are optimally collected through the internet, telephone, or mail.[38,39] Second, there was a small differential attrition at the 6- and 12-month follow-up that somewhat biased the imputation of missing data as smoking abstinence rates in favor of QuitGuide. Although iCan-

Table 4. Treatment Engagement and Satisfaction[a]

Variable	Overall (N = 2415)	QuitGuide (n = 1201)	iCanQuit (n = 1214)	OR, IRR, or point estimate (95% CI)[b]	*P* value
Engagement[c]					
No. of times opened, mean (SD)	23.9 (73.3) [median = 6; n = 1467]	9.9 (50.0) [median = 4; n = 724]	37.5 (88.4) [median = 9; n = 743]	IRR, 3.98 (3.41-4.64)	<.001
Time spent per session, mean (SD), min	3.2 (4.2) [median = 2.1; n = 1289]	2.6 (2.6) [median = 1.9; n = 636]	3.9 (5.3) [median = 2.4; n = 653]	Point estimate, 1.3 (0.8-1.7)	<.001
No. of unique days of use, mean (SD)	15.8 (38.4) [median = 5; n = 1467]	7.1 (15.8) [median = 4; n = 724]	24.3 (50.2) [median = 6; n = 743]	IRR, 3.43 (2.97-3.96)	<.001
Satisfaction					
Satisfied with assigned application, No. (%)	1638/1979 (82.8)	773/1002 (77.1)	865/977 (88.5)	OR, 2.28 (1.77-2.93)	<.001
Application was useful for quitting, No. (%)	1544/2038 (75.8)	739/1033 (71.5)	805/1005 (80.1)	OR, 1.64 (1.33-2.03)	<.001
Would recommend assigned application, No. (%)	1564/2035 (76.9)	724/1024 (70.7)	840/1011 (83.1)	OR, 2.10 (1.68-2.61)	<.001

Abbreviations: IRR, incidence rate ratio; OR, odds ratio.

[a] All items were assessed at 12-month follow-up, with the exception of the last 2, satisfaction and recommendation, which were assessed at 3-month follow-up.

[b] Results are adjusted for baseline number of alcoholic drinks per day and the 4 factors used in stratified randomization: daily smoking frequency, educational level, race/ethnicity, and depression screening result.

[c] Analysis is limited to participants with a full 12 months of smartphone application analytics data available (n = 1467).

Quit abstinence rates were still statistically significantly higher than those of QuitGuide in the analysis imputing missing as smoking despite this bias, we deem the complete-case and multiple imputation analyses to be more reliable.[24,25] Finally, owing to a technical error in the Google Analytics system, the full 12 months of application use data were available for only the first 1467 participants. Because this error occurred independently of the participants or the interventions, the resulting missing data are an ignorable threat to the validity of the current analysis.[40]

Conclusions

This trial provides evidence that, compared with a USCPG-based smartphone application, an ACT-based smartphone application was more efficacious for quitting cigarette smoking. iCanQuit can be an impactful treatment option; based on the main result, for every 100 000 smokers reached with iCanQuit, 28 000 would quit smoking.

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Concept and design: Bricker, Heffner.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Bricker, Watson, Mull, Sullivan.
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Statistical analysis: Mull.
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Supervision: Bricker.

Conflict of Interest Disclosures: Dr Bricker reported receiving grants from the National Cancer Institute during the conduct of the study; serving on the scientific advisory board for and receiving personal fees from Chrono Therapeutics outside the submitted work; and reported that the Fred Hutchinson Cancer Research Center has applied for a US patent that pertains to the content of the iCanQuit application. 2Morrow, Inc, a Kirkland, Washington–based software company, has licensed this technology from the Fred Hutchinson Cancer Research Center. Dr Bricker had no personal financial relationships with this patent application, the licensing agreement, or 2Morrow, Inc. Ms Mull reported receiving grants from the National Institutes of Health/National Cancer Institute during the conduct of the study. Dr Heffner reported receiving nonfinancial support from Pfizer outside the submitted work. None of the authors has a financial relationship with the iCanQuit application and thus will not receive any compensation when it becomes publicly available. No other disclosures were reported.

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