Participant Information Sheet

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IRAS Project ID: 366080

Full Title of Study: Feasibility and optimisation of the Smoke Free app for pregnancy, including the remote provision of NRT or a vape (eSupport)

Short Title of Study: Testing and improving the Smoke Free app for pregnancy (eSupport)

Name of Chief Investigator: Professor Felix Naughton

Invitation to take part

Stopping smoking during pregnancy can be hard – that is why we are creating a pregnancy-focused version of the Smoke Free app to help. We have made an early version of the app with the help of people who smoke during pregnancy and health workers. We are now looking for more people to test the app, or parts of it, and tell us if anything could be improved. We will do this in 3 – 4 groups, one after another, and make changes in between. The findings from this study will help us make the app more user-friendly and reliable before we test how well it works it in a larger study.

This information sheet explains what taking part in the study involves. Please take your time to read it and ask us if anything is unclear. This research is being led by the University of East Anglia (UEA). We are working with researchers at the University of Nottingham and the Smoke Free app team.

Smoke Free App (pregnancy version)

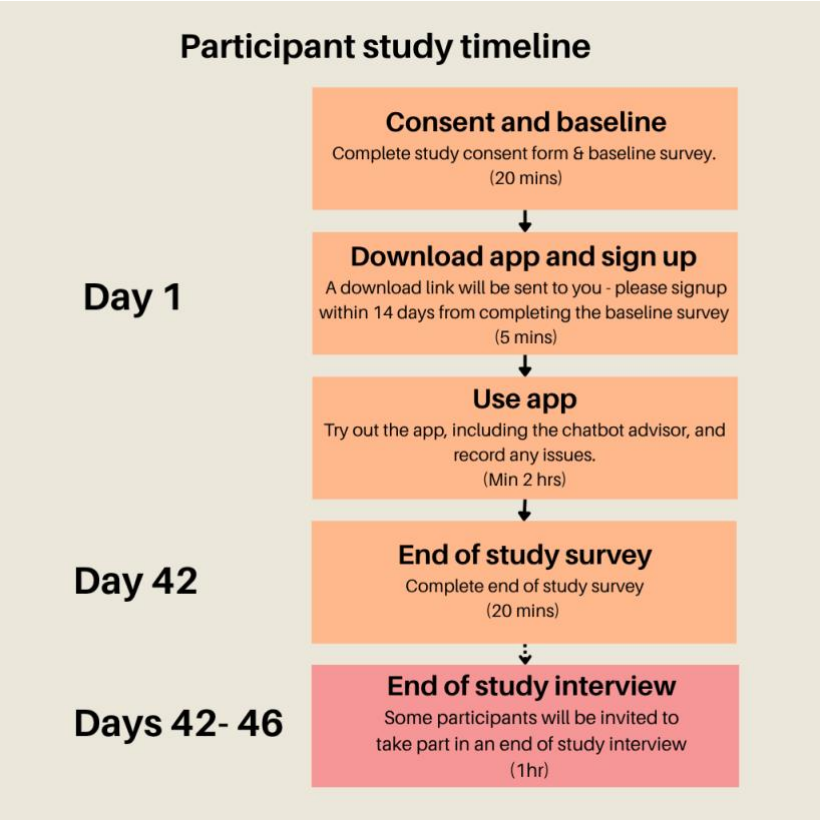
We have made a version of the Smoke Free app just for pregnancy. We are inviting you to test one or more of the following features, depending on your study group:

- A chatbot advisor which will offer short, supportive sessions to help you stop smoking. You can chat with the chatbot advisor at any time, whenever you need support.
- You can use the app to ask for either up to 4 weeks of free nicotine replacement therapy (NRT), such as patches or gum, or a free vape (e-cigarette) with up to 4 weeks of liquids. The product you choose will be posted to your address, free of charge.
- Supportive notifications and gentle reminders to keep in touch with the chatbot advisor and stay on track with your quit attempt.
- Other features, such as information library, baby development tracker, suggestions for stop smoking support for partners/family members.

What does taking part involve?

If you decide to take part in the research, you will be asked to:

- **Consent to take part** – read this information sheet and complete an online consent form. You will receive a copy for your records. If completing the online form is not possible, we will provide a different option.
- **Baseline survey and app download** - at the start of the study, you will be asked to complete a short survey about yourself and your smoking habits and download the study app.
- **Use the App** - you will be asked to use the app over a period of 6 weeks. During this time, we encourage you to try a quit attempt to help explore whether the app is helpful and accurate. NRT or a vape will be available through the app to support your quit attempt if you would like to use them. We also ask that you keep a brief record of your experience using the app, including any difficulties or issues you come across.
- **Chatbot and usage data** – if you agree, at the end of the 6 weeks, we would like to access your interactions with the app's chatbot to check the advice and responses it gave to you. This helps us identify any problems and improve the app**.**
- **End-of-study survey** - at the end of the 6 weeks, you will be asked to complete a survey about your experience using the app.
- **Optional interview** - you may be invited to take part in an individual online interview to discuss your experience of using the app in more detail.



Who can take part?

You can take part if you're less than 25 weeks pregnant, smoke at least one cigarette a day, are aged 18 or over, have a smartphone and are happy to install the app, want to try quitting smoking, and live in England.

Do I have to take part?

No, taking part in this study is completely your choice. If you decide to take part, you will be asked to sign a consent form. You are free to change your mind at any time, without giving a reason. Choosing not to take part, or deciding to withdraw later, will not influence your pregnancy care or other care in any way.

What will happen if I take part?

If you choose to take part in the study, we will ask you a few questions about you and your pregnancy. You will be sent this as an online survey, but you can also do it in person or on the phone (up to 20 minutes). After this, we will send you a link by email and text so you can download the app. You will need to download it and complete the sign-up questions within 14 days to join the study. If you do not download the app within this period, we may send up to three reminders by text and/or email, and ask for your reasons, so that we can understand any barriers and offer support if the issue is technical.

You will then be asked to make a quit attempt using the app and try its different features for 6 weeks. During this time, please make a note of any problems you have. With your consent, we would also like to look at your conversations with the AI chatbot at the end of the study. Any details that could identify you will be removed. This helps us check that the chatbot is giving safe and accurate advice. At the end of the 6 weeks, we will ask you to complete a short survey, either online or by phone (up to 20 minutes), to tell us how helpful and easy to use you found the app.

Some participants will also be invited to take part in an online or telephone interview to discuss their experiences of using the app and to suggest improvements (up to 1 hour). During this interview, if you decide to take part, you will be asked to use the app while talking through what you are doing. This is called a *'think aloud'* interview. The interview will be video recorded (if online) or audio recorded (if by telephone) so we can accurately capture what you say. The recordings will be written up and any names or identifying details will be removed, then the recordings will be deleted. You can ask the researcher to pause the recording at any time. Anonymous quotes (meaning you cannot be identified) may be used when sharing the findings. If you wish, we can send you a copy of your interview transcript.

What are the potential benefits and risks to taking part?

We do not anticipate any significant risks from taking part in this study. You will have the option to use NRT – such as patches, gum, lozenges, sprays, or inhalers – or a vape to help reduce tobacco cravings and withdrawal symptoms. NRT has been widely used in pregnancy and is considered safe when used as directed. Adults may experience mild side effects such as skin irritation (with patches), headaches, nausea, or sleep disturbance, but these are usually temporary. Numerous studies have investigated impacts on babies of smokers using

NRT in pregnancy to quit and these do not suggest that NRT is directly harmful. As NRT helps with stopping smoking, infants born to users are less exposed to tobacco smoke when in the womb, and so much more likely to be healthy.

For adults, vapes are also considered safer than smoking, however, they are not risk-free and some users experience throat irritation, coughing, or dizziness. In pregnancy vapes are recommended by the NHS instead of smoking in many areas as they do not expose the baby to carbon monoxide or many of the harmful chemicals found in cigarette smoke. There is limited evidence on how vaping might affect babies. However, the sole research trial which tested vaping during pregnancy found that babies born to vapers were heavier, and so probably healthier, than those born to smokers.

When used during pregnancy to support stopping smoking, both NRT and vapes are considered much safer for you and you baby than continuing to smoke tobacco. If you do have any concerns, please get in touch with a member of the research team using the contact details at the end of this information sheet.

Will my taking part in the study be kept confidential?

All personal information collected from you during the study will be kept strictly confidential**.** The University of East Anglia (UEA) is the sponsor of this study and the data controller for the personal data processed for this study. Your personal data is processed on the basis of our statutory authority to undertake research. Please see below for more information; if you have any further queries our Data Protection Officer can be contacted by emailing DataProtection@uea.ac.uk

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, NHS number, contact details and medical data about your pregnancy and smoking. People will use this information to do the research or to check your records to make sure that the research is being done properly.

UEA is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Research collaborators (the University of Nottingham).
- Text messaging services (TextAnywhere – operated by Commify - and Twilio)
- Application provider (23 Ltd, operating as Smoke Free)
- Digital software providers (Microsoft, Qualtrics, Anthropic)
- NRT and vape distributor (EW Fulfilment)
  We may share anonymised research data with other universities or research organisations to support future health and social care studies. This helps to reduce duplication and improve understanding. Any data shared will be fully anonymised, meaning you cannot be identified in any way.

We will keep all information about you safe and secure by:

- Storing digital data in UEA's Microsoft tenant, Qualtrics, TextAnywhere, Twilio, EW Fulfilment, and in the application developed by our partner 23 Ltd.
- Only those with a need to access the data will be able to.
- Keeping any paper data in secure locations. If you are recruited via an NHS hospital, the hospital will keep its own confidential records; personal details will be stored separately from research data.
- Video or audio interview recordings will be securely encrypted and either transcribed by a UEA-employed transcriber or auto-transcribed by the Microsoft Teams software and corrected by a UEA-employed transcriber. Identifying details will be removed, and recordings will be deleted once the pseudorandomised transcription is complete.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to our digital software / cloud storage providers.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Digital software / cloud storage providers within the European Economic Area (Microsoft, Qualtrics, and AWS – which hosts the Anthropic chatbot)
- Text message service Twilio (United States)

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- Twilio is certified under the UK–US Data Bridge, which provides an adequacy decision for data transfers to the United States.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data

when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we use information about you after the study ends?

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. Audio and video recordings will be destroyed once they have been fully transcribed and anonymised. Personal data (name, email address, postal address & telephone number) will be destroyed at the end of the study unless you give optional consent to be informed of the study results and potential follow-up studies. If consent is given, contact details will be kept for up to 3 years after the end of the study. The personal data will then be fully anonymised and securely archived or destroyed. Research data will be kept for a minimum of 7 years.

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. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- Our leaflet http://www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email dataprotection@uea.ac.uk, or
- By ringing us on [XXXXX XXXXXX].

Notifying your GP and maternity care provider

With your consent, we tell your GP and maternity care hospital that you are taking part in the study and what this involves.

Compensation

You will be offered a digital gift card as thanks for taking part. You will be given £10 digital gift card for completing the end-of-study questionnaire. If you also take part in an end-of-study interview, you will receive an additional £20 digital gift card.

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

Taking part in the study is completely voluntary. You can withdraw at any time and for any reason, and this will not affect your rights in any way. If you decide to withdraw, please contact the research team using the details at the end of this information sheet.
If you withdraw, we will keep some essential personal information, such as your consent form. We will only retain the minimum information needed to protect your rights. Any study data collected up to the point of your withdrawal will still be included in the analysis. This data will be fully anonymised so that you cannot be identified.

There may be times when it becomes difficult for you to continue taking part. If your circumstances change or you experience any issues, please let the research team know. You can contact us at any time if you would like to discuss your situation or your participation in the study.

If you experience issues installing or signing up to the app. Please contact the research team for support

If you do not install and sign up to the study app within 14 days of joining the study, we will assume you are no longer interested in taking part. We will send you a message asking for feedback. Any feedback you provide, along with the data collected up to that point, will be used to help improve the study and the study app in the future.

What will happen to the findings of the research study?

The findings of the study will be used to improve the app before we test whether it works in a larger study. We may present the findings to other researchers, at conferences and through publication in scientific and medical journals, and to public audiences. No names will be used in the results. We may use direct quotes from interviews and/or open responses to survey questions to illustrate key findings in reports and presentations, but individuals will not be identifiable. If you would like a copy of the findings, then just tick the box on your consent form.

Who is funding the research?

This research is being led by the University of East Anglia and is being funded by the National Institute for Health Research (NIHR), Programme Grant for Applied Research (Award ID: NIHR206259).

Who has reviewed this research?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given a favourable opinion by XXX. The study reference number is XXX.

What if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak with the research team at the University of East Anglia who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting: Professor Christopher Burton, Head of the School of Health Sciences, University of East Anglia, Norwich, Norfolk, NR4 7TJ.

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 East Anglia (who designs and manages the research) or the recruiting NHS Trust (who conducts the research) but you may have to pay your legal costs. The sponsor of this study, the University of East Anglia, has appropriate insurance and indemnity arrangements in place for the research and, where applicable, the NHS indemnity scheme will apply. The normal NHS complaints mechanisms will still be available to you (if appropriate).

The national smoke-free pregnancy 'incentives' scheme

In some areas, a smoke-free pregnancy incentives scheme is available. This scheme offers Love2shop vouchers to support people to stay smoke free during pregnancy if they provide regular carbon monoxide (CO) readings to show they have stopped smoking and attend meetings with a stop smoking advisor. If you take part in our app study, you may not be eligible for this incentives scheme. For more information about the scheme, speak to your local maternity stop smoking service.

Further information and contact details

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