RESEARCH ARTICLE

REVISED Relative effectiveness of a full versus reduced version of the 'Smoke Free' mobile application for smoking cessation: an exploratory randomised controlled trial [version 2; referees: 1 approved, 1 approved with reservations]

Previously titled: Relative effectiveness of a full versus reduced version of the 'Smoke Free' mobile application for smoking cessation: a randomised controlled trial

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Abstract

Background: Smartphone applications (apps) are popular aids for smoking cessation. Smoke Free is an app that delivers behaviour change techniques used in effective face-to-face behavioural support programmes. The aim of this study was to assess whether the full version of Smoke Free is more effective than the reduced version.

Methods: This was a two-arm exploratory randomised controlled trial. Smokers who downloaded Smoke Free were randomly offered the full or reduced version; 28,112 smokers aged 18+ years who set a quit date were included. The full version provided updates on benefits of abstinence, progress (days smoke free), virtual 'badges' and daily 'missions' with push notifications aimed at preventing and managing cravings. The reduced version did not include the missions. At baseline the app recorded users': device type (iPhone or Android), age, sex, daily cigarette consumption, time to first cigarette of the day, and educational level. The primary outcome was self-reported complete abstinence from the quit date in a 3-month follow-up questionnaire delivered via the app. Analyses conducted included logistic regressions of outcome on to app version (full versus reduced) with adjustment for baseline variables using both intention-to-treat/missing-equals smoking (MES) and follow-up-only (FUO) analyses.

Results: The 3-month follow-up rate was 8.5% (n=1,213) for the intervention and 6.5% (n=901) for the control. A total of 234 participants reported not smoking in the intervention versus 124 in the control, representing 1.6% versus 0.9% in the MES analysis and 19.3% versus 13.8% in the FUO analysis. Adjusted odds ratios were 1.90, 95%CI=1.53-2.37 (p<0.001) and 1.50, 95%CI=1.18-1.91 (p<0.001) in the MES and FUO analyses respectively.

Conclusions: Despite very low follow-up rates using in-app follow up, both intention-to-treat/missing equals smoking and follow-up only analyses showed the full version of the Smoke Free app to result in higher self-reported 3-month continuous smoking abstinence rates than the reduced version.

Open Peer Review

Referee Status: ? ✓

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REVISED version 2 published 09 Jan 2019		✓ report
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Comments (0)

Keywords
smoking cessation, RCT, smartphone application, smoke free

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Competing interests: David Crane is originator of the Smoke Free app and derives income from it. Harveen Kaur Ubhi has no conflict of interest. Jamie Brown has received unrestricted smoking cessation research funding from Pfizer. Robert West has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications. JB & RW are both unpaid members of the scientific steering group of the Smoke Free mobile application.

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REVISED **Amendments from Version 1**

The revised version highlights in the title and abstract that the trial was exploratory because it was not pre-registered. It also clarifies the rationale for the intervention, and a number of methodological issues. We also make clearer that including both intention-to-treat and follow-up only analyses addresses the weaknesses of each of these two methods; the first ensures that quit rates are not overstated as a result of selection bias at follow-up, and the latter removes the risk that the results arise from those in the intervention group being more likely to be followed up.

See referee reports

Introduction

Smartphone applications (apps) are used by many smokers to aid cessation but currently little evidence exists on their effectiveness. The Smoke Free app (smokefreeapp.com) is very popular worldwide, with some 4,000 new downloads per day. When it first became available, it was the subject of a trial with users finding and downloading the app from the app store being randomly assigned to a full version or a reduced version. This provided an opportunity to assess whether the full version was more effective than the reduced version in an effectiveness study closely mirroring the real-world scenario of interest. This paper reports the findings from that trial.

The Smoke Free app was developed using behaviour change techniques (BCTs) found in effective behavioural support programmes for smoking cessation[1]. A description of the app is given in Supplementary File 1. The evidence-based BCTs implemented in the full version of the app were: 1) Supporting identity change: supporting app users to think of themselves as non-smokers, 2) Rewarding abstinence: praise, virtual prizes and showing them how much money they are saving each day of not smoking, 3) Changing routines: advising on ways of avoiding smoking cues by changing routines that involve smoking, and 4) Advising on medication use: promoting the use of one of the evidence-based stop-smoking medicines. These BCTs are designed to increase resolve and prevent, reduce and counter urges to smoke.

Behavioural support delivered via a smartphone could help smokers to stop. Internet-based support has been found in some cases to aid cessation[2] and smartphone apps can provide this functionality with the added advantage of being readily accessible at almost any time. Two prospective studies of users of smoking cessation apps[3,4], a randomised controlled trial (RCT) comparing an app with a text messaging intervention[5] and two RCTs comparing mindfulness-based apps with other apps[6,7] found self-reported success rates that were higher than would be expected from unaided cessation. One RCT has found that an app acting as a decision aid for smokers interested in stopping smoking resulted in higher 6-month abstinence rates than an information-only app[8]. Another RCT examined the effectiveness of a set of app components as an aid to cessation in pregnant smokers; engagement with the app was low and no specific components were found to increase short-term self-reported abstinence rates[9]. To date, no RCTs have been published comparing apps designed to provide ongoing support for quit attempts with unaided quitting, or more intensive versus less intensive versions of an app.

Evaluating the effectiveness of smoking cessation apps versus unaided cessation in RCTs is complicated by the fact that apps are widely available and participants who are randomised to the unaided quitting condition are likely to be motivated to drop out of the study or use one of the many freely available apps. An alternative is to compare full and reduced versions of an app in which the reduced version is sufficiently credible that participants who are randomised to receive it are not motivated to drop out of the study or seek out another app. That was the approach used in the present study.

Another challenge for RCTs of apps is how to address the problem of loss to follow up. With sufficient resources, high follow-up rates can be obtained in such trials[6,10]. However, the methods used can lead to problems of generalizability; study engagement processes that involve face-to-face visits, incentives and contracts on the part of participants that may exclude a substantial proportion of the target population. Moreover, the resources required are prohibitive for the kind of agile, iterative evaluation that is required during the development of these interventions, where evaluations need to be undertaken repeatedly[11]. Automated outcome assessment using the smartphone is low cost and does not require procedures that may undermine generalizability. Despite the fact that it may result in very low follow-up rates that is the approach used in the current study.

In smoking cessation trials it is common practice to use an intention-to-treat approach with participants lost to follow up considered to have resumed smoking[12]. This may bias effect sizes downwards if loss to follow up occurs for reasons other than relapse to smoking[13]. Conversely, it may bias effect sizes upwards if the intervention condition leads to higher follow-up rates than the control condition. Only including participants who are successfully followed up may overestimate absolute success rates if participants refuse to engage with follow up because they have resumed smoking, but this would not affect the odds ratio comparing two conditions since this bias would affect both intervention and comparison groups equally. This approach is also immune to bias caused by differential follow-up in intervention and control groups. In practice 'missing equals smoking' (MES) and 'follow-up only' (FUO) approaches tend to produce very similar odds ratios in smoking cessation RCTs[14], though the percentage point difference between conditions varies considerably. Multiple imputation methods are increasingly being used to estimate values for missing data arising from loss to follow up (e.g. Westmaas *et al.*[15]). However, these are only viable when the proportion of values that are missing is low. To address biases arising from loss to follow up, both the MES and FUO approaches were used in the present study. It may be expected that the true percentage point difference and odds ratios lie somewhere between the estimates provided by these two methods.

Biochemical verification of abstinence is recommended in smoking cessation trials because of psychological pressure to claim abstinence[12]. However, this is highly resource intensive and may undermine generalizability to smokers who would use an app but not a more intensive interaction. such as this with no personal contact with a counsellor there may be expected to be no greater psychological pressure on participants to falsely claim abstinence in one condition than another' so reliance on self-reported abstinence should not bias the estimated effect size. Therefore, this study used self-report for outcome assessment.

Duration of follow up is an important consideration in smoking cessation trials. Conventionally, follow-up at least 6 months after the start of an intervention is considered appropriate for definitive trials while shorter durations are acceptable for proof of concept trials[12]. A recent systematic review of continuous abstinence rates in smoking cessation trials has recently found, however, that rates at 6-month and 12-month follow up can be accurately predicted from findings after 12 weeks[16]. Loss to follow up may be greater with longer follow up so in the present study participants were followed up 12 weeks after the target quit date.

Thus, this study addressed the question of whether the full version of the Smoke Free app would result in higher 12-week self-reported continuous abstinence rates than a reduced version of the app in smokers downloading the app and using it to set a quit date.

Methods

Study design

Participants were individually randomly allocated by the app on a 1:1 ratio to the full or reduced version and followed up automatically by the app 12 weeks after the target quit date to assess the outcome. Randomisation was by a random number generator in the app and generated a 1 or 2 during the registration process independently for each user. This study was not pre-registered because the lead author was not aware of this requirement at the time the data were collected, and so the study must be considered exploratory. We used the CONSORT-SPI checklist in preparing this report[17] (Supplementary File 2). The study was approved by the University of East London Ethics Committee.

Participants

Participants were not actively recruited and received no financial incentive for taking part. Smokers who downloaded the Smoke Free app between February 2013 and January 2015 were informed by the app that it was being used in an evaluation and asked for permission to use their data for research purposes. The app was available globally but only in the English language. If participants agreed they completed baseline measures and were randomly assigned by a computer-generated random number sequence to be offered a full or reduced version of the app. Consent was given by users by means of the touchscreen on their device. They were then included in the analysis if they met the following criteria: aged 18 years or over, smoked cigarettes at the time of registration (whether daily or non-daily), set only one quit date, and used the app at least once on or after their target quit date. Those users who had started their quit attempt before the date of registration were excluded, and if users registered more than once on the same device (as identified by the device ID) only data from the first registration was used.

Participants were aware that they were taking part in an experiment but were not aware of the details of the condition to which they had not been assigned.

Sample size was determined pragmatically by recruiting from the point where the app was in a form that was stable to the deadline for delivery of the lead author's project report. A total of 28,112 participants were included in the sample, of whom 14,228 received the full version and 13,884 received the reduced version.

Intervention and comparator

The full version of the Smoke Free app took smokers through the first month of their quit attempt by helping them maintain their resolve by setting a clear goal, monitor their progress towards that goal and become aware of benefits achieved to date. There were several components: 1) a calculator that tracked the total amount of money not spent on buying cigarettes and the number of cigarettes not smoked; 2) a calendar that tracked the amount of time elapsed since cessation; 3) a scoreboard that awarded virtual 'badges' to users for not smoking; 4) progress indicators that informed users of health improvements expected since the start of their quit attempt; and 5) daily missions that were assigned from the start of a user's quit date for one calendar month.

The daily missions included behaviour change techniques that research has suggested are likely to improve the chances of avoiding and resisting cravings and thereby promote abstinence[18–20]. A list of the daily missions can be found in the Supplementary File 1.

The full version of Smoke Free received daily push notifications for one calendar month from the start of their quit date. Users were prompted to open the app to read each day's mission. The time of the push notification was preset to 8am local time but this could be changed to a time of the user's preference. For screenshots of the app see Supplementary File 1.

The reduced version of the app was the same as the full version but without the daily missions.

Measures

After consenting to take part in the experiment, users were asked to provide information on their: age, sex, educational level (high school or secondary school, undergraduate degree, or post-graduate degree), daily cigarette consumption, and time to first cigarette of the day (<5 minutes, 5–30 minutes, 31–60 minutes, >60 minutes)[21].

After filling out the baseline questionnaire, users were then requested to record their target quit date which could be any date in the past or future (with those having already quit being excluded from the analysis).

The primary outcome measure was self-reported continuous abstinence up to 12-week follow-up. The app sent users a push notification 12 weeks after the target quit date asking them to open the app and respond to a questionnaire. The app did not send reminder notifications. The questionnaire asked: 1) "Have you smoked at all in the last three months?" to which they could respond: "No, not a puff", "1–5 cigarettes", or "More than 5 cigarettes". Those who responded "not a puff" were considered to be abstinent.

Analysis

Baseline characteristics of the two groups were compared using chi-squared tests or analyses of variance as appropriate. Outcomes were compared using logistic regression analyses with and without adjusting for all baseline variables. Two analytic approaches were used: 1) MES in which smokers who were lost to follow-up were counted as having smoked, and 2) FUO in which only smokers who responded to the 3-month follow-up were included in the analysis. Odds ratios and 95% confidence intervals were computed, along with p-values.

Data used in the analyses are available as Supplementary File 3 as an SPSS file and the SPSS syntax used to run the analyses is provided in Supplementary File 4. The full data set, including variables not included in the analysis, are provided in Dataset 1.

Results

Table 1 shows participants' baseline characteristics and Figure 1 shows the numbers allocated to each group and followed up. Participants who received the reduced version of the app were older, smoked more cigarettes per day, started smoking earlier in the day and were more likely to designate a quit date that was after the date of registration, but the differences were small. Complete data are shown in Dataset 1[22].

Of the participants, 2,114 (7.5%) were followed up (full version 1,213, 8.5%, reduced version 901, 6.5%). In the MES analysis 1.6% (n=234) of the participants in the intervention group and 0.9% (n=124) of the participants in the control group reported as being abstinent from smoking (unadjusted Odds ratio=1.86; 95% CI=1.49-2.31; p<0.001; risk difference 0.7%). In the FUO analysis, 19.3% in the intervention group and 13.8% in the comparison group reported being abstinent (unadjusted Odds Ratio=1.50; 95% CI=1.18-1.90; p<0.001; risk difference 5.5%).

Table 2 shows the results from logistic regression analyses with app version and all baseline variables entered together. In both the MES and FUO analyses, participants randomized to the full version of the app had higher odds of reporting successful abstinence with odds ratios almost identical to the unadjusted regression analyses. A number of baseline variables also

Table 1. Baseline characteristics of the study sample.

Variable	Reduced version	Full version	Total
Device type:			
Android, N (%)	1,075 (7.7)	1,044 (7.3)	2,119 (7.5)
iOS, N (%)	12,809 (92.3)	13,184 (92.7)	25,993 (92.5)
Age, mean years (SD)*	29.1 (9.4)	28.7 (9.0)	28.9 (9.2)
Sex			
Female, N (%)	6,769 (48.8)	7,015 (49.3)	13,784 (49.0)
Male, N (%)	7,115 (51.2)	7,213 (50.7)	14,328 (51.0)
Educational level			
School only, N (%)	8,734 (62.9)	8,949 (62.9)	17,683 (62.9)
Undergraduate, N (%)	3,477 (25.0)	3,598 (25.3)	7,075 (25.2)
Postgraduate, N (%)	1,673 (12.0)	1,681 (11.8)	3,354 (11.9)
Quit date			
Day of registration, N (%)	9,514 (68.5)	9,915 (69.7)	19,429 (69.1)
After registration, N (%)	4,370 (31.5)	4,313 (30.3)	8,683 (30.9)
Cigarettes per day, mean (SD)*	14.8 (7.6)	14.6 (7.4)	14.7 (7.5)
Time to first cigarette*			
<6 minutes, N (%)	3,679 (26.5)	3,569 (25.1)	7,248 (25.8)
6–30 minutes, N (%)	4,374 (31.5)	4,350 (31.8)	8,904 (31.7)
31–60 minutes, N (%)	2,788 (20.1)	2,896 (20.4)	5,684 (20.2)
>60 minutes, N (%)	3,043 (21.9)	3,233 (22.7)	6,267 (22.3)

*p<0.05 for comparison between groups, not adjusted for number of comparisons.

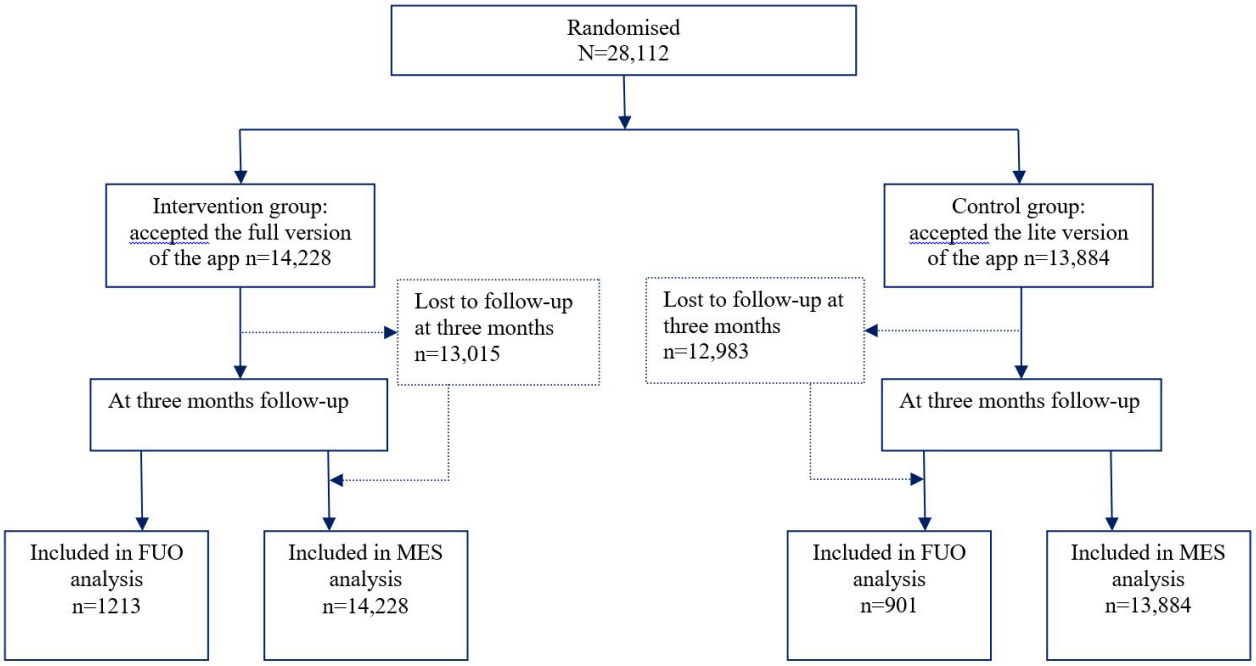

Figure 1. Flow of participants.

Table 2. Results of adjusted logistic regression analyses of outcome on to treatment group and baseline variables.

Predictor variable	Missing equals smoking analysis	Follow-up only analysis
Treatment group		
Reduced version	Reference	Reference
Full version	1.90 (1.52-2.37)*	1.50 (1.18-1.91)*
Device type		
iOS	Reference	Reference
Android	0.25 (0.12-0.50)*	0.29 (0.14-0.60)*
Age, years	1.05 (1.04-1.06)*	1.03 (1.02-1.04)*
Sex		
Male	Reference	Reference
Female	1.23 (0.99-1.52)	1.00 (0.79-1.27)
Educational level		
School only	Reference	
Undergraduate	1.06 (0.83-1.35)	0.93 (0.71-1.22)
Postgraduate	1.01 (0.73-1.39)	1.10 (0.77-1.58)
Quit date		
Day of registration	Reference	Reference
After registration	0.43 (0.33-0.57)*	0.69 (0.51-0.93)*
Cigarettes per day	1.01 (1.00-1.03)	1.00 (0.99-1.02)
Time to first cigarette		
<6 minutes	Reference	Reference
6–30 minutes	1.61 (1.21-2.14)*	1.36 (0.99-1.86)
31–60 minutes	1.53 (1.10-2.15)*	1.19 (0.82-1.73)
>60 minutes	1.27 (0.88-1.83)	0.99 (0.66-1.48)

*p<0.05 for linear trend or comparison with reference.

predicted reported abstinence. Older participants were more likely to report abstinence, while those using Android (versus iOS devices) and those whose quit date was after (versus on) the date of registration were less likely to report abstinence. In the MES analysis, participants whose first cigarette of the day was more than 5 minutes from waking were more likely to remain abstinence that those who smoked within 5 minutes of waking, but the difference was not statistically significant for those smoking their first cigarette more than 60 minutes from waking.

Dataset 1. Full de-identified data from each study participant, including download dates, quitting dates and all other data input into the app

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Discussion

In both the MES and FUO analyses the full version of the Smoke Free app produced higher self-reported abstinence rates than the reduced version 12 weeks after the target quit date. The odds ratios were 1.86 and 1.50 in the MES and FUO analyses respectively, and the percentage point differences between full and reduced versions were 5.5% and 0.7%.

Even with very low follow-up rates the study found a small but clear advantage to the full version of the app which may be attributed to the inclusion of the daily missions. The effect size in terms of odds ratios was similar to, or slightly lower, than was found in the only published RCT to date to have found a clear effect of a smoking cessation app. This effect is on top of whatever effect the reduced version of the app may have had. Even in the follow-up only analysis the abstinence rates were relatively low, and lower than is found in studies involving

face to face support or pharmacotherapy[23]. Therefore, this app should not be regarded as a substitute for those forms of support. It is possible that this app could increase abstinence rates in smokers using such forms of support but this remains to be tested.

The fact that an intervention effect was found in the FUO analyses indicates that it was not due to bias arising from differential loss to follow up. The fact that adjusting for baseline variables that are predictive of successful cessation did not influence the odds ratios adds confidence that the results were not due to smokers who found it easier to stop being more likely to be followed up in the intervention condition.

The lower success rate in participants using Android versus iOS devices needs to be investigated further. It was not explained by other baseline characteristics measured in this study. It may reflect the fact that Android users tend to have lower socioeconomic position or it could be that some of the devices do not have as high usability, e.g. in terms of screen size or resolution.

Strengths of the current study are the large sample size, the fact that it assessed an app that is very popular and therefore needs to be evaluated, and high generalizability to the population of interest, i.e. smokers finding the app on apps stores. Limitations are the very low follow-up rate, use of self-reported abstinence, the relatively short follow-up duration and the absence of process measures to assess what mediated the intervention effect. The generalisability of the study is limited by the low follow-up rate and to smokers who are willing to download an app such as this for help with stopping smoking.

Research continues into apps to support smoking cessation[24–29], with improvements in technology providing new opportunities for intervention content, such as virtual reality and use of wearable devices. The popularity of the Smoke Free app should make it a useful vehicle for testing innovations in smoking cessation support, building on the version of the app tested in this study. Research is needed into improving follow-up rates without compromising generalizability and within the resource constraints operating on companies and research groups seeking to build incrementally on app performance.

In conclusion, the full version of the Smoke Free smartphone app appears to have small effect in improving 12-week abstinence rates in smokers trying to quit. This provides a basis for building a programme of incremental improvement in effectiveness.

Data availability

Dataset 1. Full de-identified data from each study participant, including download dates, quitting dates and all other data input into the app. Data are available in SAV and CSV formats. DOI: https://doi.org/10.5256/f1000research.16148.d218541[22].

Grant information

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Supplementary material

Supplementary File 1. Details on the Smoke Free app, including each day's mission.

Click here to access the data.

Supplementary File 2. Completed CONSORT-SPI checklist.

Click here to access the data.

Supplementary File 3. Data used in the analyses.

Click here to access the data.

Supplementary File 4. SPSS command syntax for the analyses.

Click here to access the data.

References

1. Ubhi HK, Michie S, Kotz D, *et al.*: **Characterising smoking cessation smartphone applications in terms of behaviour change techniques, engagement and ease-of-use features.** *Transl Behav Med.* 2016; **6**(3): 410–7.
PubMed Abstract | Publisher Full Text | Free Full Text

2. Taylor GMJ, Dalili MN, Semwal M, *et al.*: **Internet-based interventions for smoking cessation.** *Cochrane Database Syst Rev.* 2017; **9**: Cd007078.
PubMed Abstract | Publisher Full Text

3. Ubhi HK, Michie S, Kotz D, *et al.*: **A mobile app to aid smoking cessation: preliminary evaluation of SmokeFree28.** *J Med Internet Res.* 2015; **17**(1): e17.
PubMed Abstract | Publisher Full Text | Free Full Text

4. Bricker JB, Copeland W, Mull KE, *et al.*: **Single-arm trial of the second version of an acceptance & commitment therapy smartphone application for smoking cessation.** *Drug Alcohol Depend.* 2017; **170**: 37–42.
PubMed Abstract | Publisher Full Text | Free Full Text

5. Buller DB, Borland R, Bettinghaus EP, *et al.*: **Randomized trial of a smartphone mobile application compared to text messaging to support smoking cessation.** *Telemed J E Health.* 2014; **20**(3): 206–14.
PubMed Abstract | Publisher Full Text | Free Full Text

6. Bricker JB, Mull KE, Kientz JA, *et al.*: **Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy.** *Drug Alcohol Depend.* 2014; **143**: 87–94.
PubMed Abstract | Publisher Full Text | Free Full Text

7. Garrison KA, Pal P, O'Malley SS, *et al.*: **Craving to Quit: A Randomized Controlled Trial of Smartphone app-based Mindfulness Training for Smoking Cessation.** *Nicotine Tob Res.* 2018.
PubMed Abstract | Publisher Full Text

8. BinDhim NF, McGeechan K, Trevena L: **Smartphone Smoking Cessation Application (SSC App) trial: a multicountry double-blind automated randomised controlled trial of a smoking cessation decision-aid 'app'.** *BMJ Open.* 2018; **8**(1): e017105.
PubMed Abstract | Free Full Text

9. Tombor I, Beard E, Brown J, *et al.*: **Randomized factorial experiment of components of the SmokeFree Baby smartphone application to aid smoking cessation in pregnancy.** *Transl Behav Med.* 2018.
PubMed Abstract | Publisher Full Text

10. Brown J, Michie S, Geraghty AW, *et al.*: **Internet-based intervention for smoking cessation (StopAdvisor) in people with low and high socioeconomic status: a randomised controlled trial.** *Lancet Respir Med.* 2014; **2**(12): 997–1006.
PubMed Abstract | Publisher Full Text

11. Michie S, Yardley L, West R, *et al.*: **Developing and Evaluating Digital Interventions to Promote Behavior Change in Health and Health Care: Recommendations Resulting From an International Workshop.** *J Med Internet Res.* 2017; **19**(6): e232.
PubMed Abstract | Publisher Full Text | Free Full Text

12. West R, Hajek P, Stead L, *et al.*: **Outcome criteria in smoking cessation trials: proposal for a common standard.** *Addiction.* 2005; **100**(3): 299–303.
PubMed Abstract | Publisher Full Text

13. Barnes SA, Larsen MD, Schroeder D, *et al.*: **Missing data assumptions and methods in a smoking cessation study.** *Addiction.* 2010; **105**(3): 431–7.
PubMed Abstract | Publisher Full Text

14. Blankers M, Smit ES, van der Pol P, *et al.*: **The Missing=Smoking Assumption: A Fallacy in Internet-Based Smoking Cessation Trials?** *Nicotine Tob Res.* 2016; **18**(1): 25–33.
PubMed Abstract | Publisher Full Text

15. Westmaas JL, Bontemps-Jones J, Hendricks PS, *et al.*: **Randomised controlled trial of stand-alone tailored emails for smoking cessation.** *Tob Control.* 2018; **27**(2): 136–46.
PubMed Abstract | Publisher Full Text

16. Jackson S, McGowan J, Ubhi HK, *et al.*: **Modelling continuous abstinence rates over time from clinical trials of pharmacological interventions for smoking cessation.** *Addiction (Abingdon, England).* 2018.
Publisher Full Text

17. Grant S, CONSORT-SPI Group: **The CONSORT-SPI 2018 extension: a new guideline for reporting social and psychological intervention trials.** *Addiction.* 2019; **114**(1): 4–8.
PubMed Abstract | Publisher Full Text

18. Michie S, Churchill S, West R: **Identifying evidence-based competences required to deliver behavioural support for smoking cessation.** *Ann Behav Med.* 2011; **41**(1): 59–70.
PubMed Abstract | Publisher Full Text

19. Michie S, Hyder N, Walia A, *et al.*: **Development of a taxonomy of behaviour change techniques used in individual behavioural support for smoking cessation.** *Addict Behav.* 2011; **36**(4): 315–9.
PubMed Abstract | Publisher Full Text

20. West R, Walia A, Hyder N, *et al.*: **Behavior change techniques used by the English Stop Smoking Services and their associations with short-term quit outcomes.** *Nicotine Tob Res.* 2010; **12**(7): 742–7.
PubMed Abstract | Publisher Full Text

21. Kozlowski LT, Porter CQ, Orleans CT, *et al.*: **Predicting smoking cessation with self-reported measures of nicotine dependence: FTQ, FTND, and HSI.** *Drug Alcohol Depend.* 1994; **34**(3): 211–6.
PubMed Abstract | Publisher Full Text

22. Crane D, Ubhi HK, Brown J, *et al.*: **Dataset 1 in: Relative effectiveness of a full versus reduced version of the 'Smoke Free' mobile application for smoking cessation: a randomised controlled trial.** *F1000Research.* 2018.
http://www.doi.org/10.5256/f1000research.16148.d218541

23. West R, Raw M, McNeill A, *et al.*: **Health-care interventions to promote and assist tobacco cessation: a review of efficacy, effectiveness and affordability for use in national guideline development.** *Addiction.* 2015; **110**(9): 1388–403.
PubMed Abstract | Publisher Full Text | Free Full Text

24. van Agteren JEM, Lawn S, Bonevski B, *et al.*: **Kick.it: The development of an evidence-based smoking cessation smartphone app.** *Transl Behav Med.* 2018; **8**(2): 243–67.
PubMed Abstract | Publisher Full Text

25. Schick RS, Kelsey TW, Marston J, *et al.*: **MapMySmoke: feasibility of a new quit cigarette smoking mobile phone application using integrated geo-positioning technology, and motivational messaging within a primary care setting.** *Pilot Feasibility Stud.* 2017; **4**: 19.
PubMed Abstract | Publisher Full Text | Free Full Text

26. Minami H, Brinkman HR, Nahvi S, *et al.*: **Rationale, design and pilot feasibility results of a smartphone-assisted, mindfulness-based intervention for smokers with mood disorders: Project mSMART MIND.** *Contemp Clin Trials.* 2018; **66**: 36–44.
PubMed Abstract | Publisher Full Text | Free Full Text

27. Boyd M, Wilson N: **Just ask Siri? A pilot study comparing smartphone digital assistants and laptop Google searches for smoking cessation advice.** *PLoS One.* 2018; **13**(3): e0194811.
PubMed Abstract | Publisher Full Text | Free Full Text

28. Baskerville NB, Struik LL, Dash D: **Crush the Crave: Development and Formative Evaluation of a Smartphone App for Smoking Cessation.** *JMIR Mhealth Uhealth.* 2018; **6**(3): e52.
PubMed Abstract | Publisher Full Text | Free Full Text

29. Zhang H, Jiang Y, Nguyen HD, *et al.*: **The effect of a smartphone-based coronary heart disease prevention (SBCHDP) programme on awareness and knowledge of CHD, stress, and cardiac-related lifestyle behaviours among the working population in Singapore: a pilot randomised controlled trial.** *Health Qual Life Outcomes.* 2017; **15**(1): 49.
PubMed Abstract | Publisher Full Text | Free Full Text

Open Peer Review

Current Referee Status: ? ✓

Version 2

Referee Report 22 January 2019

https://doi.org/10.5256/f1000research.19461.r42819

✓ **Jonathan Bricker**
Fred Hutchinson Cancer Research Center, Seattle, WA, USA

I accept their revision and have no further comments.

Competing Interests: No competing interests were disclosed.

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Referee Report 23 October 2018

https://doi.org/10.5256/f1000research.17634.r39534

? **Jonathan Bricker**
Fred Hutchinson Cancer Research Center, Seattle, WA, USA

This manuscript reports on the results of a fully automated RCT that compared the Smoke Free app with and without 30 days of behavior change technique skills for quitting and preventing relapse ("missions").

Major strengths:

1. The scientific premise of the study is strong. Determining the added value of behavior change techniques for smoking cessation is useful in any context (not just apps) so the study affords a real-world opportunity to test the techniques' potential effectiveness.
2. Testing the effectiveness of a widely utilized app in real-world conditions of consumers actually downloading to help them quit smoking is valuable from the point of view of implementation research. And perhaps that is the best context from which to frame this study--a real world implementation study.
3. Novelty. There is a dearth of studies comparing apps for smoking cessation so the study adds to a small and important literature.

Major weaknesses:

1. Trial was not registered. This is a very serious weaknesses that impacts ethical obligations to participants, research community, and publication bias. Reputable journals would not even

consider reviewing this paper knowing that is was not registered. The authors are aware of this weakness and I have no reason to believe they acted intentionally unethically. Nonetheless, it would be appropriate not to title the study a randomized trial or use that term in the abstract. Instead, I recommend the authors use the same term employed in methods section of the study design: "Exploratory Study." The authors themselves call it that. Now they just need to make it clear up front.

2. Very low retention rate (7.5%) that appears to imbalanced by a relative rate of 24% between arms. This is a very unfortunate weakness that could have been avoided with some small and immediate incentives given that only one question is asked in the follow-up survey. Nonetheless, it is what it is. The level of bias from this extent of missing data (92.5%) cannot be overcome with imputation methods. And the argument that the relative difference (not absolute quit rate) is what matters for this study is undermined by the imbalanced retention rates. With 24% more data in one arm than the other, it very possible that the difference in quit rates is simply driven by the difference in retention rates.

Moderate weaknesses:

1. The main outcome of continuous abstinence after baseline is biased by differences in quit dates and simply does not give people enough time to even reach their quit date before they would already be counted a smoker. Thus, the actual quit rates could be higher. Its hard to say with this outcome.
2. Generalizablity is overstated for two reasons. The low retention rate makes the sample highly biased toward the most motivated people who are most likely to be reporting that they quit. Comparing the baseline characteristics of all those enrolled vs only those completed the outcome survey item would be very important and instructive about bias. The second reason it is overstated is that the sample is limited to those who have already chosen an app and this particular app to help them quit smoking. The sample age (29) is young for a mhealth smoking study, which typically is about age 40.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Referee Expertise: mhealth for smoking cessation

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 08 Jan 2019

Robert West, University College London, UK

Major weaknesses

1. Trial was not registered. This is a very serious weaknesses that impacts ethical obligations to participants, research community, and publication bias. Reputable journals would not even consider reviewing this paper knowing that is was not registered. The authors are aware of this weakness and I have no reason to believe they acted intentionally unethically. Nonetheless, it would be appropriate not to title the study a randomized trial or use that term in the abstract. Instead, I recommend the authors use the same term employed in methods section of the study design: "Exploratory Study." The authors themselves call it that. Now they just need to make it clear up front.

Response: *We agree that the fact that the trial was not registered is a weakness. It does not affect the weakness of this trial but we note that even now, large numbers of behavioural trials published in high quality journals are not pre-registered. We gave a great deal of consideration before submitting the first version as to whether to call this an RCT and in the end decided to do so because that is what it was. We have checked authoritative definitions (e.g. the UK's National Institute for Health and Care Excellence) and they do not specify pre-registration in the definition. As the reviewer acknowledges, we make it very clear that the trial was not pre-registered. We believe that we must use the term RCT in the title etc but have added the word 'exploratory' to highlight this issue.*

1. Very low retention rate (7.5%) that appears to imbalanced by a relative rate of 24% between arms. This is a very unfortunate weakness that could have been avoided with some small and immediate incentives given that only one question is asked in the follow-up survey. Nonetheless, it is what it is. The level of bias from this extent of missing data (92.5%) cannot be overcome with imputation methods. And the argument that the relative difference (not absolute quit rate) is what matters for this study is undermined by the imbalanced retention rates. With 24% more data in one arm than the other, it very possible that the difference in quit rates is simply driven by the difference in retention rates.

Response: *We agree that the low follow up is a major weakness and prevents estimation of absolute effect size. However, we disagree that the imbalance in follow-up rates could have contributed to the relative effect. As we explain in the introduction, we conducted an additional analysis only on those followed up and still got a highly significant effect with an odds ratio of 1.5. We have explored the issue of whether results from the follow-up only sample can possibly be affected by differential follow up rate and with both analytical reasoning and extensive modelling of extreme difference we find that it cannot. We were initially surprised but once we saw it, it was obvious.*

To help see this, imagine a study of 1000 smokers with 500 allocated to each group. Then imagine 200 (40%) are followed-up in the intervention group and 100 (20%) in the control group. Imagine that in fact there is no difference in effect between the conditions so 50 (10%) are actually abstinent in each group. In an intent to treat analysis with missing equals smoking we would expect 20 (40% of 50) successes in the intervention group and 10 (20% of 50) in the control group which would translate to 20/500=4% in the intervention group versus 10/500=2% in the control group – apparently double the success rate in the intervention than control group which is clearly wrong. But in the follow-up only analysis the figures are 20/200=10% in the intervention group and

10/100=10% in the control group – correctly showing no effect. You can try this with any permutation of outcomes and it always comes out the same.

Moderate weaknesses

1. The main outcome of continuous abstinence after baseline is biased by differences in quit dates and simply does not give people enough time to even reach their quit date before they would already be counted a smoker. Thus, the actual quit rates could be higher. Its hard to say with this outcome.

Response: *We agree that the actual quit rates may well be higher. In fact, given what we observe in prospective studies of unaided quitting it would be surprising if the quit rates were not higher. We were not sure what the reviewer was referring to when saying that some participants may not have reached their quit dates by the follow up; the follow up was always 12 weeks after their designated quit date.*

1. Generalizablity is overstated for two reasons. The low retention rate makes the sample highly biased toward the most motivated people who are most likely to be reporting that they quit. Comparing the baseline characteristics of all those enrolled vs only those completed the outcome survey item would be very important and instructive about bias. The second reason it is overstated is that the sample is limited to those who have already chosen an app and this particular app to help them quit smoking. The sample age (29) is young for a mhealth smoking study, which typically is about age 40.

Response: *We now note in the discussion that the generalizability of the findings is limited by the low follow-up rate and to smokers. However, it should be noted that in the intention to treat analysis the sample was not limited to those followed up and the odds ratio was slightly higher than for the follow-up only sample and adjusting for baseline variables that are predictive of successful cessation also did not influence the finding. The data are available for anyone who would like to compare the baseline characteristics of those followed-up compared with who were not.*

Competing Interests: No competing interests were disclosed.

Referee Report 08 October 2018

https://doi.org/10.5256/f1000research.17634.r38627

Erica Cruvinel
Preventive Medicine and Public Health Department, University of Kansas Medical Center, Kansas City, Kansas, USA

This manuscript is a study of the “Relative effectiveness of a full versus reduced version of the ‘Smoke Free’ mobile application for smoking cessation: a randomised controlled trial”. The use of such applications as described therein can extend the reach of smoking cessation interventions to a large number of smokers through low-cost approaches. Thus, the results of this study will be of great interest to the tobacco treatment community. I have several questions about the details of the study and some suggested edits.

Introduction:
The introduction discusses most methodology decisions, such as those about the comparator group, follow up loss, analysis, and the measure of abstinence. But, it lacks some conceptual information. For

instance, it does not address why the full version of the app was expected to be more effective than the reduced version. I would like to see a more conceptual description used as a background to support the development of an extended version beyond the app's basic version. Also, I think methodology decisions would fit better under methods or study limitations. In addition, it is not clear what the authors mean by, "Also, in a trial where there is no greater psychological pressure to claim abstinence in one condition than another, use of self-report should not bias the estimated effect size". I'm not sure if the authors refer to a non-superiority trial since the last sentence in the introduction session shows that they expected a better result in the intervention group.
Furthermore, I would like to have more information about the app itself. For instance, are people from all over the world able to download the app? In which languages is it available?

Methods:
Study design:
Provide more details about the method used to generate the random allocation sequence (such as blocking and block size).
Participants:
Were included daily and occasionally smokers? In which countries do the participants reside? Is the app only in English?
Intervention and comparator
Show the theory that guided the development of these interventions in this section.
Measures:
Did you collect data about how often the app was used and for how long?
Analysis:
How did you control against the duplication of data, such as if someone installed the app twice?
What strategy did you use to increase follow up response rates? Did you set up a reminder function to send notifications to the user to complete the follow-up questionnaire?
How did you handle missing data? (details of any imputation method)

Results:
How did the participants use the app? If you included descriptive information from both groups, then it would help us to better understand participant interactions with the app.
Did you have information about whether participants used other methods to quit smoking? For instance, nicotine replacement therapy?
The sentence "Older participants, and in the MES analysis, those with longer time to their first cigarette of the day were more likely to report abstinence". This interpretation is confusing because the results from participants who smoke cigarettes longer than 60 minutes were not significant. Also, those whose quit date was after the date of registration were less likely to report abstinence. What was the comparator?
Table 2: It is not clear. What is the reference in table 2?

Discussion:
The fifth sentence of the introduction states: "The odds ratios ranged between 1.50 and 1.90 in the two analyses and the percentage point differences ranged between 0.7% and 5.5%". Is it not 0.85 and 0.7?
The last sentence in the third paragraph is not clear when looking at table 2. Which variable measured the difficulty of quitting?
The quit rate in this study was lower compared to other studies (ex: BinDhim, McGeechan, Trevena, 2018 [1]), as well as the follow-up rates. I would like to see more discussion about how the results from this study compare to those of other apps.
The results showed that those using Android (versus iOS devices) were less likely to report abstinence. What's the implication of this data?

References
1. BinDhim NF, McGeechan K, Trevena L: Smartphone Smoking Cessation Application (SSC App) trial: a multicountry double-blind automated randomised controlled trial of a smoking cessation decision-aid 'app'. *BMJ Open*. 2017; **8** (1). PubMed Abstract

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Referee Expertise: Smoking cessation, substance abuse

I have read this submission. I believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 08 Jan 2019

Robert West, University College London, UK

1. The introduction does not address why the full version of the app was expected to be more effective than the reduced version. I would like to see a more conceptual description used as a background to support the development of an extended version beyond the app's basic version.

Response: *We have now added this to the introduction and made reference to a paper that gives more detail.*

1. Methodology decisions would fit better under methods or study limitations.

Response: *We thought of doing this but in the end decided to keep it where it is because it made the methods section harder to follow and is part of the rationale for the study rather than what was actually done.*

1. It is not clear what the authors mean by, "Also, in a trial where there is no greater psychological pressure to claim abstinence in one condition than another, use of self-report should not bias the estimated effect size". I'm not sure if the authors refer to a

non-superiority trial since the last sentence in the introduction session shows that they expected a better result in the intervention group.

Response: *We obviously didn't make this point clear. We were referring to the pressure that respondents might feel to falsely claim that they were abstinent. We have reworded this to try to make it clearer.*

1. I would like to have more information about the app itself. For instance, are people from all over the world able to download the app? In which languages is it available?

Response: *We have now added this information. It is available globally but only in the English language.*

1. Provide more details about the method used to generate the random allocation sequence (such as blocking and block size).

Response: *We now included this information. The app generated a random number (1 or 2) with equal probability during the registration process for each user.*

1. Were included daily and occasionally smokers?

Response: *As indicated in the paper all smokers were included. We now make it explicit that this included non-daily smokers.*

1. Show the theory that guided the development of these interventions in this section.

Response: *We now include this in the explanation as to why we thought the full intervention would be more effective than the reduced version.*

1. Did you collect data about how often the app was used and for how long?

Response: *We did not collect information about number of times the app was used, unfortunately.*

1. How did you control against the duplication of data, such as if someone installed the app twice?

Response: *We already explain that if the app was downloaded more than once on the same device, we used the first occurrence only. Please see page no 5, paragraph 4 (continued on page 6).*

1. What strategy did you use to increase follow up response rates? Did you set up a reminder function to send notifications to the user to complete the follow-up questionnaire?

Response: *We already explain that push notifications appeared on the home screen of the device to solicit responses to the follow up questionnaire. We now make clear that reminders were not sent. Please see page no 7, paragraph 4.*

1. How did you handle missing data (details of any imputation method)?

Response: *We attempted to make this clear in the paper. We used both the traditional 'missing equals smoking' method and follow-up only. The aim was to address different types of bias that may arise from these two methods. As noted by reviewer 1, more sophisticated imputation methods would have required much greater follow-up rates.*

1. How did the participants use the app? If you included descriptive information from both groups, then it would help us to better understand participant interactions with the app.

Response: *Unfortunately we do not have this information.*

1. Did you have information about whether participants used other methods to quit smoking? For instance, nicotine replacement therapy?

Response: *Unfortunately not. It possible that participants in the intervention group used other methods to help them quit and indeed part of the effect of the app may have been to get them to do so since advice on medication use was one of the behaviour change techniques used.*

1. The sentence "Older participants, and in the MES analysis, those with longer time to their first cigarette of the day were more likely to report abstinence". This interpretation is confusing because the results from participants who smoke cigarettes longer than 60 minutes were not significant.

Response: *We have rephrased this to make clear that the association was only statistically significantly for the middle two categories of time to first cigarette.*

1. Also, those whose quit date was after the date of registration were less likely to report abstinence. What was the comparator?

Response: *We now make clearer that the comparator was those whose quit date was the same as the date of registration.*

1. Table 2: It is not clear. What is the reference in table 2?

Response: *This is the standard way to report results from logistic regression analyses with categorical independent variables. The 'reference' is the group against which the other groups are compared.*

1. The fifth sentence of the introduction states: "The odds ratios ranged between 1.50 and 1.90 in the two analyses and the percentage point differences ranged between 0.7% and 5.5%". Is it not 0.85 and 0.7?

Response: *We think the reviewer means the second sentence in the discussion but were still not sure what to make of this comment. This sentence just summarises the results from the comparison between the intervention and comparator conditions as stated in the results. However, to make this clearer we have rephrased this sentence.*

1. The last sentence in the third paragraph is not clear when looking at table 2. Which variable measured the difficulty of quitting?

Response: *We now make clearer that this was based on using baseline variables that predicted abstinence.*

1. The quit rate in this study was lower compared to other studies (ex: BinDhim, McGeechan, Trevena, 2018), as well as the follow-up rates. I would like to see more discussion about how the results from this study compare to those of other apps.

Response: *As noted by Reviewer 1, the follow-up rate was too low to be able to gain an accurate estimate of absolute quit rates. However, we now included discussion of how the results compare with those of previous RCTs of smoking cessation apps.*

1. The results showed that those using Android (versus iOS devices) were less likely to report abstinence. What's the implication of this data?

Response: *We now include a brief discussion of this finding.*

Competing Interests: No competing interests were disclosed.