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Study of effectiveness of a smartphone app for stopping smoking focused on use of nicotine replacement therapy

Submission date
16/03/2015

Recruitment status
Stopped

Registration date
22/03/2015

Overall study status
Stopped

Last Edited
04/09/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Nicotine replacement therapy (NRT) has been shown to be effective at helping people quit smoking in numerous clinical trials. However, the effectiveness of quit attempts with NRT purchased over-the-counter (OTC) is very low in the UK, which may be due to poor adherence to guidelines on NRT use. Therefore, stop smoking interventions focused on the use of OTC NRT could also increase the quit rates. Smartphone-based interventions delivered through applications, or apps, could be used to deliver support both for smoking cessation as well as NRT use as part of a quit attempt. However, to date no such intervention has been developed or evaluated. This study aims to test if a new app that was developed by researchers at University College London (UCL) and which focused on the use of NRT as part of a quit attempt could increase abstinence from smoking and use of NRT. The performance of the app will be compared with a reduced version of the app that offers only a minimal support with planning and monitoring of the quit attempt and brief advice on quitting, but which does not have features and extensive advice dedicated to smoking cessation and use of NRT.

Who can participate?
Adults aged at least 18, currently smoking at least 10 cigarettes per day, and who live in the UK. They should also have bought any nicotine replacement therapy (e.g., gums or sprays) over the counter, and be interested in stopping smoking completely in the next 2 weeks, and be able to use a new app for iPhone to help them.

What does the study involve?
The study compares two versions of an app for quitting smoking with NRT (either a single product, or a combination of a patch with another nicotine product, such as gums or sprays). When participants download the app and register into the study the app randomly allocates them to one of its two 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 quitting smoking and use of nicotine replacement therapy that might help them in their attempt to stop smoking. The user can also monitor their progress in terms of for how many days they have stopped smoking. The

app also sends users reminders to use the app that can be disabled. Version 2 (intervention) offers the same features as version 1. In addition, it also provides comprehensive advice on smoking cessation (including information on craving management, preparation of quit attempt, and the available cessation support). It also includes an extensive suite of interactive features and comprehensive advice to assist with use of NRT products selected by participants, including text-based guides, and tools for monitoring of daily NRT use, and feedback on NRT use. 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 and use NRT as recommended. After 8 weeks participants are asked some questions via the app, and are contacted by e-mail and phone if they do not respond via the app. They are contacted again 7 months since registration by email, and if they do not respond then also by phone with few questions. At 8 weeks since the registration, participants who report that they have not smoked in the previous 4 weeks will be invited to provide small samples of saliva via post. Some participants may be 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 with NRT. Participants invited to provide saliva samples will receive a gift voucher of £20. Participants may experience some withdrawal symptoms such as irritability or increased hunger when they try to quit smoking. Those who are using NRT may also experience some side effects, but these tend to be short-lived and not dangerous.

When is the study starting and how long is it expected to run for?
March 2015 to March 2016

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

Who is funding the study?
1. Pfizer (through a grant award scheme, GRAND, that is run by a panel of independent scientists with no decision-making input from Pfizer)
2. British Heart Foundation PhD Studentship (UK)

Who is the main contact?
1. Miss Aleksandra Herbec (Trial Lead)
aleksandra.herbec.11@ucl.ac.uk
2. Tobias Raupach (Principal Investigator)
t.raupach@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Aleksandra Herbec

ORCID ID
http://orcid.org/0000-0002-3339-7214

Contact details
Health Behaviour Research Centre
Rm 215
Research Department of Epidemiology and Public Health
University College London
London
United Kingdom
WC1E 7HB

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 intervention focused on promoting adherence to nicotine replacement therapy

Acronym
PANTHERS (Promoting Adherence to Nicotine THERapy for Smoking cessation)

Study objectives
1. The intervention 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=1.7, or 5% difference in the primary outcome – a prolonged complete 4-week abstinence from smoking prior to follow-up scheduled at 8 weeks since registration between intervention and control conditions (13% vs 8%, respectively), verified biochemically using salivary cotinine (or anabasine levels among participants reporting using electronic cigarettes or nicotine replacement therapy at the time of providing saliva samples).

2. The intervention will also result in greater NRT use, as well as higher satisfaction ratings, greater frequency of app use, and higher long-term quit rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 14/02/2014, ref: 5398/001.

Study design
Two-arm randomized controlled trial

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 the contact details to request a patient information sheet

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

Interventions
Participants are randomised to either the intervention or control condition. Both conditions provide participants with access to a free app developed for iOS (8.0+). All trial participants are followed up at 8 weeks and 7 months after registering into the trial.

The control app constitutes a 'minimum credible intervention' that provides the users with advice and tools for setting up a quit date within two weeks of registering, a possibility to change the quit date, as well as very brief advice on quitting smoking, craving management and use of NRT selected by the users, and information about the study. It also allows users to track their progress in terms of the number of days passed since the quit date.

The intervention version of the app offers the same features as the control app, but in addition it offers comprehensive advice on NRT selected by users that focuses on addressing potential causes of non-adherence (particularly intentional non-adherence), as well as interactive features for reporting, monitoring, and receiving feedback on daily use of NRT and smoking status. It also offers comprehensive text-based advice on smoking cessation, including advice on planning and preparing for the quit, management of cravings, problem solving, use of available cessation aids, and fostering identity of a non-smoker. Additionally, it includes daily tips with additional advice and encouragement (including daily tips for up to 14 days before the quit date), more information about the research team and the rationale for the focus on NRT use, as well as customisable daily reminders to use the app.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome will be self-report of not smoking in the 4 weeks prior to the follow up scheduled for 8 weeks since registration, and biochemically verified by saliva cotinine level of <15 ng/mL, or by a saliva anabasine level of <1 ng/ml among those reporting using nicotine replacement therapy or electronic cigarettes.

Participants lost to follow up will be presumed to have resumed smoking.

Secondary outcome measures
1. Self-reported abstinence rates during the 4 weeks prior to the follow-up scheduled for 8 weeks after registration (complete abstinence, and rates of smoking 5 cigarettes or less)
2. Self-reported use of nicotine replacement therapy since the registration, assessed at 8-week follow-up
3. Self-reported use of other cessation medications and support at 8-week follow-up
4. Satisfaction ratings of the intervention at 8-week follow-up
5. Quantitative indices of app use (e.g., number of times the app was opened)
6. Self-reported criteria required for the Russell Standard (RS6): self-reported continuous 6-month abstinence assessed at 7-month follow-up, defined as having no more than 5 cigarettes in the past 6 months and no cigarettes in the previous week
7. Self-reported 7-day point-prevalence abstinence assessed at 7-month follow-up.

Overall study start date
01/01/2013

Completion date
01/05/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Currently living in the UK
2. 18 years or older
3. A daily smoker (at least 10 cigarettes/day)
4. Purchased at least one nicotine replacement therapy product available in the UK (i.e., patches, gums, lozenges, microtabs, nasal or mouth spray, inhalator, or oral strips) over the counter
5. Interested to quit smoking completely (not just to cut down)
6. Has regular access to a relevant smartphone device (iOS) with access to the internet
7. Download and try using the suggested app to help them quit
8. Agree to be contacted via the app, e-mail or telephone at 8 weeks and 7 months after the registration
9. Agree to take part in testing of saliva samples, if invited.
10. Have no contraindications for NRT use (determined by the participants, for example in consultation with the pharmacist)
11. Not currently pregnant or breastfeeding

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

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
At least 1186 participants, with at least 593 participants in each condition, will be recruited. 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 size of OR=1.7, or of 5% difference in self-reported abstinence rates at 4 week follow-up, with the abstinent rates in the control condition predicted to be 8% (in the control) and expected rates of 13% (intervention). Recruitment into the main trial will stop when both groups will have 593 or more eligible participants. Due to the nature of recruitment (self-selection and registration via the app), the recruitment may continue past 1186 participants, but any additional participants recruited (including participants reporting having purchased NRT on prescription) will be included only in the secondary and sensitivity analyses.

Total final enrolment
41

Key exclusion criteria
1. Does not meet inclusion criteria
2. Only data from the first registration with the app will be included
3. Obtains NRT on prescription

Date of first enrolment
23/03/2015

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Behaviour Research Centre at UCL
Research Department of Epidemiology and Public Health
University College London
London
United Kingdom
WC1E 7HB

Sponsor information

Organisation
University College London

Sponsor details
Health Behaviour Research Centre
Research Department of Epidemiology and Public Health
University College London
London
England
United Kingdom
WC1E 7HB

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Pfizer GRAND 2013 Award

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

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
The trialists are hoping to publish the results by summer 2016 (but this might be done in two papers - to be confirmed). The trialists will also likely also publish the protocol (probably submit in the next month).

Intention to publish date

Individual participant data (IPD) sharing plan

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	02/09/2019	04/09/2019	Yes	No