Research into how technology may help smokers quit. Participant Information.

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What is this study about?

This study aims to estimate the effectiveness of two forms of digital support (website and app) designed to help smokers to quit and to continue resisting cravings. The study also aims to assess the feasibility of providing this support, of evaluating it online and of running a full-scale randomised control trial in future. We are looking for 200 cigarette smokers who are willing to quit within 14 days of volunteering to take part.

We are researchers from the University of East Anglia (UEA), the University of Cambridge, the University of Nottingham and Imperial College London. We are developing and testing effective ways to help cigarette smokers to quit, and to stay quit.

Why is this research needed?

Of the three million smokers in the UK who try to quit each year, over 90% don't succeed. Better support is needed to help smokers to quit and to stay quit.

While there are strategies that smokers can use to help them quit (e.g., self-talk), many smokers do not use these and often rely on willpower alone. Another challenge is that few quitting support programmes are designed to help smokers resist cravings triggered by their environment, such as places or situations where they usually smoke.

This research looks at the role that digital support (website, app) could have in helping more smokers to succeed in giving up. In the study we look at:

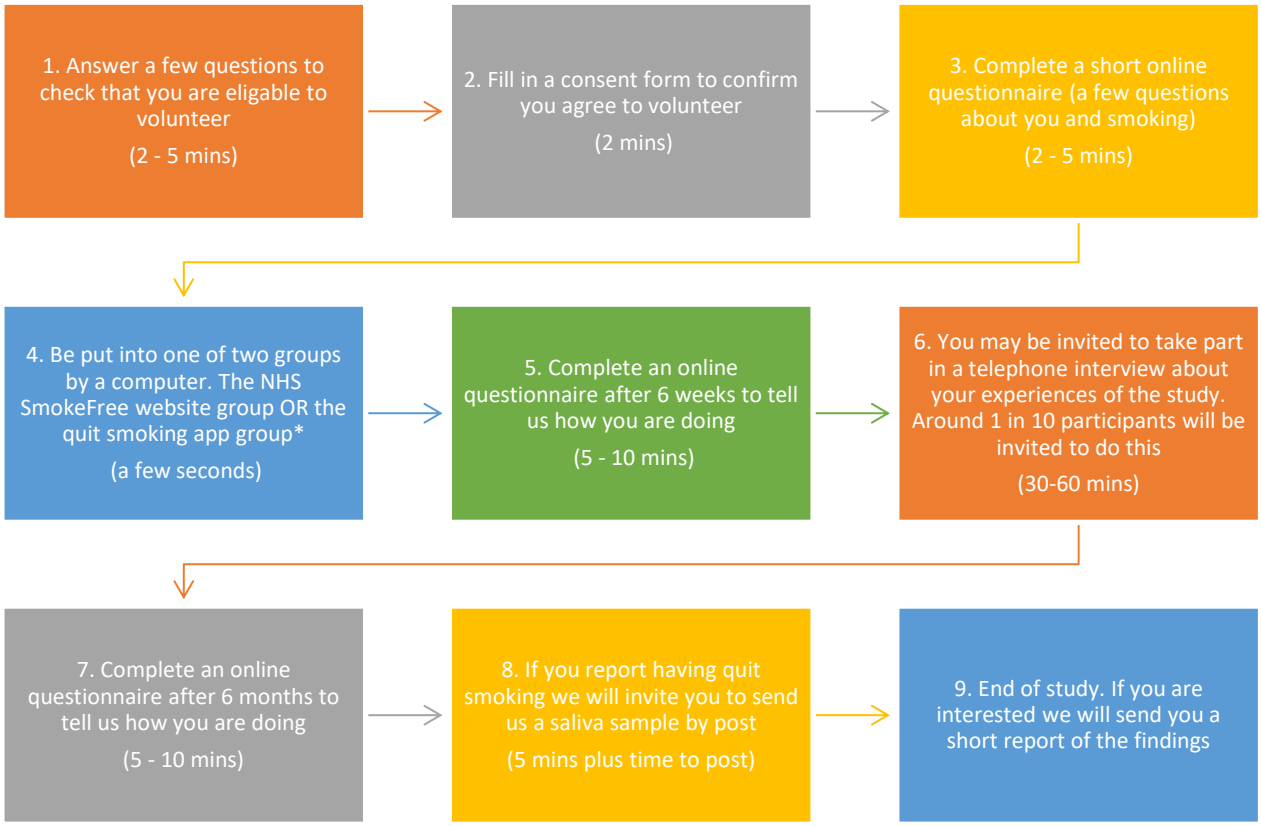
1. The NHS's SmokeFree website which includes a wide range of resources to promote quitting (e.g., personal quit plan).
2. A newly developed quit smoking app. This app uses a learning tool and location sensing to tailor the timing and content of support messages.

What would taking part involve?

If you take part, the study involves providing some information about yourself at the beginning (baseline questionnaire), receiving links to quit smoking support and then completing follow up questionnaires approximately 6 weeks and 6 months after enrolling. You may also be invited to provide feedback about this study and the support provided in an audio recorded telephone interview or by leaving a recorded audio message. We will send you links to the two online questionnaires by SMS text message when we

need you to complete them. Where we do not get a response or data is missing, we will attempt to call you in order to complete the questionnaire(s) over the phone.

We will be on hand to provide you with any reminders and/or other help you may need to take part.



*Please note that the timings given above are estimates. It may take you more or less time than we have suggested.

Volunteers will be put in groups by a computer and will have an equal chance of being in either group. The study is designed like this to ensure that our two groups of volunteers are as similar as possible. This way we can be sure that any differences between groups are due to the type of support received rather than anything else. This type of study is called a randomised control trial (RCT).

Can I take part?

If you answer YES to ALL these statements, then you can take part:

- ✓ I'm a current smoker (at least 7 cigarettes per week).
- ✓ I'm willing to make a quit attempt within 14 days of starting the study
- ✓ I own or have main use of an Android smartphone
- ✓ I'm aged 16 or above

- ✓ I live in England
- ✓ I haven't previously participated in / signed up to this study

I'm interested, how do I sign up?

If you have answered YES to ALL of the above and you want to take part, then go to the online study platform to enrol.

Do I have to take part? What if I want to leave the study?

No. It is entirely up to you. If you do take part, you may leave the study at any time without giving a reason. If you decide to leave or simply not take part, this will not affect your legal rights.

We will send occasional text messages as part of coordinating the study. However, you can stop these at any time by texting STOP to the Quit Sense number, emailing, or calling us. If you 'STOP' messages a member of the team may contact you in order to confirm your contact preferences (e.g., to check whether you would be happy to receive emails instead of SMS text messages).

If you want to leave from the study completely, you can do so at any time by emailing us at quitsense@uea.ac.uk

If you do leave the study, information collected before this point cannot be erased and will be used in the analysis. If you leave you will not be able to re-join the study.

Will my taking part be kept confidential?

Yes, personal information about you will be kept confidential (i.e., private) and stored safely and securely.

When sharing our findings, we may use direct quotes (e.g., from your feedback or interviews) but these would not be linked to you. Your name will not be used.

Are there any rewards for taking part?

To thank our volunteers for giving up their time to take part in this study we will give out a number of Amazon voucher codes during the course of the study, as follows:

- £5 voucher code for volunteers who complete the follow up questionnaire given out around 6 weeks after the study starts.
- £10 voucher code for volunteers who complete the follow up questionnaire given out around 6 months after the study starts.
- A small number of people will be invited to take part in an interview about their experiences of the study. Those who do so will receive a £20 voucher code.

- £5 voucher code for volunteers who return a saliva sample by post. Saliva test kits will be posted out to participants reporting having quit smoking at 6 months follow up.

What will happen to the results?

With your help we will improve the digital support available to people who want to quit smoking.

The information that we collect as part of this study will be analysed and fully anonymised findings will be shared in reports, presentations, and journals.

A short summary of the results will be produced and if you like, we'll send you a copy.

More about the support (website, app)

1. The NHS SmokeFree website provides a selection of digital support options to help people to quit smoking, including an online chat facility with an advisor, an email cessation programme, an SMS text message programme and the NHS SmokeFree smartphone app.
2. For those in the quit smoking app group, they will be offered access to the newly developed Quit Sense app. This app works by asking smokers, before they start trying to quit, for information about their surroundings (e.g. home, work) whenever they smoke and how they are feeling (e.g. down, stressed). Each time this happens the app uses the phone's in-built sensors (e.g. GPS) to record their location. Once smokers start a quit attempt, Quit Sense sends them advice on how to avoid smoking when they approach or spend time in a place where they previously told it they had smoked. Quit Sense collects location data along with information the person has given about their surroundings (e.g., home, work) and feelings when they smoke so that it can match advice and support to be relevant to each location.

Q & As

What are the possible pros and cons of taking part?

Pros

- While we can't promise that the study will help you to stop smoking, the important information we gain from your involvement will help us improve the support given to people in the future who want to quit smoking.
- You may find that being part of this study helps to motivate you in your quit attempt.
- You will be sent a link to the NHS SmokeFree website (everyone will be referred to this) and you may also receive the Quit Sense app.

Cons

- The quit smoking support may include advice and support notifications which some people may find unhelpful or even irritating. However, you can stop this at any point.

If you have concerns about any of the support received, you could discuss these with your GP.

What will be asked in the questionnaires?

There will be a range of questions. For example, we may ask questions about you (e.g., your age), your smoking (e.g., number of cigarettes, strength of urges to smoke, strength of motivation to quit), your mobile phone use (e.g., how often you check your phone for notifications, install apps), your wellbeing (e.g., how you rate your health).

What if I start smoking again?

We are interested in learning about your experiences of using digital support (website, app) to quit smoking.

It does not affect your involvement in the study if you start smoking again or quit successfully – we simply want to learn about how you got on.

What happens to the saliva samples?

- We will ask participants who report quitting smoking to return a saliva sample by post.
- Samples will be assessed by ABS laboratories and then destroyed.
- The saliva samples will be tested for smoking related chemicals.
- If you are asked to provide a saliva sample, only members of the research team, relevant regulatory authorities and the laboratory who test the saliva will have access to the results of your samples.

Who is has funded this study?

Quit Sense is fully funded by the National Institute for Health Research (NIHR) grant number 17/92/31.

Who has reviewed the study?

All research in the NHS is looked at by an independent group, called a Research Ethics Committee, to protect your interests. This study was approved on the 28th of January 2020 (Wales REC 7, reference 19/WA/0361, IRAS project ID 270432).

What happens when the study ends?

Once your involvement in the study has ended, you will no longer receive communications from the study team other than a copy of the findings, if you have requested one. You will be sent an SMS text message to inform you that your participation in the study has ended.

The NHS SmokeFree website support will continue be available after this study ends.

If you were in the app group, you will still be able to access and use the Quit Sense app on your mobile if you wish to do so. If you continue to use the app, it will continue to collect research data that we may use as part of the study analyses. After the study ends Quit Sense will no longer have technical support and

you will not be able to update or reinstall it. If you wish, you can uninstall the app following the usual process for removing apps from your phone.

What if there is a problem?

If you have a concern about any part of the study, you should ask to speak with the study team who will do their best to answer your questions.

Contact: quitsense@uea.ac.uk Tel: 01603 59 3053 Please leave a recorded message including your contact details and we will get back to you as soon as we can.

I want to know more about how my data will be used

If you join the study, we will use information collected from you during the research.

Personal contact information

- We will follow ethical and legal practices so that personal information about you will be kept confidential (i.e., private).
- The mobile telephone number you provide will be used by the specialist team at the University of East Anglia as part of study administration. In order to send you study-related text messages, we need to pass your number to our text message provider (Twilio). Your telephone number will be kept confidential and will *only* be used for this study. It won't be passed on to or used by anyone else.
- Any personal information will be kept strictly confidential and stored in a password protected database by the University of East Anglia.
- Your contact information will be kept by the University of East Anglia for 12 months after the end of the study, after which time it will be destroyed. Contact details are kept so we can let you know about the findings of the study (unless you instruct us that you don't wish to be contacted).
- Contact information will be kept separately from the research data collected and only those who need to will have access to it.

Research data (e.g., questionnaires*, interviews)*

- This data will be anonymised and kept securely until it is destroyed 20 years after the trial ends.
- App data. Those in the quit smoking app group will be offered access to the Quit Sense app. This app uses the phone's in-built sensors (e.g. GPS) to record location. This data is collected so that the app can send tailored support messages to help smokers manage cues to smoke. It will also be analysed to improve our understanding of how different locations influence smoking behaviour. This personally identifying data will be stored securely and separately from your contact information. All data collected by the app will initially be sent to a University of Cambridge server where it will be stored securely. The data will then be transferred to the University of East Anglia

for processing (e.g., cleaning, transcription), analysis, and secure storage. You can view the app privacy policy here.

More details about how we will look after your data

- Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Dr Felix Naughton) 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.
- Your data may be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All these people will have the duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Sharing of data and research outcomes

- In addition to the University of East Anglia, the following organisations who collaborate with us on this project will have access to the research data: The University of Cambridge, The University of Nottingham and Imperial College London.
- In accordance with the University of East Anglia, the Government, 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. Location data collected by the app, however, will not be made available as part of an anonymised open data set outside of Quit Sense collaborations.

The Quit Sense **Privacy Notice** and Quit Sense **app privacy policy** can both be viewed on the Quit Sense website: http://www.quitsense.phpc.cam.ac.uk/index.html

Why / how did I land on the Quit Sense study online platform?

Recruitment is taking place online with paid for advertising through Google and social media platforms (e.g., Facebook, Instagram). Viewers who click on these advertisements are directed to the Quit Sense online study platform. Some people may also find out about Quit Sense by other means (e.g., because their specific google search terms lead them to the Quit Sense website).