**E**ffectiveness of **E**lectronic **C**igarettes compared with combination nicotine replacement therapy for smoking cessation in patients with chronic obstructive pulmonary disease **A**nd effect on **L**ung health (ECAL trial)

# QUALITATIVE STUDY - PARTICIPANT INFORMATION SHEET

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You are invited to take part in a study exploring your experience of quitting smoking using e-cigarettes during the ECAL trial. This information sheet explains the purpose of the study and what participation involves, so you can decide whether to take part and ask any questions you may have.

**Why have I been invited?**
You have been invited because you previously took part in the ECAL trial and were allocated to the e-cigarette group. We would like to hear from you regardless of whether you were able to quit smoking or whether you used an e-cigarette.

**What will I be asked to do if I agree to participate in the study?**

You will be invited to take part in a research interview with a member of the study team, which will be audio recorded. Before the interview, we will obtain your consent. You can provide consent by completing and returning the consent form or verbally at the start of the interview. If you have already given written or electronic consent, you will be asked again at the beginning of the recording to confirm that you are happy to take part.

The interview will last around 45–60 minutes and can take place by phone or online at a time convenient for you. At the start, we will ask a few general questions (such as whether you currently smoke or vape) to help us understand the findings; this information will not identify you. The interview will be recorded securely, and all information will be handled in line with Data Protection Regulations.

**What will happen during the research interview?**
The researcher will ask about your experience of the trial, including how helpful e-cigarettes and support were in helping you quit, and any effects on your physical and mental health. You will also be asked about any unexpected effects. You can choose not to answer any questions.

**What are the benefits of taking part in this study?**
This study aims to understand what worked well in the ECAL trial and how quitting smoking support can be improved. It explores your views on your quit attempt, the support received, the usefulness of the products, any challenges, and how easy they were to use. Your feedback will help improve future support for others trying to quit.

**What are the possible disadvantages and risk of taking part?**
There are no expected risks from taking part, other than giving some of your time. You can contact the research team at any point if you have questions or concerns. There are no right or wrong answers, and you are free to ask questions before deciding to take part.

**Will I be reimbursed for taking part?**

You won't be paid to take part in this study, but as a thank you for your time, you'll receive a £25 gift voucher after completing the interview.

**Do I have to take part?**
Taking part is your choice. If you decide to participate, you will give consent but can withdraw at any time up to two weeks after the interview without giving a reason, and this will not affect your care. If you withdraw, you can contact the ECAL team by email or phone.

**Will my details be kept confidential and what are my data rights under GDPR?**

We will only collect the information needed for this study, and your details will be kept secure and confidential by authorised members of the research team, with access limited to those who need it and government regulatory staff where required. With your consent, the interview will be audio recorded using an encrypted audio recorder or platforms such as Zoom or Teams. Recordings will be downloaded onto the University of Birmingham's secure servers and stored in a password protected folder. For interviews conducted via Zoom or Teams, the recordings will be transcribed by the research team. For interviews conducted by telephone, recordings may be transcribed by the research team or transcribed using a reputable transcription company. Any approved transcription company will be required to sign a confidentiality agreement with the University of Birmingham. Once transcription has been completed, the audio recordings will be securely deleted.

At the end of the study, anonymised transcripts may be stored in a public archive, meaning anyone can access them without special permission. For example, you can see a similar archive here: https://www.data-archive.ac.uk/

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to see what information is held about you and can contact the University of Birmingham to request this or learn more about how your data is used.

**When we share the results of this research in reports, publications, or workshops, we will only use anonymised quotes so no one can identify you.**
Your pseudo-anonymised data may also be used for teaching or shared with other researchers for future studies. If you would prefer your data to only be used for this study and nothing else, you can let us know on the consent form.

**Who is organising, insuring, funding and reviewing the study?**
The study is sponsored by the University of Birmingham, coordinated by the Birmingham Clinical Trials Unit, and funded by the NIHR Health Technology Assessment programme (Ref: NIHR129593). It has been independently reviewed and approved by the Newcastle North Tyneside 2 Research Ethics Committee to ensure it meets ethical standards and protects participants.

The University of Birmingham has in place Clinical Trials indemnity coverage for this study which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The University of Birmingham is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical trial and the normal NHS complaints mechanisms will still be available to you

**How will we use information about you?**
The University of Birmingham is responsible for this study and for keeping your information safe. This means they make sure your data is looked after and used properly. Your identifiable information will be stored safely for up to 25 years, after which it will be anonymised or destroyed.
Your data will be identified by a study number rather than your name, and only authorised staff will have access to your identifiable information.

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

You may withdraw from the study at any time. Any data collected up to that point will be retained, but you can choose not to be contacted further. You also have the right to ask us to remove, change, or delete your data. In some cases, we may not be able to do this if it would affect the research, but if that happens, we'll explain why. Only the minimum necessary personal data will be used to protect your privacy. You can find more about how your information is used at: https://www.birmingham.ac.uk/privacy/index.aspx.

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

We will need to use information from you for this research study.
This information will include:

- Your name;
- Personal information, and
- Contact details

This information will only be accessed by those involved in carrying out or monitoring the research. Your identity will be protected, with your data identified by a code number rather than your name wherever possible.

**International transfers**
Your data will not be shared outside the UK.

**What will happen to the results of the research study?**
The findings from this study will be analysed by the research team and published in peer-reviewed journals and presented at conferences/events/meetings, without any reference to any named/identifiable individual. The results will also be used to guide individuals with COPD to give up smoking.

If you would like to know the results of the research, we are happy to provide you with a summary. Please let the research team know when you consent to the study that you would like to be informed.

**What if I have a concern or wish to complain?**

If you have any concerns about any aspect of this study, please speak to a member of the research team who will do their best to answer your questions and address your concerns. You can do this by contacting the ECAL team by sending an email to ecal@trials.bham.ac.uk or calling **0121 414 3105.**

**Contact for further information**
Please visit our website at www.bham.ac.uk/ecal. If you have any questions, or would like any further information, please contact the ECAL team by sending an email to z.swithenbank@bham.ac.uk or calling **0121 414 3105.**

If you have any queries about the processing of your personal data, please contact dataprotection@contacts.bham.ac.uk for the attention of the Data Protection Officer.

**Thank you for taking the time to read this information leaflet and for considering taking part in this study.**

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