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iQuit in practice: a study to examine a personalised web-and text message programme to support smoking cessation in Primary Care

Submission date
23/12/2008

Recruitment status
No longer recruiting

Registration date
02/03/2009

Overall study status
Completed

Last Edited
25/09/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

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
A randomised controlled trial to assess the feasibility, acceptability and effectiveness of tailored web- and text-based facilitation of smoking cessation in primary care

Study objectives
The proposed trial is part of a larger programme of work in the General Practice and Primary Care Research Unit, University of Cambridge, on computer-based approaches to smoking cessation. The intervention to be evaluated in this trial consists of two components:
1. A web-based program designed to be used by a practice nurse or other smoking cessation advisor (SCA); the program generates a cessation advice report that is highly tailored to relevant characteristics of the smoker
2. A three-month program of automatically generated tailored text messages sent to the smoker s mobile phone

The iQuit program is a potentially cost-effective approach which is designed to enhance the effectiveness of the consultation without requiring nurses to radically change the way they advise and treat smokers and to provide continuing support to smokers during their quit attempts, while reducing the need for them to attend the practice (except for the purpose of obtaining further supplies of nicotine replacement and attending for the routine NHS four-week follow-up appointment).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Two parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Two groups to be compared:
1. Control group: participants will receive 'usual care' for smoking cessation
2. Intervention group: participants will receive 'usual care' for smoking cessation, plus a printed patient-tailored advice report generated by web-based software, followed by a 90-day program of patient-tailored interactive SMS text messages

Follow up dates:
Routine NHS follow up: 4 weeks from quit date
Research follow up: 8 weeks and 6 months from randomisation date

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Self-reported effectiveness, using a self report of being abstinent from smoking for at least 2 weeks, at 8-week follow-up from randomisation date, as assessed by postal questionnaire or telephone interview (blinded interviewer).

Secondary outcome measures
1. Carbon monoxide (CO)-verified self-report of being abstinent from smoking for at least 2 weeks, at 4-week follow-up from quit date
2. Self-reported prolonged abstinence (at least 3 months) at 6-month follow-up from randomisation date

Overall study start date
01/04/2009

Completion date
31/01/2011

Eligibility

Key inclusion criteria
Patients can be included in the study if they meet all of the criteria below:
1. Current smoker (has smoked in the 7 days prior to randomisation date)
2. Able to read English and can provide written informed consent
3. Is seriously considering quitting smoking and is willing to set a quit date within the 14 days after randomisation
4. Aged 18 - 75 years, either sex
5. Has a mobile phone and is familiar with sending and receiving SMS text messages
6. Is willing to participate in study and follow study procedures

7. Is not currently enrolled in another formal smoking cessation study or program
8. Is not using nicotene replacement therapy (NRT), bupropion (Zyban®) and varenicline (Champix®) or other pharmacotherapy at randomisation date

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
Total approx 600 (300 in each of the intervention groups)

Key exclusion criteria
1. Do not meet all of the inclusion criteria
2. Considered by their GP to be unsuitable for the project for any reason e.g. people with severe mental impairment or severely or terminally ill

Co-morbidities, for example chronic obstructive pulmonary disease (COPD), diabetes, are not excluded from the study (unless their GP considers them unsuitable). In addition, we would not exclude entry to the trial of more than one participant per household, however, should this occur, they would be assigned to the same treatment group (to minimise the potential for contamination).

Date of first enrolment
01/04/2009

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
General Practice & Primary Care Research Unit
Cambridge

United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge (UK)

Sponsor details
Research Services Division
16 Mill Lane
Cambridge
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Sponsor type
University/education

Website
http://www.rsd.cam.ac.uk/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - School for Primary Care Research (SPCR) (ref: 4.29)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/04/2013		Yes	No
Results article	results	01/07/2014		Yes	No