

## **INFORMATION FOR PARTICIPANTS**

### **Effects of trait and state anxiety on the processing of facial expressions of emotion**

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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 will 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 research study?**

Emotional processing is something that we do whenever we come into contact with other people. It is altered in many psychiatric disorders and is associated with poor social function. Anxiety can affect many aspects of cognition and behaviour, including emotional processing. However, anxiety can either be a personality-like feature of the self (trait) or be a temporary increase in arousal as a result of feeling threatened or under pressure (state). We all experience state anxiety at various points in our lives, even if we are low in trait anxiety. While there are many studies looking at the effects of trait anxiety on behaviour, there are far fewer looking at state anxiety.

This study will address this by manipulating state anxiety using the carbon-dioxide (CO<sub>2</sub>) model of anxiety induction. The carbon dioxide challenge involves two 20-minute inhalations medical air (placebo) and of air that has a higher level of CO<sub>2</sub> concentration (i.e., 7.5%) than normal. In healthy volunteers this makes some people feel anxious and tense and reduces feelings of being relaxed and happy. It also increases blood pressure and heart rate.

We plan to recruit healthy male and female volunteers, aged between 18 and 50 years, with different levels of trait anxiety. The study will involve one study session that will include two 20-minute inhalations (i.e., 7.5% CO<sub>2</sub> enriched air and normal air [placebo]). During each inhalation participants would complete computer tasks in which they would identify the emotion present in a series of faces. The inhalations would last for the duration of the computer test, but no more than 20 minutes each. This will enable us to explore how emotional processing of facial expressions is affected by stress and how this differs across people with different levels of anxiety.

#### **Why have I been chosen?**

You have been chosen since you have enquired about our studies in healthy volunteers and requested to receive this further information following reading the summary version described

in the letter of invitation, poster advertisement or following your sign up to our research database that keeps you informed of new studies.

### **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 will be given this information sheet to keep and be asked to sign a consent form at the start of the session. 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, will not affect your future or be held against you in any way.

### **How do I take part?**

If you are interested in taking part you should go a website (link below) and complete the screening form. We ask you to do this to test basic eligibility. This helps to ensure that we do not waste your time by inviting you to the laboratory if there is a reason why you cannot take part. This will take about 7 minutes. This will involve a series of yes/no answers regarding your general health. You do not need to give any details of your medical history. Anything you do decide to disclose will be kept confidential and will only be available to researchers directly involved with the study. After you submit the form, a researcher will email and tell you if you are eligible, and if so will arrange a study session with you.

The screening form can be accessed at this website:

<https://exppsy.onlinesurveys.ac.uk/trait-anxiety-inventory-2>

If you are not eligible for this particular study on the basis of this questionnaire, the questionnaire will be destroyed and no information about you would be retained. The researcher will contact you and let you know and will also pass you information of similar studies that you may be eligible for.

### **How do I know if I am eligible to take part?**

You should be generally healthy, have no history of or current asthma or migraine, and have no present or past anxiety disorder or other mental health problem. You should be registered with a General Practitioner (GP). You should not take part if you or a close member of your family suffers from regular panic attacks or has been diagnosed with panic disorder. Your alcohol intake should not be more than 35 units\*/week if female or 50 units\*/week if male. You should have a BMI (body mass index) within a healthy range. You should not be a daily smoker. You should not have recently used illicit drugs. No other medication should have been used in the preceding 8 weeks, apart from occasional aspirin or paracetamol, or local treatments. Females should be using adequate methods of contraception and should not be pregnant or breast feeding, or considering becoming pregnant. A pregnancy test will be performed prior to entry into the study. Due to the nature of the task, you should be a native English speaker.

\*One unit equals one 25ml single measure of spirit (ABV 40%), or a third of a pint of beer (ABV 5-6%) or half a standard (175ml) glass of red wine (ABV 12%).

In addition to the list above, we require participants to be within certain ranges on our anxiety scale. You may fall outside of these ranges and not be eligible. We will calculate this from the form you submit to us and we will let you know if you fall outside our required range. If this is the case, you are likely to be eligible for our other anxiety studies and the researcher will let you know if that is the case. You would be sent a separate information sheet for that study if you are interested and if places are still available.

Please contact us if you are unsure if you would be eligible or if you have any questions. If you are found to meet our list of entry criteria, then you will be entered into the study.

### **What do I have to do on the study day?**

YOUR TIME COMMITMENT IN THE RESEARCH STUDY IS AS FOLLOWS:

Prior to the testing session you should refrain from alcohol for 36 hours. You should not drink any caffeinated drinks after midnight prior to the day of testing. This is because alcohol and caffeine have effects of their own on blood pressure and heart rate measurements and alcohol may enhance the effects of the gas. However, exception from this is if you regularly ingest caffeine in the morning. If this is the case, you should have your usual caffeinated drink to avoid withdrawal effects during the study. You should not be a regular (i.e., daily) smoker and should not have smoked within 12 hours of the study session.

You would be required to attend one test session of approximately 2.5 hours. You would remain seated in a comfortable position throughout the testing session. On arrival, we would continue a screening procedure to make sure that you are in good health and that you fit the inclusion criteria of the study. You would be required to give breath samples to measure alcohol and recent smoking, and you will be required to provide a urine sample to screen for any illicit drugs that you may have taken and for pregnancy in females. We will also measure your height and weight to calculate your BMI and take your blood pressure and heart rate. The results will be kept confidential and not passed to any third party.

You would then complete some questionnaires to measure how you are feeling. Measurements will be taken shortly after you arrive and once you are comfortable. Your heart rate and blood pressure would also be taken periodically. During the test session you would undergo two inhalation procedures (one 7.5% CO<sub>2</sub>-enriched air and the other normal [medical] air). These inhalations would last for the duration of the computer tasks, which would be no more than 20 minutes for each inhalation. The physiological measures (i.e., heart rate, blood pressure) and questionnaire measurements will be taken before and after each inhalation, and there will be a rest period between inhalations.

The gas inhalations will be administered through a mask, which covers your mouth and nose. This will be fitted prior to inhalation of the gas to enable you to become accustomed to wearing it. You will then wear the mask during the inhalation. During each inhalation you would be required to complete computer tasks where you will be asked to identify emotional expressions in a series of facial images.

Any effects of the gas inhalation are temporary, and at the end of the study session you will remain in the testing room until you feel that any effects of the gas have worn off and a taxi home will be provided if necessary. We will contact you the day after the study day to check that you are healthy and well. At the end of the test session you would receive £20 reimbursement for your time.

### **What are the gas mixtures being delivered?**

The CO<sub>2</sub> gas is a mixture of carbon dioxide and air, with the air containing the usual amount of oxygen (i.e., 21%). However, this gas contains more CO<sub>2</sub> than normal – 7.5% compared to less than 1% in normal air. The placebo gas will be medical air (or normal air) that is administered via a mask in the same way as the 7.5% CO<sub>2</sub>.

### **What are the side effects of the gas treatments?**

Carbon dioxide inhalation may cause feelings of suffocation, anxiety, unpleasantness or fear. Other physiological effects that may occur include racing of heart, dizziness, pins and needles, and breathlessness. Some people also experience a headache afterwards.

People experience and describe the effects of inhaling 7.5% CO<sub>2</sub> gas in different ways, and there is no way of knowing in advance how you will respond. Some people do not notice it at all, and some experience more marked anxiety. Most people will notice some effects, and if you do not like the effects you can ask to stop. These feelings should be short-lived and would not cause any lasting harm.

The researcher would remain near you at all times and will offer reassurance if necessary. If you feel uncomfortable breathing the gas at any time during the procedure you may indicate that you wish the procedure to stop.

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

Pregnant women should not take part in this study, and neither should women who plan to become pregnant. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. You should not take part if you have any medical condition, or have been advised to avoid stress.

If we find any clinical abnormality or medical condition during the screening process, if deemed appropriate, we shall inform your GP who will advise any relevant further tests or treatment.

Your life insurance or private medical insurance could be affected by taking part and if you have private medical insurance you should check with the company before agreeing to participate.

### **What are the possible benefits of taking part?**

You will not expect to 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 and treat patients with anxiety disorders in the future.

### **What if new information becomes available?**

We do not expect any information about the effects of the inhalation procedure to become available, but if this happens this information will be passed on to you immediately.

### **What if something goes wrong?**

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 Angela Attwood or a member of the Research and Development team at the University of Bristol. In addition the normal National Health Service mechanisms should be available to you.

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

Any medical information and research study documentation taken for this research study will remain confidential and will be available only to university research staff and government bodies which monitor whether research studies are performed properly. It will not be possible to identify you by name for any aspect of documentation or reporting for this research study.

### **What if incidental findings arise from the screening process?**

This is not a medical or diagnostic screening, however, very occasionally when a healthy volunteer is screened in this way, unexpected potential abnormalities are discovered and, if

appropriate your GP will be contacted. The staff that do the screening in this research study do not have expertise in medical diagnosis, as they do not have the relevant specialist medical training. As a result of this we will ask you to provide contact details of your GP.

### **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 be made “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?**

The study is being organised and funded by the University of Bristol.

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

The Faculty of Science Research Ethics Committee have reviewed and approved the study.

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

For further queries, contact Dr Angela Attwood at [Angela.Attwood@bristol.ac.uk](mailto:Angela.Attwood@bristol.ac.uk) or by phone 0117 331 7814. If you participate in this study you will be given a copy of this information sheet and a signed consent form to keep.

