PARTICIPANT INFORMATION SHEET

Validation of a Fat_{max} Protocol

Project Leader: Mr Oliver Chrzanowski-Smith; E-mail: O.J.Chrzanowski-smith@bath.ac.uk

Project Supervisor: Dr Javier Gonzalez E-mail: J.T.Gonzalez@bath.ac.uk

1. What is the purpose of the project?

To develop an exercise protocol that accurately measures fat use during exercising.

A high capacity to burn fat during exercise is desirable to both athletes and the general population. High rates of fat burning are associated with high levels of fitness, and a lower likelihood of becoming overweight and/or developing diseases such as Type 2 Diabetes. We want to understand the factors that influence maximum fat use during exercise and whether maximum fat use during exercise is similar within an individual. However, before we can do this we need to test that our exercise protocol accurately measures fat use during exercise. By investigating these processes, we hope to understand how exercise and nutrition can be optimised to benefit health and weight loss.

2. Why have I been selected to take part?

You have been asked to participate because you have voluntary expressed an interest to partake and have met the inclusion criteria.

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 study 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 study you are free to withdraw, without giving a reason. This would not affect the standard of care you receive. If you decide to partake in the study, please also let us know if you are happy for us to keep your contact details (via the consent form), so we can contact you about any future studies you may also be eligible for.

4. What will I have to do?

If you decide that you would like to take part you will be asked to visit the laboratory at the University of Bath on five separate occasions within 14 days (please see below and also figure 1 four an outline of the study):

Visit 1 (approx. 10 minutes):

- You will be asked to provide informed consent to participate in the study
- Complete the screening / eligibility questionnaire
- And if eligible, an activity monitor and weighed-food diary will be given to you.

It is important to be entirely honest and point out any known health problems or medication you are taking, even if they seem trivial.

We will then organise dates and run through the procedure for the remaining four visits.

Visit 2 (approx. 40 minutes)

Upon arrival to the laboratory at a previously agreed scheduled time and after not eating for between 10-12 hours i.e. in a fasted state, you will:

1) Have your body height, weight, waist and hip circumference and body fat % measured
2) Complete a study participant questionnaire (basic demographic information)
3) Then complete a maximal cardiorespiratory fitness test (FAT_{max} test). This exercise test will last approximately 25-35 minutes and takes place on an exercise bike. The test consists of stages, where you will start at an easy speed, before the difficulty increases every four-minutes (or two-minutes if the seventh stage is past), until you feel like you can no longer carry on. During this test, we will be taking samples of expired gas via a mouthpiece.

Once the FATmax test is finished, visit 2 is complete.

Visit 3, 4 and 5 (approx. 30 minutes each)

For visit 3, 4 and 5, you will be asked to arrive to the laboratory in a fasted state (between 10 – 12 hours) at the same time (+/- 1 hour) as you did for visit 2. You will be asked to complete an exercise session that consists of completing the FAT_{max} protocol up until a predefined intensity, where you will then be asked to exercise for a further ten minutes at this specified intensity. There are three different intensities that you will be asked to exercise at for ten minutes and the order these are completed *in will be randomized*, but consist of the following:

- $FAT_{max\text{-}PRE}$: Completion of the FAT_{max} protocol up until the intensity (i.e. stage of the FAT_{max} test) that ***immediately precedes the stage*** at which your rate of maximum fat use was recorded at from visit 2

- $FAT_{max\text{-}STAGE}$: Completion of the FAT_{max} protocol up until the intensity that ***coincides with the stage*** at which your rate of maximum fat use was recorded at from visit 2

- $FAT_{max\text{-}POST}$: Completion of the FAT_{max} protocol up until the intensity that ***corresponds to the stage after*** your rate of maximum fat use was recorded at from visit 2

For example, if on Visit 2 your rate of maximal fat use was measured at stage 4 of the FAT_{max} test, on Visit 3 you may complete the FAT_{max} test up until stage 3 and then exercise for 10-minutes at the intensity corresponding to stage 3 of the FAT_{max} test ($FAT_{max\text{-}PRE}$). At Visit 4 you may then complete the test up until stage 5 of the FAT_{max} test and exercise for a further 10-minutes at this intensity ($FAT_{max\text{-}POST}$), where at Visit 5 you would then complete the test up to stage 4 and exercise for 10-minutes at this intensity ($FAT_{max\text{-}STAGE}$). *Please remember the order the 10-minute steady state sessions are completed in will be randomized and may differ to the example outlined.*

Samples of expired gas via a mouth piece will be taken throughout these exercise sessions. After the exercise session is finished, each visit is complete.

General procedures for visit 2, 3, 4 and 5

The visits can be in the morning or afternoon, but must occur at a similar time (+/- 1 hour) and you must arrive in a fasted state (between 10-12 hours). On each separate visit, you will be asked to complete the following for at least the immediate day prior to your visit:

- Wear the physical activity monitor

- Record your food and drink intake (via the weighed food diary)
- And complete a physical activity log.

This is so your physical activity levels, energy expenditure and energy intake can be monitored. You will be asked to replicate, as closely as possible, your physical activity and diet for the immediate day prior to each visit. Additionally, the day before each visit you will also be asked to:

1) Perform no physical activity (outside of the study sessions) that makes you get out of breath / significantly raises your breathing rate
2) Consume no alcohol
3) And not change any other part of your habitual lifestyle.

5. What are the exclusion criteria (are there reasons why I should not take part)?

Exclusion criteria include any previous or current metabolic, cardio-pulmonary or musculoskeletal disease; not between the ages of 18-65 years; a body mass index below 18.9 kg/m^2 or above 35 kg/m^2 (body mass (kg) divided by your height (m) squared); regularly partake in exercise; plans to change your lifestyle (diet and/or physical activity) in between the study period (maximum of 14 days); or are not willing to refrain from alcohol containing drinks or physical activity that substantially increases your breathing rate (outside of the study sessions) the day before each visit.

6. What are the benefits of taking part?

You will be provided with feedback about your health and fitness upon completion of the study. These results will include your physical activity levels, dietary intake and your results from the exercise tests.

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

High intensity exercise (during our test to calculate your maximal oxygen consumption) will cause breathlessness and discomfort. You should recover within a few minutes. The maximal exercise test may also increase your risk of a cardiac event. The American College of Sports Medicine (Thompson et al., 2007) report an incident rate of approximately 6 cardiac events per 10,000 tests. This small risk is likely further lowered in individuals with no family history of cardiac events. The steady state exercise sessions will occur at low-to-moderate exercise intensities, causing an increased breathing rate, but should not cause breathlessness and the likelihood of any cardiac event is extremely small. Furthermore, you are freely able to stop exercising at any stage during the exercise test and any of the exercise sessions, where first aid trained researcher(s) and access to defibrillators are readily available, further decreasing the risk of any cardiac event.

8. Will my participation involve any psychological discomfort or embarrassment?

We will be measuring your height, weight, waist and hip circumference and body fat %. If desired, this can be performed by a researcher of the same sex, but please let us know this in advance so we can make sure to organize this. All information will be completely anonymized to further minimize any potential discomfort or embarrassment.

9. Will I have to provide any bodily samples (i.e. blood, saliva)?

No. The current study does not require you to provide any bodily samples.

10. Will my taking part be confidential?

You will only be known by members of the research team to protect anonymity. We will ask for you to provide your email and / or telephone number to ensure we can contact you throughout your involvement in the study. All data will be kept in a locked cabinet or

computerised and accessed only via a password, which will be done in accordance with the Data Protection Act of 1998. Throughout the study you will be identified on all documents with a unique code instead of your name.

11. Who will have access to the information that I provide?

Only the research team will have access to information that you provide. All records will be kept confidential except for review by regulatory authorities.

12. What will happen to the results of the study?

All personal, identifiable data will be kept in a locked cabinet or on a password protected file on the University of Bath's secure server. All data collected during the study will be anonymised which will be done in accordance with the Data Protection Acts of 1998. You will be able to access any data about your results upon request.

Recorded data will not be kept for any longer than 5 years. Collected data may be used for publication in the form of a scientific paper and/or presented at a conference.

13. Who has reviewed the study?

This study has been given a favourable opinion by the University of Bath, Research Ethics Approval Committee for Health (REACH) (REACH reference EP 16/17 141)

14. How can I withdraw from the project?

If you wish to withdraw from the project, you can inform one of the above identified researchers by email, telephone or in person. You can withdraw from the project at any point without providing reasons for doing so and without prejudice. If, for any reason, you wish to withdraw your data please contact an identified researcher within a month of your participation. After this date, it may not be possible to withdraw your individual data as some results may already have been published. As all data are anonymised, your individual results will not be identifiable in any way.

15. What happens if there is a problem?

Complaints

If you have a concern about any aspect of the study you should ask to speak to the researchers who will do their best to answer any questions. If they are unable to resolve your concern, or you wish to make a complaint regarding the study, please contact the secretary to the research ethics committee:

Email: m.c.henderson@bath.ac.uk
Tel: +44 (0) 1225 38 3400

Harm

In the unlikely event that something does go wrong and you are harmed during the research, you may have grounds for legal action for compensation, but you may have to pay your legal costs. (Please ask for more information if needed).

16. If I require further information who should I contact and how?

Thank you for expressing an interest in participating in this study. Please do not hesitate to get in touch with us if you would like some more information.

Mr Oliver Chrzanowski-Smith - **Email:** O.J.Chrzanowski-Smith@bath.ac.uk

Dr Javier Gonzalez - **Email:** J.T.Gonzalez@bath.ac.uk

Tel: 01225 384654

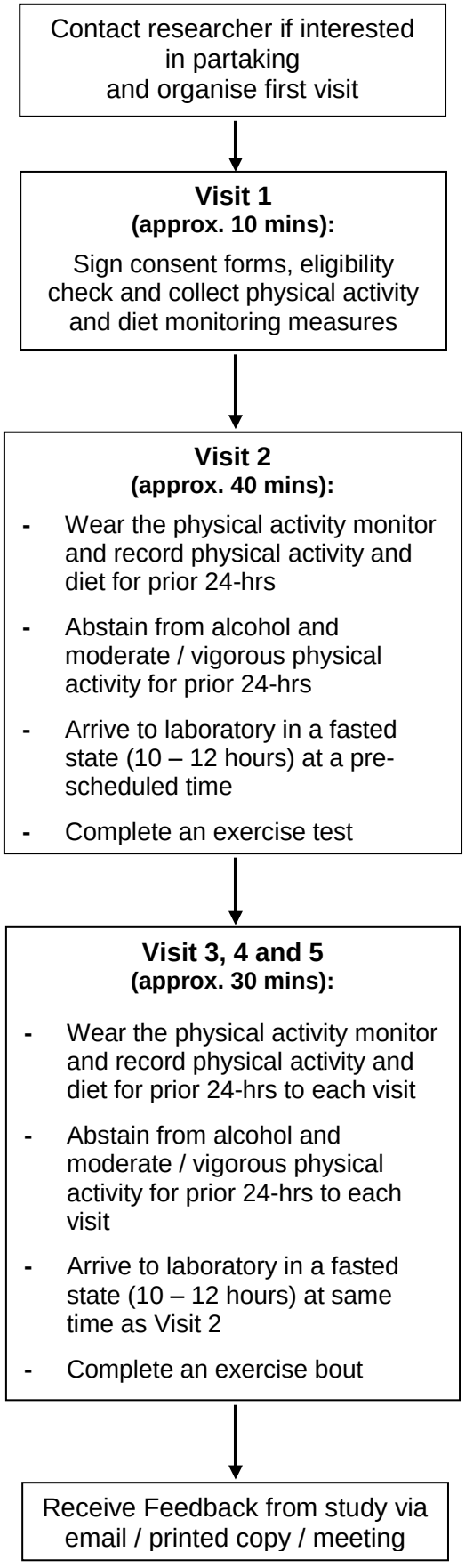

Figure 1. Study outline. Completed within 14 days.