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Community-based exercise training for continuing recovery after spinal cord injury

Submission date
06/07/2023

Recruitment status
No longer recruiting

Registration date
11/07/2023

Overall study status
Completed

Last Edited
07/08/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims

People affected by spinal cord injury (SCI) can lose the ability to move their body, including arms and legs, significantly reducing their independence in carrying out self-care and their mobility, impacting on their quality of life. Based on the standard of care, a patient with SCI stays in a spinal unit of the NHS to undergo intensive rehabilitation for approximately 3 months, then will be discharged from the hospital and return home. Once the patient leaves hospital, they have very little access to physiotherapy for their continuing recovery from the injury. Research has shown that individuals with SCI can continue to improve function for up to 2 years from the time of the injury. It is therefore necessary to provide continuing therapeutic exercise for the patients in the community. Hence, the study aims to evaluate the feasibility of a self-directed, home-based, arm-crank exercise training (ACET) programme as continuing rehabilitation for individuals with a spinal cord injury (SCI) who live at home and do not receive ongoing rehabilitation care for their continuing recovery from the injury.

Who can participate?

Patients aged 16 years or older with a spinal cord injury (SCI) who live at home and do not receive ongoing rehabilitation care for their continuing recovery from the injury.

What does the study involve?

This is a feasibility randomised controlled trial study with two study groups: the ACET group and the control group. Both groups will undertake activity-based rehabilitation exercise for 8 weeks and will undergo functional assessments, including balance and fitness tests, before and after the rehabilitation exercise at home. We will test whether individuals with SCI are willing to be recruited and randomised, to undertake the exercise at home, and to adhere to the exercise protocol. We will also interview participants and their medical teams via focus groups to understand their views about the self-directed, home-based rehabilitation programme.

What are the possible benefits and risks of participating?

The possible benefits of participating may include improved physical function and mood. There are minimal risks from participating in this study. All assessments will be performed within

participants' limits of tolerance. Some participants may experience mild muscle soreness following the exercise training. The discomfort can be managed by taking pain killers or hot/cold packs.

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

When is the study starting and how long is it expected to run for?
June 2023 to December 2024

Who is funding the study?
1. University of Birmingham (UK)
2. Academy of Medical Sciences (UK)

Who is the main contact?
Dr Shin-Yi (Chloe) Chiou, s.chiou@bham.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326143

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 326143, CPMS 56434

Study information

Scientific Title
Community-based exercise training for continuing recovery after spinal cord injury

Study objectives
Home-based arm crank exercise training programme is feasible and acceptable to individuals with spinal cord injury who is in the transition of setting back in the community from a specialised hospital after their injuries.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/06/2023, West Midlands - Black Country Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048210; blackcountry.rec@hra.nhs.uk), ref: 23/WM/0121

Study design
Multicentre feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home

Study type(s)
Quality of life, Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Adults with spinal cord injury

Interventions
The arm-crank exercise training (ACET) group will undertake 8 weeks of home-based ACET, 30 minutes/day, 5 days/week, at a moderate intensity. A stationary arm bike will be provided to each participation in the ACET group for training at home. Adherence will be recorded in a provided exercise calendar.

Participants in the control group will undergo the standard of care, which is no prescribed treatment. Participants are free to undertake any forms of exercise of their choice and will be monitored for 8 weeks.

A minimisation randomisation method will be used to ensure balance of severity of injury (AIS scores) and age being the same between the two groups. Randomisation will be performed using an online tool Sealed EnvelopeTM.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measure (pre- and post-intervention, unless specified):
1. Adherence to the intervention: exercise duration, intensity, and frequency recorded by the exercise diary will be analysed to evaluate participants' adherence to the arm-crank exercise training (ACET).
2. An exit survey for usability, perceived effectiveness, and satisfaction will be used at post-intervention only.
3. Focus groups results. Participants in the intervention group will be invited to attend a focus group to discuss their views on the ACET intervention. The focus group will consist of between 5-8 participants, last <60 minutes, and will be conducted in person in a mutually agreed place or remotely via Zoom. An experienced moderator will run the focus group and data will be audio recorded via a secure password protected digital recording device. The recorded discussions will subsequently be transcribed by members of the research team for further analysis.
4. The recruitment rate: [(number recruited/number approached) x100%]
5. The retention rate: [(number completed/number recruited) x100%]

Secondary outcome measures
Secondary outcome measures (pre- and post-intervention)
1. Muscle activity of the key muscles below the level of injury during maximal and submaximal voluntary contractions (MVCs), measured by surface electromyography.
2. Functional reach tasks. This is to assess sitting balance. Participants will be instructed to reach to multiple directions (forward, right side, and left side) with one arm as far as they can without losing balance. Muscle activity of the trunk and movement of the trunk will be recorded using surface electromyography and inertial measurement units.
3. Modified Ashworth Scale (MAS). MAS is a clinical scale that measures resistance of a muscle in response to manual passive muscle stretching. It will be manually applied by a trained experimenter to assess spasticity in the knee extensors and ankle plantar flexor.
4. Fitness and endurance will be measured by the graded exercise test and 3-minutes arm test on an arm ergometer.
5. Mobility, assessed by accelerometer worn by the participant for 7 days.
6. Pain, psychological wellbeing and health-related quality of life will be assessed via questionnaires: a visual analogue scale, the Patient Health Questionnaire-9, Generalised Anxiety Disorder Assessment (GAD-7), and the short-form 36.

Overall study start date
15/06/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria

1. Are aged 16 years old and above
2. Have a cervical or thoracic spinal cord injury (AIS A-D)
3. Have had the injury for 2 years or less
4. Have the ability to voluntarily move the elbow to operate the arm bike, bandage or active grip can be used to help holding the pedals

Participant type(s)
Patient, Resident, Service user

Age group
Adult

Lower age limit
16 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Have ongoing issues with shoulder instability or shoulder pain
2. Are unable to use the bike due to lack of muscle activity to activate the bike (e.g., ASIA B or C at cervical level). This will assess case-by-case.
3. Have contraindications to exercise or have been advised to avoid exercise by their doctor (e.g., postural hypotension, ulcers, pregnancy)
4. Are not able to understand verbal explanations or written information given in English.
5. Are currently staying in a private medical centre or in a hospital for their continuing recovery from SCI.
6. Are currently participating in a trial involving an exercise intervention.

Date of first enrolment
17/07/2023

Date of final enrolment
05/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Robert Jones & Agnes Hunt Orthopaedic Hospital
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
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Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
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Sponsor type
University/education

Website
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ROR

https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Presentations at academic conferences, manuscript publications in peer-reviewed journals.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the current study will be available upon request from the corresponding author.
s.chiou@bham.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	version 2	02/06/2023	10/07/2023	No	Yes