## INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

# Do e-cigarettes help smokers quit when not accompanied by intensive behavioural support?

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

(REC ref: 20/SW/0179; IRAS ID: 284500)

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**

Research has shown that using an e-cigarette (EC) helps smokers quit. The study showing this gave participants an e-cigarette to use and saw them for weekly appointments. This study is looking at whether face-to-face support is important or whether the advice can be provided on the phone and via support messages (e.g. email).

In this study we want to test three different ways of helping people quit: 1. 28 days of support messages (e.g. emails) via NHS SmokeFree programme with no EC, 2. EC without weekly telephone support, or 3. EC plus weekly telephone support for 5 weeks. We do not know if there will be any difference in success between these groups, this is what the study has been designed to find out. If you decide to take part in the study, a computer will decide at random (by chance) which of these treatments you receive.

**What will happen if you take part?**

The diagram shows what will happen if you join the study.

**Phone call**

A researcher will contact you to describe the study and answer any questions. Your consent to take part and information about your smoking and health will be collected either by completing an online questionnaire, or by telephone if you prefer.

You will set a quit date with the researcher. You will then be allocated to one of the three treatment groups: 1. support messages, 2. EC, 3. EC with telephone support. This is decided at random by a computer.

**Support messages**

- You will receive messages daily for 28 days from the NHS Smokefree programme, with advice on coping with cravings, using stop smoking products, and motivational messages.

**EC**

- You will receive an EC starter pack in the post with instructions on how to use it. We will also go over these instructions over the telephone.

**EC with phone support**

- You will receive an EC starter pack in the post with instructions on how to use it
- We will phone you once a week for the next 4 weeks (5 calls in total) to provide support and advice on quitting smoking and using the EC.

**Online survey/phone call – 4 weeks after your quit date (everyone)**

You will be contacted to ask questions about your allocated treatment, how you have been getting on with quitting, use of your treatment and your health.

**Online survey/phone call – 6 months after your quit date (everyone)**

You will be contacted to ask questions about your allocated treatment, how you have been getting on with quitting, use of your treatment and your health. If you have stopped smoking we will also ask you to attend an appointment to give a carbon monoxide reading. If you attend for this, you will be given £20 for your time.

**Online survey/phone call – 12 months after your quit date (everyone)**

You will be contacted to ask questions about your allocated treatment, how you have been getting on with quitting, use of your treatment and your health. If you have stopped smoking we will also ask you to attend an appointment to give a carbon monoxide reading. If you attend for this, you will be given £20 for your time.

**Who can take part?**

You will be able to take part if you:

- Are aged 18 years or over
- Are a daily smoker wanting to quit
- Have a mobile phone
- Have an email address
- Are willing to try either support messages (e.g. emails), or EC with or without telephone support
- Are willing to receive follow-up phone calls
- Are able to read/write/understand English

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

- Are pregnant
- Are currently using EC (at least weekly)

**Benefits and Risks**

We do not expect there to be any risks from using EC over the time of the study. EC do not contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. The vapour from EC contains propylene glycol which is approved for use in medications (e.g. in asthma inhalers) and vegetable glycerol, which has no known adverse effects. Use of EC for many years may over time affect the user's lungs, but these are expected to be less than 5% of risks of smoking. The most common side effects that people report experiencing when using EC are mouth/throat irritation. EC are not currently licensed as a medicine, but they are currently regulated as a consumer product.

The benefit of taking part in the study is that you will receive free stop-smoking treatment.

**What if new information becomes available?**

In the event of new information becoming available, you will be informed of this and will have the opportunity to withdraw from the study.

**GDPR and Data Protection Act 2018**

Queen Mary University of London is the sponsor for this study based in the United Kingdom.

**How will we use information about you?**

We will need to use information from you and from your medical records for this research project.

This information will include your:

- Initials
- NHS number
- Name
- Contact details
- Date of birth

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep this information about you for 25 years after the study has finished.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you may have the option to take part in future research using your data saved from this study. We will contact you about this future research if suitable.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- http://www.jrmo.org.uk/
- by asking one of the research team
- by sending an email to vapeline@qmul.ac.uk, or
- by ringing us on 0207 882 8230

**How have patients and the public been involved in this study?**

We discussed this project with our panel of smokers and they influenced our decision to do this study. We plan to continue to involve patients and the public in the study by including 2 independent members (not part of the study team) in our Trial Steering Committee.

NHS
National Institute for Health Research

**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 Anna Phillips-Waller on 0207 882 8230 or via vapeline@qmul.ac.uk if you are worried about anything or have any questions. The Chief Investigator of this study is Dr Katie Smith, Health and Lifestyle Research Unit, 2 Stayner's Road, London, E1 4AH.

A summary of the results of this study will be sent to you.

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 RLHpals.bartshealth@nhs.net.

This study has been reviewed by the NRES Committee South West – Central Bristol Research Ethics Committee (20/SW/0179).

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