

## **PARTICIPANT INFORMATION SHEET**

**Central University Research Ethics Committee Reference: R72015/RE001**

### **UNIVERSITY OF OXFORD STUDY: “FACE MASKS and EXERCISE”**

*Thank you for your interest in taking 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 contact the study team using the details below.*

#### **Why is this research being conducted?**

We are a group of research scientists at the University of Oxford seeking to determine the impact of wearing face masks during aerobic exercise, for example during a run, bike ride or row. This study is of vital importance to inform policymakers as they make decisions related to the easing of lockdown measures in England during the COVID-19 pandemic. The UK government outlined measures to enable indoor gyms and sports facilities to re-open on 25 July 2020. The current guidance states that “all forms of face coverings may restrict breathing efficiency and should not be used during exercise except on specific advice from a physician”. This is in contrast to the wider public health advice to wear face masks in public indoor settings with the aim of reducing transmission of the COVID-19 virus. We seek to measure the impact face masks have on the oxygen levels of fit and healthy young adults during exercise.

#### **What is the purpose of the study?**

The purpose of this study is to determine whether wearing a face mask during exercise causes healthy volunteers to have a lower level of oxygen in the bloodstream, alters peoples’ heart rates, or causes other symptoms such as breathlessness or headaches. We also want to know whether people find wearing a face mask impacts on comfort and ease of exercise when compared to exercise without a face covering.

#### **Why have I been invited?**

We are seeking fit and healthy 18-35 year old volunteers willing to partake in this trial. You must currently be living in the United Kingdom to be eligible to take part.

#### **Do I have to take part?**

No. You can ask questions about the research before deciding whether or not to take part. If you do agree, you may withdraw yourself from the study, without giving a reason and without

negative consequences, by advising the study team of this decision. If you decide to withdraw during the exercise session, we will record your reason for doing so. We will also retain any anonymised results recorded up to that point. If you wish to withdraw having completed the entire exercise session we will retain your anonymised results for inclusion in our analysis but will delete all other information we hold about you.

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

If you would like to take part you will need to submit an expression of interest via our website (<https://www.phc.ox.ac.uk/research/participate/face-masks-and-exercise/view>). At this stage we will ask some basic information about you to check that you are eligible to be in the study and also to allow us to get in contact directly via email. If you are selected to take part, we will contact you to arrange a time for the study session and provide details of what you will need to do on the day. If you have expressed an interest in the study but we do not think you are eligible or we have already recruited sufficient people we will contact you via email to let you know.

The study session will take place at your local university sports centre or a local park, taking into account any local government rules or restrictions on indoor exercise that might be in place at the time. A range of times will be available. You will be asked not to complete the study visit if you are unwell with a fever, cough, notice a change in your sense of smell or have other symptom of an acute illness to minimise the risk of COVID-19 spread. You will be asked to wear a face covering to the session, keep a physical distance of two metres at all times and be provided with alcohol hand gel on arrival to wash your hands.

The researcher will wait for you at reception to the sports centre or meet at a pre-arranged point in the park and hold a sign so they are identifiable. They will confirm your identity, check your understanding of what will take place during the session and offer you written information detailing the study session. At this stage you will be asked to complete an online consent form, documenting your agreement to participate in the study, if you are still happy to do so.

During the study visit you will be asked to exercise, either by running, cycling or rowing, up to when the exercise feels strenuous – typically a heart rate of approximately 200 beats per minute minus your age (e.g. a 25 year-old will exercise such that their heart rate sustains at 175bpm). You will undertake the exercise four times for 15 minutes each time – wearing three different types of mask and once without a mask. The masks will be one tight fitting mask, one soft surgical mask, and one cloth mask. These masks will be provided by the member of the study team on the day.

In between each bout of exercise you will be given 5 minutes to recover without wearing a mask or exercising. If you feel unable to continue at any point during the exercise you are free to stop and remove the face mask. At that point, you could either decide to end the study or you could opt to try again with one of the other face masks or no mask, depending on what you have left to do.

We will measure your pulse rate and oxygen levels at the start of the session before you have done any exercise. We will measure these again at the mid-point, at the end and 1 minute after completion of each 15 minutes of exercise using a monitor, which you wear on your finger. This is easy to take on and off, and harmless. We will also record how far you travel and your average speed using a simple smartphone app. We anticipate you will be

Participant information form

Version 1.0 / Date 8.4.2021

*Face masks and exercise study*  
*Professor Trisha Greenhalgh*

able to complete the exercise in under 90 minutes in a single session. You will be asked to then complete an online survey, which will ask questions about the difficulty and comfort of exercising with each mask on. No further involvement is required beyond this.

### **What should I consider?**

The main thing to consider is whether you are willing to try exercising whilst wearing a face mask and to record your oxygen levels and heart rate using a finger-tip device. Some people are fine about this while other people may feel uncomfortable at the thought of exercising whilst wearing a mask.

### **Are there any possible disadvantages or risks from taking part?**

It is possible that you will feel claustrophobic wearing the mask or more short of breath than you would usually whilst exercising. When the study team tried this they did not find this to be the case, but this does not mean you will not. If you feel unwell at any point you are free to stop and take the face mask off, which should lead to a rapid recovery. We do not anticipate there being a serious risk to your health in exercising in this way but if you do not feel better following removal of the mask and rest, the research team will help you in getting the appropriate medical assistance.

You will be required to commit around 90 minutes of your time to complete the exercise. You will be asked to provide some basic information about your general health and wellbeing. This will be seen by the research team but any personal information that could identify you will not be passed on to any third party or included in publication of the results or research.

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

You can stop at any time. Participation is voluntary and even if you originally said yes, you may change your mind at a later stage. If you withdraw from the study, unless you state otherwise, any information relating to you and the exercise completed that has been collected will be used for research as detailed in this participant information sheet. The results we collect relating to your exercise will be anonymous, so once you have supplied these they cannot be withdrawn. However, you are free to request that your personal data are destroyed at any time during or after the study.

### **What if you find something unexpected?**

If anything happens during the exercise that has a bearing on your future clinical care (for example if you disclose to us that you have a new symptom), we will discuss this with you but suggest you inform your GP as appropriate.

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

The main benefit of taking part is this is an opportunity for you to contribute to improving our understanding of how face masks impact people during exercise. Findings from the study could be used to inform changes to government policy and guidance in the wake of the COVID-19 pandemic. There will be no direct or personal benefit to you from taking part in this research.

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

No, we are not able to reimburse people for taking part in this study. We hope that you will be able to complete the single study visit close to home and without you incurring any

significant travel or expenses. We are extremely grateful to all people who volunteer their time to help with the study.

### **Will my General Practitioner/family doctor (GP) be informed of my participation?**

No, this is a standalone, voluntary study and we will not be liaising with your GP about your participation in the study.

### **What will happen to my data?**

The information you provide during the study is the **research data**. Any research data from which you can be identified, including your name, address and email is known as **personal data**. The expression of interest and consent forms are considered personal data. The exercise data you supply will not include identifiable information and therefore are considered research data.

The **personal data** you provide in the expression of interest form will be stored on a secure, password protected and networked computer at the University of Oxford for three years. Other **research data** will also be stored in separate password secured files. All research data reported from the study will be de-identified, meaning it will not be possible to link research records back to individuals once collected.

We will keep the research data (including consent forms) for up to five years after publication or public release of the work of the research. Once these are completed, all data will be destroyed.

The research team 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 study to ensure that the research is complying with applicable regulations.

### **Will the research be published?**

Our research team will analyse the data and write some papers and reports, including a 'lay summary'. We aim to publish the results in at least one academic medical journal but will also write linked blogs and promote results via social media. We will provide you with a summary of the findings if you would like us to. You will not be identified from any report or publication placed in the public domain.

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

The study team is led by Professor Trisha Greenhalgh, a GP who works at the University of Oxford; she is also custodian of the study information. Professor Greenhalgh's research is supported by Oxford NIHR Biomedical Research Centre (grant no BRC-1215-20008).

### **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 (Reference number: R72015/RE001).

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

If you have a concern about any aspect of this study, please contact Professor Trisha Greenhalgh whose details are given below, or Professor Richard Hobbs (Head of Department, University of Oxford Nuffield Department of Primary Care Health Sciences;

Participant information form

Version 1.0 / Date 8.4.2021

*Face masks and exercise study*  
*Professor Trisha Greenhalgh*

[richard.hobbs\\_pa@phc.ox.ac.uk](mailto:richard.hobbs_pa@phc.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 the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**; Email: [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk); Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

### ***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/>.

### **Further information and contact details:**

Please contact the following individual if you would like further information.

Professor Trisha Greenhalgh (Chief Investigator)  
Nuffield Department of Primary Care Health Sciences  
University of Oxford  
Radcliffe Primary Care Building  
Woodstock Rd  
Oxford OX2 6GG  
01865 617835  
[trish.greenhalgh@phc.ox.ac.uk](mailto:trish.greenhalgh@phc.ox.ac.uk)

*Thank you for considering taking part.*