PARTICIPANT INFORMATION SHEET

The Skyline Study: Measuring Smoking Behaviour

Claire Braboscz, Stuart G Ferguson, Marcus R Munafò, George Stothart, Lillian Brinken, Osama Mahmoud, Olivia M Maynard

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would 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 not clear or if you would like more information. Take time to decide whether or not you wish to take part and remember that your participation is voluntary.

What is the purpose of the study?
The Skyline study investigates the factors influencing general smoking behaviour and attitudes towards smoking. Skyline will require you to use your smartphone to complete online surveys every day for 4 weeks and to come to the laboratory at the beginning and at the end of the study to take part in an electroencephalography (EEG) experiment in which we investigate the brain activity when viewing pictures related to smoking.

Why have I been invited?
You have been invited because you have enquired about our studies or have asked to receive further information following reading the summary version described in the letter of invitation or in a study advertisement.

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 would be given this information sheet to keep and be asked to sign a consent form prior to any further procedures (excluding an initial telephone screening). If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, would not affect your future or be held against you in any way.

Am I eligible to take part?

Please note you must be aged over 18 to volunteer and may be asked to provide identification as proof of age.

Please read all of these criteria very carefully and contact the researcher if you have any doubts.
regarding your eligibility. If you do not pass the screening on the study day, you will not be able to take part, and we cannot offer reimbursement for screening failures.

In order to take part in the Skyline study, you should:

- be a current smoker, having smoked at least 100 cigarettes in your lifetime and now smoking every day and at least 10 times a day;
- not currently be trying to quit smoking;
- be in between 18 and 50 years old
- have a normal or corrected to normal vision, if you need contact lenses or glasses you will be required to wear them.

You would not be able to take part in the study if you:

- do not have a smartphone with at least a 3G network connection;
- are working night shifts.
- ever had a traumatic head injury and/or loss of consciousness;
- have any serious medical condition or an history of neurological or mental illness;
- are currently taking prescription drugs;
- have any other regular substance use apart from tobacco;
- regularly abuse alcohol;
- have hair that cannot be flattened to allow to fit the EEG electrodes cap tightly enough so a good contact can be made between the electrodes and the scalp, ensuring a good quality EEG signal can be recorded. For example if you have very thick and/or wavy hair, or have plaits you do not want to remove etc.). Please get in contact if you are unsure.

Expenses and reimbursement
Participants who are ineligible based on the criteria described above, will not be reimbursed. Please read these criteria carefully to ensure that you are eligible.

For participation in the Skyline study we would reimburse you £80 at the end of the study. If you complete the study having fulfilled at least 80% of the daily questionnaires and forms, we would reimburse you a further £10.

How much time will the study take and what will I have to do?
To take part in Skyline, you would have to come to two testing sessions in the laboratory at the University of Bristol, one at the beginning and one at the end of your participation in the study (after 4 weeks).

During your first visit (about 2 hours), we would take a measurement of exhaled (breath) carbon monoxide level (CO) and you would complete some questionnaires. We would then explain what you would need to do for the next 4 weeks.

Over the next 4 weeks, you would:
- every evening complete a questionnaire about your smoking behaviour;
- receive 3 text messages per day with a link to an online questionnaire (this would take less than two minutes to complete). At the beginning of the study you would be randomly assigned to receive one of two different sets of messages about smoking in these questionnaires.

Skyline Information Sheet
Version 2 - 18/06/2019
During your visit to the laboratory, we would use electroencephalography (EEG) to record your brain activity while you are viewing pictures presented on a computer screen related to smoking and doing some simple tasks (button press). Electroencephalography (EEG) is a well-developed imaging technique to record electrical activity along the scalp. This technique is a widely used, fully non-invasive method for measuring the brain responses during different psychological tasks.

At the start of the EEG session, we would attach some recording electrodes to your scalp. These electrodes are safe and comfortable to wear, and we would take time to familiarise you with the equipment. Attaching the electrodes would include measuring your head size, using alcohol swabs to clear small patches of your skin near the ears, placing an EEG cap on your head, placing electrodes onto the cap and injecting gel into the electrode holders of the cap. To ensure a good connection between the skin and the electrodes we would use a blunt syringe to scrub a little the surface of your scalp, which may cause a little discomfort but no pain. The cap and electrodes only sit on top of your scalp. The whole procedure is likely to take 2 hours of which 1 hour maximum would involve EEG recording. If you feel any discomfort during the procedure you should signal it immediately to the experimenter. Some gel may remain on your hair at the end of the experiment and you will be given the possibility to wash your hair.

For each of your two visits to the EEG laboratory, we would ask that you are come in well-rested and with clean hair (with no hair-gel or other hair products), to ensure good quality contact between the electrodes and the skin on your scalp.

During your second visit (after 4 weeks), you would complete some final questionnaires, we would check your compliance with the questionnaire measures and you would be reimbursed.

**What are the possible disadvantages and risks of taking part?**
There are no identified risks with taking part in Skyline. You would just need to make sure to have your smartphone with you every day for 4 weeks and complete all of the questionnaires.

During the EEG experiment we do not anticipate any particular physical discomfort, stress or effects on your well-being. During EEG recording, you would be asked to keep your head still, and we ask you to maintain concentration during the experiment.

During the EEG protocol you would also be presented with pictures, amongst them some would be showing unpleasant content. The content of the unpleasant pictures may include dead bodies, animal carcasses and injuries. You would also see smoking health warning pictures similar to those present on cigarette packs. You might feel temporarily distressed by seeing these images, but we do not anticipate that this would be more than what you can experience in your everyday life (for example by watching the news or a movie). You may immediately end your participation if any aspect of the research procedure makes you too uncomfortable to continue. If you have any discomfort or concerns after viewing the images, you are encouraged to contact the principal investigator.

**What are the possible benefits of taking part?**
You would not directly benefit from taking part in the Skyline research study and your participation is voluntary. However, the information we get from this study may help us to understand factors that influence smoking behaviour and how smokers’ brains process smoking-related pictures.

**What if there is a problem?**
Any complaint about the way you have been dealt with during the study or any possible harm you
might suffer would be addressed.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you’ve been approached or treated during the course of this study, please contact Dr Olivia Maynard (olivia.maynard@bristol.ac.uk).

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

Yes. Your identity and personal information that could identify you (e.g., name, email address, age) will be kept securely by the study team and will not be shared publicly or with other research groups. On occasion this information may be made available to university research staff and government bodies which monitor whether research studies are performed properly. However, this will only be in the context of monitoring and this information will not be used to contact you or to make your participation in this study known.

This research study will adhere to General Data Protection Regulations (GDPR). We will be using information from you in order to undertake this study and will act as the data controller for this. This means that we are responsible for looking after your information and using it properly. We will keep identifiable information about you (name, email address) until one year after the study, but this will not be shared or be part of your study data. If you agree to take part in a study, data about you will be processed for a task in the public interest, which is consistent with the University Charter for scientific research.

**What would happen to the results of the research study?**

During the study, we will collect two types of data: screening data and study data. Both types of data are anonymised. This means we give the data a unique identification number and your personal information (e.g., name, phone number, date of birth, email address) is removed, so that you cannot be identified by this information. The only personal information we will retain during the study is your email address and phone number – to be able to contact you and send you text messages.

Screening data are collected before you are fully enrolled onto the study. They identify whether you are eligible for the study, but they are not part of the study data. We keep these data securely within our research group but do not share it.

Study data refer to the information gathered once you are enrolled onto the study. These data are collected to answer our research questions.

When the study has been completed, we would analyse the study data we have collected and report the findings. This would be reported in an appropriate scientific journal or presented at a scientific meeting. You would not be identified in any way and if you would like a copy of the final paper, you may request this.

As your study data are anonymised, it would not be possible to identify you by name from any aspect of documentation or reporting for this research study.

Your rights to access your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.
At the end of the study your data would become “open data”. This means that it would be stored in an online database so that it is publicly available. Your screening data would not be shared.

**What is open data?**
Open data means that study data are made available, free of charge, to anyone interested in the research, or who wishes to conduct their own analysis of the data. We would therefore have no control over how these data are used. However, all data would be anonymised before being made available and therefore there would be no way to identify you from the study data.

**Why open data?**
Sharing research data and findings is considered best scientific practice and is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of investment through wider use, and encourages new avenues of research.

**Can I withdraw my study data after I have participated in the study?**
Yes. If you decide that you do not want your data to be used you can contact the study team and request that your data are withdrawn. You can do this up to one year after the study ends or up until the point the data are shared as “open data” (whichever comes first). At this point links between your identity and your anonymised data set would be destroyed, and therefore we would no longer be able to withdraw your data as we would no longer be able to identify which data set is yours.

**Who is organising and funding the research?**
This research is organised by Dr Olivia Maynard and Dr Claire Braboszcz who are researchers from the Tobacco and Alcohol Research Group (TARG, Bristol University School of Psychological Science). It is funded by an ESRC New Investigator’s Award, awarded to Dr Olivia Maynard (ES/R003424/1) and Medical Research Council Integrative Epidemiology Unit at the University of Bristol (MC_UU_00011/7).

**Who has reviewed the study?**
The study has been reviewed by the University of Bristol’s School of Psychological Science Research Ethics committee and have received the approval code 28021982303.

**Who can I contact for further information?**
For further information, please contact Dr Claire Braboszcz (claire.braboszcz@bristol.ac.uk) or Dr Olivia Maynard (olivia.maynard@bristol.ac.uk). If you are interested in taking part, please complete the online screening survey at this link: [https://bristolexpppsych.eu.qualtrics.com/jfe/form/SV_9zYlrIK7Tk7ESkR](https://bristolexpppsych.eu.qualtrics.com/jfe/form/SV_9zYlrIK7Tk7ESkR)

If you participate in this study you would be given a copy of this information sheet and a signed consent form to keep.