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A feasibility study of an early exercise intervention to improve health in individuals with acute spinal cord injury

Submission date
06/04/2021

Recruitment status
No longer recruiting

Registration date
14/05/2021

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Spinal cord injury (SCI) is known to decrease levels of physical fitness, and in the process contribute to medical complications such as diabetes (a disease caused by having too much sugar in the blood) and overweight/obesity, which occur earlier in the lives of people living with paralysis. Beginning an exercise programme of high-intensity interval training (HIIT) during inpatient rehabilitation in newly injured individuals with SCI may serve as a preventative measure to reduce the burden of long-term disease and set in healthy lifestyle behaviours. The aim of this study is to test a new exercise intervention for people with SCI during their time in rehabilitation at The Duke of Cornwall Spinal Treatment Centre, Salisbury District Hospital (SDH).

Who can participate?
Patients aged over 18 years admitted to the spinal unit at Salisbury District Hospital who have had their injury for less than 6 months, can bend their elbows against gravity, and spend over 75% of their waking day in a wheelchair

What does the study involve?
This research involves short intense exercise training to give a safe but challenging workout, three times a week for 18 weeks using an arm cycle. The project will discover if patients are willing to sign up to the study whilst in hospital, to find out if the exercise is manageable, and to discover if people are happy to keep up the exercise when they go home. The researchers will also ask the NHS physiotherapy and occupational therapy staff about their views on the new programme and how it is delivered.
Forty patients with SCI will be asked to take part in this research. They will be recruited from the Duke of Cornwall Spinal Treatment Centre, Salisbury District Hospital and will be chosen at random to either take part in the exercise group or to continue usual standard care. Patients will be asked to fill in questionnaires and have physical tests on health and fitness at the beginning, middle and end of the study. A small sample of patients, physiotherapists and occupational therapists will be interviewed at the beginning and end of the project to find out more about their experiences with the new exercise training during the research.

What are the possible benefits and risks of participating?
There are no direct benefits for taking part in this study. At the end of the study, participants will be given a copy of their test results and personalised feedback regarding their physical activity levels (e.g. how many calories they use per day compared to how they consume in their diet); blood test results including cholesterol, glucose, insulin; and information regarding the impact on their health of the 18-week exercise intervention (if assigned to this group).
Participants will be required to give up some of their time to take part in this study; about 3 hours for assessments on three occasions at the beginning, middle and end of the study and about 30 minutes to complete the online survey on two occasions. The phone interview will take about 60 minutes on two occasions.
Using a cannula can sometimes cause minor bruising, however, this is only temporary if it does occur. There is a very small risk of infection or embolism (a bubble or fragment of plastic becoming lodged in a blood vessel which could potentially interfere with blood flow), but these events are very rare and risks are kept to a minimum by our strict adherence to best practice.
The total volume of blood taken during the trial day is about 85 ml, which is about a sixth of the volume taken when a person donates blood and so is a relatively small amount.
Participants may find the exercise sessions tiring, and as with all physical exercise there is a small inherent risk of physical injury. However, the in-hospital exercise sessions will be supervised by a research team member. When participants are discharged, a member of the research team will visit their home to ensure that the arm crank ergometer is set up appropriately to continue the exercise safely. Participants will receive follow-up phone calls every week to give them the opportunity to discuss any issues with an investigator. Participants are expected to be supervised during each exercise session as agreed on completion of the informed consent form.
There will be a considerable level of cardiovascular strain associated with the performance of the graded maximal exercise test. A health screen will be completed before participating in the study. Participants with an SCI above the level of T6, depending on completeness of injury, can be susceptible to autonomic dyresflexia (sudden onset of excessively high blood pressure). To mitigate the risks of dyresflexia, participants will be instructed to empty their bladder before exercise.

Where is the study run from?
The Duke of Cornwall Spinal Treatment Centre, Salisbury District Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2020 to February 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283367

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48260, IRAS 283367

Study information

Scientific Title
A feasibility study of high-intensity interval training to reduce cardiometabolic disease risks in individuals with acute spinal cord injury

Study objectives
This study will descriptively (descriptive statistics, qualitative analysis) assess the feasibility of the intervention. Tests of the intervention effectiveness hypotheses will occur in a future randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/03/2021, North West – Liverpool Central Research Ethics Committee (HRA and Health and Care Research Wales (HCRW), 3rd Floor, Barlow House, HRA NRES Centre, Manchester, M1 3DZ, UK; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), REC ref: 21/NW/0029

Study design
Randomized; Both; Design type: Treatment, Process of Care, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Acute spinal cord injury

Interventions
The study will involve a total of three assessment visits (~5 hours each) which will take place before, at the midpoint and after an 18-week exercise intervention (or control group). For these visits, participants will be asked to arrive after an overnight fast (>10 hours). During these visits, the researchers will first assess basic anthropometrics (weight and height). A trained member of the research team will then insert a cannula into a vein on the forearm to allow regular blood samples to be taken for 2 hours following the oral consumption of glucose drink. During the 2-hour glucose test, participants will be asked to complete two questionnaires on independence and quality of life. Participants will then be given lunch and asked to perform a maximal exercise test on an arm-crank ergometer. Participants will be asked to wear a physical activity monitor for 5 days following the initial visit, midpoint visit and in the final week of the 18-week period. Participants will also be asked to complete an online survey on the acceptability of the intervention on two occasions; week 6 and week 16. A small subset of participants will be asked to participate in a semi-structured interview over the phone or on a video call in weeks 9 and 18. Clinicians will also take part in the survey (at the start of the study) and interview (upon completion of the study) portion of the feasibility to assess their acceptability of the intervention.

After baseline testing, eligible consenting participants will be randomly allocated (1:1) to a high-intensity interval training intervention (HIIT) or a standard care control group (CON) using a

block randomisation plan. Both HIIT and CON groups will continue to participate in standard care throughout the duration of their inpatient rehabilitation stay. In addition to standard care sessions, participants randomised to the intervention group will perform an additional 3 days per week of HIIT exercise (30 minutes per session) on an arm cycle ergometer. The research team member will provide physical assistance with setting up for the exercise as well as encouragement and verbal guidance regarding exercise performance for the first 4 weeks. At the start of week 5, participants will begin to transition to autonomous training, in preparation for discharge, with the goal of being fully autonomous by the end of week 6-8. During the transition period, the research team will provide minimal guidance only when participants struggle to remember proper set-up or execution. Participants will be asked to wear a chest-worn heart rate monitor for every training session to monitor adherence, compliance and effort. Participants will be given training logs to be completed after each session.

At discharge, participants will receive an arm ergometer (the same model they have used during inpatient care) for continuing the intervention in their own homes for the remainder of the 18-week intervention. A member of the study team will visit participant's homes to ensure proper set-up of the device. Participants will be asked to continue to perform three sessions per week and avoid performing two exercise training sessions on the same or consecutive days. Participants will be asked to continue to use the chest-worn heart rate monitor and complete their training logs. Participants will receive a weekly phone call from study staff to confirm compliance. The CON group will be asked to continue lifestyle maintenance. During this time, participants will have continued access to self-referral to SDH.

Intervention Type
Behavioural

Primary outcome measure
All measured at the completion of the study:
1. Participant recruitment rate: the proportion of eligible patients who accept the invitation to participate in the research study
2. Retention and adherence: the proportion of participants who complete the study and, for those in the intervention group, the proportion of intervention sessions completed.
3. The acceptability of the intervention, study design and outcome measures as well as participants' and clinicians' experiences with the intervention, assessed qualitatively using open-ended surveys and interview data for patient and staff groups analysed using thematic analysis
4. Completion rates for each outcome measure evaluated to determine if an outcome measure should be removed

Secondary outcome measures
1. Shoulder pain measured using the Wheelchair Users Shoulder Pain Index (WUSPI) (questionnaire) weekly throughout the study
2. Free-living energy expenditure measured using a wrist-mounted physical activity monitor (GENEActive) at week 0, 9, 18
3. Cardiorespiratory fitness measured using the peak oxygen consumption test on an arm cycle ergometer at week 0, 9, 18
4. Insulin resistance/sensitivity measured using the oral glucose tolerance test (OGTT) at week 0, 9, 18
5. Cardiovascular disease risk measured using fasting blood samples (triglycerides, total cholesterol, non-esterified fatty acids, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol) at week 0, 9, 18
6. Quality of life measured using the Medical Outcome Study SF-36 - wheelchair adapted

(questionnaire) at week 0, 9, 18
7. Independence measured using the Spinal Cord Injury Measure - III (SCIM-III) (questionnaire) at week 0, 9, 18

Overall study start date
01/12/2020

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Males and females
2. Aged greater than 18 years
3. Individuals who have had their SCI for less than 6 months (any level injury/AIS grade assuming the remaining criteria are met)
4. Sufficient upper extremity motor function to complete arm crank ergometry exercise (we will acquire visual confirmation of the participant's ability to perform four upper extremity movements: elbow flexion against gravity, wrist extension against gravity, elbow extension against gravity, and making a fist with the thumb on the outside)
5. Use a wheelchair for at least 75% of their day

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
Current exclusion criteria as of 15/11/2022:
Individuals presenting with any of the following will be excluded from participating in the trial:
1. Unresolved pressure ulcer
2. Upper limb pain that limits exercise
3. Recurrent acute infection or illness
4. Previous (<4 weeks) MI or cardiac surgery
5. Intubation or tracheostomy
6. Individuals who self-report significant upper extremity pain (score of > 60 on the Wheelchair Users Shoulder Pain Index (WUSPI)
7. Women who become pregnant will be advised to notify clinical staff, and upon notification, will be withdrawn from the trial.

8. Cognitive impairment deemed a risk by the healthcare team for participation in the trial (e.g. diagnosis of neurodegenerative disease)
9. Unable to understand explanations and/or provide informed consent
10. Any condition and/or behaviour that would pose undue personal risk or introduce bias into the trial

Previous exclusion criteria:
Individuals presenting with any of the following will be excluded from participating in the trial:
1. Unresolved pressure ulcer
2. Upper limb pain that limits exercise
3. Recurrent acute infection or illness
4. Previous MI or cardiac surgery
5. Taking medications for diagnosed type 1 or 2 diabetes
6. Intubation or tracheostomy
7. Currently taking anti-hypertensive medication (excluding drugs for acute autonomic dysreflexia)
8. Individuals who self-report significant upper extremity pain (score of > 60 on the Wheelchair Users Shoulder Pain Index (WUSPI)
9. Women who become pregnant will be advised to notify clinical staff, and upon notification, will be withdrawn from the trial.
10. Cognitive impairment deemed a risk by the healthcare team for participation in the trial (e.g. diagnosis of neurodegenerative disease)
11. Unable to understand explanations and/or provide informed consent
12. Any condition and/or behaviour that would pose undue personal risk or introduce bias into the trial

Date of first enrolment
15/05/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
The Duke of Cornwall Spinal Treatment Centre
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201591

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal within a year of the trial completion. No additional documents will be available. The study protocol will be published in a peer-reviewed journal at a later date.

Intention to publish date
28/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository and are/will be available upon request.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/02/2023	06/02/2023	Yes	No
HRA research summary			26/07/2023	No	No