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PARTICIPANT INFORMATION SHEET

PASSIVE MEASUREMENT OF CIGARETTE SMOKING

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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 School of Psychological Science at the University of Bristol has a number of projects exploring new ways to capture data about lifestyle behaviours. One such behaviour is smoking. Traditional methods for measuring smoking require participants self-report their smoking behaviours. Measurements taken this way are known to be subject to a number of biases and errors, so new ways to record these behaviours with less bias and more accuracy are of considerable interest.

In this project, we are testing a prototype of a system that will passively measure smoking behaviours. By 'passively', we mean the system will detect the act of smoking without the person having to take any actions to record it themselves. The system is based on a single, commercially available smartwatch. It uses the motion sensors in the smartwatch, and looks for the particular

patterns of hand movement that are the motion signature of smoking. We have completed some initial validation of the system in natural settings, but now need to validate the system on the next generation of smartwatches, which bring a range of improvements including improved battery life and ease of setup.

For this, we are asking participants to view a brief YouTube video to receive training in using the smartwatch system and then to wear the smartwatch over a 24-hour period as they go about their normal daily activities. The version of the smartwatch system they will wear has been modified slightly so that it can capture 'ground truth' data from the person (i.e. whether the detection by the smartwatch was correct or not). Participants will also be asked to keep a paper diary of their smoking behaviours. We will compare the ground truth data from the smartwatch and the paper diaries, to the data from the smartwatch smoking detection system to derive the accuracy and precision of the system in free living conditions.

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. 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 you should:

- You should be a daily smoker, smoking at least 10 cigarettes per day (not e-cigarettes)
- You should smoke with your right hand, and not have any mobility issues affecting your right hand or right arm
- You must not have any food allergies or intolerances
- You must be aged 18 or over
- You must be willing to keep a smoking diary during the 24 hours of the study

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

- do not meet all of the above criteria

Expenses and reimbursement

You will be reimbursed £15 for taking part. Participants who are ineligible on the testing day based on the criteria described above, will not be reimbursed or given course credit. Please read these criteria carefully to ensure that you are eligible.

How much time will the study take?

- Watching an initial YouTube training video (approximately 6 minutes long).
- Wearing the smartwatch system for 24 hours in your natural living conditions.
- A brief online feedback survey which will take about 5 minutes to complete.

What will I have to do?

A smartwatch and charger will be mailed to you, together with reply-paid packaging for its return, and a paper form to record details of your smoking. We are asking participants to complete a brief Zoom training session, and to wear the smartwatch over a 24-hour period as they go about their normal daily activities. You will be given a link to a YouTube training video lasting approximately 6 mins in which you will be introduced to the smartwatch device, and shown how to respond using the ground truth app. You will then wear the smartwatch for approximately 24 hours. You will then return the equipment and the paper form where you have recorded your smoking, using the reply-paid packaging supplied by us. You will then be emailed a link to a quick online survey which will give you an opportunity to provide any thoughts about your experience with the system, potential improvements, etc.

You can remove the smartwatch to sleep and shower/wash. You will be provided with a charger in case the device runs out of power.

What are the possible disadvantages and risks of taking part?

There are no known risks associated with participating in this study, other than the usual risks associated with smoking. You would not be smoking any more than your usual amount during this study, so the study itself would not present any additional risks.

What are the possible benefits of taking part?

You would not directly benefit from taking part in this research study and your participation is voluntary. However, the information we get from this study will contribute towards our group's research on tobacco related behaviour.

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 Andy Skinner (andy.skinner@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, date of birth) 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 Regulation (GDPR) and the Data Protection Act (DPA) 2018. 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, date of birth, email address) is removed, so that you cannot be identified by this information.

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.

The smartwatch system is designed to record only instances of smoking. It does not record raw movement data, or any other sensor data, and cannot detect any other behaviours.

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 study is funded by and is part of an HDR-UK Fellowship awarded to Dr Andy Skinner.

Who has reviewed the study?

This study has been approved by the School of Psychological Science Human Research Ethics Committee. The reference number for this approval is 99922.

Who can I contact for further information?

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

For further information about the study, please contact Chris Stone (chris.stone@bristol.ac.uk)