**Participant Information Sheet**

**Study Title: Evaluating the CO2 experimental model of anxiety in immersive Virtual Reality**

**Researchers**: Neslihan Özhan, Prof Matthew Garner, Dr Erich Graf, Diana Herlea

**ERGO number: 48138**.A3

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

Anxiety disorders are more common than many other psychiatric disorders, and individuals with anxiety often experience reduced quality of life. Research has shown that using the inhalation of 7.5% CO2 for 20 minutes can make healthy volunteers temporarily feel anxious and tense and can reduce feelings of being relaxed and happy. It also temporarily increases blood pressure and heart rate.

In this study we will evaluate the effects of the CO2 inhalation during exposure to social situations within virtual reality. Specifically, we will measure levels of anxiety during +/- CO2 +VR exposure to social environments on subjective anxiety, autonomic arousal and social performance in a subsequent presentation task (conducted within VR).

**Why have I been asked to participate?**

You have been invited to participate since you have enquired about our advertised studies.

**What will happen to me if I take part?**

There are two main parts to the study:

1. **10-minute telephone screening**

Before entering the research study, the researcher will contact you and ask specific questions about your physical and mental health, to check that you are eligible to take part in the study. This should take no longer then 10 minutes and will be arranged at your convenience. All information will remain confidential. As part of the study, we will ask for some personal information regarding your health and wellbeing, and demographic information (e.g. race, gender). If you do not want to answer any of those questions, please remember that you are free to withdraw at any time.

You should be generally healthy, have no history of or current asthma, migraine, seizures, cardiac illness, kidney disease, myasthenia gravis or gastrointestinal disease, and have no present or past anxiety disorder or other mental health complaint. You should not take part if 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 recommended guidelines; 28 units per week (males), or 21 units per week (female). Note that one unit of alcohol equals one 25ml single measure of whisky (ABV 40**%**), or a third of a pint of beer (ABV 5-6**%**) or half a standard (175ml) glass of red wine (ABV 12**%**).

You should not be a regular smoker (more than 6/day). 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 be considering becoming pregnant. You will be notified later by email about your eligibility of the study. If you meet our list of entry criteria, then you will be invited to enter the study. Else, you will be debriefed by email.

1. **Laboratory session**

On confirming your eligibility, you will attend our lab at the University of Southampton.

You will complete some questionnaires that ask about your physical and mental health. Throughout the lab session we will take several measures of your current mood (short questionnaires), blood pressure and heart rate (arm cuff). The study will involve wearing a Fitbit activity monitor (Fitbit Charge 2) throughout the experiment to measure heart rate. The 20-minute gas inhalations will be administered through a mask, which covers your mouth and nose.

You will be randomised to take part in one of four experimental conditions. During the experiment, you will be asked to inhale either CO2 or air while exposed to a virtual environment that is presented through an Oculus Rift headset. After the inhalation you will be asked to give a 5 min presentation in virtual environments while wearing the Oculus headset. During this phase, you will be audio-recorded so that we may later transcribe and analyse the results. Your mood before and after your presentation will be measured. Please remember that you are free to withdraw at any time.

All the procedure including the telephone screening should last 3 hours maximum

Any effects of the gas inhalation are temporary and typically resolve within a minute after inhalation. At the end of the lab session you will remain in the lab room until you feel that any effects of the gas have worn off.

Prior to the testing sessions you should refrain from alcohol for 36 hours. You should not drink any caffeinated drinks after midnight prior to the lab day. 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, the 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.

We will contact you within 24 hours after the lab day to check that you are healthy and well.

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

The 7.5% CO2 gas is a mixture of carbon dioxide and air, with the air containing the usual amount of oxygen. The air will be normal/medical air that is administered via a mask in the same way as the CO2 inhalation.

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

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

People experience and describe the effects of inhaling 7.5% CO2 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 (typically resolving within a couple of minutes) and would not cause any lasting harm.

The researchers will always remain near you 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 if new information becomes available?**

Any new information about the effects of the inhalation or VR procedure (that becomes known within 12 months of the end of the study) can be passed on to you using the contact details that you have provided (contact details will be stored in a separate password protected file).

**Are there any benefits in my taking part?**

Psychology students will also be eligible to receive up to 36 research participation credits. Participants who complete the study will be able to receive £20 if they are not receiving credits.

Beyond this you should not expect to directly benefit from taking part in this research study. However, the information we get from this study may help us to understand and treat patients with anxiety disorders in the future.

**Are there any risks involved?**

Participants who meet any of the exclusion criteria should not take part in the study. This includes pregnant women or women who are breastfeeding, and women who plan to become pregnant. All women will therefore be asked to answer some short questions about their use of contraception to exclude the possibility of pregnancy. The screening procedure will ask participants some questions about their physical and mental health. Information about local support services will be available to any participant that is concerned about their physical and mental wellbeing.

The virtual reality headset will place you in an immersive 360-degree virtual environment. Some individuals can experience dizziness during VR. Participants will have the opportunity to stop and withdraw from the study at any point.

**What data will be collected?**

The physiological data will be collected and recorded through the head movements in VR. Heart rate and blood pressure will be recorded before and after inhalation. In addition, the continuous heart rate data from Fitbit tracker will be collected and stored behind a password-protected login. In addition, participant names or number identifiers will not be stored alongside the online activity-monitor data.

Questionnaire-based data will be collected via online survey (Qualtrics). Your personal information will not be used in the analysis or presentation of the data to ensure that they remain confidential. Audio recordings will be transcribed before being deleted. All data (self-report questionnaire, behavioural data, physiological measures and transcribed recordings) will be stored on password protected servers and accessed only by those directly involved in running the experiment or analysing the data.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

All data is anonymized and confidential. You will be assigned a unique participant number that will be used to identify your data – your name will not be linked with or stored with any of your data. Any information and research study documentation taken for this research study will remain confidential and will be available only to the principal investigator and members of the research team directly involved in the project. As a limitation to confidentiality, if you provide any information that will cause us concern about your safety and well-being, my research team and I have a duty to disclose this information with the relevant authorities.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason. You will be paid £20 (or 36 credits for psychology students from the University of Southampton) **on completion of the study.** If you withdraw from the study early, you will be paid £3 (or 6 credits) for your screening participation. In case of ineligibility during phone screening, NO credits/payment will be given.

You might wish to withdraw from the study at any point. If you withdraw from the study, we might keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only. However, you can request full deletion of your online and/or stored data if you wish within A WEEK OF PARTICIPATION (You can contact Nesli Ozhan at [n.ozhan@soton.ac.uk](mailto:n.ozhan@soton.ac.uk) for such request). After that I won’t be able to match your data with your personal identifying information which makes the data deletion impossible.

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

When the study has been completed, the research team will analyse the data and report the findings. The results will be included in research reports written by members of the research team, including research student projects and papers for publication/presentation at scientific conferences. You would not be identified in any way and if you would like a copy of the final paper, you may request this.

**Where can I get more information?**

For further queries, please contact Nesli Ozhan at [n.ozhan@soton.ac.uk](mailto:n.ozhan@soton.ac.uk)

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers (Neslihan Özhan at [no1y17@soton.ac.uk](mailto:no1y17@soton.ac.uk), Matt Garner at [M.J.GARNER@soton.ac.uk](mailto:M.J.GARNER@soton.ac.uk) and Erich Graf at [E.W.GRAF@soton.ac.uk](mailto:E.W.GRAF@soton.ac.uk) who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, [rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

**Thank you for taking time to read the information sheet and considering taking part in the research.**