# Participant Information Sheet

**UCL Research Ethics Committee Approval ID Number: 1248**

**Researchers: Prof Lion Shahab** (lion.shahab@ucl.ac.uk)

**Dr Dimitra Kale** (dimitra.kale.09@ucl.ac.uk)

**Project title: Effectiveness of digital recommendations on medication use and smoking cessation in adults using a smoking cessation app: a randomised controlled trial.**

**Department:** Behavioural Science and Health, University College London

You are being invited to take part in a staff led research project. Before you decide to take part, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is unclear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading.

## What is the purpose of this project?

This study looks at how digital tools can help people stop smoking by recommending specific stop smoking medication. Smoking is still the top cause of preventable illness and early death in the UK. Even though support programmes and stop smoking medication can help people quit smoking, many smokers do not use them. This makes it harder for them to quit for good. More people are now using digital health tools, like phone apps, to get help with quitting. This study will test how well these digital tools work in real life. People in the study will get a digital suggestion to use specific stop smoking medication. The goal is to see if these tools help more people use stop smoking medication and quit smoking. As more people use digital health tools, this study could help guide future plans to lower smoking rates.

## Why have I been chosen?

You are **eligible** to take part in this study if:

- You are between 18 and 65 years old.
- You are able to consent.
- You are English speaking and live in UK.
- You are current cigarette smoker.
- You are willing to be followed up by email and complete online questionnaires after two and seven months of completing the first study questionnaire.
- You are interested in making a quit attempt within the next month.
- You have downloaded and signed up to the Smoke Free app within the past week.

You are **not eligible** to take part in this study if:

- You are currently enrolled in another smoking cessation programme/study.
- You currently use any smoking cessation medication (including e-cigarettes)
- You have used varenicline and/or cytisine in the past 12 months.
- You are pregnant/breastfeeding/planning to get pregnant.
- You have a moderate/severe kidney impairment.
- You take treatment for active/latent tuberculosis.
- You have experience of a heart attack, stroke or severe angina within the previous 2 weeks,
- You have uncontrolled high blood pressure (> 150 mmHg systolic, > 100 mmHg diastolic),
- You have a history of seizures.

**Do I have to take part?**

Participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, you will be emailed this information sheet and be asked to sign a consent form. Refusal to participate involves no penalty. You can withdraw from this study at any time, without giving a reason and without penalty or loss of benefits to which you are otherwise entitled. If you withdraw, you will not receive any more communications about this project. If you would like to withdraw your consent for the storage and analysis of any information you have provided, you can do so by contacting the Principal Investigator. You can do this at any time point up to 4 weeks after completing each survey. After that, you will not be able to trace back your information nor will it be possible to connect the information provided with your identity.

**What will happen to me if I take part?**

If you meet the eligibility criteria and do not meet any of the exclusion criteria (as checked through a secure online survey), you will be asked to give information about your age, gender, ethnicity, education, financial status and smoking habits. Collecting these characteristics is essential to ensure that the study findings are meaningful across different populations; as such, all participants are required to provide this information to take part in the study. This questionnaire will take approximately 10 minutes to complete. You will then be automatically and randomly allocated to one of the three study groups. The first group will not receive a specific stop smoking medication recommendation. The second and third groups will get a recommendation for different stop smoking medications, which are safe to use and commonly prescribed. You will be advised to use a stop smoking app (Smoke Free app). You will be contacted (by email, phone call, or text message) to complete more online questionnaires at two and seven months later. These follow-up questionnaires will check your use of stop smoking medication and your smoking status and each of these will take around 5 minutes to complete. If you report that you have not smoked during that time in the 7-month follow-up questionnaire, we will ask you to measure your carbon monoxide (CO) levels in a video call with a researcher to verify smoking abstinence. This will take approximately 15 minutes. We will send you a CO monitor, which you can keep. To measure your CO levels, you need to blow into a machine that measures the amount of CO in your breath. To do this, you have to take a deep breath, hold it for 15 seconds and then blow into the machine. More information on how CO levels will be measured could be found here: https://www.icoquit.com/manual/en/

You will get a £10 gift voucher for completing the 2-month questionnaire, and an extra £5 gift voucher if you complete it within 24 hours. You will also get a £5 gift voucher for completing the 7-month questionnaire. If you report not smoking in the 7-month questionnaire and give a CO reading, you will get another £5 gift voucher and keep the CO monitor.

**What are the possible disadvantages and risks of taking part?**

In the first few weeks after quitting smoking, withdrawal symptoms such as cravings, low mood and difficulties concentrating are common and may be unpleasant. You will therefore have free access to an evidence-based stop smoking app (Smoke Free app), which contains an automated chatbot and the opportunity to chat to trained smoking cessation counsellors who are available 24/7.

**What are the possible benefits of taking part?**

Quitting smoking is the single most important thing that you can do to improve your health and quality of life. Your participation will help us gain a better understanding of the effectiveness of digital recommendations for stop smoking medication on smoking cessation medication use and their impact on increasing quit rates. These insights could inform future public health strategies aimed at reducing smoking prevalence.

If you would like to receive a report of the results of this study when they are available, you can request this by contacting the principal researcher.

**What if something goes wrong?**

If you wish to raise a complaint, you should discuss this with the Principal Investigator of the study (Prof Lion Shahab, lion.shahab@ucl.ac.uk). If you feel that your complaint has not been handled to your satisfaction, you should e-mail the Chair of the UCL Research Ethics Committee (ethics@ucl.ac.uk), who will take the complaint forward as necessary.

**Will my taking part in this project be kept confidential?**

To ensure confidentiality, we will not include your name or other identifying information in any reports or publications of this project. All data will be pseudonymised and personal data from the surveys (i.e., names, e-mails, mobile phone numbers) will be held securely until the end of the research project in UCL's Data Safe Haven (DSH) (approximately till the end of 2026).

**What will happen to the results of the research project?**

Results from this study will be published in academic, peer-reviewed journal articles and presented at scientific conferences.

**Who is organising and funding the research?**

This research is funded by Cancer Research UK.

**Contact for further information.**

If you would like to receive any further information about the study or have any questions, please contact Dr Dimitra Kale (dimitra.kale.09@ucl.ac.uk) or Prof Lion Shahab (lion.shahab@ucl.ac.uk).

**Data Protection Privacy Notice**

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data and can be contacted at data-protection@ucl.ac.uk . UCL's Data Protection Officer can also be contacted at data-protection@ucl.ac.uk.

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice.

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices. Your personal data will be processed for the purposes outlined in this notice.

The lawful basis for processing your personal data will be 'public task' and 'research purposes' for special category data. The only special category data that will be collected in this study is ethnicity. Your personal data will be processed only as long as they are required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this and will endeavour to minimise the processing of personal data wherever possible.

If you are concerned about how your personal data are being processed, please contact University College London's Data Protection Office in the first instance (data-protection@ucl.ac.uk).

***Thank you for reading this information sheet and for considering participating in this research study.***