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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

Submission date
01/02/2017

Recruitment status
No longer recruiting

Registration date
01/02/2017

Overall study status
Completed

Last Edited
30/04/2020

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Prolonged periods of time spent inactive and sitting (sedentary) 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). Heart disease is the leading cause of death in people with spinal cord injury which may be because they are highly sedentary. The aim of this study is to find out whether breaking up prolonged sedentary time lowers the heart disease risk of inactive people with spinal cord injury.

Who can participate?
Men and women aged 18-60 with a spinal cord injury below T6

What does the study involve?
Participants are weighed and they undergo a dual energy x-ray absorptiometry (DXA) scan. This scan shows their bone density, fat mass and fat-free mass (bone and muscle) levels. Participants then take part in two different activities that each last 5.5 hours, with a break of at least 6 days between each activity. The two activities are (1) uninterrupted sitting, where participants remain seated at a desk for the 5.5 hour day and (2) sitting plus activity breaks, where participants carry out 2-minute bouts of moderate-intensity exercise every 20 minutes over the 5.5 hour day. During the inactive periods the participants carry out desk-based activities on a computer, read, talk, or watch DVDs. Participants' markers of heart disease risk are measured before and during the study, including levels of blood sugar and cholesterol after eating, insulin levels and blood pressure.

What are the possible benefits and risks of participating?
Breaking up prolonged sedentary time with regular short activity breaks may be an effective way to lower the risk of heart disease in people with spinal cord injury and a simple strategy that they are more likely to take part in. In the long term, the results will help to inform new physical

activity and clinical care guidelines to reduce the risk of heart disease in people with a sedentary lifestyle including those with spinal cord injury. The benefit of having a DXA scan is that if participants are found to have low bone density they can consult their doctor about ways of reducing their risk of breaking a bone at a later date. Participants also receive information on their body fat levels from this scan. The risks of physical activity include: heart/muscle/bone damage, breathing problems, sickness, fainting, dehydration and overheating. Risks are minimised by asking participants to complete a health questionnaire before the activity and only allowing people who are healthy to complete exercise that is appropriate to them. These risks are very rare in healthy people. Participants may stop the test at any time. If any of the above symptoms occur, they are asked to stop the test and monitored for a reasonable time. There is a very small risk of contamination from blood sample collection and from using facemasks. However, these risks are minimised by using protective equipment, disinfecting all re-usable equipment and screening all participants with health questionnaires before they take part in the study. People with any blood borne disease or virus are not permitted to take part in the study. Only trained researchers take the blood samples and they adhere to guidelines to reduce the risk of cross-infection, which is very rare. As a part of this study participants are exposed to a very small amount of X-rays during their DXA scan(s). X-rays can cause harmful effects such as the development of cancer, but the amount used in this study is very, very tiny and there is a similar risk from less than 2 days of natural background radiation in the UK.

Where is the study run from?
University of Bedfordshire (UK)

When is the study starting and how long is it expected to run for?
November 2016 to February 2019

Who is funding the study?
Heart Research UK

Who is the main contact?
Dr Daniel Bailey
daniel.bailey@beds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Bailey

ORCID ID
http://orcid.org/0000-0003-3772-630X

Contact details
Centre for Human Performance, Exercise and Rehabilitation
Sport, Health and Exercise Sciences
CHLS - Life Sciences
Brunel University London
Uxbridge
London

United Kingdom
UB8 3PH
+44 (0)1895 265363
daniel.bailey@brunel.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
220036

ClinicalTrials.gov number

Secondary identifying numbers
1, IRAS 220036

Study information

Scientific Title
The Spinal Cord Injury Move More (SCIMM) study: benefits of breaking up prolonged sedentary time on cardiovascular disease risk markers in people with spinal cord injury

Acronym
SCIMM

Study objectives
Current hypothesis as of 10/11/2017:
It is hypothesised that breaking up prolonged sedentary time will result in improved cardiovascular disease risk marker responses compared with prolonged uninterrupted sedentary time in people with spinal cord injury.

Previous hypothesis:
It is hypothesised that breaking up prolonged sedentary time will result in similar cardiovascular disease risk marker responses to a continuous energy-matched exercise session and that both of these conditions will result in more favourable risk marker responses than prolonged uninterrupted sedentary time in people with spinal cord injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge South NHS Research Ethics Committee, 13/05/2017, ref: 17/EE/0076

Study design
Randomised two-condition cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Spinal cord injury

Interventions
Current interventions as of 10/11/2017:
This is a randomised crossover design with two trial conditions that each last 5.5 hours with a minimum washout of at least 6 days between each condition. The study will test the heart disease risk marker responses to the two conditions below. A researcher who is not involved in participant recruitment and intervention will create a randomization list using the block randomization method (software: Research Randomizer, https://www.randomizer.org). This list will be provided to the study investigators. The investigator responsible for enrolment will remain blinded to the intervention allocations until 48 hours prior to the first main trial for each participant.

The trial conditions are:
1. Uninterrupted sitting (SIT): participants will remain seated uninterrupted at a desk during the 5.5 hour trial period
2. Sitting + activity breaks (SIT-ACT): participants will perform 2 min of moderate-intensity arm crank exercise every 20 min during the 5.5 hour day with the first bout taking place 20 min after breakfast.

The moderate-intensity exercise in the SIT-ACT condition will be performed at a Rating of Perceived Exertion of 13 (somewhat hard). During the inactive periods the volunteers will carry out desk-based activities on a computer, read, talk, or watch DVDs.

Before and during the trial, the researchers will measure each participant’s levels of blood sugar and cholesterol after eating, insulin levels and blood pressure. There is no follow-up.

Previous interventions:
This is a randomised crossover design with three trial conditions that each last 7 hours with a minimum washout of at least 6 days between each condition. The study will test the heart disease risk marker responses to the three conditions below. A researcher who is not involved in participant recruitment and intervention will create a randomization list using the block randomization method (software: Research Randomizer, https://www.randomizer.org). This list will be provided to the study investigators. The investigator responsible for enrolment will remain blinded to the intervention allocations until 48 hours prior to the first main trial for each participant.

The trial conditions are:
1. Uninterrupted sitting (SIT): participants will remain seated uninterrupted in their wheelchair at a desk during the 7 h trial period
2. Continuous physical activity (CONT): participants will perform a continuous 40 min bout of moderate-intensity arm crank exercise 20 min after consuming a standardised breakfast meal, which will be followed by uninterrupted sitting at a desk for the rest of the day
3. Sitting + activity breaks (SIT-ACT): participants will perform 2 min of moderate-intensity arm crank exercise every 20 min during the 7 h day with the first bout taking place 20 min after breakfast. These 20 breaks will equate to 40 min and will match energy expenditure of the CONT trial condition

The moderate-intensity exercise in the CONT and SIT-ACT conditions will be performed at a power output corresponding to 40% VO2Reserve. During the inactive periods the volunteers will carry out desk-based activities on a computer, read, talk, or watch DVDs.

Before and during the trial, the researchers will measure each participant's levels of blood sugar and cholesterol after eating, insulin levels and blood pressure. There is no follow-up.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 10/11/2017:
Postprandial plasma glucose concentration incremental area under the curve, measured with a benchtop analyser from whole blood samples collected at baseline and then regularly during each of the two trial conditions

Previous primary outcome measures:
Postprandial plasma glucose concentration incremental area under the curve, measured spectrophotometrically from venous blood samples collected at baseline and then hourly during each of the three trial conditions

Secondary outcome measures
Current secondary outcome measures as of 10/11/2017:
1. Incremental area under the curve for postprandial triglycerides, measured with a benchtop analyser from whole blood samples collected at baseline and then regularly during each of the two trial conditions
2. Incremental area under the curve for HDL, with a benchtop analyser from plasma collected at baseline and then regularly during each of the two trial conditions
3. Incremental area under the curve for insulin, measured using an enzyme immunoassay from plasma samples collected at baseline and then regularly during each of the two trial conditions
4. Systolic and diastolic blood pressure, measured using an automated oscillatory blood pressure monitor at baseline and then regularly during each trial

Previous secondary outcome measures:
1. Incremental area under the curve for postprandial triglycerides, measured spectrophotometrically from venous blood samples collected at baseline and then hourly during each of the three trial conditions
2. Incremental area under the curve for HDL, measured spectrophotometrically from venous blood samples collected at baseline and then hourly during each of the three trial conditions
3. Incremental area under the curve for insulin, measured using an enzyme immunoassay from

venous blood samples collected at baseline and then hourly during each of the three trial conditions
4. Total area under the curve for IL-6, measured using an enzyme immunoassay from venous blood samples collected at baseline and then hourly during each of the three trial conditions
5. Systolic and diastolic blood pressure, measured using an automated oscillatory blood pressure monitor at baseline and then hourly during each trial

Overall study start date
16/11/2016

Completion date
04/02/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/11/2017:
1. Male and female
2. Aged 18-60 years
3. Not highly active: engaging in less than <300 min per week of moderate-to-vigorous physical activity
4. Have a chronic spinal cord injury (≥1 year since injury)
5. Injured at Thoracic level 6 to Sacral Level 5 (mild to low level paraplegia). These individuals have intact sympathetic innervation to the heart and resting blood pressure is typically normal

Previous inclusion criteria:
1. Male
2. Aged 18-50 years
3. Physically inactive: engaging in less than <150 min per week of moderate-to-vigorous physical activity
4. Have a chronic spinal cord injury (≥1 year since injury)
5. Injured at Thoracic level 6 to Sacral Level 5 (mild to low level paraplegia). These individuals have intact sympathetic innervation to the heart and resting blood pressure is typically normal

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Male

Target number of participants

20

Total final enrolment
18

Key exclusion criteria
Current exclusion criteria as of 10/11/2017:
1. Diagnosed diabetes, hypertension, hypotension, renal failure, liver disease, or history of severe cardiovascular complications
2. Body mass index >45 kg/m2 (severe obesity)
3. A history of autonomic dysreflexia
4. Taking glucose-lowering medication
5. Smoking
6. Major illness or other health issues that may limit ability to perform the exercise protocols

Previous exclusion criteria:
1. Diagnosed diabetes, hypertension, hypotension, renal failure, liver disease, or history of severe cardiovascular complications
2. Body mass index >45 kg/m2 (severe obesity)
3. A history of autonomic dysreflexia
4. Taking glucose or lipid-lowering medication
5. Smoking
6. Major illness or other health issues that may limit ability to perform the exercise protocols

Date of first enrolment
03/04/2017

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bedfordshire
Polhill Avanue
Bedford
United Kingdom
MK41 9EA

Sponsor information

Organisation
University of Bedfordshire

Sponsor details
Polhill Avenue
Bedford
England
United Kingdom
MK41 9EA

Sponsor type
University/education

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
Charity

Funder Name
Heart Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
04/02/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Daniel Bailey (daniel.bailey@beds.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/02/2017	21/02/2017	No	Yes
Protocol article	protocol	22/06/2018	24/10/2019	Yes	No
Results article	results	01/08/2020	30/04/2020	Yes	No
HRA research summary			26/07/2023	No	No