ISRCTN10548241 https://doi.org/10.1186/ISRCTN10548241

Study of effectiveness of a smartphone application for quitting smoking.

Submission date
10/02/2015

Recruitment status
No longer recruiting

Registration date
17/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Smartphone-based interventions (in the form of applications or apps) have the potential to help smokers quit smoking. Additionally, due to their being highly assessible, apps could offer users with constant support with managing sudden cravings for cigarettes. Craving cigarettes is one of the main reasons why people start up smoking again once they have stopped. However, there still isn't enough evidence to show that apps do help people quit smoking or whether they work in helping people manage their cravings for cigarettes. This study aims to test if a new app developed by researchers at University College London (UCL) and Bupa, can successfully help people to stop smoking. This app focuses on helping smokers with manage their craving for cigarettes on a moment to moment basis. The performance of the app will be compared with a reduced version that offers only a minimal support with planning and monitoring of the quit attempt, and brief advice, but which does not have features and extensive advice dedicated to craving management.

Who can participate?
Adults aged at least 18, are currently smoking at least 5 cigarettes per day, and live in the UK. They should also be interested in stopping smoking in the next 2 weeks and be able to use a new app for Android or iPhone to help.

What does the study involve?
The study assesses different tools for quitting smoking available within two versions of a new app for quitting smoking. When participants download the app and join the study the app randomly allocates them to one of its versions, which they will then use to support them though an attempt to quit smoking. Version 1 of the app (control) allows users to set up the date to quit (within two weeks of joining the study) and provides brief information on medications and lifestyle changes that might help them in their attempt to stop smoking. The user can monitor their progress in terms of for how many days they have stopped smoking, how much money they have saved and gives feedback on successful abstinence on a daily basis or on lapse into smoking. The app also sends users reminders to use the app that can be disabled, and lets them share their progress (number of smoke-free days) on social media or e-mail. Version 2 (intervention) offers the same features as version 1. It also provides an extensive suit of features, advice and an interactive "gaming" element that aim to provide assistance with

managing cravings for cigarettes on a moment-to-moment basis. These includes feedback on the level of cravings and encouragement to use stop smoking medication, particularly nicotine replacement therapy in case of higher craving levels, and statistics the cravings reported. The app also offers a 'toolbox' of craving aids that includes distraction activities (e.g. game), motivational content (video diaries of smokers, and text-based stories and information), challenges and exercises known to support craving management (for example deep breathing exercises), relaxation audio-recordings with meditation and music. Version 2 also offers a system of point collection through app use that gradually unlocks some of the craving management content. All participants in both groups select a quit date within 2 weeks of signing up to the study after which they try to quit smoking completely, using the app as a support tool. After 4 weeks, each participant is asked some questions via the app and are contacted by phone if they don't respond to the app. They are contacted again 6 months later by email and then by phone with a few questions. Participants that report that they have stopped smoking 4 weeks into the study and then after 6 months may be invited to take part in a remote measurement of the level of carbon monoxide (CO) in their exhaled air. This test is done using a personal carbon monoxide monitor that is posted free of charge. Some participants are invited to a follow-up interview study about their experiences with the app.

What are the possible benefits and risk of participating?
By taking part in the study, participants are more likely to quit smoking, which would be one of the most beneficial things that one can do to improve health. They will also receive access to a new and free app for quitting smoking that will also help them to monitor their craving levels. Participants invited to take part in the remote CO measurement can keep the device for personal use in the future. Participants may experience some withdrawal symptoms such as irritability or increased hunger when they try to quit smoking.

When is the study starting and how long is it expected to run for?
July 2014 to August 2016

Where is the study run?
The study is conducted remotely on smartphones in the UK, and is managed by Bupa and researchers at University College London (UK)

Who is funding the study?
1. Bupa (UK)
2. British Heart Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial to evaluate the effectiveness of a smartphone-based smoking cessation aid delivering extensive craving management tools.

Acronym
SCRAP (Smoking Craving Reduction using a smartphone APplication)

Study objectives
Current hypothesis as of 27/05/2016:
1. The intervention app will increase abstinence rates at short term follow-up in comparison with the control condition. Specifically, it is predicted that there will be an effect size of OR=1.6 (a difference of 8%) on the primary outcome – self-reported complete abstinence rates during the 2 weeks prior to follow up scheduled for 4 weeks after the target quit date (17% vs. 25% for control and intervention arms respectively). The estimates are based on the findings from an

observational study of a similar smartphone-based intervention (SmokefreeFree28, SF28) on which BupaQuit app is based, in which self-reported prolonged quit rate at 4-week follow up were 19%. It is expected that the intervention version of BupaQuit will offer more effective support that the SF28 app, while the control condition will offer less effective support than SF28.
2. In comparison with the control condition, the intervention will result in higher satisfaction ratings and app engagement, as well as higher long-term quit rates.

Previous hypothesis:
1. The intervention app will increase abstinence rates at short term follow-up in comparison with the control condition. Specifically, it is predicted that there will be an effect size of OR=1.6 (a difference of 8%) on the primary outcome – complete abstinence rates during the 2 weeks prior to follow up scheduled for 4 weeks after the target quit date (17% vs. 25% for control and intervention arms respectively), verified biochemically using CO levels in the exhaled air. The estimates are based on the findings from an observational study of a similar smartphone-based intervention (SmokefreeFree28, SF28) on which the app is based, in which self-reported prolonged quit rate at 4-week follow up were 19%. It is expected that the intervention version of the quitting smoking app will offer more effective support that the SF28 app, while the control condition will offer less effective support than SF28.
2. In comparison with the control condition, the intervention will result in higher satisfaction ratings and app engagement, as well as higher long-term quit rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 10/10/2014, ref: 6212/001

Study design
The study involves a two-arm randomized controlled trial conducted on smartphones. The study is conducted in the UK and on smartphones.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cigarette smoking

Interventions

Participants are randomized to either an intervention or control version of the quitting smoking app with randomization embedded in the registration process in the App. Both conditions provide participants with access to a free app developed using html5 and available on iOS (6.0+) and Android (4.0+). All trial participants are followed up at 4 weeks and 6 months since their selected quit date. The app was developed based on an existing stop smoking pp (SF28; www.sf28.co.uk). In the development process Bupa has purchased a non-exclusive perpetual licence to SF28 source code to develop it further, and based on it two versions of the app were developed: an intervention and control version.

The control app offers a 'minimum credible intervention' that provides users with brief advice on setting the quit date within two weeks of joining the study, brief information on stop smoking medications and on lifestyle changes that facilitate cessation. It also provides tools for monitoring of the quit progress in terms of craving levels, days passed since the quit date and money saved, as well as provides brief feedback on successful abstinence on a daily basis or on lapse into smoking. The app also sends users reminders to use the app that can be disabled, and enables sharing of progress (number of smoke-free days) on social media or e-mail.

The Intervention version of the app offers the same features as the control app. In addition, it provides an extensive suit of features, advice and gamification elements that aim to provide assistance with managing cravings for cigarettes on a moment-to-moment basis and encourage the use of the app for this purpose. These includes feedback on the level of cravings and encouragement to use stop smoking medication, particularly nicotine replacement therapy in case of higher craving levels, and statistics on the cravings reported. The app also offers a 'toolbox' of craving aids that includes distraction activities (e.g. game), motivational content (video diaries of smokers, and text-based stories and information), challenges and exercises that were shown to support craving management (e.g. isometric exercises or deep breathing exercises), relaxation audio-recordings with meditation, as well as music files. The intervention app also offers a system of point collection through app use that gradually unlocks some of the craving management content. It also provides additional pre-quit and post-quit daily advice addressing motivation and management of cravings and withdrawals, information about lifestyle supporting abstinence that is updated weekly, as well as brief salient information about gains from quitting smoking provided on the main timeline in the app.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 27/05/2016:
The primary outcome will be self-report of not smoking in the two weeks prior to the follow up scheduled for 4 weeks. Smokers lost to follow up will be presumed to have resumed smoking, as per intention-to-treat principle.
Note: participants with missing data on the exact scheduled Quit Date will be followed-up 5 weeks and 195 days since their registration.

Previous primary outcome measures:
The primary outcome will be self-report of not smoking in the two weeks prior to the follow up scheduled for 4 weeks, and biochemically verified by a reading of <10ppm CO at the 4-week follow up. Smokers lost to follow up will be presumed to have resumed smoking, as per intention-to-treat principle.

Secondary outcome measures

Current secondary outcome measures as of 27/05/2016:
Secondary outcomes assessed at 4-week follow-up since the quit date:
1. Self-reported complete abstinence rates during the 2 weeks prior to follow up scheduled for 4 weeks after the target quit date biochemically and remotely verified by a reading of <10ppm on personal CO monitors
2. Self-reported use of cessation medications and other support at 4-week follow-up
3. Satisfaction ratings of the intervention at 4 week follow up, including ratings of app helpfulness to manage cravings (scale 1-5)
4. Ratings of acceptability and ease of use of the personal CO monitoring devices, as well as time since last cigarette (measured in weeks) assessed through CO monitoring software (prepared by Bedfont Scientitic Ltd for the purpose of the current trial)

Secondary outcomes and process data collected by the App throughout the trial:
5. Quantitative indices of App use (number of times the App)
6. Craving levels reported (scale 0-4) in the first week of use
7. Self-reported smoking status during App use
8. Ratings of helpfulness of individual components in the intervention version of the App

Secondary outcomes assessed at 6-month follow-up since the quit date (participants were contacted at 6 months and 2 weeks to account for a 'grace period' of the first 2 weeks since quit date):
9. Russell Standard (RS6) self-reported continuous 6-month abstinence, defined as having no more than 5 cigarettes in the past 6 months and no cigarettes in the previous week (self-reported rates; and rates verified by carbon monoxide levels in the exhaled air <10ppm)
10. 7-day point-prevalence abstinence at 6-month follow-up (self-reported rates; and rates verified by carbon monoxide levels in the exhaled air <10ppm)

The CO monitoring devices used in the study are COmpact Smokelyzer developed by Bedfont Scientitic Ltd. Due to a limited supply of CO monitoring devices (up to 390 devices are available for the trial), the assessment of CO levels in the exhaled air using personal CO monitors will be conducted up to among the first eligible 390 participants who self-report being abstinent from smoking at 4 week follow up, with remaining CO monitors being sent to eligible participants at 6 months who have not yet receive one, as long as the supplies last.

Previous secondary outcome measures:
1. Self-reported complete abstinence rates during the 2 weeks prior to follow up scheduled for 4 weeks after the target quit date
2. Self-reported use of cessation medications and other support at 4-week follow up
3. Satisfaction ratings of the intervention at 4 week follow up, including ratings of app helpfulness to manage cravings (scale 1-5)
4. Ratings of acceptability and ease of use of the personal CO monitoring devices, as well as time since last cigarette (measured in weeks) assessed through CO monitoring software (prepared by Bedfont Scientific Ltd for the purpose of the current trial)
5. Quantitative indices of app use (e.g. number of times the App was opened)
6. Craving levels reported (scale 0-4) in the first week of use.
7. Self-reported smoking status during App use
8. Ratings of helpfulness of individual components in the intervention version of the app
9. Russell Standard (RS6) self-reported continuous 6-month abstinence, defined as having no more than 5 cigarettes in the past 6 months and no cigarettes in the previous week (self-reported rates; and rates verified by carbon monoxide levels in the exhaled air <10ppm).
10. 7-day point-prevalence abstinence at 6 month follow-up (self-reported rates; and rates verified by carbon monoxide levels in the exhaled air <10ppm)

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Overall study start date
01/07/2014

Completion date
15/12/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/05/2016:
1. Currently living in the UK
2. 18 years or older
3. A daily smoker
4. Willing to set a Quit Date and try to make a serious quit attempt in the next 2 weeks
5. Have regular access to a smartphone (iOS or Android) with access to internet
6. Download and try using the suggested App to help them quit
7. Agree to be contacted via the App, e-mail or telephone at 4 weeks and 6 months after the Quit Date
8. Agree to, if invited, to remotely confirm abstinent status with a personal carbon monoxide monitor that will be posted to you for free

Participants also have to provide informed consent to participate in the study, agree to End User Licence Agreement for BupaQuit set by Bupa, and complete the registration into the trial via the App.

Previous inclusion criteria:
1. Currently living in the UK
2. 18 years or older
3. A regular daily smoker (at least 5 cigarettes/day)
4. Willing to set a Quit Date and try to make a serious quit attempt in the next 2 weeks
5. Have regular access to a smartphone (iOS or Android) with access to the internet
6. Download and try using the suggested App to help them quit
7. Agree to be contacted via the app, e-mail or telephone at 4 weeks and 6 months after the Quit Date
8. If invited, agree to remotely confirm abstinence status with a personal carbon monoxide monitor that will be posted to participants for free.

Participants also have to provide informed consent to participate in the study, agree to End User Licence Agreement & Privacy Policy for the app set by Bupa, and complete the registration into the trial via the app.

Participant type(s)
Patient

Age group
Other

Lower age limit
18 Years

Sex
Both

Target number of participants
A total sample of at least 816 participants, and at least 408 in each condition, will be recruited into the trial and included in the analysis of the primary outcome. The sample size was calculated a priori, with alpha set to 5% (two-tailed), and power to 80%. The sample size was set to detect an expected effect of OR=1.63 in self-reported abstinence rates at 4 week follow-up, with the abstinent rates in the control condition predicted to be 17% bases on the observational study of SF28 (Ubhi et al, 2015) and expected rates of 25% in the intervention. The recruitment may continue past 816 participants, but any additional participants will only be included in sensitivity and secondary analyses.

Key exclusion criteria
1. Does not meet inclusion criteria
2. Only data from the first registration will be included

Date of first enrolment
18/02/2015

Date of final enrolment
16/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Behaviour Research Centre
Research Department of Epidemiology and Public Health
University College London
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Sponsor information

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University College London

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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Organisation
Bupa

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BUPA House, 6th Floor
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Sponsor type
Other

Website
http://bupa.com/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bupa Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2018	17/12/2020	Yes	No
Results article		23/11/2021	08/03/2023	Yes	No
Results article		22/02/2021	08/03/2023	Yes	No