ISRCTN17864031 https://doi.org/10.1186/ISRCTN17864031

Combined arm cycling and standard exercise training for improving trunk function after spinal cord injury

Submission date
20/10/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

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
Core control is essential for carrying out activities of daily living but is very often impaired after a spinal cord injury, hindering functional recovery. This project aims to study the effectiveness of combined arm cycling and standard exercise training in improving trunk function in individuals with a spinal cord injury. It is hoped that the arm cycling exercise will enhance the effectiveness of standard exercise training at improving trunk function in individuals with spinal cord injury.

Who can participate?
Adults (aged 18 years and above) with a stable, chronic cervical or thoracic, incomplete spinal cord injury are eligible to participate in the study. Additional inclusion criteria are to be able to voluntarily pedal the arm bike and to have some residual trunk control.

What does the study involve?
All participants will undertake exercise training for improving trunk control three times a week for 8 weeks. Of these, half of them will undertake an additional arm cycling exercise at home, and the other half will undertake static sitting exercise at home. Neural and functional assessments will be performed at the beginning and after 4 and 8 weeks. A follow-up assessment will be carried out at 8 weeks after completing the intervention.

What are the possible benefits and risks of participating?
Participants will benefit from the arm cycling exercise and rehabilitation training by directly exercising muscles of the arms and the core, thereby improving mobility and strength. Participants may experience muscle soreness of the arms and shoulders as a result of 30 minutes of arm cycling. However, the muscle soreness should last no longer than 3 days and can be eased by gentle stretching of the muscles. Some participants may experience a mild headache after the neural assessment. Taking a painkiller before the assessment or resting after the assessment usually can release the headache effectively.

Where is the study run from?
The study is run by a research team at the University of Birmingham in collaboration with the

Midland Centre for Spinal Injuries at the Robert Jones and Agnes Hunt Orthopaedic Hospital NHS FT, and with the National Spinal Injuries Centre, Stoke Mandeville Hospital Buckinghamshire Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2024

Who is funding the study?
The INSPIRE Foundation (UK)

Who is the main contact?
Dr Chloe Chiou
s.chiou@bham.ac.uk

Study website
https://www.youtube.com/watch?v=o7vkwhU7_hQ

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289841

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 289841

Study information

Scientific Title
Functional activity of upper extremities to improve trunk function after spinal cord injury

Study objectives
It is hypothesised that SCI participants undertaking the combined intervention will increase the ability to recruit trunk muscles for postural stability to a greater extent compared to those undertaking the therapeutic exercise training alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2021, West Midlands - Edgbaston Research Ethics Committee, REC ref: 21/WM /0047

Study design
Two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stable, lower cervical or upper thoracic, incomplete spinal cord injury

Interventions
Participants will be randomized into one of the two groups: the experimental group and the control group using minimisation methods ensuring balance in prognostic factors (e.g. level of injury, years since injury) between groups. All participants will receive standard exercise training focusing on improving trunk control and postural stability 3 times per week for 8 weeks. Participants in the experimental group will undertake arm cycling exercise at home using a stationary arm bike provided by the research team for 30 minutes, 5 days per week, for 8 weeks. Participants in the control group will be instructed to practise static sitting without back support for the same amount of time. After completing the intervention, all participants will be followed

up for 8 weeks to monitor whether the interventional effects outlast or not. Neurophysiological and functional assessments will be performed during the course of the intervention to monitor improvements in trunk control. Participants will stay in the trial for 16 weeks in total (8 weeks of intervention and 8 weeks of follow-up).

Intervention Type
Behavioural

Primary outcome measure
Dynamic sitting balance assessed by multidirectional reach test at baseline, 4, 8 and 16 weeks

Secondary outcome measures
1. Neuromuscular and corticospinal function of the trunk muscles measured using non-invasive transcranial magnetic stimulation at baseline, 4, 8 and 16 weeks
2. Mobility measured using time of 3-meter walking or wheelchair transfer at baseline, 4, 8 and 16 weeks
3. Pressure relief measured using a force plate at baseline, 4, 8 and 16 weeks
4. Trunk control measured using trunk impairment scale at baseline, 4, 8 and 16 weeks
5. Function of upper extremities measured using a dynamometer and the Action Research Arm Test at baseline, 4, 8 and 16 weeks

Overall study start date
04/01/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
SCI participants will be included if they have:
1. A stable, lower cervical or upper thoracic, incomplete spinal cord injury.
2. Ability to voluntarily move the elbow to operate the arm bike.
3. Visible motor evoked potentials (MEPs) in erector spinae (ES) muscles induced by transcranial magnetic stimulation (TMS). This is to ensure changes in corticospinal function are measurable

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Participants will be excluded if they meet the criteria for exclusion for the use of TMS (Rossi et al., 2011):
1. Metal implants, cardiac pacemaker, history of epilepsy or fits, previous brain injury, neurosurgery of the brain, neurological disorders other than spinal cord injury, psychological disorders, actively taking antidepressant or other neuromodulatory drugs
2. Participants are pregnant or breastfeeding
3. Participants are under the age of 18

Date of first enrolment
01/07/2021

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Midland Centre for Spinal Injuries
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHSFT
Oswestry
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SY10 7AG

Study participating centre
The National Spinal Injuries Centre
NSIC, Stoke Mandeville Hospital
Buckinghamshire Healthcare NHS Trust
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Sponsor information

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Sponsor type
University/education

Website
https://www.birmingham.ac.uk/index.aspx

Funder(s)

Funder type
Charity

Funder Name
Inspire Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. The researchers are planning to publish the study protocol in a peer-reviewed journal
2. Results will be published in peer-reviewed journals and presented at major conferences in both the scientific and clinical fields

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the principal investigator Dr Shinyi Chiou (s.chiou@bham.ac.uk). Neurophysiological and behavioural data that are fully anonymous will be accessible for research /academic purposes after the data are analysed and published in peer-reviewed journals (estimated January 2025 for 10 years, per University Data storage policy). Data will be shared as a spreadsheet and only for non-commercial use.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No