NUFFIELD DEPARTMENT OF CLINICAL NEUROSCIENCES

West Wing, Level 6
John Radcliffe Hospital, Oxford, OX3 9DU
www.ndcn.ox.ac.uk www.ndcn.ox.ac.uk/research/respiratory-control

**Dr Kyle S Pattinson DPhil FRCA**
**Tel**: +44(0)1865 231509 **Email**: kyle.pattinson@ndcn.ox.ac.uk

## PARTICIPANT INFORMATION SHEET

# Breathlessness in a virtual world

We'd like to invite you to take part in our research study. Before you decide, 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 the study?

Chronic breathlessness is a life limiting condition that is often very difficult to treat, particularly when for some people their feelings of breathlessness do not match the physical status of their lungs. We know that breathlessness is not just about the lungs but also about the brain. Therefore, it may be that, for some people, over time the senses become mismatched leading to unexplained breathlessness.

We want to investigate the role of the brain in creating this mismatch using virtual reality technology and are asking healthy volunteers and people with asthma to visit us at the University of Oxford for one 2-hour session.

In this study we are asking people to exercise on a static bicycle while wearing a virtual reality headset. Over the course of each session we will change the virtual terrain, how hard it is to cycle and your own breathing sounds, which may be played back to you via headphones. We will be interested to know how immersive you find the session and how breathless you feel when cycling. We will also ask you some questions about your mood. Additional measurements may be taken, the exact combination of which will depend on the stage of the study. These measurements could include your lung volumes and exhaled air (measuring levels of oxygen and carbon dioxide), heart rate and rhythm, blood pressure, oxygen levels, height and weight.

By combining the results of these tests, we will establish whether exercising in virtual reality is feasible and whether changing feedback from the virtual world affects how you feel and perform in the real world. We will also find out whether people with chronic breathlessness conditions such as asthma experience breathlessness in the virtual world differently to those people who do not live with breathlessness.

### Why have I been invited?

You have been invited to consider taking part in this study because you are healthy, aged 18 years or over and are able and comfortable riding 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. 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).

**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. If you are happy to take part, then please contact us using the details provided and we can answer any questions or arrange a convenient time/date for your visit. You are free to withdraw at any time, without giving a reason.

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

If you take part, you will be asked to visit us at the University of Oxford **on one occasion.** In these visits we will ask you cycle on a static bicycle while wearing a virtual reality headset. We will also ask you to complete some questionnaires and may take some additional measurements as listed below.

Please avoid vigorous exercise and eating a large meal 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.

Each session will last no more than 2 hours. All participants will complete a medical assessment, the cycling task and questionnaires. The selection of questionnaires and any additional measurements you are asked to complete may vary depending on the stage of the study or the specific research question being explored. You will be informed in advance which questionnaires and measurements apply to you.

The study procedures will include:

**Medical assessment –**We would like to collect some personal details, such as your age, height and weight.

**Questionnaires -** We will ask you to complete questionnaires that are designed to assess your general mood, and how immersive, tolerable, enjoyable and motivating you found the session. The selection of questionnaires you are given may vary depending on the stage of the study or the specific research question being explored. Questionnaires will be completed before, during and after the cycling exercise. The questionnaires to be completed before the cycling exercise will be available to complete at home via an online platform should you wish to do so before your visit.

**Cycling tasks -** You will be asked to cycle on a static bicycle while 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.

**Additional measures (may vary) –** Just before and during the cycling task additional measures may be collected depending on the stage of the study or the specific research question being explored. These may include recording your heart rate and rhythm through electrodes that stick to the skin, oxygen levels using a finger monitor, blood pressure using a cuff on your arm and breathing rate using an elastic belt across the chest. Additionally, your lung volumes as well as the oxygen and carbon dioxide levels in your exhaled breath may be measured via a cushioned face mask, an example of which can be seen in figure 1. This mask is made of plastic with an air cushioned seal around the face. If used, it will be tightened to ensure there is no air leak but not to the point of discomfort.

Figure 1. Example of cushioned face mask to be used when measuring oxygen and carbon dioxide levels in exhaled air.

**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 in the study you become dizzy then we will help you remove the headset and you may stop the session should you wish to. Some people may find the mask that measures exhaled air unpleasant. If at any point this is the case and you want to remove it we will help you to do so 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 asthma.

**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 securely in locked cabinets in University of Oxford facilities for the duration of the study and for up to 5 years after study closure if you consent to be contacted regarding future studies. If you do not consent to be contacted for future studies we will destroy your personal information upon study completion.

**Other research data** (including consent forms) will be stored for at least 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 researcher 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 your permission 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.

You can find out more about how we use your information by contacting the University's Data Protection Officer at data.protection@admin.ox.ac.uk.

**Will I be reimbursed for taking part?**

If you take part in this study you will receive £20 for your time and reasonable travel expenses will be reimbursed for each session.

**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.

**What will happen to the results of this study?**

We may 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 or by phone 01865 231 509 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 the University of Oxford Research Governance, Ethics & Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on +44 (0)1865 616480.

**Who is organising and funding the study?**

This study is sponsored by the University of Oxford and is running from within the Nuffield Department of Clinical Neurosciences, which is part of the University of Oxford and is based at the John Radcliffe Hospital. It is being funded by the Oxford Biomedical Research Centre.

**Who has reviewed the study?**

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Ethics Ref: R68447/RE007).

**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 http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

**Participation in future research:**

We may wish to get in touch with you in the future about other ethically approved research projects. If you consent to this future contact you are not obliged to take part in any future project. Your participation is completely optional.

**Further information and contact details:**

You should contact Dr. Kyle Pattinson for further information. You can contact Dr Pattinson via email kyle.pattinson@nda.ox.ac.uk or by telephone 01865 231509.

*Thank you for reading this information sheet.*