

UCL RESEARCH DEPARTMENT OF PRIMARY CARE
AND POPULATION HEALTH



UCL



Advisor Training for Taster Sessions



NIHR Health Technology
Assessment programme
funded project



UNIVERSITY OF
CAMBRIDGE

THE UNIVERSITY *of* York

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Start2quit Trial

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Introduction

Start2quit is a randomised controlled trial aiming to increase the number of people attending the specialist NHS Stop Smoking Services.

Funding

This research is funded by the Health Technology Assessment programme (HTA) which is part of the National Institute for Health Research (NIHR). This body provides funding to independent research investigating the effectiveness of different healthcare treatments in the NHS. It identifies the most important questions that the NHS needs to answer and commissions the most important research.

Background

As smoking cessation advisors, you will be aware that NHS Stop Smoking Services (SSS) are effective in helping people to quit smoking but are significantly under used. Previous research in this area has identified a number of key reasons why smokers may not be inclined to utilise NHS SSS. These include: a perception that help is not necessary or available, a desire to quit independently and a sense of a lack of empathy from health professionals. Other studies have also suggested that many smokers are not aware of, or have insufficient knowledge of the NHS SSS which are available to them.

Current guidance suggests that health professionals should provide brief advice to smokers and refer them to the NHS SSS. However, in reality, the percentage of smokers receiving such advice is low and those who do receive advice are often left to follow up their referral and contact the NHS SSS to make their own appointment.

Research has emerged to address the problems in smokers' knowledge of smoking cessation services and in the perceived accessibility of these services. Lichtenstein and colleagues (1992) proactively recruited and referred smokers by providing all smokers with detailed information on the structure of a smoking cessation session. Of the participants who received this information, 11.3% attended a first session of a

smoking cessation programme compared to only 0.006% of participants in the control group who received brief advice only. Similar findings have been reported by other researchers. This suggests that if smokers are proactively and personally invited to use the services, the resultant use will be higher than standard referral by health professionals or by open advertising.

Individually computer-tailored self-help materials intended to meet the needs of one specific person, have also emerged as an important avenue for research in behaviour change. These materials involve an assessment of an individual's health related behaviour and the use of a computer program to select the correct communication content for each individual based on their assessment. This information can be formatted into a letter and advice encouraging the individual to improve or maintain their health related behaviour is also included. A key strength of these methods in smoking cessation is that they have the potential to engage with a large proportion of the smoking population on a personal level, in a relatively inexpensive way. Evidence suggests that computer tailored interventions can improve health-related behaviours.

The current study combines research on computer-tailored feedback and proactive recruitment with the provision of detailed information on NHS SSS. Further detail is provided in the next section.

Start2quit

As part of this study current smokers will be identified from GP records and sent a smoking questionnaire. Those who return this questionnaire and give full consent will be randomly assigned to the control or intervention group. Those in the intervention group will be sent computer generated letters containing personal tailored risk information based on both their answers to the questionnaire and on information in their medical records. An invitation to a 'Come and Try it' taster session will be also be enclosed. The aim of these taster sessions will be to introduce smokers to the NHS SSS and to encourage those who attend to sign up for a 6 week group or one-to-one NHS SSS course.

Those in the control group will be sent a generic letter advertising the NHS SSS, asking the smoker to contact the service to make an appointment to see an advisor.

Smokers who are willing to participate in the study but are ineligible will be sent an ineligible letter.

The primary objective of this study will be to assess whether those receiving a letter containing personal tailored risk information and an invitation to a taster session are more likely to attend NHS SSS than participants who only receive a generic letter advertising NHS SSS. Secondary objectives of this study include an assessment of the effectiveness of the intervention in increasing cigarette abstinence, determining the predictors of attendance at both the taster sessions and the NHS SSS and exploring the effectiveness of the intervention by socio-economic status and social deprivation.

Start2quit will involve the recruitment of participants from 12 GP practices across 2 NHS SSS areas (Camden and Oxfordshire) in the pilot phase, and a further 48 practices in 8 different NHS SSS areas, representative of the NHS SSS, across England, in the main trial. With an estimated response rate of 7% based on previous research, we aim to recruit 2520 participants in total across the intervention and control groups. This figure will be broken down to 504 participants in the pilot phase and 2016 in the main trial.

Practical implications

If the results of this trial find that participants in the intervention group were more likely to attend NHS SSS it is possible that these methods could be introduced as standard practice in GP surgeries across the country. As computer generated letters containing personal tailored risk information are relatively inexpensive, this is a potentially cost effective method of increasing uptake of the NHS SSS. Even a modest success rate in this aim could make a valuable contribution to public health by lowering smoking prevalence.

Research Methodology

Regulatory approvals and trial conduct

Start2quit has received ethical approval from the South West London REC 4 (reference number 10/H0806/20). This trial also adheres to the principles of Good Clinical Practice and in accordance with these principles, the rights, safety and well-being of trial participants are protected and the results of the trial will be credible and accurate. Confidentiality will be maintained at all times and participants will have the option of withdrawing from the study at any time.

Randomised controlled trials

The randomised controlled trial (RCT) is considered the most reliable method to determine whether or not an intervention is effective. The strength of this type of study lies in the equal chance of participants being randomly allocated to either the intervention group which receives the intervention being investigated, or the control group which does not receive the intervention. This methodology eliminates the chance of participants being assigned to a particular group based on any specific factor which could influence the outcome of the study. These participants are then followed up at a later date to assess whether there are any differences in outcome between the two groups.

A crucial element of the RCT is that those within each group are exposed to the same intervention. Only when this is the case can accurate comparisons be made between the control and intervention groups. As such, in this study, it is essential that the taster sessions are standardised and that all participants in the intervention group who attend different sessions have as similar an experience to each other as possible. In this way the researchers can ascertain whether or not these taster sessions are truly effective in increasing the uptake of NHS SSS, increasing quit attempts and reducing cigarette consumption. In addition, standardisation of taster sessions is important to ensure that any difference between those who attend the taster sessions can be attributable to each individual rather than differences in the presentation of the taster session that they attended.

Role of advisor and RCT standards

Taster session presentation

In this study there will be a number of different advisors facilitating taster sessions across England. Due to the nature of these taster sessions it is possible that there will be some degree of variation across sessions due to participant contribution, the style of the advisor etc. However, it is essential that advisors adhere to the taster session protocol. The same information should be communicated in the same manner at each taster session. This principle of standardisation ensures that all intervention group participants respond to the same research stimulus. This will make any assessment of the effectiveness of these sessions much more reliable.

As part of our efforts to ensure standardisation, we aim to audio record each of the taster sessions. This will be used only in the analysis of the results of the study and is not intended to be a method of evaluating advisors. Thus before the start of each taster session attendees will be asked to sign an audio recording consent form (Appendix 1).

Recording attendance

In addition, it is crucial that the advisor ensures every attendee signs the attendance sheet (Appendix 2) at the beginning of each taster session. Advisors will also be asked to gather details from any person who attends the session whose details are not on the attendance form. This is particularly important if an individual is attending with a friend/family member who has been invited to the taster session. Accurate gathering of this information is essential in allowing the researchers to keep track of the group (control or intervention) to which each attendee is allocated, at each taster session. For example, in the unlikely event of a member of the intervention group attending a taster session with a friend/neighbour/family member who is in the control group it is essential for the researchers to have a record of this. Without this level of accuracy and attention to detail, the results of the study could be compromised.

Encouraging sign up to NHS SSS

Finally, it is important that the advisor encourages as many taster session attendees as possible to sign up for a full NHS SSS course. In the event that an attendee does not want to sign up, it is important that they be given the contact details of the NHS SSS in their area in case they change their mind in the future.

At the end of each taster session the attendees are asked to fill out an evaluation form. These forms should be retained by the advisors as a record of attendee contact details in the event of it not being possible to organise an NHS SSS appointment immediately. All of these forms should be returned to the research team when the advisor has finished with them.

For statistical purposes we also require each advisor running taster sessions to complete a Stop Smoking Advisor Details form.

Taster Sessions: Protocol

The purpose of these taster sessions is to inform attendees about the NHS Stop Smoking Services and to encourage them to sign up for an NHS stop smoking course. It is not intended to replicate the first session of an NHS Stop Smoking course.

During this session you will:

- Inform the attendees about the NHS Stop Smoking Services in general.
- Discuss ways to remain smokefree including behavioural strategies and smoking cessation medication.
- Explain and conduct carbon monoxide (CO) monitoring.
- Provide practical information about the NHS Stop Smoking Services in your area.
- Show the Start2quit DVD.
- Distribute evaluation and consent forms, and collect when completed.

This session should aim to enhance motivation and boost self confidence of participants.

Advisors delivering this session should:

- Emphasise the benefits of the NHS Stop Smoking Services
- Build a rapport with participants
- Elicit client views
- Provide reassurance

Information outlined in boxes:	Point of interaction
<i>Italics:</i>	Information to be conveyed directly to attendees
Regular text:	Instructions for advisor

1. Introduction

Upon arrival attendees should be welcomed and asked to sign the attendance sheet (Appendix 2). A note should be made of anyone in attendance who is not recorded on the attendance sheet (include name, age and address).

Ask attendees to sign the audio recording consent form (Appendix 1). Emphasise the fact that the session will be audio recorded only to ensure that all taster sessions are delivered in as similar a manner as possible by each Stop Smoking advisor. All audio recordings will be anonymous, stored securely on a UCL computer for 5 years and only accessed by the Start2quit research team. The tapes will be analysed to ensure that the taster sessions are standardised.

If any of the attendees decline to consent, do not record the session.

Ask attendees to switch their phones off.

Congratulate attendees on coming to the session (for two reasons):

a) *“Quitting smoking is the most important thing you can do for your health, in both the short and long term.”*

- Short term benefits: Breathing improves, more energy
- Long term benefits: Reduction in risk of developing lung disease, emphysema, cancer.
- General:
 - No longer put others at risk from second hand smoke
 - Reduction in health anxiety which many people experience when smoking
 - More money to spend on other things
 - Clothes and home won't smell of cigarettes.

b) *“The fact that you have come here this evening suggests that you are motivated to stop smoking, and this is a very important step in the process of quitting.”*

Advisor introduces him/herself and describes his/her background/expertise.

2. The Services

General:

“The NHS Stop Smoking Services are based on well researched evidence and attending an NHS SS course has been proven to be the best way to help people to quit smoking.”

“People who take advantage of these free services and sign up to a course are four times more likely to stop and stay stopped than if those who try to quit on their own.”

Explain that the NHS SSS support smokers to stop smoking completely and not to cut down.

- Evidence also indicates complete abstinence is more likely to result in remaining quit in the long-term.

Structure:

“Courses last for (insert number of sessions). These courses may be run by a Specialist Stop Smoking Advisor or by a fully trained Practice Nurse.”

“The first session is spent helping you to prepare for stopping smoking which is very important. We will discuss with you the reasons why you want to stop smoking and also the reasons why you don’t want to quit smoking”

“How many of you enjoy smoking?”

Encourage attendees to share their opinions.

“A lot of people like smoking so to quit they have to give up something that they enjoy. This is difficult however in the first session you will be helped to weigh up the pros and cons of stopping smoking which is the best way to make a strong decision to quit.”

“One thing we won’t do is tell you to stop smoking. The important thing is that we help you to decide that giving up smoking is something that you want to do.”

“We will also encourage you to set a quit date during your first few sessions. This is a really good idea as it gives you something to aim for, something to prepare for.”

“There will be a minimum of weekly sessions for at least 4 weeks following the Quit Date.”

“The remaining sessions are used to support you as you get used to your new life as a healthy non-smoker.”

Emphasise that weekly contact is extremely important.

Explain that stopping smoking with the NHS SSS involves a rule of not smoking a single puff after their Quit Date because cutting down gradually is not an effective approach to quitting smoking.

“However it is important to mention that we understand if you slip up and have a cigarette after you’ve quit. Don’t think that you can’t come back to the services. You can come back and we will help you work out why you had the cigarette and work out strategies for avoiding further slips in the future.”

Identify reasons for wanting and not wanting to stop smoking.

“Would any of you like to give a summary of why you are considering giving up smoking?”

Encourage attendees to take part in this discussion.

3. Ways to remain smokefree:

Strategies:

“A key aspect of an NHS Stop Smoking course is helping you to develop strategies to avoid smoking.”

“Smoking is a very habitual addiction and throughout the day there are many trigger points that remind people that they want to smoke. These trigger points are different for every smoker, they can range from having a cup of coffee, waiting at a bus stop to getting up in the morning.”

“It is very important that you develop strategies to break the association between these trigger points and smoking and we can help you achieve this.”

Stop Smoking Medication:

“Another important part of quitting smoking is the use of medication.”

*“When you have a cigarette you are taking in nicotine which makes you feel good. If you are deprived of this nicotine you **may** experience withdrawal symptoms.”*

“Can anyone tell me some common withdrawal symptoms?”

Encourage attendees to take part.

If no withdrawal symptoms are suggested by the group, the advisor should mention some common symptoms.

“These symptoms can include anxiety, feeling stressed or angry, lower concentration and increased appetite or weight gain. However it is important to know that not everyone will experience these withdrawal symptoms.”

“The good news is that there is medication available which can reduce cravings while a person gets used to not smoking.”

“Nicotine replacement therapy is one such type of medication. NRT is available in various forms and it works by replacing the nicotine you get in cigarettes with nicotine in a clean controlled form. It is important to remember that nicotine is not the harmful part of cigarettes, it’s just the part that causes the addiction.”

“There are various types of NRT available including; lozenges, patches, gum and inhalators. There is one to suit everyone which is important because if you find the one that suits you, you will be more inclined to use it regularly. You can find out more about NRT at an NHS Stop Smoking Service course.”

“Advisors can help you decide which form of NRT would be most appropriate for you.”

“Other medications are also available including Zyban which has been on the market for about ten years, and Champix which is a newer medication. These treatments can help reduce the desire to smoke. You can also get more information and advice on using these medications by attending an NHS Stop Smoking Service course.”

Ensure that client has a realistic expectation of what medication use can add to a quit attempt.

Behavioural support:

“An important function of the NHS SSS is to give support to help you to change your behaviour.”

Emphasise that medication is not a miracle cure, and that smokers will also need to change their behaviour. Stop Smoking advisors will provide support during this process of change. That is the reason why weekly contact is extremely important for the full duration of the course, including the final visit.

4. Practical information

Give information regarding the NHS Stop Smoking Sessions in your area.

- *“Each group session lasts approximately (insert length of sessions) and can have up to (insert approximate maximum number of attendees) attendees”*
- *“Each one-to-one session lasts approximately (insert length of session)”*
- *“Both types of courses last for (insert number of sessions)”*
- *“In this area, sessions are offered in (insert locations of sessions)”*
- *“We can discuss the times and dates of these sessions in further detail with you at the end of this talk and we will also give you the opportunity to sign up for a course.”*

5. Carbon monoxide monitoring

Explain that carbon monoxide (CO) is a poisonous gas contained in cigarette smoke and that there is a simple test that can be carried out to determine CO levels in the body.

“One thing that we often do during the NHS Stop Smoking Service courses, and that we can show you now, is measuring the level of CO in people’s expired air.”

“CO is a toxic gas you inhale when you smoke. It is particularly dangerous because it takes the place of oxygen in your red blood cells so as a smoker you don’t get the oxygen supply that you need. Your blood then tries to compensate for the presence of CO by producing more red blood cells so your blood literally becomes thicker and this can impair your circulation. A lot of smokers have cold finger tips because blood can’t get to their peripheries.”

“The good news is that as soon as you stop smoking the CO levels in your blood drop right down so immediately your circulation improves, and your chance of experiencing any health problems relating to this (such as a heart attack and stroke) are reduced.”

“Measuring CO is also a great way of showing the immediate benefits of quitting smoking and proving that you really are doing something very positive for your health.”

Encourage attendees to have their CO levels measured.

“We will now measure your CO levels. Who would like to go first?”

“You will be able to compare your measurement today to a measurement you can have at an NHS Stop Smoking Service course after you’ve quit.”

In the case that CO measurement is low: *“I realise that you haven’t smoked a cigarette for a day or two but if I measured your CO after smoking you would have a high reading”.*

6. DVD

At this point the DVD should be shown to attendees. This DVD includes stop smoking sessions in progress and testimonials from previous successful attendees at an NHS SSS session.

7. Questions

Answers to attendees' questions should be kept as succinct as possible. They should be reminded that further information will be available during the NHS SSS courses.

8. Summary

Provide a brief recap of the main points of the taster session:

"There are huge benefits to stopping smoking in both the long and short term".

"Attending a free NHS Stop Smoking Services course makes it four times more likely that you will successfully stop smoking."

"These courses will help you develop strategies to avoid smoking and will also provide you with information regarding the medication available to make quitting smoking easier."

Thank attendees for attending.

Remind attendees to complete the evaluation form and hand it to an advisor.

Emphasise that immediate sign up for an NHS Stop Smoking Service course is possible when they give their evaluation form to an advisor.

The evaluation forms should be retained by the advisor for organising NHS SSS sign up and following this, should be returned to the research team.

Six month follow up

Participants will be contacted by telephone six months after randomisation (by an independent telephone interviewer) to complete a follow up questionnaire. As part of this questionnaire, participants will be asked about their attendance at the SSS and their current smoking status. Both of these aspects of the questionnaire will need to be externally validated with the assistance of the SSS.

Postal kits to collect saliva samples to test for cotinine will be sent to all participants claiming abstinence at this follow up interview. Participants will be compensated for providing this sample with a £5 voucher.

Stop Smoking Service attendance

It is necessary to determine attendance of both control and intervention groups at the SSS in the six months following the date of randomisation. At the six month follow up the research team will supply the SSS with a list of all participants and their study ID numbers. The service records should then be searched for these names and relevant information recorded on each participant who has attended the SSS using the case report form. Once completed, these forms should be returned to the research team.

Appendix 1: Audio recording consent form



Consent form for attendees at Start2quit Stop Smoking taster sessions

You have already agreed to participate in the Start2quit trial. We are now asking for your permission to allow us to audio record this Stop Smoking Taster session as part of this research study.

Throughout the Start2quit study there will be a large number of Stop Smoking Taster sessions held across England. By audio recording these sessions we will make sure that they are delivered as similarly as possible by each Stop Smoking advisor. This will help make these sessions effective in encouraging more people to quit smoking. The audio recording of this Stop Smoking Taster session will be used only for this purpose. All recordings will be anonymous, stored securely on a UCL computer for 5 years and only accessed by the Start2quit research team. The recordings will be analysed to ensure that the taster sessions are standardised.

I confirm that the proposed purpose of the tape recording has been explained to me and that I fully understand the proposed use of this material. As such, I agree to this Stop Smoking Taster session being audio recorded for the purposes explained to me and detailed above.

Name (please print) _____

Signature _____

Date _____

Address _____

Appendix 2: Attendance Sheet

Attendance sheet

Advisor name: _____

PCT: _____

Place: _____

Date: _____

Time: _____

Taster Session

Name	Signature