iQuit in Practice

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

Study information

Scientific Title

Improving quit rates among smokers in primary care: Pragmatic trial of effectiveness and costeffectiveness 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

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