Does addition of craving management tools in a stop smoking app improve quit rates among adult smokers? Results from BupaQuit pragmatic pilot randomised controlled trial.

A pre-print

Authors: Aleksandra Herbec* [a,b,c] MSc, Lion Shahab[a,c], PhD, Jamie Brown[a,c,d], PhD, Harveen Kaur Ubhi[a,c], PhD, Emma Beard[a,c,d], Alexandru Matei[e,f], MSc, Robert West[a,c], PhD.

[a] Department of Behavioural Science and Health, University College London, 1-19 Torrington Place, London, WC1E 6BT, UK,

[b] UCL Centre for Behaviour Change, Department of Clinical, Educational and Health Psychology, University College London, 1-19 Torrington Place, London, WC1E 6BT, UK

[c] UCL Tobacco and Alcohol Research Group (UTARG), University College London, 1-19 Torrington Place, London, WC1E 6BT, UK

[d] Department of Clinical, Educational and Health Psychology, University College London, 1-19 Torrington Place, London, WC1E 6BT, UK

[e] Bupa Centre Medical, Bupa, 15-19 Bloomsbury Way, London, WC1A 2BA

[f] Department of Computer Science, University College London, London, WC1E 6BT, UK

*** Corresponding Author:** Aleksandra Herbec, Department of Behavioural Science and Health, University College London, 1-19 Torrington Place, London WC1E 6BT, UK. E-mail: a.herbec@ucl.ac.uk and aaherbec@gmail.com

Trial registration: ISRCTN10548241 (http://www.isrctn.com/ISRCTN10548241; 17/02/2015)

OSF: https://osf.io/ge6vh/

Project OSF DOI: 10.17605/osf.io/ge6vh

Abstract

Introduction: Delivery of craving management tools (CMTs) via smartphone applications (apps) may improve smoking cessation rates, but research on such programmes remains limited, especially in real-world settings. This study evaluated the effectiveness of adding CMTs in a cessation app (BupaQuit).

Methods: The study was a two-arm pragmatic pilot parallel randomised controlled trial, comparing a fully-automated BupaQuit app with CMT with a control app version without CMT. A total of 425 adult UK-based daily smokers were enrolled through open online recruitment (February 2015-March 2016), with no researcher involvement, and individually randomised within the app to the intervention (n=208) or control (n=217). The primary outcome was self-reported 14-day continuous abstinence assessed at 4-week follow-up. Secondary outcomes included 6-month point-prevalence and sustained abstinence, and app usage. The primary outcome was assessed with Fisher's exact test using intent to treat with those lost to follow-up counted as smoking. Participants were not reimbursed.

Results: Re-contact rates were 50.4% at 4 weeks and 40.2% at 6 months. There was no significant difference between intervention and control arms on the primary outcome (13.5% vs 15.7%; p=0.58;RR=0.86, 95% Confidence Interval (CI)=0.54-1.36) or secondary cessation outcomes (6-month point prevalence: 14.4% vs. 17.1%, p=0.51;RR=0.85, 95%CI=0.54-1.32; 6-month sustained: 11.1% vs 13.4%, p=0.55,RR=0.83,95%CI=0.50-1.38). Bayes factors supported the null hypothesis (B[0, 0,1.0986]=.20). Usage was similar across the conditions (mean/median logins: 9.6/4 vs. 10.5/5; time spent: 401.8/202s vs. 325.8/209s).

Conclusions: The addition of craving management tools did not affect cessation, and the limited engagement with the app may have contributed to this.

Implications

Craving management tools within the automated BupaQuit app did not affect quitting. Engagement with the app was relatively limited, which could partially explain low effectiveness. Creating a single stop smoking app platform that randomizes users into intervention and control groups enables conducting a randomized control trial remotely, but evaluating such an app is resource-consuming and challenging, especially in terms of recruitment and follow-up. Future research should identify more engaging ways of delivering tools to support momentary cravings for cigarettes, as well as more effective strategies for recruitment into randomized trials of apps that are live on app stores.

INTRODUCTION

Use of face-to-face and telephone-based smoking cessation support is low even when it is free at the point of access [1]. Smartphone apps may appeal to smokers not willing to use these forms of support [2]. In 2016, over 85% of the UK population had access to a smartphone [3]. However, most cessation apps do not offer evidence-based support [4-7]. Results of two small randomised controlled trials (RCTs) [8,9] and three observational studies [10-12] have not yet provided clear evidence that such apps can aid cessation. Recently a decision-aid app improved self-reported quit rates over a control app version [13]. The present pilot RCT assessed how far the inclusion of craving management tools (CMTs) in an app could improve cessation. Furthermore, in order to recreate for the participants a more authentic experience of app download, and to increase the generalisability of findings, the study involved limited contact with the researchers and low participant burden at enrolment, in contrast to earlier research [8,9,11].

Cigarette craving can be defined as the experience of strong motivation (desire, need or urge) to smoke and is predictive of relapse [14]. Several techniques reduce momentary cravings, including distraction, imagining pleasant experiences [15], relaxation [16], physical exercise [17] and yogic breathing [18]. Cessation interventions that include behaviour change techniques (BCTs) [19] that reduce, or improve coping, with cravings appear to improve success rates [19]. An advantage of apps, also over SMS texting, is that they could be used online and offline, present multimedia content, and thus offer an opportunity to deliver or prompt use of different CMTs when appropriate. In principle, such apps could improve quit rates.

The SF28 (‘SmokeFree28’) app is an existing app that supports smokers to be smoke-free for 28 days as the first step to long-term abstinence, through offering features to set up a quit date

and monitor progress, as well as advice on cessation and medication use, and motivational content (http://www.sf28.co.uk/) [10,20]. SF28 is informed by PRIME theory of motivation, which postulates that quitting requires maintaining sufficiently high desire and capacity to override emerging impulses to smoke [21]. In an observational study, SF28 produced self-reported short-term abstinence that was higher than would have been expected with unaided cessation [10]. This app was also judged to contain all the evidence-based features that might be expected to improve cessation [22] and achieved relatively high engagement rates (8.5 (SD=9.0) mean logins)[10]. SF28 was therefore chosen as the basis for the development of a new app to evaluated specific CMTs. The new app was sponsored by the healthcare company Bupa and was called 'BupaQuit'. The appearance of SF28 was redesigned while keeping the key logic, content, and the user flow was similar.

Two versions of BupaQuit were created: one with a set of CMTs, and the other without them. The control app was designed to be a minimal credible intervention (MCI)[23], and to be similar to the intervention app in many respects (e.g. user journey, layout, core advice), but not to offer key intervention components. Provision of a true inactive control condition or a waitlist in smartphone research may be impossible given the availability of other free quit smoking apps, and so the control version of BupaQuit was judged to be fairer and a more realistic comparison for the trial. Using an MCI would also support enrolment and follow-up, and ensure comparable user experience and data collection across study arms. Furthermore, a poorly performing control app could lack credibility, damage the long-term reputation of BupaQuit program, undermine cessation rather than simply being 'neutral', and encourage users to seek alternative apps [23].

Aims

This study aimed to estimate the impact of the inclusion of CMTs within an app that was live

on app stores on cessation and engagement levels, compared with an app version without those features, and to assess the feasibility of remote enrolment and follow-up procedures.

METHODS

Design

This study was a two-arm parallel double-bind pragmatic pilot RCT conducted remotely in the UK, with participants randomised automatically within the app (after registration) in 1:1 ratio to either the intervention or control app (random numbers generated using a standard JavaScript library). The study was prospectively registered on an international trial registry (ISRCTN10548241). Additional documentation is available on the Open Science Framework (OSF, https://osf.io/ge6vh/). The protocol was amended before data were unblinded (for details see Box A.1).

Participants recruitment and eligibility

Participants were enrolled between 18th February 2015 and 16th March 2016 through open and remote online recruitment[13], with no researcher involvement and minimal participant burden. The study was advertised through paid advertisements on Twitter and Facebook, supplemented by emails and posters within Bupa and the University. Participants were invited to a study conducted in collaboration between the University team and Bupa comparing different features within the BupaQuit app. The differences between conditions were not disclosed. The app could also be found through online searches and on UK app stores. Interested participants were directed to the project website (Figure A.1), with a study

information sheet that was also available upon app download, and then to download the app for free.

Participants were eligible if they were (a) UK-based, (b) 18 years or older, (c) smoked daily, (d) wanted to make a serious quit attempt, (e) completed registration, (f) were willing to set a quit date within 2 weeks of registration, (g) agreed to follow-up, (h) agreed to, if invited, confirm abstinent with a personal CO monitor posted to them for free, (i) consented and agreed to Bupa's End User License Agreement (EULA). Criteria (a)-(e) were assessed through a baseline questionnaire. Criteria (f)-(i) were part of consent and app onboarding. Eligibility screening was automated but later supplemented by manual checks based on the unique device ID, name and contact details (24/32, or 75% of duplicate accounts were identified manually).

Sample size

Given limited information, the effect size estimates were based on SF28 results [10], assuming that the control app would be slightly less effective and the intervention app slightly more effective, with predicted success rates of 17% and 25%, respectively (OR=1.6). This expected difference would be clinically meaningful [24]. A sample size of 812 would be required to detect this effect in two-tailed analysis with alpha=0.05 and 80% power. Due to slower recruitment than anticipated, and thus under-recruitment within the time and resources available, the final study sample was 425 participants, which had 51% power to detect the predicted effect. We addressed this limitation by calculating Bayes Factors for the abstinence outcomes (see 2.6.2. below) [25].

BupaQuit platform

BupaQuit was developed for iOS and Android by Bupa (www.bupa.com), with the process overseen primarily by the first and sixth author (for details see Box A.2). This involved adapting the original SF28 content [10], creating new content and designs to reflect Bupa branding, adding Bupa and University logos, and developing a bespoke database. The control version of BupaQuit was developed simultaneously to act as a minimum credible intervention, proving basic functionality that users could expect from a cessation app. The quit plan, and look and feel of the control and intervention versions were identical. The Appendix provides BupaQuit screenshots (Figure A.2), comparison of SF28, BupaQuit intervention and control on functionality and BCTs [26] (Table A.1), participant journey through the trial (Figure A.3) and app (Figure A.4). BupaQuit was accessible offline, except for changing the quit date and completing follow-up questionnaires to enable data synchronisation. Participants were free to use the app *ad libitum*, but the app encouraged regular (daily) use through push notifications. Due to study protocol and policy changes in iTunes store on data collection within the apps, no changes or bug fixes to BupaQuit could be made during the trial, except for increasing the size of the control app to match that of the intervention app to minimise differences on download (implemented after 196 users were enrolled).

BupaQuit control app

The control app required setting a quit date within two weeks of app download, encouraged use of cessation medications, offered minimal support for up to 6 weeks (14 days before the quit date: *pre-quit*, and up to 28 days after the quit date: *post-quit*), including advice on pharmacotherapy, lifestyle changes, daily push-notifications that could be disabled, brief

feedback on smoking status, sections 'about the study', 'about the app', a timeline with progress and tracking of money saved, a meter for momentary cravings (a scale from 0-4 [27]), and an option to share the progress on social media.

BupaQuit Intervention app

In addition to the functionality in the control app, the intervention app included CMTs that were suggested to users reporting ≥1 on the craving meter during *post-quit* app**.** The CMTs included components from SF28, and were informed by research or theory that suggested potential usefulness at managing cravings: a game promoting distraction [15,28], *4Weeks2Freedom* videos presenting self-recorded accounts of smokers trying to quit, which was designed to boost motivation and self-efficacy [29], music, audio recordings of guided relaxation routines (e.g. 'body scan') [30,31], descriptions of exercises and activities (e.g. fist clenching, brisk walking [17,32,33]), and motivation boosting tips (e.g. strengthening ex-smoker identity) [19]. The app also offered gamification features (e.g. unlocking of craving aids when engaging with the app), a new piece of brief advice on lifestyle changes that unlock in weeks 2-4, and a longer feedback on smoking status. Some intervention content (e.g. videos, or music) was available for free upon additional download.

Trial Procedures

Figure 1 presents the flowchart of participants. After download, participants provided consent and accepted EULA (via tick box), set a quit date, registered and provided contact details, completed baseline, and received access to the allocated app version. Participants meeting eligibility criteria were followed-up at 4 weeks and 6.5 months after the final quit date set during their first quit attempt (to account for two week grace period following the quit date

[34]). Early in the trial we found out that for some participants (*app-data-missing*) usage-related data were missing (due to database architecture, these included data on the quit date, operating system, cigarettes smoked per day, and weekly spent). The possible causes were: (i) a failure of synchronization due to offline use (for seven users the data synchronized with a delay), (ii) interrupted installation, or (iii) not accessing the app after registration. Consequently, in the absence of quit date information, these participants were followed-up at 5 weeks and 7 months since registration. These participants were excluded in sensitivity analyses.

Tables A.2 and A.3a-b outline the schedule of procedures and questionnaires. All assessors were blind to condition allocation. At 4-weeks, the follow-up was via the app (up to three push notifications), e-mail (two emails), and phone (up to four calls). At 6.5 months, the follow-up was via email and phone. Phone follow-up asked only about smoking status. We trialled follow-up through SMS texting, but it was not successful and was discontinued. We also attempted remote biochemical verification of abstinence using personal carbon monoxide monitors developed by Bedfont® Scientific Ltd (COmpact Smokerlyzer®), but this proved to be an infeasible method, with only 15% of CO readings returned from participants reporting abstinence (the majority confirming abstinence). Possible reasons could include insufficient contact with participants and lack of reimbursement [8,11].

Measures

Baseline measures

The baseline survey was mandatory, and collected data on socio-demographic characteristics; smoking, quitting, restriction on phone use, and recruitment channel (Table A.2). We recorded operating system (iOS, Android, or Unkown for participants with app-missing-data),

and the quit date.

Primary and secondary outcomes

The primary outcome was self-reported abstinence in the past 14 days at 4-weeks [35,36]. As per intention to treat, participants lost to follow up were presumed to have resumed smoking.

Secondary outcomes were (1) 6-month point prevalence (not smoking in the past 7-days) and continuous 6-month abstinence (allowing for smoking of ≤5 cigarettes, and not smoking in the past 7 days) [34]; (2) follow-up channel; (3) app usage (logins, time spent, time/login, proportion of users accessing pre- and post-quit app, accessing craving aids); and (4) satisfaction (only 31 participants provided this data via app or email; the findings are reported in Table A.5).

Data analysis

Data analyses were conducted by the first author, with no Bupa involvement. Information on group assignment was kept separate from the primary outcome data until an analysis plan was registered on OSF. The primary outcome data were analysed by Fisher's exact test using intention-to-treat (ITT). Relative risk (RR) and 95% confidence intervals were calculated. We also assessed abstinence at short and long term using log-binomial regressions with and without adjustment for baseline characteristics. Analyses of secondary outcomes were conducted using t-test and Mann U-Whitney test, and chi-square. All tests were 2-sided with alpha initially set to 0.05. Sensitivity analyses were conducted [* denotes pre-registered analyses] that were limited to (a) complete cases*, (b) *Users Sample**, (c) *Post-Quit app Users* (as in SF28 analysis [10]). We also calculated Bayes Factors using an online calculator

(https://medstats.github.io/bayesfactor.html). This analysis can distinguish between the likelihood of both the null and alternative hypotheses, and assess whether the data are insensitive [25,29,37]. We used a uniform distribution with an expected effect size of OR of 1 to 3 vs 1*. We also used a conservative approach with half-normal distribution, with the mode at 0 (no intervention effect), and the standard deviation equal to the expected effect size of OR=1.6, and other plausible effects of OR=1.2 and OR=2.5.

RESULTS

Participants

Out of 695 complete registrations, 425 participants met the inclusion criteria (217 were randomised to the control and 208 to the intervention; Figure 1). Participants were 33 years old on average, 45.5% were female, the majority had post-16 education and had previously used cessation support, and 49.3% had a manual occupation (Table 1). Among the trial sample, 34% classified as app-data-missing participants (i.e. they either did not access the app after registration, used it offline, or the data failed to synchronise with the server for other reasons). Except for the Users Sample being slightly older (31 vs 34 years, p=.01), there was no statistically significant differences on baseline characteristics between participants with and without the app data (Table A.4).

Cessation outcomes

The overall abstinence rate was similar between the groups on the primary (13.5% vs 15.7%, *p*=.58) and secondary cessation outcomes (sustained 6-month abstinence: 11.1 vs 13.4%; and 6-month point prevalence: 14.4% vs 17.1%, see Table 2). The findings did not change after

adjustment for baseline characteristics and in sensitivity analyses. On the primary outcome, the Bayes factor calculated using a uniform distribution supported the null hypothesis (Bu[0, 0,1.0986]=.201. The Bayes factors using the half-normal distribution suggested that the data were insensitive for low effect sizes, but that for OR=2.5 the data supported the null hypothesis. Conclusions from Bayes factors analyses were similar for the secondary cessation outcomes (see Table 2).

Follow-up rates

At 4-week and 6.5-month, 54.1% and 40.2% participants were contacted, respectively, primarily via the phone (Table 3). There were no statistically significant differences in follow-up rates between the study arms, participants with or without the app data, or across baseline characteristics, except for men more likely being contacted at 6 months (p=.004) (data not reported).

App usage

Usage data between intervention and control participants were similar in terms of the login times (median=4 vs. 5, p=.45; mean=9.55 vs. 10.5, p=.63), total time spent using the app (median=202s vs. 209s, p=.54; mean=401.8 vs. 325.8, p=.20), or the proportion of sample accessing only pre-quit content of the app (23.2% and 16.3%) (Table 3). Intervention users tended to spend more time on app per login (median=44.6s vs. 32.9s, p=.01; mean=64.0s vs. 43.5, p=.003). Only 48 (23.1% of all intervention participants, 44% among those using BupaQuit post-quit where craving aids were available), accessed any craving aids (median=3 aids accessed, range: 1-34).

Discussion

Craving management tools offered within the BupaQuit app had no detectable effect on quit rates. The self-reported quit rates were within the ranges reported in other studies [8,11,13] and were comparable to those in SF28 study when the analysis was restricted to a similar sample of participants (users who used the app post-quit date) [10]. The engagement levels were comparable to SF28 app [10], but were nevertheless relatively low, including with the craving aids, which is a possible explanation for low effectiveness, which echoes findings from similar studies [38]. The lack of contact with researchers at enrolment might have contributed to suboptimal engagement [39]. It is also plausible that even with greater engagement, any impact of craving management tools would be too small to be detected, especially over and above the impact of other active components and evidence-based advice offered within the control app version, including setting up the quit date, monitoring of progress, and using pharmacotherapy [40,41].

Methodological observations

We conducted open and automated recruitment into an RCT embedded within a cessation app that was available to anyone on UK app stores, which involved the collection of contact details. This enrolment process differed to those used in other studies that included intermediary steps of contacting the researchers or completing additional screening procedures [8,9,13]. Most users who initiated registration completed baseline with all fields mandatory, and provided plausible contact details. However, policies of app stores may limit what identifiable data could be requested from users, thus affecting study procedures. Furthermore, reliance on the automated screening of app registrations emerged as insufficient. Additionally, most participants were recruited during paid advertisement campaigns. These observations suggest that dedicated budgets and human resources may be required for recruitment, enrolment, data management and follow-up in smartphone-based studies.

Nevertheless, a major challenge for conducting an evaluation of apps through randomized control design, and for recruitment into apps that are live on app stores, is that any informational and promotional materials (e.g. leaflets, but also information on app stores) must conceal the differences between the conditions. This prevents promoting many of the core features offered only within the intervention app version and may result in a recruitment campaign that is less appealing and thus likely to be less effective than one that would actively highlight the intervention features. To improve the reach of recruitment campaigns, future studies could explore diversifying promotional strategies and partnering with national or local organizations to support app promotion within their networks.

Furthermore, the telephone follow-up was the most successful, but it rarely allowed for a longer discussion with participants, while the re-contact via app, email or texting yielded very poor results. This limits the volume of secondary outcomes that can be feasibly collected in such studies. Finally, sensitivity analysis suggests that participants accessing BupaQuit app post-quit, which offered additional features (monitoring and feedback on smoking in both app versions, and craving aids in the intervention), might had higher quit rates than those who set the quit date in the future but never access the app post-quit. Future research should explore and account for the impact that different pre- and post-quit features in stop smoking apps might have on user behaviour and cessation.

Limitations

First, the study was underpowered to detect the original effect expected, but the Bayes factors suggest it is unlikely that a greater sample would bring support for the alternative hypothesis. Second, only a minority of participants responded to the app or e-mail follow-up, thus providing data on satisfaction. Third, despite the relatively intensive follow-up outside of the app [35,36,42], the follow-up rates were falling within the lower end of the spectrum for re-contact

rates in other studies [8,35,43]. The lack of incentives has likely negatively affected both recruitment and follow-up [8]. Fourth, self-reported abstinence rates tend to overestimate the actual quit rates, although the bias may be lower in remote interventions, and should not differ across study arms [44,45]. Fifth, we were missing app usage data from a third of participants who met trial eligibility criteria and could not account for this data missingness. Importantly, except for being younger, these participants did not differ from those with complete data, and excluding them from the analyses has not affected conclusions. Finally, the burden of joining this study was higher than accessing normal apps on the market but lower than that in previous studies of cessation apps [8,9,11]. Nevertheless, this is limiting the generalisability of the findings to a wider population of smokers using apps.

Future directions

Managing cigarette cravings can benefit cessation [15,17], and it has been mentioned by smokers as a desired feature of digital interventions [46,47]. Future research should explore new ways of delivering more engaging and usable CMTs. This could involve utilisation of user-centred approaches [48] and other research designs, such as Multiphase Optimization Strategy (MOST; [49,50]), to assess usability and impact of a range of, or a combination of, craving aids, as well as different app architectures and user journeys. It would also need to be ascertained if greater contact with researchers at enrolment could improve engagement and outcomes.

Conclusions

In this pragmatic trial, the addition of craving management tools to the BupaQuit app did not affect cessation, and limited engagement with the app may have contributed to this.

Funding

The costs of app development and of conducting the study (including participant recruitment, data collection, the cost of purchasing CO monitors) were covered by Bupa. AH was leading the trial as part of her PhD funded by British Heart Foundation 4-year PhD Studentship at UCL (FS/13/59/30649). Authors from UCL supported Bupa in developing BupaQuit app. Raw data from BupaQuit app was managed by Bupa. Data management and sharing with UTARG was governed by a bespoke Data Licence Agreement, according to which anonymised data from BupaQuit were shared with RW and his team for further independent processing, analysis, and dissemination. In accordance with the Data License Agreement, the final manuscript was submitted to Bupa for review prior to publication to ensure that no confidential or patentable information was included in the manuscript. Authors could accept any suggestions in good faith, but were under no obligation to make any suggested changes to the manuscript. Following Bupa review no changes were made. JB & EB salaries are funded by a programme grant from Cancer Research UK (CRUK; C1417/A22962). EB also receives funding from the NIHR SPHR. RW's salary was funded by CRUK for part of the preparation of this manuscript. The funders had no influence over the study design, data collection, analysis, findings interpretation, and preparation of the manuscript.

Declaration of Interests

AH led the BupaQuit trial as part of her PhD funded by British Heart Foundation 4-year PhD at UCL, and has been employed at Bupa in a casual role as Research Partner and Expert Advisor as part of BupaQuit development (June 2014-April 2015). AH has received unrestricted funds as part of a project *Global Bridges at Mayo Clinic and Pfizer* Independent *Grants* for Learning and Change Request for Proposals (RFP): *EUROPEAN PROGRAM*. LS has received honoraria for talks, an unrestricted research grant and travel expenses to attend meetings and workshops from Pfizer and Johnson&Johnson, and has acted as a paid reviewer for grant awarding bodies and as a paid consultant for health care companies. Other research has been funded by the government, a community-interested company (National Centre for Smoking Cessation) and charitable sources. JB and EB have received

an unrestricted research grant from Pfizer. AM worked as Digital mHealth Manager at Bupa. RW undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, J&J, McNeil, GSK, Nabi, Novartis, and Sanofi-Aventis). JB & RW are both unpaid members of the scientific steering group of the Smoke Free mobile application. The views presented are not necessarily the views of the funders. HKU has no conflicts of interest.

Acknowledgements

BupaQuit trial was conducted as part of a collaboration between Bupa and UCL. Among Bupa team (*former) we would like to especially acknowledge and thank for their support during the project: Alan Payne (Digital Director*), Lesley Payne (Head of the Global Institute for Digital Health Excellence and Senior Project Manager*), Fiona Adshead (Chief Wellbeing Officer*), Ann Sandy (Senior Project Manager*), Tuan Nguyen (Programmer*) and Ekaterina Volkova-Volkmar (Data Scientists*); as well as Dr Jenny Leeser (Clinical Director Occupational Health) and Dr Clare Scully (Director of Clinical Development) for reviewing the final manuscript and feedback. We would like to thank Bupa for offering financial support, office facilities, and resources enabling conducting of the study and data collection, and Bupa's legal and internal and external communications teams for their assistance in finalising study materials and facilitating participant recruitment. We would also like to thank and acknowledge Bedfont® Scientific Ltd for providing personal CO monitoring devices for the trial, as well as for their ongoing support with CO personal monitors use, and for adapting the software for CO reading to BupaQuit trial. We are also grateful to Michael Ussher for his advice and materials on craving management activities described in BupaQuit. Finally, we would like to acknowledge the invaluable contribution of research assistants in recruitment and collection of follow-up data: Olga Perski, Courtney Kwan, and Georgina Knock. AH, LS, JB, EB, & RW are part of UKCTAS.

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Table 1: Baseline Characteristics of BupaQuit trial participants

	Total (n=425)	**Intervention (n=208)**	**Control (n=217)**
Age (years) Mean (SD)	32.9 (11.19)	33.05 (10.10)	32.76 (11.40)
CPP[1] Mean (SD)	15.32 (7.17)	15.08 (7.32)	15.58 (7.03)
Weekly spent on cigarettes (GBP)* Mean (SD)	39.92 (50.11)	39.85 (66.08)	40.01 (24.02)
Smokes within 5min of waking up % (N)	21.4 (91)	19.7 (41)	23.0 (50)
Confidence to stop (1-7) Mean (SD)	4.88 (1.36)	4.98 (1.35)	4.78 (1.37)
Female % (N)	45.5 (193)	44.7 (93)	46.1 (100)
Occupation % (N)			
Manual	49.2 (209)	51.0 (106)	47.5 (103)
Non-manual	26.4 (112)	25.0 (50)	28.6 (62)
Other (incl. retired, unemployed, student)	24.5 (104)	25.0 (52)	24.0 (52)
Has post-16 yrs qualification % (N)	68.7 (29)	70.2 (146)	67.3 (146)
Time with urges (0-5) Mean (SD)	3.71 (.99)	2.7 (.95)	2.7 (1.05)
Strength of urges (0-5) Mean (SD)	2.81 (.86)	2.75 (.86)	2.8 (.94)
Made an attempt to quit last year % (N)	63.1 (268)	63.9 (133)	62.2 (135)
Stopped smoking for more than 1 week % (N)	76.0 (323)	77.9 (162)	74.2 (161)
Recruitment channel			
Advertisement on Twitter/Facebook	33.9 (144)	33.7 (70)	34.1 (74)
App store searches	36.5 (155)	39.4 (82)	33.6 (73)
Other (email, word of mouth, poster)	29.6 (126)	26.9 (56)	32.3 (70)
Restricted phone access during the day % (N)	23.3 (99)	22.1 (46)	24.4 (53)
Used any cessation aids in the past[#] % (N)			
No aids	19.1 (81)	18.8 (39)	19.4 (42)
Stop smoking services	31.1 (132)	31.2 (65)	30.9 (67)
Medications	52.7 (224)	47.6 (99)	57.6 (125)
E-cigarettes	50.1 (213)	51.4 (107)	48.8 (106)
Apps	20.2 (86)	21.2 (44)	19.4 (42)
Other incl. websites and quitline	16.2 (69)	17.3 (36)	15.2 (33)
Current use of cessation aids *,[#] % (N)			
No aids	54.2 (150)	59.2 (84)	48.9 (66)
Stop smoking services	5.1. (14)	4.9 (7)	5.2 (7)
Medications	19.9 (55)	14.8 (21)	25.2 (34)
E-cigarettes	26.0 (72)	24.6 (35)	27.4 (37)
Other (incl. apps, websites, quitlines)	6.1 (17)	7.0 (10)	5.2 (7)
Operating system* % (N)			
iOS	36.2 (154)	36.1 (75)	36.4 (79)
Android	28.9 (123)	32.2 (67)	25.8 (56)
Unknown	34.7 (148)	31.7 (66)	37.8 (82)
Set Quit Date to Today[*]	68.9 (190)	69.7 (99)	67.4 (91)

***** Data available for 277 participants (135 from control and 142 from intervention). The data missing from the remaining participants could be due to failed synchronization, use of app offline only, or not opening the app after registration. **#** Participant could select 'no aids used' or select one or more aids.

Table 2: Abstinence rates at 4 weeks and 6.5 months in BupaQuit trial.

	Intervention	**Control**			**Bayes Factor[a] distribution**	
Outcome (all self-reported)	% (n/N)		***p*[1]**	**RR (95% C.I.) (unadjusted)[2]**	**uniform**	**half-normal**
Continuous abstinence at 4-weeks						
14-day [FS, ITT]	13.5 (28/208)	15.7 (34/217)	.58	.86 (.54 to 1.36)	**.20**	.64[b], .34[c], **.19[d]**
14-day [FS, CC]	25.7 (28/109)	28.1 (34/121)	.77	.91 (.60 to 1.40)	**.25**	.73[b], .41[c], **.23[d]**
14-day [US, ITT]	14.1 (20/142)	16.3 (22/135)	.62	.86 (.50 to 1.51)	**.15**	.47[b], .73[c], **.24[d]**
14-day [US, CC]	26.3 (20/76)	28.2 (22/78)	.86	.93 (.56 to 1.56)	.34	.82[b], .52[c], **.30[d]**
14-day [PQU ITT]	16.5 (18/109)	19.5 (22/113)	.60	.85 (.48 to 1.49)	**.27**	.73[b], .43[c], **.24[d]**
14-day [PQU CC]	30.0 (18/60)	32.8 (22/67)	.85	.91 (.54 to 1.53)	.34	.81[b], .52[c], **.30[d]**
Abstinence at 6.5-month						
Sustained [†, FS, ITT]	11.1 (23/208)	13.4 (29/217)	.55	.83 (.50 to 1.38)	**.21**	.65[b], **.35[c], .19[d]**
Sustained [FS, CC]	29.1 (23/79)	30.4 (29/92)	.74	.92 (.59 to 1.46)	**.29**	.77[b], **.47[c], .27[d]**
Sustained [US, ITT]	10.6 (15/142)	14.1 (19/135)	.46	.75 (.40 to 1.42)	**.23**	.67[b], **.38[c], .21[d]**
Sustained [US, CC]	26.8 (15/56)	32.8 (19/58)	.54	.82 (.46 o 1.44)	**.29**	.74[b], **.45[c], .26[d]**
Sustained [PQU ITT]	12.8 (14/109)	15.9 (18/113)	.57	.81 (.42 to 1.54)	**.30**	.73[b], .44[c], .25[d]
Sustained [PQU CC]	31.1 (14/45)	35.3 (18/51)	.83	.88 (.50 to 1.56)	.36	.81[b], .54[c], **32[d]**
7-day PP [FS, ITT]	14.4 (30/208)	17.1 (37/217)	.51	.85 (54 to 1.32)	**.18**	.61[b], **.32[c], .17[d]**
7-day PP [FS, CC]	38.0 (30/79)	40.2 (37/92)	.88	.94 (.65 to 1.38)	**.29**	.77[b], **.46[c], .26[d]**
7-day PP [US, ITT]	14.1 (20/142)	18.5 (25/135)	.33	.76 (.44 to 1.30)	**.19**	.62[b], **.33[c], .18[d]**
7-day PP [US, CC]	35.7 (20/56)	43.1 (25/58)	.45	.83 (.52 to 1.31)	**.26**	.70[b], **.41[c], .23**[d]
7-day PP [PQU ITT]	15.6 (17/109)	21.2 (24/113)	.30	.73 (.42 to 1.29)	**.20**	.62[b], **.33[c]**, **.18**[d]
7-day PP [PQU CC]	37.8 (17/45)	47.1 (24/51)	.41	.80 (.50 to 1.29)	**.26**	.70[b], .41[c], .42[d]

[FS] Full Sample eligible at baseline; [ITT] Intention-to-treat analysis; [CC] Complete Case analysis (excluding participants who were not reached at follow-up); [US] Users Sample (excluding participants with app-data-missing). [PQ] Post-Quit Users (limited to participants who used the app after the quit date, when more features were available, including craving meter and craving aids); [†]Sustained abstinence = smoking 5 cigarettes or less in the past 6 months and not smoking in the past 7 days; PP = point prevalence. [1]p-value from Fisher's exact test. [2]We conducted adjusted analyses of short and long-term abstinence among the full study sample, which did not affect the results. [a] For Bayes Factor calculation using uniform distribution [pre-registered] we set the expected effect to be between odds ratio of 1 and 3, versus 1. For Bayes Factors calculation using the half-normal distribution [exploratory], the effect sizes used to *specify the* standard deviation of the theory (normal logarithm of ORs) for the half-normal distributions representing the alternative hypotheses were as follows: [b] OR=1.2; [c] OR=1.6, [d] OR=2.5 (Brown et al, 2016; Naughton et al, 2017). The Bayes Factors presented in bold mean that the findings supported the null hypothesis, and the rest suggested the data to be insensitive.

Table 3: Follow-up rate, follow-up channels and app usage in BupaQuit trial.

	Intervention	Control	*p*
Follow-up rate at 4 weeks % (n/N)	52.4 (109/208)	55.8 (121/217)	.49
Follow-up channel for primary outcome at 4 weeks % (n/N)			
App	7.3 (8)	12.4 (15)	.58
Email	9.2 (10)	9.9 (12)	
Phone	80.7 (88)	76.0 (92)	
SMS	2.8 (3)	1.7 (2)	
Follow-up rate at 6.5 months % (n/N)	38.0 (79/208)	42.4 (92/217)	.35
Follow-up via phone at 6.5 months % (n/N)	77.2 (61/79)	84.8 (78/92)	.21
Usage data available (during trial only) % (n/N)	68.3 (142/208)	62.2 (135/217)	.19
Total logins, Median (IQR)	4.0 (8.0)	5.0 (9.0)	.45
Mean (SD)[a]	9.6 (14.7)	10.5 (18.0)	.63
Total time (sec)[¥] Median(IQR)	202.0 (423.3)	209.0 (342.0)	.54
Mean (SD)[a]	401.8 (551.8)	325.8 (418.3)	.20
Time per login (sec) [¥] Median(IQR)	44.6 (59.9)	32.9 (37.9)	.01
Mean (SD)[a]	64.0 (70.6)	43.5 (40.6)	.00
App usage classification[§]			
Accessed only pre-quit app	23.2 (33)	16.3 (22)	.20
Accessed only post-quit app	25.4 (36)	33.3 (45)	
Accessed both pre- and post-quit app	51.4 (73)	50.4 (68)	

[¥]Total time, excluding registration, from the first use until follow-up. The time spent is an underestimate: (a) data from offline app use save locally on user's device but would not synchronize if users had not accessed the app while being online on a future occasion; and (b) the interaction between an app page and the server occurs when a page is loaded. No further communication with the server occurs until another page is loaded. Hence, it is not possible to identify the exact duration of the last interaction when it ends with exiting the app. [§]Only assessed among the sample with usage data available. Pre-quit app use only means that participants set the quit date in the future and accessed only pre-quit content; only the post-quit intervention app offered craving aids. [a] we provide Means to enable comparison with other studies. However, the usage data were skewed and hence we conducted and report results from non-parametric tests comparing usage between the two study arms.