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Brief report
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COach2Quit: A Pilot Randomized Controlled Trial of a Personal Carbon Monoxide Monitor for Smoking Cessation

Nandita Krishnan MSPH[1], Jessica L. Elf PhD[2,3], Sandy Chon MHS[3], Jonathan E. Golub PhD[1,3]

[1]Department of International Health, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD; [2]Schroeder Institute for Tobacco Research and Policy Studies, Washington, DC; [3]Center for Tuberculosis Research, Johns Hopkins School of Medicine, Johns Hopkins University, Baltimore, MD

Corresponding Author: Nandita Krishnan, MSPH, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, 615 N Wolfe Street, Baltimore, MD 21205, USA. E-mail: nkrishnan12@gmail.com

Abstract

Introduction: Mobile phone–based messaging support and biomarker feedback independently show evidence of increasing an individual's likelihood of quitting smoking. However, the combination of these two strategies to facilitate smoking cessation has not been adequately explored.
Methods: We conducted a randomized controlled trial in Baltimore, Maryland, to assess the efficacy of COach2Quit, a smartphone application that provides exhaled carbon monoxide readings with message support. The primary outcome was self-reported and biochemically verified smoking cessation at 30-day follow-up. Secondary outcomes were reduction in smoking, motivation to quit, and engagement and satisfaction with COach2Quit. An intention-to-treat analysis was conducted.
Results: Adult smokers were randomized 1:1 to receive brief advice and COach2Quit (intervention, $n = 50$) or brief advice only (control, $n = 52$). Thirteen participants were lost to follow-up. At 30-day follow-up, one participant in each arm quit smoking. Median change in carbon monoxide levels (in parts per million (ppm)) (intervention: –3.0 [interquartile range (IQR) –12.0, 2.0]; control: –2.5 [IQR –9.0, 2.0]) and median change in number of cigarettes smoked per day (intervention: –5.5 [IQR –14.0, –1.0]; control: –6.0 [IQR –10.0, –2.0]) was similar between study arms. There was no significant difference in mean percent change in the Reasons for Quitting scale score (intervention: 6.3 [95% confidence interval = –2.2% to 14.8%]; control: –3.6 [95% confidence interval = –9.2% to 2.1%]). A majority ($n = 32$, 91%) of participants liked having COach2Quit to help them quit smoking.
Conclusions: There were no significant differences in smoking cessation, smoking reduction, and motivation to quit between study arms. However, high satisfaction with the COach2Quit application indicates its feasibility and acceptability as a smoking cessation tool.
Implications: Smoking is the leading preventable cause of morbidity and mortality in the United States. Although counseling and pharmacotherapy are efficacious for smoking cessation, they are not easily accessible or desirable to all smokers, highlighting the need for identifying other interventions. There is evidence for the efficacy of mobile phone–based messaging support for smoking cessation. However, there is limited research on the efficacy of biomarker feedback, much less interventions that combine these two approaches. This research contributes to filling this gap and identifying novel interventions to facilitate smoking cessation.

Introduction

Although rates of tobacco use have decreased over the last decade, tobacco use is still the leading preventable cause of morbidity and mortality in the United States.[1] Identifying effective smoking cessation interventions is essential to helping smokers quit and achieving further reductions in smoking rates.

Mobile phone–based approaches to smoking cessation are widely accessible, and smoking cessation text-messaging programs have been developed and shown to be effective.[2,3] Smartphone applications (apps) offer a new platform to provide smoking cessation interventions with interactive features unavailable in standard text-messaging programs. Several apps are currently available, but many do not follow key clinical practice guidelines and have not been tested for efficacy.[4]

In recent years, real-time biomarker feedback has emerged as a novel method of promoting health behavior change, but evidence of efficacy is mixed.[5] Exhaled carbon monoxide (eCO) is a commonly used biomarker for measuring adherence to smoking cessation,[6] and evidence from clinic-based use of eCO suggests that motivation to quit increases significantly following measurement, though the impact is short-lived.[7] A pilot study by Beard and West found that more frequent and personal use of eCO may be an effective cessation tool.[8]

Although mobile phone–based messaging support and real-time biomarker feedback in clinical settings both independently show evidence of increasing an individual's likelihood of quitting smoking, the combination of these two strategies into a single system for facilitating smoking cessation has not been explored. We developed COach2Quit, a smartphone app that interacts with a portable and compact individualized carbon monoxide (iCO) monitor to provide eCO readings along with feedback messages to the user. The objectives of this study were to assess (1) the efficacy of the COach2Quit app in facilitating smoking cessation and (2) the feasibility and acceptability of the COach2Quit app among adult smokers in Baltimore, Maryland.

Methods

Study Design and Participants

The trial was conducted between May and December 2017 in Baltimore, Maryland. Participants were individually randomized 1:1 to receive brief advice (control) or brief advice along with the iCO monitor and COach2Quit app (intervention). Follow-up visits were conducted at 14 days and 30 days from baseline. Inclusion criteria were as follows: (1) at least 18 years of age; (2) current, daily smokers; (3) own an Android phone compatible with the app; and (4) willingness to set a quit date within 2 weeks of the baseline assessment. Exclusion criteria were as follows: (1) medical condition precluding the use of the CO monitor (eg, chronic obstructive pulmonary disease); (2) current use of smokeless tobacco, including electronic cigarettes; (3) current use of pharmacotherapies; (4) pregnant; or (5) negative urine cotinine result and a CO reading of less than or equal to 10 parts per million (ppm) at baseline.

Participants were recruited through posters advertising the study around the Johns Hopkins Medical Institutions East Baltimore campus, from Johns Hopkins Medical Institutions clinics, inpatient and outpatient facilities, and through participant referrals. Participants received $25 gift cards for the baseline and 14-day follow-up visits, and a $50 gift card for completing the 30-day follow-up visit as compensation. This study was approved by the Johns Hopkins Medical Institutions Institutional Review Board, and all participants signed written informed consents before participating.

Study Procedures

At each study visit, participants completed a tablet-based survey administered by study staff and received brief advice from a trained smoking cessation counselor, following the National Cancer Institute's 5A's model.[9] At baseline, participants in the intervention arm were provided with an iCO monitor (Bedfont Scientific Ltd) and they downloaded the COach2Quit app on their phone. The approximate dimensions of the iCO monitor are 28 mm (diameter) × 115 mm (length); it weighs 35 g. Participants received instructions on the use of the monitor with the app and were guided through completing an initial eCO breath test. Results were monitored through a web portal and participants were contacted by the counselor if they had missing measurements on consecutive days.

Description of Intervention

On installation, the app prompts the user to set a quit date and reminds the user to take an eCO breath test twice a day. Following each breath test, the app sends response messages to the user based on CO result from a predefined text message library. The app also provides users with a graphical display of their CO readings, instructions, and contact information for help.

Measures

The primary outcome was self-reported and biochemically verified smoking cessation at the 30-day visit. Smoking status was verified by two biomarker measurements: an eCO measurement in PPM using the piCO Smokerlyzer (Bedfont Scientific Ltd) and a urine cotinine measurement semi-quantified on the basis of color change, using SmokeScreen, a rapid colorimetric assay (GFC Diagnostics Ltd). Smoking abstinence was defined as an eCO measurement of less than or equal to 10 ppm and the absence of a color change in the urine sample.

Secondary outcomes were reduction in smoking, motivation to quit smoking, and engagement and satisfaction with COach2Quit. Reduction in smoking was assessed through changes in CO levels and number of cigarettes smoked per day between baseline and 30-day follow-up. Change in motivation to quit smoking was measured using the Reasons for Quitting (RFQ) scale.[10] The range of possible scores for the RFQ scale is 0–4, with a higher value indicating greater motivation to quit smoking. Engagement with the app was measured as frequency (days) of use. Satisfaction was assessed through responses to statements about the iCO monitor and COach2Quit app at the 30-day follow-up visit via a five-point Likert scale ranging from strongly disagree to strongly agree.

Data Analysis

The data were analyzed using an intention-to-treat approach. Differences in baseline characteristics between study arms were assessed using Student's *t* tests or the Wilcoxon's rank sum test for continuous variables and chi-square tests for categorical variables. Changes in CO levels and cigarettes smoked per day were calculated as the median of the difference between measurements at baseline and 30 days, and the difference between the study arms was compared using the Wilcoxon's rank sum test. Change in RFQ scores was calculated as the percent change in score from baseline to

30 days, and the unadjusted difference in the mean change between study arms was assessed using the *t* test. The adjusted difference was calculated using a linear regression model that adjusted for baseline scores and relevant baseline characteristics. A two-sided *p* value of less than .05 was considered statistically significant. All statistical analyses were conducted using Stata Statistical Software, v. 14 (StataCorp, College Station, TX).

Results

A total of 160 participants were assessed for eligibility; 58 did not meet inclusion criteria, resulting in 102 participants (intervention = 50, control = 52) enrolled in the trial. Thirteen participants were lost to follow-up (nine at the 14-day visit and four at the 30-day visit), and the sample size for the analysis was 89. The proportion of participants lost to follow-up was significantly higher in the intervention arm (22%) compared to the control arm (3.85%) (p = .006). There were no significant differences in baseline characteristics between participants lost to follow-up and those who completed the study.

Sample Characteristics

The median age of participants was 52 (interquartile range [IQR] 45, 56) years, and 58.4% were females. Most participants had at least a high school education (66.3%), were African American (78.7%), and were unemployed (83.2%). Median number of cigarettes smoked per day was 10 (IQR 8, 20), and the median number of quit attempts within the past year was 2 (IQR 1, 2). Participants had a mean Fagerström Test for Nicotine Dependence score of 2.69 (SD = 1.43). The distribution of demographic and smoking characteristics was similar between study arms except for employment (Table 1).

Primary and Secondary Outcomes

At 30-day follow-up, one participant in each study arm had quit smoking (self-reported and biochemically verified). A greater proportion of participants in the control arm (18%) had reduced their CO level to less than or equal to 10 ppm compared to those in the intervention arm (5%; p = .07). There were no significant differences between study arms in median changes in CO levels or cigarettes smoked per day between baseline and 30-day follow-up (Table 2).

There was a mean increase of 6.3% in RFQ score for participants in the intervention arm (95% CI = −2.2% to 14.8%) and a mean decrease of 3.6% in RFQ score for participants in the control arm (95% CI = −9.2% to 2.1%) (Table 2). The unadjusted difference in the mean percent change in RFQ scores between study arms was 9.8% (p = .05). After adjusting for baseline RFQ score, employment status, cigarettes smoked per day at baseline, number of quit attempts in the past 12 months, and Fagerström Test for Nicotine Dependence score, the difference in RFQ score was not statistically significant (5.7% p = .42).

Participants used the app for a median of 12 (IQR 6, 25) days. Most participants in the intervention arm (91%) liked having the iCO monitor and COach2Quit app to help them quit smoking. Feedback on design and ease of use indicated that 89% participants found the iCO and app easy to use, 97% found the messages easy to understand, and 100% found the iCO easy to carry around. Eighty-six percent of participants reported that using the iCO monitor and COach2Quit app motivated them to quit smoking.

Discussion

To the best of our knowledge, this is the first study to explore the efficacy of a system combining real-time biomarker feedback with messaging support to facilitate smoking cessation. We found no significant differences in smoking cessation, smoking reduction, and motivation to quit smoking between study arms. However, a high percentage of participants in the intervention arm expressed positive feedback about the iCO monitor and COach2Quit app.

Table 1. Baseline Characteristics of Participants in the COach2Quit Trial

	Total (n = 89)	Intervention (n = 39)	Control (n = 50)
Age (years), median (IQR)	52 (45, 56)	53 (47, 57)	51 (39, 54)
Gender			
Male	37 (42)	16 (41)	21 (42)
Female	52 (58)	23 (59)	29 (58)
Education			
Less than high school	30 (34)	17 (44)	13 (26)
High school or more	59 (66)	22 (56)	37 (74)
Race			
White	15 (17)	5 (13)	10 (20)
Black/African American	70 (79)	33 (85)	37 (74)
Mixed race/other	4 (4)	1 (2)	3 (6)
Employment			
Employed (full/part-time)	15 (17)	3 (8)*	12 (24)*
Unemployed/do not work	74 (83)	36 (92)*	38 (76)*
Cigarettes/day, median (IQR)	10 (8, 20)	10 (6, 20)	10 (8, 20)
Quit attempts in past 12 months, median (IQR)	2 (1, 2)	2 (2, 2)	2 (1, 2)
FTND score, mean (SD)	2.69 (1.43)	2.54 (1.39)	2.80 (1.47)

IQR = interquartile range; FTND = Fagerström Test for Nicotine Dependence.

All data are n (%) unless otherwise mentioned. The Wilcoxon's rank sum test was used to compare medians between the intervention and control groups. *t* tests were used to compare means between the intervention and control groups. Chi-square tests were used to compare proportions between the intervention and control groups.

*p < .05.

Table 2. Primary and Secondary Outcomes in the COach2Quit Trial

	Intervention (n = 39)	Control (n = 50)	p Value
COppm baseline, median (IQR)	23.0 (18.0, 33.0)	22.0 (14.0, 30.0)	
COppm 30 days, median (IQR)	19.5 (15.0, 26.0)	18.5 (10.0, 28.0)	
COppm change (30 days – baseline), median (IQR)	−3.0 (−12.0, 2.0)	−2.5 (−9.0, 2.0)	.52
Cigarettes/day baseline, median (IQR)	10.0 (6.0, 20.0)	10.0 (8.0, 20.0)	
Cigarettes/day 30 days, median (IQR)	5.0 (4.0, 10.0)	6.0 (3.0, 10.0)	
Cigarettes/day change (30 days – baseline), median (IQR)	−5.5 (−14.0, −1.0)	−6.0 (−10.0, −2.0)	.84
≤10 COppm at 30 days, n (%)[a]	2 (5)	9 (18)	.07
Self-reported and biochemically verified cessation at 30 days, n (%)	1 (3)	1 (2)	
RFQ score baseline, mean (95% CI)	2.6 (2.4% to 2.8%)	2.6 (2.4% to 2.8%)	
RFQ score 30 days, mean (95% CI)	2.7 (2.4% to 3.0%)	2.5 (2.3% to 2.7%)	
Unadjusted % change in RFQ score, mean (95% CI)	6.3 (−2.2% to 14.8%)	−3.6 (−9.2% to 2.1%)	.05

IQR = interquartile range; CI = confidence interval; RFQ = Reasons for Quitting scale.
The Wilcoxon's rank sum test was used to compare medians between groups. t tests were used to compare means between groups. Chi-square tests were used to compare proportions between groups.
[a]Only includes participants who had baseline CO levels >10 ppm.

The theoretical basis underlying biomarker feedback is that an individual's knowledge of their risk or harm exposure may motivate them to change their behavior. An assumption of the health belief model is that high perceived susceptibility to a disease contributes to increased motivation to change behavior.[11] In a similar smoking cessation trial conducted by McClure et al., the authors surmised that in the absence of concrete evidence of smoking-related harm such as physical symptoms, counseling and biomarker feedback likely failed to increase perceived risk,[7] which could have also been the case in our study. These individuals may benefit from pairing biomarker feedback with other smoking cessation tools such as pharmacological therapy. A pilot study found that for smokers using varenicline, decreases in eCO significantly predicted future abstinence.[12]

A systematic review of qualitative studies identified poor digital literacy, difficulty or negative experience using the digital health intervention, lack of support from social network members, and busy lifestyle with competing priorities as barriers affecting engagement with digital health interventions.[13] In our study, the median number of days the app was used was 12 (IQR 6, 25). Therefore, a potential reason for the absence of an intervention effect is insufficient adherence to the intervention.

However, most participants reported that they liked having the COach2Quit app to help them quit smoking and expressed positive feedback about various aspects of the app. Therefore, socioeconomic stressors could likely have contributed to suboptimal use of the app. A high percentage of participants in our study were unemployed and regular app usage could have given way to competing priorities (eg, financial issues, health problems, and finding a job).

Limitations of the study include the small sample size, short follow-up duration, and large loss to follow-up. Self-reported measures could be subject to recall bias and social desirability bias. We also did not collect information on substance use. However, a strength of the study is the use of two biomarkers to verify smoking status.

Conclusions

We found no significant differences in smoking cessation, smoking reduction, and motivation to quit smoking between study arms over a 30-day period. Engagement with the app was below the recommended level but many participants expressed satisfaction with it, indicating feasibility and acceptability of biomarker feedback integrated with messaging support as a smoking cessation tool. Future studies should address barriers to optimal engagement with the technology and identify populations for which it might be most effective. More comprehensive trials with longer follow-up periods are needed to examine the independent efficacy of this technology as well as its efficacy in combination with other smoking cessation strategies.

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Declaration of Interests

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