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 sedentary time on heart disease risk in people with spinal cord injury

Dear Participant,

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 even if the person is active at other times. This means that even people who meet the 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 SCI. This study aims to compare the short-term heart disease risk marker responses to 1) breaking up prolonged sedentary time with 2 minutes of moderate-intensity exercise every 20 minutes over 7 hours and 2) a single prolonged moderate-intensity exercise session performed in the morning followed by uninterrupted sedentary time with 3) uninterrupted prolonged sedentary time in people with SCI.

**What type of participant is needed?**

We are looking for inactive **male** participants who suffered a spinal cord injury at least 1 year ago injured at 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, Hypertension, Hypotension, Renal failure, Liver disease
* A history of autonomic dysreflexia
* Taking glucose or lipid-lowering medication
* Are a smoker
* Anyone who has had an X-ray examination with contrast medium in the 3 weeks prior to their DXA scan
* Anyone who has recently had, depending on its nature, a Nuclear Medicine diagnostic or therapy investigation
* Anyone with significant internal metalwork or irremovable external metal work

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 where you will have body mass 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, legs straight out. 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 and after putting a heart rate monitor on to measure your heart rate you will then be asked to complete an exercise test to determine your fitness levels. This will involve exercising to volitional exhaustion (too fatigued to continue).

*Main trial days*: You will be asked to refrain from caffeine and alcohol for 24 hours prior to each main trial and exercise for 48 hours prior to each main trial. 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 trial days you will be asked to attend the Sport and Exercise Science Laboratories at the University of Bedfordshire in the morning following an overnight fast and avoid active travel to the laboratory. Resting blood pressure will be measured and a cannula will be inserted into a vein on your arm so we can take blood samples at regular intervals during each trial. You will commence the 7 hour trial period following a breakfast meal. The three trial conditions are as follows:

(1) Uninterrupted sitting; volunteers remain seated in their wheelchair at a desk with no breaks for a 7 hour day

(2) Prolonged physical activity; volunteers will carry out a 40-minute bout of exercise using an ergometer in the morning followed by uninterrupted sitting for the rest of a 7 hour day

(3) Sitting plus activity breaks; volunteers will carry out 2-minute bouts of moderate-intensity arm activity every 20 minutes over a 7 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. Breakfast will consist of cornflakes and whole milk and lunch will be a chicken sandwich, salted crisps and chocolate bar (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.



**What are the possible risks of taking part in the study?**

*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 taking part in the study be kept confidential?**

Yes. 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 project?**

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 or other expenses required to take part in the study 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 Daniel Bailey or Louise Croft any questions at anytime. See details below for specific contact details.

Should you want to participate in this study then please complete the attached consent form, which needs to be returned before commencing the study.

This project has been reviewed and approved by the NHS Research Ethics Committee.

Many Thanks,

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