

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

Trial of Electronic Cigarettes (TEC)

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

We would like to invite you to take part in a research study. The information which follows tells you about it. It is important that you understand what is in this leaflet. Please ask any questions you want to about the research and we will try our best to answer them.

The Study

Current treatments for smokers do not typically address the behaviours and sensations associated with the act of smoking (e.g. handling a cigarette, inhaling, taste and feel of smoke on the throat).

Electronic cigarettes (EC) are battery-operated devices that attempt to mimic the act of smoking and thus provide these effects. We already know that EC can alleviate urges to smoke, but do not know if they are as effective in helping smokers quit as the existing stop-smoking medicines (e.g. nicotine replacement treatment, NRT).

Half of the people in the study will receive an EC to use, whilst the other half will receive NRT via the stop smoking services' usual practice. A computer will decide at random which group you will be allocated to.

Regardless of which group you are in you will receive treatment from specialist stop smoking advisors and psychologists. Smokers who use this treatment are some four-five times more likely to quit compared with no support.

Study sessions begin one week prior to your agreed quit date and continue for four weeks thereafter.

What will happen if you take part?

You will be asked to attend one of our clinics in London, Leicestershire or East Sussex weekly for 6 weeks. On the next page are details of the treatment.

Baseline session	<p>We will describe the study and go through this information sheet. You will then have the opportunity to ask any questions. We will ask you to sign a consent form to show that you have agreed to take part. Information about your smoking, mood, health and lifestyle will be collected. We will also measure the amount of carbon monoxide (CO) in your breath (this shows how much smoke you inhale).</p> <p>We will discuss how best to stop smoking.</p>
Target Quit Date (TQD)	<p>You will receive either an EC starter kit with a 2 week supply of refills, or NRT via the stop smoking services' usual practice and we will explain how to use the product you have been given. We will collect some information about your mood and smoking over the previous week and measure the amount of CO in your breath.</p> <p>You will be asked to stop smoking after this session.</p>
1, 2, 3 and 4 weeks after TQD	<p>We will discuss your progress, record your EC/NRT use and provide advice and guidance. We will also record whether you smoked or not, whether you found the EC/NRT helpful, ask some questions about your health and measure the amount of CO in your breath. If you were allocated to receive NRT you will be given more as needed, via the stop smoking services' usual practice. If you were allocated to the EC you will purchase any additional refills yourself.</p> <p>At 1 and 4 weeks after your TQD we will also ask you to answer some questions about your mood and your experience with EC/NRT.</p>
6 months after TQD	<p>We will telephone you and complete a short questionnaire about your smoking, health, lifestyle and EC/NRT use.</p>
12 months after TQD	<p>We will telephone you and complete a short questionnaire about your smoking, health, lifestyle and EC/NRT use. If you report that you are not smoking, or have reduced your smoking by 50% or more, we will ask you to provide a CO reading. You will receive £20 travel expenses for attending this extra session.</p>

Who can take part?

You will be able to take part if you are:

- Aged 18 years or over

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

- Are pregnant or breast feeding
- Are unable to read/write/understand English
- Have a strong preference to use or not to use NRT or EC in your quit attempt
- Are currently involved in another treatment based research project
- Are currently using EC or NRT

Risks/Side effects

We do not expect there to be any risks from using EC. EC do not contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. As a result they pose no increased risk compared to your normal cigarettes. The most common side effects that people report experiencing when using EC are mouth/throat irritation, nausea and sleep disturbance. EC are not currently licensed as a medicine, but they are currently regulated as a consumer product.

Data Protection

If you agree to take part any information you give us will be kept confidential, and only study staff at your local site, and the main site (Queen Mary, University of London) will have access to this data. We will inform your GP, with your consent, that you are taking part in this study. Should you choose to withdraw from the study and do not wish for us to contact you for any follow up data, you can let us know and we will only use data collected up until the point of your withdrawal (unless you would like us not to). 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. After the study is completed the university will store all data collected from this study for 20 years, as per standard practice.

Your Rights

Your participation in this study is entirely voluntary, and you are free to drop out of the study at any time. Your records will be kept strictly confidential and your ordinary medical care will not be put at risk if you decide not to take part or drop out.

What happens if you are concerned or have any questions?

You will be able to contact Katie Myers Smith (0207 882 8230) if you are worried about anything or have any questions. The Chief Investigator of this study is Professor Peter Hajek, Tobacco Dependence Research Unit, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, 2 Stayner's Road, London, E1 2AH, 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 London - Camden and Islington REC.

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