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Improving upper limb movement after spinal cord injury with a wearable device

Submission date
01/07/2021

Recruitment status
No longer recruiting

Registration date
07/07/2021

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many spinal cord injury (SCI) survivors find that they have an imbalanced weakness in the upper limb: while flexor muscles regain considerable strength after the injury, the extensors such as triceps remain permanently weak. In the Baker group in Newcastle University, we have developed a novel wearable device which can deliver paired stimuli for long periods while a person goes about their normal everyday activities. We have shown that this device can enhance the control of upper limb muscles. In stroke survivors, we have shown that applying this device to extensor muscles can produce a significant improvement in arm and hand function. In this study, we will carry out a clinical trial to test whether the device can also enhance movement in SCI survivors.

Who can participate?
Individuals attending the Neurokinex community gyms with chronic spinal cord injury if they fulfil our Inclusion and Exclusion Criteria.

What does the study involve?
Each participant will receive two different intervention protocols (device, control) for one month each. Participants are asked to wear the device for at least four hours each day for 4 weeks. At baseline, after 4 weeks and after 8 weeks, several electrophysiological measurements will be taken. These include electromyography recordings (EMG) from triceps (including maximal contraction), responses to transcranial magnetic stimulation (TMS), reaction time tasks, reaching tasks and the Capabilities of Upper Extremity Questionnaire.

What are the possible benefits and risks of participating?
Application of the same protocol to the forearm extensor muscles of stroke survivors produced a small but significant improvement in upper limb function. SCI participants could possibly benefit from a similar improvement in upper limb function of the stimulated limb. Participants will help basic research. There are no associated risks in participating.

Where is the study run from?
The study will be conducted in the Neurokinex centres (UK). The participants will be examined in the centre and dispensed the wearable device for domestic use. All further scheduled

assessment will take place at the centre. All required equipment will be brought to the Neurokinex centre by Newcastle University (UK) for the duration of the study.

When is the study starting and how long is it expected to run for?
April 2019 to February 2022

Who is funding the study?
The study is funded by a Nathalie Rose Barr award from the International Spinal Research Trust (UK)

Who is the main contact?
Prof. Stuart Baker, stuart.baker@newcastle.ac.uk
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Contact information

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Additional identifiers

Protocol serial number
Protocol Wearable Device clinical study SCI v4

Study information

Scientific Title
Investigating electrophysiological changes in triceps after paired stimulation from a wearable device in chronic spinal cord injury survivors

Study objectives
In this study, we intend to test the impact of long term use of a wearable stimulating device on upper limb function in chronic spinal cord injury. We will compare the device, which will stimulate the triceps 10 ms before auditory click, with a group which will not receive any stimulation. We do not expect any plastic changes in reticulospinal tract or limb function in the second protocol; this serves as a control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/04/2019, Ethics committee of the faculty of medical sciences at Newcastle University (The Medical School, Newcastle University, Framlington Place, Newcastle upon Tyne, NE2 4HH, UK; no telephone number provided; fmsethics@ncl.ac.uk), ref: 2020/5319/2020

Study design
Multicentre interventional randomized prospective study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Subjects fulfilling the selection criteria will be randomized (via computer generated code) to one of the two equal size parallel arms of the study.
Group A: Will first receive the wearable device (electrical stimulation of triceps 10 ms before auditory click) and then spend 4 weeks without the device (control).
Group B: Will first spend 4 weeks without the device (control) and then 4 weeks with the stimulation device.

The study device is comprised of a plastic box about the size of a smart phone, containing an electrical stimulator and audio amplifier, powered by an internal battery which can be recharged via a standard microUSB port. The wearable device generates constant-current electrical stimulation to the target muscle through surface electrodes (220 V compliance, 150 µs pulse width). A knob on the device allows adjustment of the stimulus intensity, which is set to be just below the motor threshold (defined as a visible muscle twitch). Adequate care will be taken to prevent accidental increment of stimulus strength. Auditory stimuli are generated by delivering a 0.1 ms wide, 12 V square excitation pulse into a miniature earpiece; this produces a brief click with an intensity of 110 dB SPL. The earpiece is placed in the contralateral ear. An internal flash memory with plasticity stimulus protocol will be inserted under the cover. The back side of the device will be custom made according to participants' preference of carrying the device during his/ her awake hours. They can either clip it on their belt/ keep it on a specialized arm pouch or just keep inside the pocket of their trousers. The correct length of the wire will be chosen and the backside of the device will be custom made (fitted with a loop/ clip) accordingly during dispensing. An inbuilt clock will record the on and off time of the device which can be subsequently retrieved from the internal flash memory to monitor compliance. The participants will be instructed to use the device for at least four hours per day during their awake hours, at any time except during shower or bathing.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Newcastle Wearable Device

Primary outcome(s)
Measured at baseline, after 4 and 8 weeks:
1. Electrophysiological changes in triceps muscle are measured using EMG
2. Motor evoked potential (MEP) size measured using transcranial magnetic brain stimulation
3. Maximal voluntary contraction measured using a force transducer and EMG
4. Reaction time measured using a StartReact paradigm
5. Reaching parameters such as speed and trajectory accuracy measured using a custom built planar reaching task
6. Upper extremity function measured using CUE questionnaire

Key secondary outcome(s))

1. Compliance (how long subjects use the device each day) using the device clock data and participants' filled-up diary.
2. Adverse event profile among participants using our intervention device.
3. Range, speed and accuracy of upper limb movement (reaching task with Polhemus motion tracking system) before and after intervention
4. Maximum voluntary contraction force of elbow flexion and extension before and after intervention
5. Auditory startle response (StartReact paradigm) of triceps before and after intervention. This assay will examine the change of reticulospinal tract activity by the intervention (if any).
6. Auditory startle response (startle + TMS paradigm) of triceps before and after intervention. This assay will examine the change of reticulospinal tract activity by the intervention (if any).
7. Motor evoked potentials by transcranial magnetic stimulation (TMS with 2 different coil orientations) before and after intervention. This assay will examine the change of corticospinal tract activity by the intervention (if any).

Completion date
02/02/2022

Eligibility

Key inclusion criteria
1. Chronic (>1 year) cervical injury (C2-C7)
2. Male or female at least 18 years of age
3. Detectable EMG activity in triceps
4. Without upper limb fracture or subluxation/ dislocation of joints within last six months.
5. Be able to follow study instructions and perform study tasks.
6. Willing to provide written informed consent; if necessary through an independent witness should the subject be unable to write themselves due to their injury.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Exhibit major medical problems or poor physical conditions that would interfere with participation, as reported by the participant.

2. Excessive pain in any joint that might limit examination.
3. Participants with contraindications for TMS as confirmed by 'TMS Adult Safety Screen' questionnaire (Keel et al. 2001).

Date of first enrolment
30/07/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Neurokinex Hemel
Ground Floor North Wing Focus
31 Mark Rd
Hemel Hempstead
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HP2 7BW

Study participating centre
Neurokinex Gatwick
Unit 3, Satellite Business Village
Fleming Way
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RH10 9NE

Study participating centre
Movement Laboratory
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Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

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

Individual participant data (IPD) sharing plan
Each subject will be identified by a code and the individual identity and other sensitive information of the subjects will be kept strictly confidential at all time. However, the investigator will maintain a separate Subject Enrolment Log with details of the subject's identification and contact information in case they are needed, for example, in the event of an SAE. All study related documents, study device and other materials will be maintained in secure storage at the trial site, and afterwards in the investigator's offices at the Movement Laboratory, Newcastle University. All trial related documents will be archived safely at the Movement Laboratory following completion of the study. Such archival will be done for a period of at least two years from the date of study completion.

Data will be uploaded to https://data.ncl.ac.uk . Data generated by this project will be in the form of computer files holding surface EMG signal waveforms recorded in response to stimuli. These files will be recorded by the Spike2 software package. Data will be made available after

we publish the papers arising from the study. Data will be stored on https://data.ncl.ac.uk for at least 10 years and available to be downloaded by anyone. Raw data is uploaded in anonymous form and participants be asked to give consent for this at the beginning of the study.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/07/2023	18/08/2023	Yes	No