Participant Information Sheet
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IRAS Project ID: 287771

Title of Study: **Testing an app to record smoking, vaping and use of nicotine replacement therapy (NRT)**

Short title: **iCO App Study**

Name of Chief Investigator: Professor Tim Coleman (University of Nottingham)
Local Researcher(s): Ms Miranda Clark, Dr Sue Cooper (University of Nottingham); Dr Joanne Emery, Professor Felix Naughton (University of East Anglia)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.

What is the purpose of the study?

- We want to improve the support that pregnant people receive to help them stop smoking.
- The growing use of electronic tools, such as smartphone apps, has created new opportunities to reach pregnant people with more convenient stop smoking support.
- As part of this, we have created a smartphone app *('myCOtrak)*. This lets people record how much they smoke or use e-cigarettes (vapes) or nicotine replacement therapy (NRT).
- We designed the *myCOtrak* app to work with a device called an *'iCO monitor'* for measuring how much carbon monoxide (CO) people breathe out; the amount of carbon monoxide on people's breath is a very strong marker of how much they smoke.
- In this study, we need pregnant or recently pregnant people who smoke to use the *myCOtrak* app with the iCO monitor for 28 days and, afterwards, to tell us what they think of this.
- The study will tell us how closely the *myCOtrak* app data on heaviness of smoking matches CO readings in breathed out air. This information will help us decide how best to use *myCOtrak* and *iCO monitors* in research or to help pregnant people stop smoking.

Why have I been invited?

We are inviting you to take part because you have told us in the screening questions that you are currently smoking at least one cigarette per day. We are inviting up to 20 people to take part who have smoked in pregnancy within the past 12 months. To join the study, you can be trying to quit or not, and using vapes and / or NRT or not.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

At least 24 hours after you see this PIS, a researcher from the University of Nottingham (UoN) or University of East Anglia (UEA) will contact you to check that you are eligible and willing to take part in this study, and to answer any questions you might have. If you are eligible and willing, they will ask you to sign an electronic consent form and then discuss convenient dates when you could test the app (a 28-day period is required for testing) and will send you a study package (*details below*).

Your contact details will be stored anonymously, in a secure electronic location, and destroyed at the end of the study unless your consent is given for these to be kept (see "**Will my taking part in the study be kept confidential?"** below).

Before the study starts

Before the study starts you will be asked to sign an electronic consent form and we will send you a copy of this to keep for your records. You will be sent the study package to your home address; the study package will contain:

- Hand-held device for measuring carbon monoxide in your breathed out air (*'Bedfont iCO monitor'*), for you to use in the study, and then keep
- Instructions for downloading the Bedfont *'iCOquit Mums to Be'* app, which is needed for operating the Bedfont iCO monitor so that it can take your daily breath reading
- Instructions for downloading the *myCOtrak* app, which is used to record your daily smoking and other nicotine use
- Personal identification number / login for the *myCOtrak* app
- Instructions / link to a video explaining how to send your daily breath reading to the *myCOtrak* app

A researcher will then contact you by email, text or telephone soon after to check that you have received the package and successfully downloaded (and logged into) the *iCOquit* and *myCOtrak* apps. You will then agree on a start and end date for app testing with the researcher.

Study start (Day 0)

At a date and time of your choice (by telephone or videocall), a researcher will contact you and will ask about smoking in the home and how many weeks pregnant you are. Then (s)he will guide you in using the *Bedfont iCO monitor* and app to measure carbon monoxide in your breathed out air, and also the *myCOtrak* app to record your daily smoking, vaping and / or NRT use. Once you can do both tasks, the researcher will help you to give your first study CO reading and information.

App testing (days 1-28)

Once daily for the next 28 days, on your own, we will ask you to take a breathed out air CO reading (using the *iCOquit* app and monitor), send your reading to the *myCOtrak* app, and also tell the *myCOtrak* app about your smoking, e-cigarette and NRT use (if any). Data collection should take you no more than a few minutes daily. Your daily CO reading and information is transferred to an online storage 'cloud' database when you press the 'submit' button on the *myCOtrak* app – no reports are stored on the *myCOtrak* app itself. You can contact the researcher if you are having any difficulties using the apps or iCO monitor.

We will ask you to answer your daily *myCOtrak* app questions around the same time as you provide your breathed out air CO reading. If you continue to smoke during the study, we will ask you to provide this CO reading within 1-2 hours of you smoking a cigarette. The *myCOtrak* app asks about

your previous 24 hours of nicotine use. You are asked whether you smoked (yes/no) and, if so, how many; whether you used an e-cigarette/vape (yes/no); whether you used any NRT products (yes/no).

We will give you details of available stop smoking support should you wish to use this - if you stop smoking during the study, you can carry on testing the app and providing CO readings.

Feedback to researcher, after Day 28

A researcher will contact you to arrange to collect your feedback soon after you finish testing the app (e.g. any problems, features you liked or disliked). You can choose to give your feedback by email or brief telephone/videocall interview with a researcher (maximum 30 minutes).

If you choose to give your feedback by telephone or videocall interview, this will be audio-recorded and/or video recorded but you will be able to ask the researcher to pause recording at any time and you are free to stop should you wish to do so. After giving your feedback, the researcher will check that you are happy for your comments to be included in study reports, but with your name removed so that you are not identifiable. Recordings will only be used to help write study reports and, once this has been done, these will be deleted. Upon request we can send you a written copy of your comments.

Expenses and payments

To thank you for taking part, we will offer you up to £30 in shopping vouchers. The amount you receive will depend on how many of the 28 daily reports you complete, and on providing feedback to the researcher.

What are the possible disadvantages and risks of taking part?

We do not foresee there being any risks from taking part in this study. However, we appreciate that taking part will use your time and may therefore be inconvenient.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information you provide to us during the study will be valuable in helping us improve support for pregnant people who want to stop smoking. If you are trying to stop smoking, it is possible that monitoring your daily smoking and carbon monoxide levels may be helpful to you, and you will have an *'iCO monitor'* to help you do this.

What happens when the research study stops?

If you are interested in reading the findings from this study, you can agree for us to keep your contact details after the end of the study when you complete the online consent form, so that we can share the overall results with you once these are available. If you don't want to read the study findings or be contacted about further research opportunities, then we will delete all your contact details at the end of the study. We will delete your home address once we have sent you your shopping vouchers.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the NHS Complaints Procedure. For advice on making a complaint, contact your local Patient Advice and Liaison Service (PALS) at your local hospital. PALS offers confidential advice, support and information on health-related matters and can provide patients with more information about the complaints procedure and the Independent Complaints Advocacy Service (ICAS).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored on a secure network with built-in encryption to keep all data safe. You will be given a unique participant study number, and this will be used to identify your research data. Any personal details (e.g. name) and any audio/video recordings will be stored securely and separately from your research data. Only members of the research team and University-approved transcribers will have access to recordings where you could be identified. Recordings will be put into writing by the research team or approved transcribers, and any potential identifiable information will be removed from the transcript. Recordings will be deleted after transcription. Any transcripts will be stored on a secure network separately from your personal details.

In order to log into the Bedfont '*iCOquit Mums to Be*' app you will need to enter your email address.

The app also asks for additional personal data including:

- your name
- age
- due date, and
- quit date

However, if you prefer, you can enter dummy (fake) data for these categories; only a working email address is absolutely necessary. Bedfont have provided assurance that no data is shared outside of the app and that all user information is deleted once the user deletes their account (this is easily done from inside the app), however the level of security of the Bedfont app, privacy policies and security settings are outside the University's remit, and we have no control over them. Sometimes these fall under international jurisdictions which have different applicable laws and the University has no control over them as well. You can read more about how Bedfont use you data here: https://www.icoquit.com/icoquit-app-privacy-policy/.

It is important to note that the data we collect will be processed in line with the University of Nottingham privacy statement, policies and UK Data Protection regulations. However, we cannot guarantee this for the Bedfont app itself.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact details will be destroyed at the end of the study unless you consent for these to be kept. If you consent, your contact details will be kept by the University of Nottingham for up to three years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies. This information will be kept separately from the research data collected and only those who need to will have access to it. All research data apart from audio/video recordings will be kept securely for seven years or longer if required. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way will be anonymised (so that you could not be identified).

What will happen if I don't want to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you want to withdraw from the study, you can do so at any time by texting or calling 079 667 48334, or by emailing joanne.emery@uea.ac.uk If you stop smoking during the study, you do not have to withdraw.

If you withdraw, we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained, such as your consent form, as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Involvement of the General Practitioner/Family doctor (GP)

There is no GP involvement in this study.

What will happen to the results of the research study?

The results of the study may be presented to other researchers, at conferences and through publication in scientific and medical journals. No names will be used in the results and individuals will not be identifiable in any written reports or presentations. It is also intended that the findings will be used to design a new electronic support package to help stop smoking in pregnancy.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is funded by the National Institute for Health Research School for Primary Care Research (NIHR-SPCR), Grant reference number:585.

Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London Bloomsbury Research Ethics Committee.

Further information and contact details

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Above two colleagues, same address as Prof Coleman

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