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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
23/12/2008		[X] Protocol	
Registration date 02/03/2009	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited 25/09/2018	Condition category Mental and Behavioural Disorders	[] Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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

Sponsor information

Organisation

University of Cambridge (UK)

Sponsor details

Research Services Division 16 Mill Lane Cambridge England United Kingdom CB2 1SB

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 summaryNot 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