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Early rehabilitation promoting motor recovery from spinal cord injury

Submission date
12/07/2022

Recruitment status
No longer recruiting

Registration date
19/07/2022

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
An injury to the spinal cord can stop the communication between the brain and the body, causing a loss of function below the injury, such as sensation and volitional control of the body. Many people with spinal cord injury (SCI) have reduced control of their trunk (torso) muscles, which help maintain an upright posture and ensure stability while carrying out functional activities such as self-care and transferring, hindering recovery towards independence. Currently available interventions for trunk rehabilitation require substantial input from healthcare professionals. This limits how much resource-intensive interventions can be used (e.g. can only be used in therapy departments, or at home but with a carer present), which may impact the progress of patients' recovery. Hence, new therapies to improve trunk control are urgently needed.

The research of the Chief Investigator has shown that arm-crank exercise can strengthen the connections between the brain and muscles of the trunk in healthy adults and in adults with SCI. The effect likely results from the physiological interaction between the arms and the trunk, a phenomenon termed cross-education. Using the concept of cross-education for SCI rehabilitation enables SCI individuals to use the part of the body that is functioning to rehabilitate the parts that are affected by the injury (i.e., below the level of injury). Indeed, ongoing work from the research group has shown that people with cervical (neck) or high-thoracic (upper back) SCI improved dynamic sitting balance and volitional control of the trunk muscles after unsupervised, home-based arm-crank exercise (ACE) training. ACE training may be a solution to overcome the barrier of access to professionals for trunk rehabilitation after SCI.

Early on following injury, the body is doing all it possibly can to repair the communication channels between the brain and the muscles. This project will test whether early initiated ACE training, with simple and inexpensive equipment, can help SCI patients staying in rehabilitation units achieve better and quicker recovery. It is thought that if ACE training is applied much earlier when repair processes have a greater chance of success, the improvements will be larger, leading to better independence and quality of life for SCI patients. The project will involve two national rehabilitation units for spinal injuries (Sheffield and Middlesbrough) to participate, paving a way for a multi-centre, larger-scale, clinical trial in the nearer future.

Who can participate?
Adults who have suffered a spinal cord injury at the neck or upper back within the past 2 months leading to a partial loss of sensation below the level of injury.

What does the study involve?
The study will evaluate a group of participants before and after ACE training. Participant muscle strength, trunk function, and health-related quality of life will be measured and data will be compared with another group of participants with the same injuries but receiving standard care. Participants will be allocated to receive either ACE training or standard care only, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given.

The ACE training sessions will occur 5 days a week, for 8 weeks in total. Exercise duration will start from 20 min per session and progressively increase to 30 min per session over the 8-week period. Exercise intensity will be maintained at moderate intensity and the time spent training will be recorded by fitness watches worn by participants.

What are the possible benefits and risks of participating?
Participants may improve strength of their arms from undertaking arm-crank exercise training. Some may experience muscle soreness in muscles of the upper body after each exercise session. Instruction for warm-up and cool-down will be given to the participants by the research team.

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

When is the study starting and how long is it expected to run for?
From March 2022 to January 2024

Who is funding the study?
International Spinal Research Trust (UK)

Who is the main contact?
Dr Shin-Yi Chloe Chiou
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Study website
www.birmingham.ac.uk/arm-cycling

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
312585

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRAS 312585, CPMS 52685

Study information

Scientific Title
Early self-initiated upper-body exercise to improve volitional control below the level of injury after spinal cord injury

Study objectives
Patients with SCI who undertake 8 weeks of arm-crank exercise training (ACET) will have better volitional control of the muscles below the level of injury compared to those with similar injuries who receive the standard of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2022,North of Scotland Research Ethics Committee (1) (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0054

Study design
Multicentre interventional single-blinded two-arm randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Traumatic and non-traumatic cervical and thoracic spinal cord injury.

Interventions
The intervention will start after the randomisation. Both the arm-crank exercise training (ACET) and control groups will continue the standard of care in-patient rehabilitation; the study intervention does not interfere with the standard care. A minimisation randomisation method (Altman and Bland, 2005) will be used to ensure balance of covariates, including sex, age, types of injury, levels of injury, and motor scores of the AIS below the level of injury, being the same between the two groups. According to the Altman and Bland's statistical paper published in the BMJ, the procedure starts from the first participant being allocated in a study group at random. For each subsequent participant we determine which study group would lead to better balance between the groups in the variables of interest. The randomisation will be performed by the local principal investigators who will not be involved in assessment. It is however not possible to blind the participants in the ACET group. The study is a single-blinded randomised controlled trial.
Participants in the ACET group will undertake an arm-crank exercise training programme in an upright seated posture, 5 days a week, for 8 weeks in total. Exercise duration will start from 20 min per session and progressively increase to 30 min per session. Exercise intensity will be maintained at moderate intensity, Borg CR-10 rating of perceived exertion (RPE) at 4, and at 60 revolutions per minute (rpm). Time spent on ACET will be recorded by fitness watches worn by participants; this information will be used to evaluate compliance and adherence to the intervention protocol.
Participants in the control group will not receive additional treatment. Participants in the control group will be offered the ACET intervention after they complete the study.

Intervention Type
Behavioural

Primary outcome measure
1. Muscle activity of the key muscles during maximal voluntary contractions (MVCs) measured by surface electromyography at baseline, 4 weeks, post-intervention, and 3 months after the intervention
2. Motor impairment measured using the American Spinal Injury Association Impairment Scale (AIS) motor scores below the level of injury at baseline, 4 weeks, post-intervention, and 3 months after the intervention

Secondary outcome measures
1. Adherence to the intervention measured as exercise duration, intensity, and frequency recorded by the fitness watches throughout the intervention
2. Sitting balance measured using two inertial measurement units (IMUs) placed over the upper

and lower parts of the back to record postural sway during a stability test at baseline, 4 weeks, post-intervention, and 3 months after the intervention. In this test participants will be asked to maintain upright seated position in a standardised chair without a back support for 10 s and will also be asked to raise bilateral arms in response to a visual cue while maintaining their stability.
3. Dynamic sitting balance measured using two IMUs placed over the upper and lower parts of the back to record angular displacement of the trunk during functional reach tasks at baseline, 4 weeks, post-intervention, and 3 months after the intervention. In these tasks participants will be instructed to reach in multiple directions (forward, right side, and left side) with one arm as far as they can without losing balance (Field-Fote and Ray, 2010).
4. Spinal excitability below the level of injury measured using surface electrodes placed over muscle bellies of the triceps surae bilaterally and a stimulator probe placed at the popliteal fossa to stimulate the tibial nerves to induce maximal motor response (M-waves) and Hoffmann (H-) reflexes using electrical stimulation (Chiou et al., 2017) while participants are in supine lying position at baseline, 4 weeks, post-intervention, and 3 months after the intervention
5. Spasticity in the knee extensors and ankle plantar flexor measured using the Modified Ashworth Scale (MAS) at baseline, 4 weeks, post-intervention, and 3 months after the intervention
6. Self-care, respiration, sphincter management, and mobility measured using the Spinal Cord Independence Measure (SCIM-3) questionnaire at baseline, 4 weeks, post-intervention, and 3 months after the intervention
7. Pain, psychological wellbeing and health-related quality of life measured using a visual analogue scale (Bryce et al., 2007), the Hospital Anxiety and Depression Scale (Zigmond et al., 1983), and the Short-form 36 (Forchheimer et al., 2004) at baseline, 4 weeks, post-intervention, and 3 months after the intervention

Overall study start date
01/03/2022

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Cervical or upper thoracic sensory incomplete spinal cord injury (American Spinal Injury Association Impairment Scale [AIS] Grade B, C, or D)
3. Had the injury within the past 2 months
4. Able to voluntarily move the elbow to operate the arm bike. Bandage or active grip can be used to help hold the pedals.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Ongoing issues with shoulder instability or shoulder pain
2. Unable to use the bike due to lack of muscle activity to activate the bike (e.g. American Spinal Injury Association Impairment Scale [AIS] Grade B or C at cervical level). This will be assessed on a case-by-case and discussion with the medical care team will be in place prior to study participation.
3. Contraindications to exercise in an upright posture (e.g. postural hypotension, ulcers)
4. Pregnant
5. Unable to understand what is involved in the study or cannot understand written or verbal English

Date of first enrolment
01/08/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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Study participating centre
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University/education

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ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
International Spinal Research Trust

Alternative Name(s)
Spinal Research

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 peer-reviewed journal.

Intention to publish date
31/07/2024

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 Shin-Yi Chloe Chiou (s.chiou@bham.ac.uk). Access to anonymous data can be requested after the study findings are published. Data is strictly for the use of research purposes. Consent from participants for data sharing will be sought during the study consent and hence no additional consent will be needed for the anonymous data being shared with other research groups. Anonymous data will be shared with encrypted spreadsheets via Microsoft OneDrive.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	09/05/2022	15/07/2022	No	Yes
HRA research summary			28/06/2023	No	No