PARTICIPANT INFORMATION SHEET

Are cognitive deficits associated with tobacco abstinence mediated by nicotine withdrawal?

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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 purpose of this study is to understand how computer-based measures are influenced by nicotine in abstinent smokers. Understanding how cognition is affected by tobacco withdrawal can help us to develop novel smoking cessation methods.

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 aged 18-60 years
- smoke at least 5 cigarettes per day
- have smoked for at least 6 months
- have English as a first language or a similar level of fluency
- have visual acuity within normal limits
- be willing to abstain from smoking for both sessions for about 20 hours
- be willing to wear a nicotine patch and use a nicotine nasal spray for one session and a placebo patch and a placebo spray at the other session (you would not be made aware of the order of the conditions at any point of the study)
- if female: be willing to take a pregnancy test before the start of the study

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

- currently have a mental health condition, or had a mental health condition in the past
- are currently taking any psychoactive medication
- are actively trying to give up smoking
- have no current or previous substance or alcohol misuse or dependence (other than nicotine and cannabis)
- if female: are pregnant, breast feeding or trying to conceive
- have extensive dermatitis/other skin disorder that precludes patch use
- had acute coronary syndrome or a stroke within the past three weeks

Expenses and reimbursement

You will be reimbursed £80 by the end of the second session for your time and expenses

What will I have to do?

You would be required to come to the School of Experimental Psychology on two separate days (at least 1 week apart) in the morning between 8 am and 11 am.

On each day, a nicotine patch would be applied to your arm. Then you would be asked to spend about 2 hours at the testing site, completing four computerised tasks. After that you would be provided with a mobile phone and asked to indicate how you are currently feeling using the phone for the next ~6 hours. This should only take a minute or so each time, and you would be asked to do so about once per hour. You will be free to leave the testing site during that time. At the end of the ~6 hour period you would be asked to bring the mobile phone back to the testing site.

At the end of the second session you would be fully debriefed as to the purpose of the study, and reimbursed for your time and expenses.
**What does the study involve?**

This study involves testing on two separate days. Furthermore you would be asked to abstain from smoking on both of the days **from midnight before the testing day until about 6 pm of the following day**. You would have to wear a nicotine patch and use nicotine nasal spray on one day and a placebo patch and use placebo nasal spray on the other day from the morning until the afternoon. You would not be made aware at any point of the order in which you receive placebo or active patches and spray. The placebo patches would contain colloidal silicone dioxide IP/BP/EP, polyacrylate adhesive-04 I.H, butylated hydroxy toluene IP/BP, D&C red 17 (CI26100) I.H, ethyl acetate BP, backing membrane (PET Film) I.H. and siliconized coated PET Film I.H. and the nasal spray would contain sodium dihydrogen phosphate dehydrate, disodium phosphate dodecahydrate, colloidal silicone dioxide, polysorbate 80, methyl paraben, propyl paraben, disodium edetate, sodium chloride, anhydrous citric acid, beta-ionone and purified water.

Testing at the site would involve completing four computer-based tasks. One of the tasks would use equipment to measure your eye-movements whilst doing a reaction time task. Furthermore you will be required to complete a memory task, a decision-making task and another reaction time task. After testing you would be equipped with a mobile device and will be shown how to use it. You would then be free to leave the testing site. You would be required to answer several questions about your smoking behaviour on the device, which you should answer as soon as possible after receiving a prompt to do so.

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

You might experience discomfort during the abstinent session due to the acute tobacco abstinence. This will be comparable to any discomfort experience in a regular attempt to stop smoking for a similar period.

**What are the side effects of any treatment received when taking part?**

Side effects such as headaches, dizziness or an upset stomach can be experienced when using nicotine replacement therapy. None of the side effects are expected to be seriously harmful or dangerous.

**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 underlying mechanisms of tobacco withdrawal. This is important in order to develop novel treatments to aid smoking 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).
**Will my taking part in this study be kept confidential?**

Any personal information and research study documentation taken for this research study would remain confidential and would be available only to university research staff and government bodies which monitor whether research studies are performed properly.

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

When the study has been completed, we would analyse the 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.

Your study data will be anonymised. This means that it will be given an identification number and any identifying information about you will be removed. Therefore, it will not be 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.

**What is open data?**

Open data means that 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 up until the point the data are shared as “open data” (whichever comes first). At this point links between your identify 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 part of an ESRC-funded PhD project with co-funding from Rusan Pharma Ltd, who are also providing and manufacturing the nicotine patches and matching placebo as well as the nicotine nasal spray and matching placebo.

**Who has reviewed the study?**
This study has been reviewed and approved by the Faculty of Science Research Ethics Committee at the University of Bristol (ethics approval code: 06081521803).

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.