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Participation Information Sheet

Virtual Reality Cycling at High Altitude. An investigation in International Trekkers to understand the symptoms of high altitude

Thank you for your interest in our study. Before you decide to take part, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. *If there is anything that is not clear, or if you would like more information, please ask us.*

What is the purpose of this study?

We know at altitude that the air is thinner and this makes people breathless, and can make them sick (acute mountain sickness). We also know that the brain plays an important role in regulating breathing and perceiving symptoms.

We are trying to find out to what extent the brain plays a role in the symptoms of high altitude. In this study, we are asking people to exercise on a static bicycle while wearing a virtual reality headset, and basic monitoring equipment to measure your vital signs. During the task we will change the virtual terrain, how hard it is to cycle. We will be interested in how breathless you feel when cycling and how much effort you perceive. We will also ask you some questions about your mood and measure your heart rate and oxygen saturations. Participation will be during one visit and will last between 1.5-2 hours.

Where is this study taking place?

This study will take place at our research station at high altitude on the Mount Everest Trail.

Why have I been invited?

You have been invited to consider taking part in this study because you are 18 years or older who normally lives below 1000m altitude above sea level that can comfortably ride a bicycle.

You must not have any of the following: significant cardiac disease (e.g. heart failure, pacemaker), significant neurological disease (e.g. stroke, neurodegenerative disease), significant psychiatric disease (active treatment under psychiatric care), significant metabolic disease (e.g. uncontrolled insulin dependent diabetes), inadequate understanding of verbal

and written information in English, history of prescription & non-prescription drug dependency (including alcoholism), previous history of cardiac tachyarrhythmia (irregular fast heart beat).

You must also not be currently suffering, or think you may be suffering, from high altitude cerebral oedema (HACE), high altitude pulmonary oedema (HAPE) or severe acute mountain sickness.

Do I have to take part?

No - taking part in this study is voluntary. Please read this information sheet carefully and contact us if you have any questions. You are free to withdraw at any time, without giving a reason. If you are happy to take part, then please contact us using either the email address or telephone number on the study poster. Alternatively you may visit us in person at our research station.

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

If you decide to take part, you will have to stop by our research station. During your visit, you will be asked to fill in some questionnaires, and complete a cycling task on a static bike whilst wearing a virtual reality headset and basic monitoring equipment. Please avoid vigorous exercise and eating large meals in the 4 hours before the session. We also ask that you bring or wear clothes that you are comfortable to exercise in as well as enclosed shoes such as trainers. The session will take between 1.5- to 2 hours and will include:

1. **Medical assessment** – We would like to collect some personal details, such as age, height, and weight and ask you your medical history (including medications).
2. **Questionnaires** – We will ask you to complete a set of questionnaires that are designed to assess your general mood, how immersive and tolerable you found the session, symptoms of high altitude and how you perceive bodily sensations. We will also ask for any feedback you might have about the virtual reality application so we can improve it in the future.
3. **Cycling tasks** – You will be asked to cycle on a static bicycle, whilst wearing a virtual reality headset. During this task, we will ask you how hard you are finding it to cycle and how breathless you feel. The exercise effort will be set as a percentage of your own capacity and so should not be unpleasant. During the task we will record your heart rate oxygen levels using a finger monitor.

Are there any possible disadvantages or risks from taking part?

Virtual reality has been shown to make some people dizzy. This rapidly resolves once the headset is removed. If at any point you become dizzy then we will help you remove the headset and you may stop the session should you wish to.

What are the possible benefits of taking part?

There is no direct benefit to you if you take part in this study. We hope that the information we get from this study may help us to better understand human physiology at altitude.

What happens to the data provided?

The information you provide during the study is **research data**. Any research data from which you can be identified such as your name and contact details is known as **personal data**.

Personal / sensitive data will be stored on encrypted devices whilst in Nepal, and uploaded to secure servers at University of Oxford facilities for the duration of the study.

Other research data (including consent forms) will be stored 5 years after publication or public release of the work of the research. At the start of the study you will be assigned a unique identifier. This will be used instead of your name to identify your data.

The researchers and or supervisor will have access to the research data. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research. We would like to use anonymised data in future studies, and to share data with other researchers (e.g. in online databases). All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

Will I be reimbursed for taking part?

To thank you for taking part we would offer you the cash equivalent of a coffee and cake at the local cafe.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason. A decision to withdraw or to not take part will not affect you in any way. If you withdraw from the study any data collected will be anonymised as described above and may still be used for research purposes unless you request otherwise.

What will happen to the results of this study?

We aim to publish the results of this study in a scientific journal. We may also present the results at a scientific conference, at a seminar in a university or on our website.

We will be happy to discuss the results of the study with you and to send you a copy of the published results. It will not be possible to discuss your individual results with you or to identify you in any report or publication.

What if there is a problem?

If you have a concern about any aspect of this study, please contact Dr Kyle Pattinson via email: kyle.pattinson@nda.ox.ac.uk and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rgea.complaints@admin.ox.ac.uk or on +44(0)1865 616480. You may also contact the Nepal Health Research Council (NHRC), Ramshah path, Kathmandu, Tel.: +977 425 4220 (Ext no 125), approval@nhrc.gov.np, ethicalreviewb@gmail.com,

Our ability to address queries in a timely fashion may be limited whilst we are in the field in Nepal.

Who is organising and funding the study?

The study is organised and sponsored by the University of Oxford. The study is funded by the Birmingham Medical Research Society Trust Fund, administered by the JABBS Foundation

Who has reviewed the study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Tropical Research Ethics Committee (OxTREC reference:545-24), and also by the Nepal Health Research Council (NHRC)

Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study.

The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest.

Further information about your rights with respect to your personal data is available from <https://compliance.web.ox.ac.uk/individual-rights>

Further information and contact details.

You should contact Dr. Kyle Pattinson or Dr Santosh Banyia for further information. You can contact Dr Pattinson via email kyle.pattinson@nda.ox.ac.uk or by telephone +44 (0)1865 231509. You can contact Dr Baniya via email baniyasantosh@iom.edu.np or by telephone +977-9851 231 372

Thank you for reading this information sheet.