Sheffield Hallam University

Information for participants

Title of the study:

Comparison between a validated cycle ergometer test and an arm crank ergometer test in assessing maximal oxygen uptake in healthy adults.

Introduction

We are inviting you to participate in a research study. Before you decide whether you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with us and/or friends if you wish. If you require more information or any further clarification on the information given to you we will gladly be at your disposal to answer at any relative inquiry. Please take your time to decide whether or not you wish to take part.

Background and purpose of the study

Maximal oxygen uptake test is a validated measurement that is used to assess the capacity of the human body to intake and consume oxygen while performing physical activity. This test is essential when is implemented in the clinical settings not only in assessing the health status of the patients but also in prescribing exercise that will be an important aid for a further improvement to their disease state.

The purpose of this research is to add to our knowledge of a validated arm crank ergometer test which will be able to measure accurately the peak oxygen uptake in any patients. Multiple disease states present limited lower limbs mobility and thus, are considered to be a major contraindication to perform a peak oxygen uptake test on a treadmill or a cycle ergometer. Therefore, we aim to compare a validated commonly used cycle ergometer test to an arm crank ergometer test that will further enlighten the current knowledge about the clinical utility of arm ergometry.

Sheffield Hallam University

Am I suitable participant for the study?

We are recruiting men and women ≥ 45 and ≥ 55 years old, respectively which are apparently healthy. The study can be divided in three phases. Only the apparently healthy will be eligible to participate in Phase B and C. During the study proceedings you have the right to withdraw at any time you wish to.

What will happen if I take part?

All the assessments will take place at the facilities of Sheffield Hallam University in the Collegiate Hall laboratories. Phase A consists of the baseline measurements and a health risk stratification. After the assessment, participants presenting a cardiovascular disease, cardiovascular risk or are suspected to have a cardiovascular risk will be excluded from the study. The apparently healthy participants will take part in Phase B (second visit) soon after their first visit probably within 1-4 days where they will randomly perform one of the maximal oxygen uptake tests after the baseline measurements. Finally, Phase C will require the participants to a third visit in our labs after 6-7 days of the first assessment to perform the other maximal oxygen uptake test. Table 1 outlines what will happen in each visit.

Table 1: Overview of the study

Visit number	Study days	Purpose of visit	Duration of visit
1	0	**Pre-testing procedure: Phase A** Screening questionnaire, blood pressure assessment	15 minutes
2	1-4	**Phase B:** Maximal exercise test (cycle or arm ergometer), Body composition: % Body Fat, height, body weight	35-40 minutes

3	11-12	**Phase C:** Maximal exercise test (cycle or arm ergometer)	35-40 minutes

Screening (1st visit)

Before testing and once you have given consent, you will be screened by the researchers by use of a questionnaire. You will be asked to disclose lifestyle information (alcohol, smoking, physical activity – through a physical activity recall questionnaire), diagnosed conditions and medications, plus family history of medical conditions. You will also have your height, weight and blood pressure (BP) measured.

Maximal exercise test (2nd and 3rd visit)

If you are eligible and willing to participate in our study you will be requested to visit us again to perform the exercise test. This test will last 8-12 minutes. The intensity will increase progressively up to a maximal level which will only be sustained for a few seconds. Heart rate, blood pressure as well as the electrical activity of your heart may also be monitored (ECG) and expired air will be collected via a mouthpiece. The sequence of the two tests will be determined through the randomisation process.

What do I have to do?

Before each exercise test you will be requested to abstain from vigorous exercise, alcohol, caffeine and tobacco for a period of 24h but also to be at least 2h fasting prior to the assessment as these parameters could affect your responses. Moreover, we encourage you to wear sport clothing that will allow for a more comfortable movement during exercise test. Prior to the test we will place you to an appropriate position on the cycle ergometer or arm ergometer and you will be required to breath via a mouthpiece while your nose will be kept sealed with a nose clip to ensure no air leak occurs. The test will commence with an unloaded light pace exercise for a period of 2-3 minutes and afterwards the intensity will progressively increasing accordingly to your estimated physical performance and you will be requested to maintain a specific pace. The test will be terminated at the point you reach volitional exhaustion, the point that you cannot longer maintain the required pace or if any other contraindication sign/s are present during the test which will be evaluated by the researcher.

Directly after the termination of the test you will be requested to continue exercising in an unloaded light pace for 2-3 minutes to allow for an active cool-down and recovery of the physiological responses close to the resting levels.

What are the possible benefits of taking part in this study?

This study is being undertaken for research purposes and to advance our knowledge in the use of arm ergometry as an exercise test in the clinical settings by comparing it to a validated clinical exercise test on a cycle ergometer (Wasserman's protocol). The main benefit to you will be the opportunity to have a state of the art tests to determine your current fitness status and to assess your risk factors for cardio-metabolic disease. Moreover, this information will give further data to the researcher to make any recommendations upon your lifestyle activities if you wish for it.

What happens if something goes wrong?

All of the experimental procedures that will be used in this study have been rigorously tested to ensure that they meet health and safety standards. These tests are all routinely and regularly performed on patients and healthy volunteers alike. The researchers who perform the tests are all trained and skilled to do so. If we show any signs, as regards your health status, that may cause you harm by participating, you will be informed and withdrawn immediately from the study.

Will taking in this study be kept confidential?

All information collected about you will be kept strictly confidential, other than to those of us who are involved directly with the study. Any information that leaves Sheffield Hallam University has our name and address removed so that you cannot be recognised from it. As a group of participants you will receive feedback, but all names will be removed from the individual data set. A participant's ID number will be your identification for us instead of your name.

Sheffield Hallam University

Who will be working on the study?

The researcher in charge is Mr. Alexandros Mitropoulos (PhD student in Clinical Exercise Physiology) assisted and supervised by Dr. Markos Klonizakis (Senior Research Fellow in Clinical Physiology).

What will happen to the results of the study?

Once the study has been completed all data will be anonymised and stored as per current data protection laws. The results will be written up for publication in academic journals and possibly used at academic conferences. Anything with your personal details (name, DOB, contact details etc.) will be kept securely in a locked filing cabinet by the Principal Investigator. Results will also be made available to you (the participants) on request at any time throughout the study. Moreover, information provided by the participant will be stored at Sheffield Hallam Research Facilities in Sheffield for further analyses until the end of the project. After the completion of the project, the samples will be disposed according to the guidance on disposal provided by the HTA Code of Practice on the Removal, Storage and Disposal of Human Organs and Tissue (see http://www.hta.gov.uk/guidance/codes_of_practice.cfm).

Contact for further information

If you require further advice about this study, at any time during participation, you may contact Mr Alexandros Mitropoulos, Dr. Markos Klonizakis, Dr. Rob Copeland or Dr. Anil Gumbler at Sheffield Hallam University.

Study Team Contact Details

Health and Wellbeing Faculty, Centre of Sport and Exercise Science,

Collegiate Hall, Collegiate Campus, Sheffield, S10 2BP.

Principal Investigator:

Mr Alexandros Mitropoulos

E-mail: alexandros.mitropoulos@student.shu.ac.uk

Investigators:

Dr. Markos Klonizakis

Sheffield Hallam University

E-mail: hwbmk6@exchange.shu.ac.uk

Dr. Anil Gumbler

E-mail: hwbag1@exchange.shu.ac.uk

Dr. Helen Crank

E-mail: slmhc@exchange.shu.ac.uk