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

**Submission date**
08/12/2009

**Recruitment status**
No longer recruiting

**Registration date**
10/12/2009

**Overall study status**
Completed

**Last Edited**
21/02/2018

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

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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### Study website
http://www.ucl.ac.uk/start2quit/

# Contact information

### Type(s)
Scientific

### Contact name
Dr Hazel Gilbert

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

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

### 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 measure
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.

## Secondary outcome measures
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

### Overall study start date
01/04/2010

### 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

### Age group
Adult

### Lower age limit
16 Years

### Sex
Both

### Target number of participants
2520

### 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**
England

United Kingdom

**Study participating centre**
**UCL Medical School**
London
United Kingdom
NW3 2PF

# Sponsor information

**Organisation**
University College London (UCL) (UK)

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**Sponsor type**
University/education

**Website**
http://www.ucl.ac.uk/joint-rd-unit/about-us

**ROR**
https://ror.org/02jx3x895

# Funder(s)

**Funder type**

Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**
01/10/2016

**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 | 18/10/2012 | | Yes | No |
| Results article | results | 28/12/2016 | | Yes | No |
| Results article | results | 01/01/2017 | | Yes | No |
| Results article | results | 25/02/2017 | | Yes | No |