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University of Bedfordshire

Institute for Sport and Physical Activity Research
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PARTICIPANT INFORMATION SHEET

The Spinal Cord Injury Move More (SCIMM) study

Benefits of breaking up prolonged periods of inactivity on heart disease risk in people with spinal cord injury

Thank you for showing an interest in participating in this study funded by Heart Research UK http://heartresearch.org.uk/spending-money/exercise-and-people-spinal-cord-injury. Please read this information sheet carefully before deciding whether to participate.

What is the aim of the project?

Prolonged periods of time spent sitting and being inactive increases the risk of heart disease in able-bodied individuals, even if the person is active at other times. This means that even people who meet the able-bodied government guidelines of 150 minutes of moderate physical activity per week may have a higher risk of heart disease if they spend long periods being sedentary (sitting with no activity). Heart disease is the leading cause of death in people with spinal cord injury (SCI) which may be because they are highly sedentary. Breaking up prolonged sitting with regular short bouts of activity reduces heart disease risk markers over a single day in able-bodied individuals compared with uninterrupted sitting or a single continuous exercise bout. No research has examined the short-term heart disease risk marker response to breaking up prolonged sedentary time in people with an SCI.

This study aims to compare the short-term heart disease risk marker responses to three different 5½ hour conditions in people with an SCI: 1) breaking up prolonged sedentary time with 2 minutes of moderate-intensity exercise every 20 minutes over 5½ hours and 2) a single prolonged 30 minute moderate-intensity exercise session performed in the morning followed by uninterrupted sedentary time with 3) uninterrupted prolonged sedentary time for 5½ hours.

What type of participant is needed?

We are looking for inactive male and female participants who obtained a spinal cord injury at least 1 year ago injured below Thoracic level 6 to Sacral Level 5 (mild to low level paraplegia) aged 18-50 years.

You will not be able to take part if you have any of the following:

- Diagnosed diabetes, high blood pressure, low blood pressure, kidney failure, liver disease
- A history of sudden onset of severe high blood pressure
- Taking glucose or lipid-lowering medication
- Are a smoker
- If you think you have a blood borne infection then you should NOT take part in the study

You may also not be able to take part in the study if, depending on its nature, you have had any medical examinations or treatment that have involved you being administered or exposed to radioactive materials. If you have any large metalwork within your body (e.g. pins, wires or screws for hip replacement or fixation of the spine) or metalwork externally on your body that cannot be removed (e.g. pins or clamps to keep bones and limbs stable), you will also not be able to take part in this study. Depending on the type of any X-rays you have had in the last 3 weeks, the time at which you start participating in the study may be delayed.

It is possible that other medical health problems not listed here may limit your ability to take part in this project. These may be identified on a health questionnaire we will ask you to complete and at that stage we will review your suitability for taking part in the project.

What will participants be asked to do?

Preliminary testing visit: You will be asked to attend a preliminary testing session at the Sport and Exercise Science Laboratories at the University of Bedfordshire where you will have body weight measured and body fat% measured using Dual energy x-ray absorptiometry (DXA). This scan shows your bone density, fat mass and fat free mass (bone and muscle) levels. The scan is pain free - you don't feel anything. You are not enclosed or encased by the equipment. You will have a whole body scan which requires simply lying flat on your back with your legs in a comfortable position. The equipment moves over you and above you without touching you and does not make a noise. This scan takes about 5 minutes. Resting blood pressure will be measured by inflating a cuff around the arm and then letting the air out slowly using an automatic monitor. You will be asked to complete an exercise test to determine your fitness levels. You will wear a heart rate monitor during the test so we can measure your heart rate. You will exercise using an arm ergometer (see picture below) until you are too fatigued to continue. You will begin with a 5 minute warm up at a low intensity and the intensity will then be increased every minute by increasing the resistance against the arm cranks. Once you are too fatigued to continue you will stop this part of the test and be asked to complete 5 minutes of active rest (exercising at a very low intensity). After 5 minutes, we will ask you to exercise again at a slightly higher intensity than you achieved during the previous part of the test until you can no longer continue. This is to check that we have accurately determined your maximum fitness level. After a rest, we will ask you to exercise for 15 minutes at the intensity (moderate) that will be used during your main trial days described below.

Main trial days: After your preliminary testing visit, you will attend the Sport and Exercise Science Laboratories at the University of Bedfordshire on 3 separate days with a gap of 1 to 3 weeks between each day to take part in all of the following study conditions:

(1) Uninterrupted sitting; volunteers remain seated in their wheelchair at a desk for 5.5 hours
(2) Prolonged physical activity; volunteers will carry out a 30 minute bout of exercise at a moderate-intensity (it will make you breathe harder and feel warmer) using an arm ergometer (see picture below) in the morning followed by uninterrupted sitting for the rest of the 5.5 hours
(3) Sitting plus activity breaks; volunteers will carry out 2-minute bouts of moderate-intensity arm exercise every 20 minutes over the 5.5 hour day.

You will be able to perform daily desk-based activities (you will be provided a laptop with internet access), read, talk, or watch DVDs during each trial. Except during the activity bouts, you will remain inactive and only leave your desk to void and consume breakfast and lunch meals in a research kitchen; you will be aided by a member of the research team when moving to these locations to remain inactive. You will be provided with breakfast (bran flakes, whole milk, croissant, and orange juice) and lunch (chicken sandwich, salted crisps and an apple) during the study days. Please let us know if you are not able to consume any of these items and we will try to identify alternatives for you. Water will be available throughout the trials.

You will be asked to refrain from caffeine and alcohol for 24 hours prior to each of the 3 trials and exercise for 48 hours prior to each of the 3 trials. You will be provided with a food diary and digital scales to record volume and timings of all food and liquids consumed in the 24 h period prior to the first trial. You will be asked to replicate this food diary the day before all other visits. On the 3 trial days you will be asked to

attend the Laboratories in the morning following an overnight fast and travel to the laboratory using an inactive method such as by car or bus.

Blood pressure will be measured 7 times during each study as described above. A cannula will be inserted into a vein on your arm so we can take 10 blood samples at regular intervals during each study day. We will collect 10 mL each time, which means a total of 100 mL of blood will be taken during each study day and 300 mL taken in total across the whole study. A normal amount of blood collected when donating blood is 450 mL.

What are the possible risks of taking part in the study?
This study has been reviewed and approved by the Cambridge South NHS Research Ethics Committee.

Physical Activity
The risks of maximal physical activity include: Cardiac events, Stress fractures, Muscle damage, Respiratory problems, Sickness, Fainting, Dehydration, Overheating. Risks will be minimised by asking you to complete a health questionnaire before activity and only allowing individuals who are healthy to complete exercise that is appropriate to them. These risks, if you are healthy, are very rare. The researchers will ensure that you are aware that you may stop the test at any time. If any of the above symptoms are evident, you will be asked to stop the test and you will be monitored for a reasonable time.

Contamination
There is a very small risk of contamination from blood sample collection and from using facemasks. However, these risks will be minimised by using protective equipment, disinfecting all re-usable equipment and screening all participants with health questionnaires before you take part in the study. Individuals with any blood borne disease or virus will not be permitted to take part in the research. Only trained researchers will take blood samples and they will adhere to published guidelines to reduce the risk of cross-infection, which is very rare.

Radiation
As a part of this study you will be exposed to a very small amount of X-rays (ionising radiation) during your DXA scan(s). X-rays can induce harmful effects such as the development of cancer. However, the amount used in this study is very, very tiny and you experience a similar risk from less than 2 days of natural background radiation (to which we are all exposed) in the UK. The benefit of having a DXA scan is that if you have low bone density this will be picked up so you can consult your doctor about ways of reducing your risk of breaking a bone at a later date. We will also be able to give you accurate information on your body fat levels from this scan.

Will my GP be notified of my taking part in this study?
Yes, we will notify your GP that you are taking part in this study. We will not provide your GP with any of the information you provide to us and we will not share any of the data we obtain from you with your GP. If your GP has any concerns with you taking part in this study they will be able to contact the research team to obtain further information.

Will my taking part in the study be kept confidential?
Other than informing your GP that you are taking part in this study, your participation in this study will be kept confidential. We will follow ethical and legal practice in accordance with the Data Protection Act (1998). All information and results collected will be held securely at the University of Bedfordshire and will only be accessible to senior members of the research team. Access to identifiable data (name, address etc.) will be limited to selected members of the research team and will be kept on secure University computers. This information and other personal details will not be included in analysis, or in publications or reports. All information collected during the study will be identified by a unique code so that you cannot be identified

from it. All data will be kept on secure computer servers and in locked filing cabinets within a locked office at the University of Bedfordshire.

What if you decide you want to withdraw from the study?
If, at any stage you wish to leave the project, then you can. There is no problem should you wish to stop taking part and it is entirely up to you. There will be no disadvantage to yourself should you wish to withdraw. If you lose capacity to consent during your participation in the study, you will be withdrawn from the study - identifiable data already collected with consent may be retained and used in the study.

What will happen to the data and information collected?
Everyone that takes part in the study will receive their own results from the DXA scan and will receive a summary report of the study findings and any recommendations that we make. All information and results collected will be held securely at the University of Bedfordshire and will only be accessible to related University staff. Results of this project may be published, but any data included will in no way be linked to any specific participant. Your anonymity will be preserved.

What do I get for participating?
The main benefit to you in participating in this study will be information about how strong (or weak) your bones are and your body fat levels. The results obtained from everybody's contribution may help scientists better understand if breaking up prolonged periods of sedentary time in people with spinal cord injury can help lower their heart disease risk. **Any travel costs will be paid back to you. You will also receive £25 for each of the main trial days you attend to thank you for your time (£75 in total).**

What if I have any questions?
Questions are always welcome and you should feel free to ask Thomas Withers or Daniel Bailey any questions at anytime. See details below for specific contact details.

Who do I contact if I have a problem?
If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact: Dr Andrew Mitchell, Acting Director, Institute for Sport and Physical Activity Research, University of Bedfordshire, Andrew.mitchell@beds.ac.uk, Tel: 01234 793363.

How do I sign up to take part in this study?
If you would like to participate in this study then please complete the attached consent form and return it by email to Thomas.Withers@beds.ac.uk or the address below.

Many Thanks,

Tom Withers

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Dr Daniel Bailey: daniel.bailey@beds.ac.uk (Principal Investigator)