

## INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

# Cohort follow-up study of dual users of e-cigarettes and conventional cigarettes (DUO)

**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. We will go through this information sheet with you and you are free to discuss the study with others (e.g. GP/family). There is information at the end of the leaflet on how to contact us if you have any questions or concerns.

### **The Study**

**The study is being run by the Health and Lifestyle Research Unit at Queen Mary University of London, and is funded by Pfizer Ltd.**

For clarification on the details contained in this information sheet, please contact Sarrah Peerbux, Research Health Psychologist, managing the study, by phone (0207 882 8230) or e-mail ([health-research@qmul.ac.uk](mailto:health-research@qmul.ac.uk)). The Principal Investigator of this study is Professor Peter Hajek ([p.hajek@qmul.ac.uk](mailto:p.hajek@qmul.ac.uk)).

Many smokers who start to use e-cigarettes (EC) continue using conventional cigarettes (CC) as well. Little is known about the way such use develops over time, and how much nicotine such 'dual users' obtain from smoking and from vaping. Most dual users aim to stop smoking altogether, but it is also not clear how many succeed and what proportion is interested in receiving extra support to do so.

We are inviting some 200 dual users who aim to stop smoking altogether to take part in the study which aims to clarify these issues. If you take part, we shall follow you up for 12 months to monitor any changes in your smoking and vaping. Study participants who want help with stopping smoking will have access to standard stop-smoking treatment combining telephone support over 12 weeks together with stop smoking tablets (Champix). We will collect saliva samples at baseline and at 3, 6 and 12 months to assess changes in your intake of nicotine from these two sources. This is done by detecting two chemicals in the saliva, one showing the total nicotine intake (from both vaping and smoking) and the other showing intake of cigarette smoke.

We hope that the results of this trial will inform NHS stop smoking treatment and advice on e-cigarettes that doctors will provide in future.

### What will happen if you take part?

You will be asked to provide information about your smoking and vaping and to send us saliva samples at baseline and again at 3, 6 and 12 month follow-ups. If you decide to opt for stop-smoking treatment, you will also receive stop-smoking medication and weekly telephone support from our expert advisor. Here are the details of each contact.

Baseline phone call/ email	This provided information about the study, and collected data about your smoking and vaping and your contact details. If you were eligible for the study and interested to take part, we have sent you this study information, a consent form, a questionnaire to complete and a saliva sampling kit with instructions. You will receive £20 for this saliva sample.
Phone call after you receive the study materials	We shall check that you received the materials above and that you still agree to take part in the study. You will have an opportunity to ask about any study details. We will also guide you through the saliva sampling procedure if needed. You will send the sample back to us together with your forms in a self-addressed envelope provided. The phone call will take some 15 minutes.
Those who opted for treatment	<p>If you opted for treatment to help you stop smoking altogether, our Clinic doctor will check your questionnaire and if you are eligible for the stop smoking medication Champix, you will be posted a supply with a note asking you not to start taking your medication until you have received a call from a specialist stop-smoking advisor.</p> <p>You will receive up to 6 weekly phone calls followed by up to 3 calls every 2 weeks. At these calls, your advisor will be guiding you through the quitting process, checking your progress, monitoring your medication and sending you further supplies as needed, and providing suggestions and advice to help you cope with temptations to smoke and to avoid relapse. The phone calls will take some 10 minutes each.</p>
3 month phone call	We will send you another saliva sampling kit and will call you a few days later. At this call we will check you received the kit and will ask you about your smoking and vaping. The phone call will take some 15 minutes. You will receive £10 for this saliva sample.
6 month phone call	We will send you another saliva sampling kit and will call you a few days later. At this call we will check you received the kit and will ask you about your smoking and vaping. The phone call will take some 15 minutes. You will receive £10 for this saliva sample.
12 month phone call	We will send you the final saliva sampling kit and will call you a few days later. At this call we will check you received the kit and will ask you about your smoking and vaping. The phone call will take some 15 minutes. You will receive £20 for this saliva sample.

## **Who can take part?**

You will be able to take part if you:

- Are aged 18 years old or over
- Are currently using both EC and CC
- Smoked at least 10 cigarettes a day for more than a year before you started using your EC; and used EC for at least one month
- Want to quit smoking altogether
- Are willing to provide saliva samples and complete follow-up calls at 3, 6 and 12 months.

You will not be able to take part if you are unable/unwilling to provide saliva samples or are unlikely to be available for the 3, 6 and 12 month follow-ups.

Please note, if you are pregnant you will not be eligible to receive varenicline.

## **Risks/Side Effects**

Taking part in the cohort follow-up study presents no risks.

Participants who opt for treatment will be offered standard stop-smoking support and medication. The medication, varenicline (Champix) can have some side effects; the most common of these is nausea. If you opt for treatment, the study doctor would check your medical history before prescribing the medicine and your advisor will discuss the treatment with you in details and will monitor your reactions and progress throughout the treatment period.

## **What will happen to your saliva samples?**

The samples will be kept frozen at the university until the end of the study. They will then be sent to a laboratory (ABS Laboratories Ltd Biopark, Broadwater Road, Welwyn Garden City, Herts, UK) to be analysed for levels of cotinine (a metabolite of nicotine) and anabasine (a chemical you only receive from smoking). Your samples will be anonymised to laboratory staff before they are sent there. This will enable us to determine any changes in the amount of nicotine you are receiving from cigarettes and from e-cigarettes. Samples will then be destroyed in accordance with the Human Tissue Act.

## **Data Protection**

If you agree to take part, any information you provide will be kept confidential, and only study staff will have access to this data. If you opt for treatment, we will inform your GP, with your consent, that you are receiving stop-smoking medication.

Should you choose to withdraw from the study, only your data up to the point of your withdrawal will be analysed. After the study is completed the university will store all data collected from this study as per standard practice

## **How will the results of the study be published?**

The results of this study may be presented at scientific conferences and will be published in a scientific journal. All data will be anonymised and there will be no information included which could identify you.

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

## **Your Rights**

Your participation in this study is entirely voluntary, and you are free to drop out of the study at any time.

## **What if something goes wrong?**

You will be able to contact Sarrah Peerbux, Research Health Psychologist, managing the study, by phone (0207 882 8230) or e-mail ([health-research@qmul.ac.uk](mailto:health-research@qmul.ac.uk)). The Principal Investigator of this study is Professor Peter Hajek, Health and Lifestyles Research Unit, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, 2 Stayner's Road, London, E1 4AH, Tel: 0207 882 8230.

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 contact INVOLVE on 023 8065 1088 or via email on [admin@invo.org.uk](mailto:admin@invo.org.uk) or the Patient Advice and Liaison Service (PALS) on 0203 594 2040/2050 or you can email them at [pals@bartshealth.nhs.uk](mailto:pals@bartshealth.nhs.uk).

**Thank you for your interest in this study.**