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Promoting spinal cord injury recovery through arm cycling exercise

Submission date
14/02/2024

Recruitment status
No longer recruiting

Registration date
27/02/2024

Overall study status
Ongoing

Last Edited
30/12/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims:
An injury to the spinal cord can disrupt the communication between the brain and the body, causing a loss of function below the injury, such as sensation and limb movement. In the early stages following the injury, the body is doing all it possibly can to repair these communication channels. Although early intensive rehabilitation improves recovery from spinal cord injury (SCI), the evidence regarding the effects of early-initiated, intensive rehabilitation and research exploring the potential mechanisms underpinning recovery post-SCI is inconclusive. The aim of this study is to find out whether a self-initiated arm cycling exercise training programme enhances motor recovery below the level of injury in individuals with a recent SCI.

Who can participate?
Adults aged 18 years and above who have suffered an incomplete spinal cord injury at the neck or upper back within the past 6 months and are able to use the arm bike.

What does the study involve?
Participants are randomly allocated to two groups. One group (the experimental group) will do the arm cycling training in addition to the standard care. The other group (the control group) will continue with standard care.
The researchers will compare the muscle strength, trunk function, and health-related quality of life between the groups.
The arm cycling training programme will consist of cycling 3 x 30 minutes per week for weeks 1-2; 4 x 30 minutes per week for weeks 3-4; 5 x 30 minutes per week for weeks 5-8 in an upright seated posture.

What are the possible benefits and risks of participating?
Patients with spinal cord injury may improve the strength of their arms and trunk after doing the arm-cycling exercise training. Participants might experience muscle pain after or during the arm cycling exercise, this will be monitored by the therapist-researcher.

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

When is the study starting and how long is it expected to run from?
September 2023 to October 2026

Who is funding the study?
1. The International Spinal Research Trust (UK)
2. The Academy of Medical Sciences (UK)

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

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
312585

Central Portfolio Management System (CPMS)
52685

Study information

Scientific Title
The effects of early self-initiated arm cycling exercise on improving volitional control below the level of injury after spinal cord injury

Acronym
RPM

Study objectives
Patients with spinal cord injury (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.

The researchers' first study “Early self-initiated upper-body exercise to improve volitional control below the level of injury after spinal cord injury” (https://www.isrctn.com /ISRCTN89333770) was a feasibility study. In this new study “The effects of early self-initiated arm cycling exercise on improving volitional control below the level of injury after spinal cord injury” they want to check the effects of the intervention. In the feasibility study, the intervention was 5 days a week for 8 weeks and at 60 revolutions per minute (rpm). In this new study, there is a progressive training protocol (3-5 days a week of exercise) suggested by PPI participants to be more acceptable to patients at early stages of SCI. The follow-up timepoint in the feasibility study was 3 months, and in this new study is 6 months for a better understanding of long-term effects. In this new study the researchers have added a self-efficacy and motivation questionnaire. The eligibility of the patients in the first study was patients who had the injury within the past 2 months, and in this new study it is patients who had the injury within the past 6 months.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/10/2023, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0054

Study design
Pilot single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
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 Altman and Bland's statistical paper published in the BMJ, the procedure starts with the first participant being allocated to a study group at random. For each subsequent participant, the researchers determine which study group would lead to a 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; thus the study is a single-blinded randomised controlled trial.

The intervention will start after the randomisation. Both the ACET and control groups will continue the standard of care in-patient rehabilitation; the study intervention does not interfere with the standard care.

Participants in the ACET group will undertake an arm-crank exercise training programme consisting of 3 x 30 minutes per week for weeks 1-2; 4 x 30 minutes/week for weeks 3-4; 5 x 30 minutes/week for weeks 5-8 in an upright seated posture. This progressive training protocol was suggested by PPI participants to be more acceptable by patients at early stages of SCI. Exercise intensity will be maintained at moderate intensity. Time spent on ACET will be recorded with an exercise diary; this information will be used to evaluate compliance and adherence to the intervention protocol.

Participants in the control group will not receive additional treatment.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 17/07/2025:

1. Trunk control neurophysiological mechanisms measured by surface electromyography (EMG), and spinal excitability below the level of injury, assessed by eliciting motor evoked potentials of the spinal cord using electrical stimulation
2. Dynamic sitting balance assessed using functional reach tasks. Participants will be instructed to reach in multiple directions with one arm as far as they can without losing balance. One inertial measurement unit (IMU) and surface EMG will be placed over the upper part of the back, and a video recording will be used to capture angular displacement and trunk muscle activity during the tasks.

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for

the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

Previous primary outcome measure as of 12/08/2024:

1. Muscle activity of the key muscles during maximal and submaximal voluntary contractions, measured by surface electromyography (EMG)
2. Dynamic sitting balance assessed using functional reach tasks. Participants will be instructed to reach in multiple directions with one arm as far as they can without losing balance. Two inertial measurement units (IMUs) and surface EMG will be placed over the upper and lower parts of the back to record angular displacement and muscle activity of the trunk, respectively, during the tasks.

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

Previous primary outcome measure:

1. Muscle activity of the key muscles during maximal and submaximal voluntary contractions, measured by surface electromyography (EMG)
2. Motor impairment measured using the American Spinal Injury Association Impairment Scale (AIS) motor scores below the level of injury

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

Key secondary outcome(s))

Current secondary outcome measures as of 17/07/2025:

1. Adherence to the intervention: exercise duration, intensity, and frequency documented in the exercise diary will be analysed to evaluate participants' adherence to the ACET.
2. Motor impairment measured using the American Spinal Injury Association Impairment Scale (AIS) motor scores below the level of injury
3. Self-care, respiration, sphincter management, and mobility assessed using the Spinal Cord Independence Measure (SCIM-3) questionnaire

4. Pain, psychological wellbeing and health-related quality of life assessed via questionnaires: the DN4 questionnaire, the Patient Health Questionnaire-9, Generalised Anxiety Disorder Assessment (GAD-7), Short Form-36 (SF-36)
5. Motivation to engage in the ACET and self-efficacy regarding confidence to perform the arm-crank exercise at the duration and intensity recommended over the course of the programme, assessed using a self-efficacy and motivation questionnaire.
6. Physical activity will be measured with the Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ-SCI). This outcome was approved in our most recent ethics amendment.
7. Recording physical activity with a wrist-worn accelerometer for 7 days before and 7 days after the intervention.

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

Qualitative outcome:
A subset of approximately 15 participants will be invited to attend a focus group to discuss their views on the ACE intervention. The discussion will cover the study protocol, clinical applications, and feasibility of administering the intervention outside hospitals (e.g., at home, local gyms). The focus group will consist of 5-8 participants and will be conducted in person or remotely via Zoom. The research team has a Zoom licence to ensure the data are secured. The licence also allows participants to join the meeting using their telephone (i.e., dial-in numbers). 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. Feedback will be included when designing a new study for a grant application, i.e., NIHR, to ensure that the research meets patients' needs.

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Previous secondary outcome measures as of 12/08/2024:

1. Adherence to the intervention: exercise duration, intensity, and frequency documented in the exercise diary will be analysed to evaluate participants' adherence to the ACET.
2. Motor impairment measured using the American Spinal Injury Association Impairment Scale (AIS) motor scores below the level of injury
3. Spinal excitability below the level of injury. Participants will be in a semi-sitting position. Surface electrodes will be placed over muscle bellies of the back extensors and knee extensors bilaterally and a pair of stimulus electrodes will be placed behind the neck and on the upper back, respectively, to elicit motor evoked potentials of the spinal cord using electrical stimulation.
4. Self-care, respiration, sphincter management, and mobility assessed using the Spinal Cord Independence Measure (SCIM-3) questionnaire
5. Pain, psychological wellbeing and health-related quality of life assessed via questionnaires: the DN4 questionnaire, the Patient Health Questionnaire-9, Generalised Anxiety Disorder Assessment (GAD-7), Short Form-36 (SF-36)
6. Motivation to engage in the ACET and self-efficacy regarding confidence to perform the arm-

crank exercise at the duration and intensity recommended over the course of the programme, assessed using a self-efficacy and motivation questionnaire.
7. Physical activity will be measured with the Leisure Time Physical Activity Questionnaire for People with Spinal Cord Injury (LTPAQ-SCI). This outcome was approved in our most recent ethics amendment.
8. Recording physical activity with a wrist-worn accelerometer for 7 days before and 7 days after the intervention.

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

Qualitative outcome:
A subset of approximately 30 participants will be invited to attend a focus group to discuss their views on the ACE intervention. The discussion will cover the study protocol, clinical applications, and feasibility of administrating the intervention outside hospitals (e.g., at home, local gyms). The focus group will consist of 5-8 participants and will be conducted in person or remotely via Zoom. The research team has a Zoom licence to ensure the data are secured. The licence also allows participants to join the meeting using their telephone (i.e., dial-in numbers). 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. Feedback will be included when designing a new study for a grant application, i.e., NIHR, to ensure that the research meets patients' needs.

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Previous secondary outcome measures:

1. Adherence to the intervention: exercise duration, intensity, and frequency documented in the exercise diary will be analysed to evaluate participants' adherence to the ACET.
2. Dynamic sitting balance assessed using functional reach tasks. Participants will be instructed to reach in multiple directions with one arm as far as they can without losing balance. Two inertial measurement units (IMUs) and surface EMG will be placed over the upper and lower parts of the back to record angular displacement and muscle activity of the trunk, respectively, during the tasks.
3. Spinal excitability below the level of injury. Participants will be in a semi-sitting position. Surface electrodes will be placed over muscle bellies of the back extensors and knee extensors bilaterally and a pair of stimulus electrodes will be placed behind the neck and on the upper back, respectively, to elicit motor evoked potentials of the spinal cord using electrical stimulation.
4. Self-care, respiration, sphincter management, and mobility assessed using the Spinal Cord Independence Measure (SCIM-3) questionnaire
5. Pain, psychological wellbeing and health-related quality of life assessed via questionnaires: a visual analogue scale, the Patient Health Questionnaire-9, and Generalised Anxiety Disorder Assessment (GAD-7)

6. Motivation to engage in the ACET and self-efficacy regarding confidence to perform the arm-crank exercise at the duration and intensity recommended over the course of the programme, assessed using a self-efficacy and motivation questionnaire.

Assessment will be conducted at the spinal units of the collaborating NHS Trusts. Two repeated baseline assessments (T0 and T1) will be performed prior to the start of the ACET to allow for the estimation of spontaneous recovery. A post-assessment will be performed at the completion of the ACET (T2), followed by a follow-up assessment at 6 months after the post-assessment (T3). A 6-month follow-up will allow the researchers to evaluate any long-term changes in physical and psychological function as a result of ACET. The same assessment time points will be applied to the control group.

A subset of approximately 30 participants will be invited to attend a focus group to discuss their views on the ACE intervention. The discussion will cover the study protocol, clinical applications, and feasibility of administering the intervention outside hospitals (e.g., at home, local gyms). The focus group will consist of 5-8 participants and will be conducted in person or remotely via Zoom. The research team has a Zoom licence to ensure the data are secured. The licence also allows participants to join the meeting using their telephone (i.e., dial-in numbers). 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. Feedback will be included when designing a new study for a grant application, i.e., NIHR, to ensure that the research meets patients' needs.

Completion date
31/10/2026

Eligibility

Key inclusion criteria
Updated inclusion criteria as of 18/07/2025:
1. Aged 18 years and above
2. Post-injury < 6 months
3. Cervical or thoracic incomplete SCI
4. Able to sit without support for 30 seconds
5. Sufficient upper-limb function to voluntarily perform arm cycling movement on a stationary arm bike, with or without use of gripping aids

Previous inclusion criteria:
1. Are aged 18 years and above
2. Have a cervical or upper thoracic sensory incomplete spinal cord injury
3. Have had the injury within 6 months
4. Are able to sit with support/independently for 30 seconds
5. 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 18/07/2025:
1. Ongoing issues with shoulder instability or shoulder pain
2. Contraindications to exercise in an upright posture (e.g., postural hypotension, unresolved pressure ulcer, uncontrolled cardiovascular conditions)
3. Pregnancy
4. Unable to understand explanation of the study and/or instructions of the intervention

Previous 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., AIS B or C at cervical level). This will assess case-by-case and discussion with the medical care team will be in place prior to study participation.
3. Have contraindications to exercise in an upright posture (e.g., postural hypotension, ulcers).
4. Are pregnant.
5. Are not able to understand what is involved in the study or who cannot understand written or verbal English will not be recruited given the scale of the study being a pilot study and the exercise is self-initiated.

Date of first enrolment
29/02/2024

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Pinderfields General Hospital
Aberford Road
Wakefield
England
WF1 4DG

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
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S5 7AU

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research organisation

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

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

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.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/08/2025	22/08/2025	Yes	No