INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Helping people cope with temptations to smoke to reduce relapse: Main Study

Barts and The London School of Medicine and Dentistry,
Queen Mary University of London

We invite you to take part in an international research study being run in the UK and Australia. The information which follows tells you about it so you understand what participation involves. Please feel free to ask any questions about the research before deciding whether to take part. Even if you are very confident about remaining quit, your participation is still extremely valuable, as finding out what works for you may help others.

The Study

Stop smoking services (SSS) like the one you have attended and the stoptober campaign are effective at helping people stop smoking in the short-term, but unfortunately relapse rates after one year can be as high as 70%. Effective strategies are therefore needed to help prevent relapse back to smoking.

This study will look at the effectiveness of a number of promising relapse prevention approaches. If you agree to participate, you will be randomly allocated, by a computer, to **one or more** of the following approaches:

1. Smoking replacement product – you will be offered a supply of one of a choice of products to use if/when you are tempted to smoke. The products include oral nicotine replacement therapies (NRT) and electronic cigarettes (EC).
2. Online support tool – you will have access to an online tool, which provides detailed and personalised advice with a particular focus on strategies to deal with temptations to smoke.
3. Support from a series of text messages sent to your phone for up to 5 months (you can stop them if you stop finding them useful)

If you agree to take part, we will also ask you to complete some questionnaires online, or over the telephone if you prefer. The table overleaf shows when the questionnaires will be completed.

During the study, you may also be invited to participate in up to two additional sub-studies to explore your experiences of quitting in more detail (please see separate information sheets for further details).

What will happen if you take part?

The table overleaf shows what is involved.

4 weeks after your quit day	After consenting to participate either online or over the phone, you will complete a questionnaire about your previous smoking, current quit attempt, mood, health, use of health services and quality of life. You will then be randomly allocated to **one or more** of the approaches described above and helped to get started. We will call you after a week to answer any questions you may have.
3 months after your quit day	We will ask you to complete a questionnaire about your smoking status, cravings to smoke, what you are doing to stay quit (or what happened if you have relapsed back to smoking), and feedback on the intervention you received. You will receive £10 for completing this questionnaire.
6 months after your quit day	We will ask you to complete a similar questionnaire to the one you completed at 3 months. Again you will receive £10 for completing it.
12 months after your quit day	We will ask you to complete a final questionnaire, similar to those you have completed before and you will receive £20 for completing it. You may also be asked to send us a saliva sample. If so, we will send you a saliva sample kit in the post and ask you to return the sample in a stamp addressed envelope. You will receive £20 for returning it.

Who can take part?

You will be able to take part if you:

- Have been quit for at least two weeks when we invite you into the study
- Have attended a UK stop smoking service for your current quit attempt
- Are aged 18 years and older
- Own a mobile phone
- Have Internet access
- Are able to read and understand English
- Willing to try a smoking replacement product or online behavioural support tool if allocated to use

You will **not** be able to take part if you:

- Are currently involved in any other stop smoking research
- Are already using oral NRT or an e-cigarette **AND** are planning on using it for longer than 3 months

What do I do now?

- If after reading this you decide to take part, you can log on to the study website by clicking on the link we email you
- Or you can wait until you receive a call from our research team and sign up over the phone

Risks/Side effects

We do not expect there to be any risk from using the online support tool or from receiving the text messages. We do not expect there to be any risks from using a smoking replacement product (e.g. EC or NRT). These products do not contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. The most common side effects that people report when using these products are mild mouth/throat irritation, nausea and sleep disturbance.

Data Protection

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep identifiable information about you for 20 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at http://www.jrmo.org.uk/.

Queen Mary University will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Barts Health NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. Queen Mary University will pass these details to Barts Health NHS Trust along with the information collected from you. The only people in Barts Health NHS Trust who will have access to information that identifies you will be people who need to contact you for the purpose of the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

Any information you give us will be kept confidential. If you decide to take part you will be given a unique ID number so that the data you provide will be anonymised (it will not identify you in any way). Your contact details will be collected for the purposes of the study team contacting you only. Your contact details will not be shared with anyone outside of the study team. Your contact details will be kept separate from your study data, with the exception of your mobile number and email address which needs to be stored with your questionnaire responses in order to send the intervention text messages and reminders. The data will be collected on a secure website, which only the study team have access to. If you are asked to give a saliva sample, this will be anonymised with your unique ID number and it will only be used to test for tobacco exposure. The results of this study may be presented to other individuals working in the field of smoking cessation or may be printed in journals. However, all data will be anonymised and there will be no information included which could identify you.

Your Rights

Your participation in this study is entirely voluntary; you do not have to take part and this will not affect your ordinary medical care. If you decide to take part you are free to drop out of the study at any time. Your records will be kept strictly confidential.

What happens if you are concerned or have any questions?

Please contact Anna Phillips, Research Manager on 0207 882 8230 if you are worried about anything or have any questions. The Chief Investigator of this study is Professor Peter Hajek, Health and Lifestyle Research Unit, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, 2 Stayner's Road, London, E1 4AH, Tel: 020 7882 8230.

A summary of the results of this study will be available upon request.

We believe that this study is safe and do not expect you to suffer any harm or injury because of your participation in it. However, Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

If you wish to raise a complaint or would like to seek independent advice outside the study team, you can call the local patient advice and liaison service (PALS) on 0203 594 2040/2050 or you can email them at pals@bartshealth.nhs.uk.

This study has been reviewed by the NRES Committee South East Coast.

This study is funded by the National Institute for Health Research Health Technology Assessment Programme (NIHR HTA Project 13/155/05).

NHS
National Institute for Health Research

We would like to thank you for your interest in this study.