

## **PARTICIPANT INFORMATION SHEET**

### **THE EFFECT OF AN ACUTE BOUT OF EXERCISE ON VITAMIN D STATUS IN ADULTS**

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This information sheet forms part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. Please read this information sheet carefully and ask one of the researchers named above if you are not clear about any details of the project.

#### **1. What is the purpose of the project?**

Vitamin D deficiency is a public health concern here in the UK, with an estimated 30 - 40% of the UK population said to be vitamin D deficient from October to March. This is because our main source of vitamin D is from the sun and during these winter months, the sun in the UK is not strong enough for our bodies to make sufficient vitamin D. Although the food we eat provides us with some vitamin D, this tends to be a small amount and is usually not enough to meet our requirements alone.

Interestingly, most people have quite a lot of vitamin D 'trapped' in their adipose tissue (body fat). Recent research indicates that physical activity may be able to 'unlock' existing stores of vitamin D trapped in fat tissue and move it into the blood so it can be utilized by the body for several important functions. These include



keeping our bones healthy, helping to reduce inflammation, helping cells to grow and keeping our immune systems healthy to name a few.

This study will aim to investigate whether (and to what extent) just a single bout of endurance exercise may mobilize vitamin D from fat stores and increase vitamin D levels in the blood.

## **2. Who can be a participant?**

In order to participate in this study, you must satisfy all of the following criteria:

- ✓ Aged 25 to 65 years old
- ✓ Healthy (See Exclusion Criteria)
- ✓ Non-smoker

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

It is completely up to you to decide if you would like to participate. Before you decide to take part, we will describe the project and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. However, if at any time you decide you no longer wish to take part in the project you are free to withdraw, without giving a reason.

## **4. What will I be asked to do?**

We will ask you to attend the laboratory at the University of Bath on six occasions in total (which includes an initial screening meeting). If you are driving to the University, we will provide you with Parking Permits for each visit. We would advise you to attend the visits in comfortable clothing suitable for exercising. We have included a summary of what you can expect during each of the visits.

### **Visit 1**

This initial screen session will help us determine whether you are eligible to participate in the study. This visit will last approximately 1 hour. This visit will involve talking through the study which will include checking your eligibility to participate against the inclusion and exclusion criteria, answering any questions you may have and filling in a health and food frequency questionnaire. If at this stage you meet the criteria and are happy to continue and provide us with consent, we will arrange further visits at this stage. At the end of your visit, we will provide you with factor 50 sunscreen and ask you to wear it if outside for the duration of the study.

It is important to note that each visit after this one will require you to arrive at the University having fasted from the night before and therefore, these visits are likely to take place during the early morning at a time convenient for yourself.

### **Visit 2**

You will arrive at the University fasted. Once in the physiology laboratory, we will firstly assess how much energy you 'use up' when your body is completely at rest. We will do this using a comfortable ventilated 'hood' which will measure the gas you breathe

out when you are at rest. This will take approximately 20 minutes. We will then take several simple measures which will include your weight, height and waist circumference /hip circumference (which will be measured using an inelastic measuring tape). Finally, we will ask you to undertake a maximal exercise test, which is otherwise known as a  $VO_{2\text{ MAX}}$  test. This test measures the maximum volume of oxygen your body can process when you're exercising. You will start by walking at a low intensity which will become progressively harder over time as the incline and speed are increased. The test will end when you feel that you have reached your maximal exercise capacity. Your heart rate will be monitored throughout the test via a strap fitted around your chest. Following this test, we will ask you to perform a short exercise session lasting approximately 15 minutes at a certain percentage of your maximal exercising capacity. At the end of your visit, we will provide you with a MotionWatch (which will monitor your physical activity levels) which we will ask you to wear for the duration of the study.

It is important to note that 24 hours before visits 3 and 5, we will ask you please **refrain from undertaking any strenuous or structured physical activity**. We will also ask you to **replicate your dietary intake and physical activity 24 hours prior to both visits**. You may find it helpful to note down what you ate the day before your 3<sup>rd</sup> visit so that you can remember. We will give you a sheet to do this but we will not be asking you to give it back to us.

### **Visit 3/ Visit 5**

You will arrive at the University fasted and once in the lab we will take a measure of your weight. During these visits, you will be prepared to undertake a second exercise session on the treadmill. This exercise session will differ slightly to the previous one in that you will not be exercising to your maximum capacity, but at a constant rate based on your abilities. You will firstly undertake a 5-minute 'warm up' on the treadmill at a comfortable walking speed before the exercise session which will last 60 minutes in total. We will monitor your heart rate via a strap around your chest for its duration.

We will also be taking 3 small blood samples during this visit; before your exercise session, immediately after your exercise session, and 1 hour after your exercise session. We will take these samples from a small, thin plastic tube that we will insert into a vein in your arm before you start the exercise session. This visit will last approximately 2 ½ hours in total. At the end of the visit, we will provide you with standardized meals which we will ask you to eat for the rest of the day. You will be asked to replicate the timings in which you eat these meals on the day of visit 3 and 5.

### **Visit 4/6**

We will schedule this visit to take place the day after Visit 3/5. This visit will be very brief and will simply involve taking a small blood sample and a measure of your weight. This visit should not last more than 15 minutes.

The duration of your participation in the study in total will be a minimum of 8 days and a maximum of 16 days, depending on logistics and your availability.

## **5. What are the exclusion criteria?**

You will not be able to take part in this study if you meet any of the following criteria:

- Current or recent use (within the last three months) of weight loss drugs, medication that would interfere with study outcomes, sunbeds, or dietary vitamin D supplementation
- Change in weight of more than 5% in the last six months, or a significant change in lifestyle in the last two months
- Positive responses to the Physical Activity Readiness Questionnaire (PAR-Q)
- Presence of coronary heart disease, chronic kidney disease, type 2 diabetes, stroke, heart failure, peripheral arterial disease, severe hypertension (blood pressure >180/110 mmHg)

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

There are no obvious direct or financial benefits of taking part in the project, however we will be able to reimburse your travel to and from the University. In addition, the information that you and the other participants provide will help us to better understand how exercise may improve vitamin D status and you will also be provided with a personalised summary of your own data from the project. We very much appreciate your time.

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

There are no obvious disadvantages to you taking part in the project. However, any vigorous physical activity causes increased risk of cardiovascular emergency above that at rest but this risk is very small in persons not exhibiting risk factors for coronary heart disease. We will be vigilant at all times in observing you performing under the prescribed exercise conditions, and we are ready to end any testing session should you feel unduly stressed, or if we think you are unduly stressed.

You may find the exercise demanding and this might be uncomfortable for a short period of time. However, these feelings of tiredness and discomfort are transient and will pass quickly. You will be familiarized with all equipment and procedures to minimize any discomfort.

*If you have any concerns at any stage, please feel free to ask any questions that you have and remember that you are free to withdraw from the study at any time.*

## **8. Will my participation involve any discomfort or embarrassment?**

We do not expect you to feel any discomfort or embarrassment if you take part in the project. If at any time you feel, or appear to be, uncomfortable then we will be prepared to end the testing immediately.

### **9. Who will have access to the information that I provide?**

Only the lead researcher (Sophie Davies) will have access to the personal information you provide, and all records will be treated as confidential, including personal contact details. When project data is collected (i.e. results from the testing), it is anonymized as described below. Anonymized data may be shared with other members of the research team during the analysis or published.

### **10. What will happen to the data collected and results of the project?**

All data collected, including personal, identifiable data will be treated as confidential, with hard copies kept in a locked cabinet in a locked room, and all other data stored on a password protected file on the University of Bath's secure server.

The only documentation in this study that includes personally identifiable information will be the consent form and health questionnaire, which will be securely stored for ten years after your completion of the study on an X-drive under password protection. This storage of data will be done in accordance with the Data Protection Act. We will have a separate secured document which links the data we collect in testing to your unique study identification code (ID). We will keep this document linking identifiable information to your unique ID for two weeks after we have given you your personalized feedback from the study. No identifying information will be disclosed in any presentation or publication of the research.

### **11. Who has reviewed the project?**

This project has been given a favourable opinion by the University of Bath, Research Ethics Approval Committee for Health (REACH) [EP 19/20 026]

### **12. How can I withdraw from the project?**

If you wish to stop participating before completing all parts of the project, you can inform one of the above identified researchers in person, by phone, or by email. You can withdraw from the project at any point without providing reasons for doing so and without consequence to yourself.

If, for any reason, you wish to withdraw your data either during participation or after you have completed the testing, please contact an identified researcher any time between your completion of the study and two weeks of receiving your personalized feedback. After this date, it will not be possible to withdraw your data as the document linking your personal details to your unique study ID code will have been destroyed.

### **13. What happens if there is a problem?**

If you have a concern about any aspect of the project you should ask to speak to the researchers, and we will do our best to answer any questions. If we are unable to resolve your concern, or you wish to make a complaint regarding the project, please contact the Chair of the Research Ethics Approval Committee for Health:

Professor James Betts

Email: [j.betts@bath.ac.uk](mailto:j.betts@bath.ac.uk)

Tel: +44 (0) 1225 38 3448

### **14. What should I do now?**

Thank you for expressing an interest in participating in this project – it really is hugely appreciated. If you feel that you are eligible and would like to participate in this study, or you would like some more information further before making your decision, please get in touch with Sophie Davies by email ([sd2175@bath.ac.uk](mailto:sd2175@bath.ac.uk)).