ISRCTN14598016 https://doi.org/10.1186/ISRCTN14598016

Testing a novel home-based approach for strengthening motor pathways

Submission date
16/04/2026

Recruitment status
Recruiting

Registration date
16/04/2026

Overall study status
Ongoing

Last Edited
16/04/2026

Condition category
Nervous System Diseases

[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
After a spinal cord injury, many people experience weakness or loss of movement in their hands. This happens because the injury damages the pathways that carry signals from the brain to the muscles. Although some of these pathways may survive the injury, they are often too weak to control movement effectively.

We have developed a new approach designed to strengthen these surviving pathways. It works by pairing a precisely timed hand movement with an electrical stimulus delivered to a nerve in the wrist. When the movement and the stimulation happen at exactly the right time together, the brain and spinal cord are encouraged to strengthen their connections — a process similar to how we learn new skills. We have already shown this works in healthy volunteers. This study aims to find out whether the same approach can improve hand function in people living with spinal cord injury.

Who can participate?
Adults aged 18 or over who have had a cervical spinal cord injury for at least one year which resulted in hand weakness. Participants must be able to make a well-timed hand movement in response to a visual cue. People cannot participate if they have an implanted device (e.g. pacemaker), ongoing cord compression or a spinal cord disease, a history of seizures or head injuries, uncontrolled medical problems (e.g. heart disease) or an aversion to loud sounds.

What does the study involve?
Participants will attend three laboratory visits at their agreed rehabilitation gym or Newcastle University Medical School, each separated by six weeks. At each visit, a range of assessments will be completed to measure hand strength, dexterity, and the strength of nerve connections between the brain and the hand. These assessments include standard clinical tests, grip strength measurements, and non-invasive brain stimulation techniques.

Between visits, participants will use a small portable device at home for six weeks. The device connects to a mobile phone app, which takes the form of a simple game. To play the game, participants make a hand movement in response to a visual cue on their phone screen. Each time the movement is made, the device delivers a small electrical stimulus to a nerve in the wrist. This

stimulus is not painful, though participants may feel a mild tingling sensation. The aim is to complete around 20 minutes of the game each day.

Participants will be randomly allocated (computer randomisation) to one of two groups. One group will use the device in the first six weeks of the study, and the other group will use it in the second six weeks. This means all participants receive the intervention, just at different times.

To help with motivation, participants can choose to provide contact details of a family member or friend. If the game has not been completed by an agreed time each day, an automatic reminder message will be sent to that person. Participants can opt out of this at any time.

What are the possible benefits and risks of participating?
Participants may experience improvements in hand strength or function as a result of taking part, although this cannot be guaranteed. The electrical nerve stimulation used in this study is the same type routinely used in medical diagnosis and is entirely safe. Some participants may experience mild, short-lived skin irritation from the adhesive electrodes. The brain stimulation techniques used during laboratory visits are also widely used in research and clinical settings and are considered low risk.

Where is the study run from?
The study is run from the Biosciences Institute at Newcastle University, Newcastle upon Tyne, UK. In person visits will take place either in Newcastle University Medical School, or in either the Bristol or Gatwick Neurokinex rehabilitation gyms. Participants will use the device at home between visits.

When is the study starting and how long is it expected to run for?
The study is expected to start in April 2026 and run until January 2027. Each participant will be involved for 12 weeks in total.

Who is funding the study?
The study is funded by the INSPIRE Foundation and the Rugby Football Union Injured Players Foundation.

Who is the main contact?
For more information about the study, please contact: Lillian Clements at the Biosciences Institute, Newcastle University
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Contact information

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Scientific, Public

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Additional identifiers

Study information

Scientific Title
Strengthening residual motor pathways in individuals with spinal cord injury

Study objectives
1. To demonstrate that the movement-paired nerve stimulation protocol strengthens descending motor pathways in individuals with cervical spinal cord injury.
2. To determine whether the protocol can be effectively delivered in a home setting using a portable device.
3. To determine whether the protocol leads to measurable improvements in hand function in people with spinal cord injury.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/03/2026, FMS Ethics Committee (Newcastle University Medical School, Framlington Place, Newcastle Upon Tyne, NE2 4HH, United Kingdom; +44 (0)191 208 6000; fmsethics@newcastle.ac.uk), ref: 71057

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Individuals who have had a cervical spinal cord injury which resulted in hand weakness

Interventions
This study uses a randomised crossover design. Participants are allocated to one of two groups via randomisation (computer randomisation). Both groups receive the same intervention but in different orders across the 12-week study period.

Group A receives the intervention device after visit 1. They use the device for at least 20 minutes daily for six weeks, returning it at visit 2. The six weeks following device return serve as the control period, with visit 3 occurring at week 12.

Group B receives no intervention between visit 1 and visit 2 (control period). They receive the intervention device after visit 2, using it daily for six weeks before returning it at visit 3.

Intervention: Participants perform a precisely timed hand movement in response to a visual cue presented via a mobile phone game. At the moment of movement, a brief electrical stimulus is delivered to a peripheral nerve via adhesive electrodes connected to a custom Bluetooth device. Participants complete approximately 300 paired stimulations per day throughout the six-week intervention period in their home environment.

Total duration: 12 weeks per participant, comprising one six-week intervention period and one six-week control period. Participants attend three laboratory visits at weeks 0, 6 and 12.

Intervention Type
Device

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
MoveMend Stimulator

Primary outcome(s)

1. Upper limb motor function measured using GRASSP (Graded Redefined Assessment of Strength, Sensibility, and Prehension) at Weeks 0, 6, and 12

2. Corticospinal excitability measured using Motor evoked potentials (MEPs) elicited by transcranial magnetic stimulation (TMS) at Weeks 0, 6, and 12

Key secondary outcome(s)
1. Self-reported upper limb capability measured using Capabilities of Upper Extremity Questionnaire (CUE) at Weeks 0, 6, and 12

2. Gross manual dexterity measured using Box and Block Test at Weeks 0, 6, and 12

3. Grasp strength measured using Dynamometer during precision and power grip at Weeks 0, 6, and 12

4. Independence of finger movement measured using Custom built device using force sensors at Weeks 0, 6, and 12

5. Reticulospinal drive to voluntary movement measured using StartReact test at Weeks 0, 6, and 12

6. Cortical inhibition and excitation measured using Paired-pulse TMS and TMS combined with peripheral nerve stimulation at Weeks 0, 6, and 12

Completion date
22/01/2027

Eligibility

Key inclusion criteria
1. >1 year post injury
2. Have a cervical spinal cord injury (C2-C7) resulting in hand weakness
3. Able to make a well-timed hand movement

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
1. Uncontrolled medical problems including pulmonary, cardiovascular or orthopaedic disease
2. Psychosis or altered cognitive status which would affect consent
3. History of head injury or stroke
4. Fitted with cardiac pacemaker (a contraindication for TMS)
5. Metal plate in skull (a contraindication for TMS)
6. History of seizures (a contraindication for TMS)
7. Pregnant females
8. Ongoing cord compression or a syrinx in the spinal cord or spinal cord disease such as spinal stenosis, spina bifida or herniated cervical disk
9. An aversion to loud sounds

Date of first enrolment
04/05/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
Newcastle University Medical School, Framlington Place
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Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type

Funder Name
Inspire Foundation

Alternative Name(s)
inspirefoundationuk, inspirefndtn, The INSPIRE Foundation, INSPIRE

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Rugby Football Union Injured Players Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available