

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

How does dual use of e-cigarettes and conventional cigarettes change over time?

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

Thank you for your interest in this study. The information which follows tells you about it. It is important that you understand what is in this leaflet before you consent to take part. There is information at the end of the leaflet on how to contact us if you have any questions or concerns. Your participation is completely voluntary and will not affect any access to treatment or services that you may be currently receiving.

The Study

This study is being run by the Health and Lifestyle Research Unit at Queen Mary University of London, and is funded by Cancer Research UK (CRUK).

Many people who smoke conventional cigarettes also use an e-cigarette and this is called 'dual use'. Little is known about the way such use develops over time. Most dual users aim to stop smoking altogether, but many people continue using both products. It is not clear at present how many of these dual users stop smoking, at which time point, and what factors help them to stop.

We are inviting up to 500 dual users to take part in a study which aims to gain a greater understanding of these issues. If you take part, we will ask you questions about your vaping and smoking over the telephone or internet at 3 monthly intervals, over a 12-month period. The surveys should take approximately 10 minutes each to complete. You will receive a £15 voucher as compensation for your time. The study is funded for 1 year initially, but if we obtain further funding, we will extend the follow-up period to 10 years.

We hope that the results of this trial will inform what advice doctors and other health professionals give on e-cigarettes in the future.

Who can take part?

You will be able to take part if you are:

- Aged 18 years or over
- Currently using both an e-cigarette and conventional cigarettes either on the same or separate days for at least one day a week, and practiced such use for at least one month

- Willing to provide data on your vaping and smoking at baseline, 3, 6, 9 and 12 months
- Are not currently taking part in another conflicting study

What will happen if you take part?

Baseline phone call/ email	<p>If you are interested in taking part in this study, we will check that you are eligible and email you a web-link to provide your consent to take part and to complete the initial questionnaire online.</p> <p>If you do not have internet access, we will ask you the eligibility questions over the phone and will post a consent form to you, along with a paper version of the baseline questionnaire. You would then be asked to return these completed documents back to us using a self-addressed envelope provided.</p> <p>You will receive a £5 voucher for completing the first questionnaire.</p>
3, 6, 9 and 12 month follow up	<p>We will send you another questionnaire to complete by email or post. You will receive a £5 voucher for completing the questionnaires at 6 and 12 months.</p>

Risks/Side effects

Taking part in the follow-up study presents no risks. In terms of the benefits, your participation in the study will generate new knowledge that may help smokers stop smoking in future.

Data Protection

If you agree to take part, any information you give us will be kept confidential, and only study staff will have access to this data. Should you choose to withdraw from the study 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 will be published but there will be no information included which could identify you. A copy of the study results will be available upon request. After the study is completed, the university will store the data securely, 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 Sarrah Peerbux (0207 882 8230 or email health-research@qmul.ac.uk) if you are worried about anything or have any questions. If this is unsuccessful, or not appropriate, please contact the Secretary at the Queen Mary Ethics of Research Committee, Room W117, Queen's Building, Mile End Campus, Mile End Road, London or research-ethics@qmul.ac.uk. 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.

This study presents no risk of harm or injury but 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.

This study has been reviewed and approved by the Queen Mary University of London's Ethics of Research Committee (QMREC2017/41)

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