

Increasing use of smoking cessation services with risk information and taster sessions

Submission date 08/12/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 10/12/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/02/2018	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Most smokers say they want to quit but only a tiny proportion make use of the free service provided by the NHS. We are conducting a study comparing two different methods of attracting and encouraging smokers to the service to assess which method attracts more smokers to attend the NHS stop smoking service. We will also assess which group is more likely to be abstinent at the 6 month follow-up.

Who can participate?

Current smokers who want to quit and have not previously attended NHS services

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives a standard invitation letter advertising the NHS service and asking them to contact the service and make an appointment. The other group receives a personal letter from their GP that includes information specific to the patient, based on information in their medical records, plus an invitation to a 'Come and Try it' taster session to find out more about the services. The letter is personalized and tailored to target different groups according to their known characteristics and medical conditions (e.g. heart disease, diabetes, lung disease), offering risk information for each group. The 'Come and Try it' taster session, run by advisors from the local service includes a video of previous successful attendees and excerpts from sessions, and the opportunity to ask questions about the service. Attendees are encouraged to sign up to a group or one-to-one session at a convenient time. Participants who attend the taster session receive a £10 voucher to cover their expenses. Participants who fail to attend receive a further invitation and appointment 3 months later to encourage attendance. We measure the number of people attending the first session of a 6-week course over a period of 6 months. We also measure the number of people who have abstained from smoking for at least 7 days at a 6-month follow-up checked by a cotinine test (a saliva test to detect smoking in the last 7 days). In addition we assess the number of smokers attending the taster session, the number completing the 6-week NHS course, and daily cigarette consumption. In addition we look into reasons for not attending and barriers to attendance, as well as individual differences between people who attend the services in the two groups. We assess any delayed effect on the uptake of service, of sending repeat reminders to smokers, and look at the differences in numbers attending by socio-economic status. We also measure the

cost of providing the interventions and their value for money, by assessing how quality of life improves for people in the two different services. A service-use questionnaire also measures patients' use of health and social care services at the start of the study and at follow-up.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
UCL Medical School (UK)

When is the study starting and how long is it expected to run for?
April 2010 to March 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Hazel Gilbert
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 08/58/02

Study information

Scientific Title
A randomised trial to increase the uptake of smoking cessation services using personal tailored risk information and taster sessions

Acronym

Start2quit

Study objectives

Smokers, identified from general practice records, sent brief personal tailored letters based on characteristics available in their primary care medical records and on a short screening questionnaire, and invited to a 'Come and Try it' taster session designed to inform them about the NHS services, are more likely to attend the services than those who receive a standard generic letter advertising the service.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South London REC 4, 21/04/2010, ref: 10/H0806/20

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

Control group:

A standard generic letter sent from the surgery advertising the NHS stop smoking service and asking the smoker to contact the service to make an appointment to see an advisor.

Intervention group:

There are two components to the intervention:

1. A brief motivational letter sent from the GP that includes information specific to the patient. The letter will be personalised and tailored using known characteristics (i.e. age and gender), and information obtained from the screening questionnaire (i.e. dependence, previous quit attempts, motivation and confidence). Information from medical records about the patients general health status and about chronic conditions e.g. heart disease, diabetes, lung disease, will also be used to offer risk information and to offer help to improve their condition by quitting smoking. The letter will include an invitation and an appointment to attend a 'Come and Try it' taster session to find out more about the services.

We will maximise the amount of tailoring within the constraints of the short screening questionnaire and brief letter. The exact content of the letter will be developed in collaboration with GPs and primary care experts with greater knowledge of medical information available in records.

2. The 'Come and Try it' taster session, run by advisors from the local service. This session will include:

- 2.1. An explanation that the advice and help offered by the NHS service is based on evidence, with a higher likelihood of success
- 2.2. Information about the services offered, i.e. one-to-one or group sessions, the length of a session and the length of the course, nicotine replacement therapy (NRT) or other pharmacotherapy as well as behavioural support
- 2.3. Information about what to expect when they attend and the content of advice (e.g. help dealing with weight gain, the correct use of NRT, depression, expected outcomes)
- 2.4. A measurement of expired-air carbon monoxide (CO) with an interpretation
- 2.5. A 10 to 15 minute video showing group and one-to-one sessions in progress, and testimonials from previous successful attendees. This will be standardised on the understanding that, while services may differ in the way they are organised, the protocols for delivering advice are standardised.
- 2.6. The opportunity to ask questions about the service
- 2.7. The expectations of the service, i.e. willingness to set a quit date

Each PCT will run 6 taster sessions, and approximately 25 participants will be invited to each session which will last approximately 1.5 hours. Attendees will be encouraged to sign up to a group or one-to-one session at a time convenient to them, at the end of the taster session. Participants who fail to attend will receive a further invitation three months later to encourage attendance.

Intervention Type

Behavioural

Primary outcome(s)

The proportion of people entering the smoking cessation service (i.e. attending the first session of a 6-week course) over a period of 6 months from the receipt of the invitation letter. Self-reported attendance data will be validated by records of attendance at the NHS services.

Key secondary outcome(s)

1. 7-day point prevalent abstinence at the 6-month follow-up, validated by salivary cotinine for all participants reporting abstinence in both the intervention and control groups
2. Prolonged periods of abstinence of 7 days to 24 weeks measured by self-report
3. Self-reported changes in daily cigarette consumption, quit attempts, and changes in motivation and intention to quit in continuing smokers
4. Use of NRT or Zyban or Champix and other smoking cessation aids
5. The number completing the 6-week NHS course
6. Process measures:
 - 6.1. The number of smokers attending the taster session (intervention group only)
 - 6.2. Perception of the personal invitation letters
 - 6.3. Reasons for non-attendance at the taster session and barriers to attendance at the NHS services

Completion date

31/03/2014

Eligibility

Key inclusion criteria

All current smokers:

1. Willing to participate and returning the signed consent form

2. Aged 16 years and over, either sex
3. Able to read English
4. Motivated to quit
5. Have not previously attended the NHS services

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Key exclusion criteria

Exclusion criteria are minimal because the aim is to recruit all smokers into the services. However, smokers younger than 16 will be excluded because of the need for parental consent to participate for this age group, and any patients identified who are considered by the GP to be unsuitable for the project, e.g. severely or terminally ill, will be excluded.

Date of first enrolment

01/04/2010

Date of final enrolment

31/03/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

UCL Medical School

London

United Kingdom

NW3 2PF

Sponsor information

Organisation

University College London (UCL) (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/12/2016		Yes	No
Results article	results	01/01/2017		Yes	No
Results article	results	25/02/2017		Yes	No
Protocol article	protocol	18/10/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes