ISRCTN44559004 https://doi.org/10.1186/ISRCTN44559004

iQuit in Practice

Submission date 13/07/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 21/07/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/08/2023	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-programme-to-help-people-give-up-smoking-iquit

Contact information

Type(s)
Public

Contact name
Ms Joanna Mitchell

ORCID ID
http://orcid.org/0000-0003-2138-3402

Contact details
Department of Public Health and Primary Care, Institute of Public Health
Forvie Site
University of Cambridge School of Clinical Medicine
Box 113
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

30934

Study information

Scientific Title
Improving quit rates among smokers in primary care: Pragmatic trial of effectiveness and cost-effectiveness of a tailored web- and text message-based intervention for smoking cessation (iQuit in Practice)

Study objectives
The aim of this study is to establish the effectiveness and cost-effectiveness of the iQuit in Practice intervention compared to routine care alone.

This study is a follow up study to a pilot study available via: http://www.isrctn.com /ISRCTN56702353

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge East Research Ethics Committee, 29/02/2016, ref: 16/EE/0030

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Public Health; UKCRC code/ Disease: Cancer/ Malignant neoplasms of respiratory and intrathoracic organs, Cardiovascular/ Pulmonary heart disease and diseases of pulmonary circulation, Respiratory/ Lung diseases due to external agents, Stroke/ Cerebrovascular diseases

Interventions
Patients will be randomly allocated to either the control or intervention group during the consultation through the on-line iQuit software.

Control group: Participants receive usual care alone. This involves having a face to face discussion on reasons why a patient smokes and why they may want to quit; a breath test to measure CO and a discussion on stop smoking treatments that are available such as nicotine replacement therapies and Champix. Patients are also offered follow-up support and advice on how to avoid potential pitfalls that might get in the way of a successful quit attempt.

Intervention group: Participants receive the iQuit intervention. In addition to 'usual care' and the tailored report generated from the iQuit software, participants will begin to receive text messages the day before their quit date and 0, 1 or 2 messages each day for 90 days. The following are examples of text messages a participant might receive.

"Hi Sarah, welcome to iQuit in Practice, a personal program of quitting support. We hope you enjoy it and that it helps in your quit attempt. The iQuit team."

"As well as removing cigarettes and ashtrays, ask any visitors not to smoke inside. Now's a great time to freshen up the curtains and wipe away any smoke stains."

"Quitting is great for your skin. Several studies have found measureable improvements in the skin tone of quitters, often within in the first four weeks!"

"By staying quit, your immune system will start to recover, meaning you'll soon be better able to fight off colds and other illnesses."

"After all your effort to get this far, make sure you reward yourself. It's a real achievement, and this time it's for good. :-)"

"Don't believe 'just one' is okay: A 2010 review found that even 'light' smokers were at much more risk of lung problems and cataracts compared to non-smokers."

"Hi Sarah, great job so far. Just make sure you don't give yourself any excuses. You decided to quit because you wanted to QUIT."

Follow up is at 4 weeks and 6 months post quit date: Follow-up is a CO test (at 4 weeks), a questionnaire and saliva test (at 6 months).

Intervention Type
Other

Primary outcome measure
Self-reported abstinence from smoking for 6 months endorsed by biochemical verification measured 6 months after the participant's quit date. Abstinence from smoking will be measured 6 months after the participant's quit date using a questionnaire (sent by the research team) followed by biochemical verification. All participants that have stated in the questionnaire they have not smoked for 6 months will be sent a kit to collect a saliva sample. The sample will be analysed for cotinine (a nicotine metabolite). If the sample is positive for cotinine then the sample will also be assayed for anabasine to differentiate whether the cotinine has come from tobacco, E-Cig or NRT.

Secondary outcome measures
1. Abstinence is measured using carbon monoxide (CO) testing at baseline and the routine follow-up 4-week appointment in the patient's GP practice
2. Abstinence is measured through self-reporting using a questionnaire deigned for this study at

6 months (not biochemically validated)
3. Cost-effectiveness of the intervention is determined using a questionnaire at 6 months post quit date will determine NHS costs accumulated during the previous 6 months through questions on GP visits and medications prescribed, including NRTs

Overall study start date
11/07/2016

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Current smoker aged 16 - 75
2. Wants to quit and willing to attending for smoking cessation support at a GP practice
3. Owns a mobile phone and familiar with sending/receiving text messages
4. Able to read and understand English, and give informed written consent
5. Willing to set a quit-date within 14 days of starting the study
6. Not currently involved in another formal smoking cessation study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1452; UK Sample Size: 1452

Key exclusion criteria
1. Not meeting the inclusion criteria
2. Their GP feels that it would not be appropriate for them to participate (e.g. severe complex additional health problems)

Date of first enrolment
11/07/2016

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alconbury and Brampton Surgery
School Lane
Alconbury
Huntingdon
United Kingdom
PE28 4EQ

Study participating centre
Cathedral Medical Centre
Princess of Wales Hospital
Kilkenny Avenue
Lynn Road
Ely
United Kingdom
CB6 1DN

Study participating centre
The Riverside Practice
23 Marylebone Road
March
United Kingdom
PE15 8BG

Study participating centre
Prospect Medical Practice
95 Aylsham Road
Norwich
United Kingdom
NR3 2HW

Study participating centre
Hanscombe House Surgery
52A St Andrew Street
Herford
United Kingdom
SG14 1JA

Study participating centre

The Cornerstone Practice
Elwyn Road
March
United Kingdom
PE15 9BF

Study participating centre
The Old Exchange
East Street
St. Ives
United Kingdom
PE27 5PB

Study participating centre
Sawston Medical Centre
London Road
Sawston
United Kingdom
CB22 3HU

Study participating centre
The Peninsula Practice
Mill Hoo
Alderton
United Kingdom
IP12 3DA

Study participating centre
Mundesley Medical Centre
Munhaven Close
Mundesley
Norwich
United Kingdom
NR11 8AR

Study participating centre
Beccles Medical Centre
St. Mary's Road
Beccles
United Kingdom
NR34 9NX

Study participating centre
Fakenham Medical Practice
Meditrina House
Trinity Road
Fakenham
United Kingdom
NR21 8SY

Study participating centre
Wellside Surgery
45 High Street
Sawtry
Huntingdon
United Kingdom
PE28 5SU

Study participating centre
Welland Medical Practice
142 Eye Road
Peterborough
United Kingdom
PE1 4SG

Study participating centre
Feltwell Surgery
Old Brandon Road
Feltwell
United Kingdom
IP26 4AY

Study participating centre
Oak Street Medical Practice
Oak Street
Norwich
United Kingdom
NR3 3DL

Study participating centre

Hingham Surgery
Hardingham Street
Hingham
United Kingdom
NR9 4JB

Study participating centre
The Maples Health Centre
Vancouver Road
Broxbourne
United Kingdom
EN10 6FD

Study participating centre
The Chesterfield Drive Practice
29 Chesterfield Drive
Ipswich
United Kingdom
IP1 6DW

Study participating centre
Grove Surgery
Grove lane
Thetford
United Kingdom
IP24 2HY

Study participating centre
Hoveton and Wroxham Medical Practice
Stalham Road
Hoveton
United Kingdom
NR12 8DU

Study participating centre
Kirkley Mill Surgery/Falkland Surgery
Clifton Road
Lowestoft
United Kingdom
NR33 0HF

Study participating centre
Leighton Road Surgery
1 Leighton Road
Leighton Buzzard
United Kingdom
LU7 1LB

Study participating centre
Flitwick Surgery
Highlands
Flitwick
United Kingdom
MK45 1DZ

Study participating centre
Greensands Surgery
The Health Centre
Oliver Street
Ampthilll
United Kingdom
MK45 2SB

Study participating centre
Pemberley Surgery
32 Pemberley Avenue
Bedford
United Kingdom
MK40 2LA

Sponsor information

Organisation
University of Cambridge

Sponsor details
School of Clinical Medicine
Addenbrooke's Hospital
Box 111
Hills Road
Cambridge

England
United Kingdom
CB2 0SP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The main papers to come out from this trial will be the protocol paper and trial results. Recruitment and follow-up is expected to be complete by the autumn of 2019 with trial publications being published in early 2020. At around this time it is expected that findings will also be presented at academic conferences and GP research forums.

Intention to publish date
31/10/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/07/2020	17/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 6.0	25/05/2018	30/08/2023	No	Yes
Participant information sheet	iQuit in practice participant consent form version 3.0	06/12/2016	30/08/2023	No	Yes