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The impact of a home-based exercise program on health and fitness in wheelchair users

Submission date
11/07/2014

Recruitment status
No longer recruiting

Registration date
29/07/2014

Overall study status
Completed

Last Edited
30/07/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
People with spinal cord injury (SCI) are at increased risk of long-term diseases. For example, they are four times more likely to develop type 2 diabetes. As a result, heart disease is the leading cause of death in individuals with SCI, occurring earlier in life. The contribution of regular physical activity (PA) to achieve weight balance, metabolic control and cardiac fitness is well documented and broadly accepted in healthy people. People with a SCI can have many psychosocial/environmental barriers which prevent them from exercising. At present, there is a lack of evidence as to whether structured exercise reduces the risk of long-term diseases in individuals with a SCI. Hence, the aim of this study is to find out whether a 6-week home-based moderate-intensity arm crank ergometry intervention can improve metabolic function and parameters of functional capacity in individuals with a SCI. The studys findings could help to improve our understanding of the mechanisms whereby exercise may impact chronic disease risk, and help to inform physical activity guidelines for people with a SCI.

Who can participate?
This study aims to recruit 24 volunteers with a long-term SCI who are less physically active.

What does the study involve?
Participants will visit the Centre for Disability Sport and Health (DASH) laboratory at the University of Bath on two separate mornings before and after a 7-week period. These visits will require participants to have fasted overnight. Body composition and metabolic rate at rest will be assessed upon arrival. A thin needle (cannula) will be inserted into a forearm vein for repeat blood sampling and a tissue sample will be taken from the tummy. Participants will then consume a glucose-based solution and we will take blood samples over the following 2 hours. Following this, participants will perform an arm crank ergometer test and various upper body strength assessments. Following the first laboratory visit participants will undergo a week of habitual physical activity (PA) and nutrition monitoring. Eligible participants are randomly allocated to 6 weeks of moderate-intensity arm crank exercise or a control group. During the final week of the intervention, participants in both groups habitual PA and nutrition will be monitored again.

What are the possible benefits and risks of participating?
Participants will be given a copy of their results and personalised feedback regarding their body composition, diet, patterns of physical activity and various blood measurements that would otherwise not normally be available to them. Individuals might see the time spent in the visits as an inconvenience. Body composition will be assessed using a very sophisticated and precise technique, dual energy x-ray absorptiometry (DEXA. This technique is routinely used in hospitals and with elite athletes but does involve some exposure to a small amount of radiation. The radiation dose is often compared to the small exposure experienced during a short flight (e.g. London to Paris) and is similar to the amount of background radiation that you would receive in a normal day living around Bath, UK (and a tiny fraction [1/30th] of the amount of radiation experienced during a typical chest x-ray). The risks associated with this amount of radiation are described as minimal (less than 1 in ten million per whole body scan). A small tissue sample will be taken on each of the two study days from around the waist. All tissue samples will be taken by someone who has been specially trained to do so and a numbing agent will be used in order to minimise discomfort. There may be some bruising for a few days after taking this sample, but this is normal and the small chance of infection is reduced by good practice. The exercise sessions may be tiring, and as with all physical exercise there is a small inherent risk of physical injury. During home-based training sessions, participants will be required to exercise under the supervision of a spouse or carer. There will be a certain level of strain to your heart associated with performance of the graded maximal exercise test to find out maximal oxygen uptake. All participants will fill out a health screen prior to participating in the study and if necessary, will need written consent giving clearance to exercise from a GP.

Where is the study run from?
The study has been set up by the Centre for Disability Sport and Health (DASH) at the University of Bath, UK

When is the study starting and how long is it expected to run for?
June 2014 to June 2016

Who is funding the study?
University of Bath (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Influence of a home-based exercise intervention on human health indices in individuals with chronic spinal cord injury (HOMEX-SCI): a randomised controlled trial

Acronym
HOMEX-SCI

Study objectives
It is hypothesised that 6 weeks of moderate-intensity exercise would lead to improvements in metabolic function, markers of inflammation, immune competency, functional capacity and quality of life in a cohort of individuals with a spinal cord injury compared to a spinal cord injury control group. The null hypothesis is that there will be no difference in improvement /deterioration in outcome measures between the exercise and control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee South West of England - Cornwall, Plymouth & Exeter, 17/06/2014, ref. 14/SW/0106

Study design
Single-centre randomised controlled trial with minimisation to match groups for confounding variables

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Spinal cord injury (SCI), moderate-intensity exercise, metabolic health, obesity, cardiovascular disease

Interventions
Current interventions as of 01/02/2016:
Participants will be randomly assigned to either a 6-week home-based exercise intervention or a control group at a ratio of 2:1, using a minimisation approach aiming to match groups for confounding variables.

Participants assigned to the exercise group will be prescribed 30-45 minutes of arm crank ergometry (ACE), four times per week at a moderate intensity (60-65% VO2 peak). Arm crank ergometry will be performed on a portable desktop rehab ergometer within a home-based setting and will be supervised by a spouse or carer. Over the course of the first week participants will be expected to progressively increase exercise duration from 30 to 45 minutes of continuous ACE at 70-80 revolutions per minute (rpm). Compliance will be monitored using a validated physical activity monitor worn on the wrist.

Previous interventions:
Participants will be randomly assigned to either a 6-week home-based exercise intervention or a control group at a ratio of 2:1, using a minimisation approach aiming to match groups for the confounding variable of time since injury.

Participants assigned to the exercise group will be prescribed 30-45 minutes of arm crank ergometry (ACE), four times per week at a moderate intensity (60-65% VO2 peak). Arm crank ergometry will be performed on a portable desktop rehab ergometer within a home-based setting and will be supervised by a spouse or carer. Over the course of the first week participants will be expected to progressively increase exercise duration from 30 to 45 minutes of continuous ACE at 70-80 revolutions per minute (rpm). Compliance will be monitored using a validated physical activity monitor worn on the wrist. In the intervention group we also wish to observe the extent to which behaviour is modified four weeks after cessation of the intervention and the degree to which improvements in certain biomarkers have been maintained.

Intervention Type
Behavioural

Primary outcome(s)

Changes in insulin sensitivity and glycaemic control measured at baseline and at the end of the intervention/control (i.e. after 6 weeks).

Key secondary outcome(s))
1. Other blood measurements related to metabolic function and inflammation (e.g. cholesterol, non-esterified fatty acids (NEFA), triacylglycerol, interleukin-6 [IL-6], leptin and adiponectin)
2. Changes in maximal oxygen uptake, peak power and upper body strength
3. Changes in body composition
4. Changes in adipose tissue gene/protein expression related to metabolic function and inflammation
5. Changes in immune competency
6. Changes in quality of life and other psychological variables focussed around self-efficacy, independence and fatigue
7. Changes in physical activity and eating behaviours

Measured at baseline and at the end of the intervention (i.e. after 6 weeks)

Completion date
24/06/2016

Eligibility

Key inclusion criteria
1. Individuals with a chronic SCI (> 12 months post-injury) below T2 or other disabling condition with a similar level of impairment
2. Motor-complete SCI (American Spinal Injury Association scale A or B)
3. Aged between 18 to 65 years
4. Objectively measured physical activity level ≤ 1.6
5. Regular manual wheelchair user (> 70% of ambulation)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals with an acute SCI (< 12 months post-injury)
2. Pregnant women
3. Under 18 years old
4. Cardiovascular contra-indications for testing according to the American College of Sports

Medicine (ACSM)
5. Severe musculoskeletal complaints of the upper extremities that contraindicate performance of wheelchair propulsion/arm crank ergometry
6. Individuals with active medical issues; pressure sores, urinary tract infections, or heart disorders
7. Plans to change lifestyle, e.g. diet or physical activity

Date of first enrolment
30/06/2014

Date of final enrolment
29/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bath
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bath (UK)

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
University/education

Funder Name
University of Bath (UK)

Alternative Name(s)
UniofBath

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results (primary outcome plus secondary outcomes 1, 2, 3, 4 & 7):	01/12/2017		Yes	No
Results article	results (secondary outcome 6):	01/10/2018		Yes	No
Protocol article	protocol	08/06/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes