



School of Psychological Science  
12a Priory Road  
BRISTOL BS8 1TU  
United Kingdom

Angela Attwood  
Email: [angela.attwood@bristol.ac.uk](mailto:angela.attwood@bristol.ac.uk)  
Phone: +44 (0) 1173317450  
[www.bristol.ac.uk](http://www.bristol.ac.uk)

## **PARTICIPANT INFORMATION SHEET**

### **Effects of acute smoking on health-related biomarkers**

Angela Attwood, Stephen O’Rahilly, Jennifer Ferrar, Marcus Munafò

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 you wish to take part and remember that your participation is voluntary.

#### **What is the purpose of the study?**

It is possible to identify or predict health outcomes by measuring certain chemicals in the body. These are often called “biomarkers” as they are biological indicators of factors related to health. They are important for medicine as they can act as early predictors of disease. Chronic cigarette smoking is associated with several disease states, and this study will examine whether levels of two biomarkers (Advanced Glycation Endproducts (AGEs) and growth differentiating factor 15 (GDF-15)) change as people smoke. Therefore, we will measure and compare these biomarkers after a relatively heavy bout of smoking compared to a day of smoking abstinence.

#### **Why have I been invited?**

You have been chosen because you have enquired about our studies and requested to receive this 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.**

In order to take part you should:

- Be 18-40 years old;
- Be a non-daily current cigarette smoker defined as smoking at least twice a month, but not daily;
- Smoke at least 6 cigarettes in a 3-hour bout of smoking at least twice a month;
- Be in good physiological and psychiatric health;
- Have English as first language (or equivalent level of fluency);
- Be willing and able to attend 2 late-afternoon (3-6 pm) sessions (at the same time of day) on 2 separate days approximately a week apart
- Be willing and able to attend an early afternoon session (12-3 pm) 3 hours before one of the late-afternoon sessions
- Be willing and able to smoke 6-10 cigarettes (depending on typical smoking behaviour) during the 3-hour period prior to one of the sessions
- Be willing and able to abstain from smoking\* before the other session (last cigarette would be the night before the study session).

\*You will not be able to use nicotine replacement methods (including e-cigarettes) during the abstinence condition.

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

- Consume alcohol 24 hours before either session (verified by alcohol breath test)
- Failure to remain abstinent from smoking before the **one** study session that requires abstinence (verified by breath test)
- Failure to smoke 6-10 cigarettes during the 3-hour period before the **one** study session that requires smoking (verified by breath test)
- Are pregnant or breastfeeding (females who are unsure will be provided with a urine test for pregnancy)
- Have an uncorrected visual or auditory impairment

### **Expenses and reimbursement**

You will be reimbursed £30 for your time and expenses after completion of both study sessions. Since you will be asked to smoke a number of your own cigarettes for this study, we will replace these cigarettes (your preferred brand) after completion of both study sessions.

### **What does the study involve?**

Before the study we would ask you to complete an online questionnaire to check that you are eligible to take part. If you are eligible, a researcher will contact you to explain the study procedures and you would have the opportunity to ask any questions you may have. You would then be able

to decide if you want to take part in the study. If you do not want to take part, we would destroy any information you have provided. If you would like to take part, we would then arrange your study sessions. Study sessions would take place at the School of Psychological Science at the University of Bristol (12a Priory Road, BS8 1TU). You would the lab on two separate weekdays, approximately a week apart. The researcher will tell you which order you will complete the sessions in, i.e., whether you will do the abstinence condition for your first or second session. On the day when you are required to abstain from smoking (and nicotine replacement methods, including e-cigarettes), we would ask you to attend the laboratory between 3-6 pm for a 30-minute session. You would be able to smoke the night before the session (i.e., last cigarette before going to bed no later than 11pm), but you would not be able to smoke on the day of the session. On the day when you are required to smoke, we would ask you to attend the laboratory at the same time of day as your other session for another 30-minute session. In addition, we would also ask you to attend the laboratory 3 hours before this session for a brief 15-minute session. You should avoid drinking alcohol for 24 hours before both study days.

Upon arrival at the first study session, you would be given the opportunity to read this information sheet again and ask any questions you may have. We would then ask you to complete two identical consent forms (one for you to take and one for us to keep). We would then screen you for eligibility. You will be asked to complete some questionnaires telling us about yourself and your smoking history and patterns.

On the smoking day, you will complete screening measures during both the earlier 15-minute session and the later 30-minute session. At the beginning of the 15-minute session, we will test for recent smoking (using a breath test and a urine test) and then you will be given instructions for 3-hour smoking period. After the 3-hour smoking period, you will return to the lab for your 30-minute session. We will test again for recent smoking (using smoking breath tests and a urine test) to ensure that you smoked as per instructions. We will also test for recent alcohol consumption (using a breath test). On the abstinence day, there is only a single 30-minute session to attend. At the beginning of this session, we will test for recent smoking to ensure that you abstained for the abstinence session and for recent alcohol consumption (using a breath test).

If you fail any of the screening tests, we would not be able to test you on that day and would not be able to reimburse you. After the screening measures, you would complete the following measures (once per session, twice over the whole study). You would complete a questionnaire which asks about how you are feeling, and we will measure the biomarkers with two further tests. To measure AGEs, you would undergo a simple non-invasive test that requires you to put your arm on top of an AGE reader device. This device uses light technology to read AGE levels in your skin and therefore you will not feel anything while the reading is being taken. It takes about 1 minute to complete. Please note, that for this device to read properly, your arm needs to be clean and free of moisturiser or tanning products. Please do not use these products on the days of the sessions. You may be required to wash your arm before the reading. To measure GDF-15 we require a sample of blood (5 ml). This will be taken by a trained researcher from a vein in your inner arm.

At the end of session two, you would be fully debriefed as to the purpose of the study and reimbursed.

### **What are the possible disadvantages and risks of taking part?**

During one of the study days, you will be asked to smoke a number of cigarettes in a 3-hour period, but will not be asked to smoke more cigarettes than you would normally smoke. That is, the number of cigarettes you smoke will be equivalent to a number you would sometimes smoke by choice in

the same period of time. If you decide you do not wish to smoke this amount of cigarettes, you may withdraw from the study at any point.

We will require a small blood sample to be taken at each session. This may involve some mild discomfort, but will be comparable to other situations where blood is taken. The researcher is a trained and experienced phlebotomist (blood taker). If they are unable to get blood at the first attempt, they will try once more from your other arm. If they fail a second time, they will not try again.

### **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 may help us to understand the effects of smoking and health benefits associated with cessation.

### **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 will 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 Liam McKervey ([liam.mckervey@bristol.ac.uk](mailto:liam.mckervey@bristol.ac.uk)).

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

Yes. Personal information that could identify you (e.g., name, email address) 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 staff, funders or government bodies which monitor whether research studies are performed properly. However, this information will not be used to contact you or to make your participation in this study known.

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

The data we collect will be anonymised. This means we give the data a unique identification number and your personal information (e.g., name, email address) will be removed, so that you cannot be identified by this information. The blood and urine that we take will also go through a special centrifuging process. This makes it "acellular". This means your cells (that contain biological information about you in your DNA) are removed and destroyed. We will not extract or store any DNA information about you. Your centrifuged blood and urine will be sent to specialist laboratories to extract the GDF-15 and smoking metabolites. The blood and urine will then be disposed of and not used in any other way.

When the study has been completed, we analyse the study data we have collected and report the findings. This will be reported in an appropriate scientific journal or presented at a scientific meeting. If you would like a copy of the final paper, you may request this. As your study data are anonymised, it will not possible to identify you by name from any aspect of documentation or reporting for this research study.

At the end of the study your data will become “open data”. This means that it will be stored in an online database so that it is publicly available. Your screening data will 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 will therefore have no control over how these data are used. However, all data will be anonymised before being made available and therefore there will be no way to identify you from the research 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 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 will be destroyed, and therefore we will no longer be able to withdraw your data as we will no longer be able to identify which data set is yours.

### **Who is organising and funding the research?**

This research is funded by the Medical Research Council (MRC) Integrative Epidemiology Unit at the University of Bristol.

### **Who has reviewed the study?**

This study has been reviewed and approved by the School of Psychological Science Research Ethics Committee at the University of Bristol (reference: 64541).

### **Who can I contact for further information?**

For further information please contact Angela Attwood via email: [angela.attwood@bristol.ac.uk](mailto:angela.attwood@bristol.ac.uk) or telephone : +44 (0) 117 331 7450.

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