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# Using brain signals to control functional electrical stimulation during the intention to move a weak arm after a stroke

**Submission date**
03/12/2021

**Recruitment status**
No longer recruiting

**Registration date**
06/01/2022

**Overall study status**
Completed

**Last Edited**
24/04/2025

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Movements of different parts of the body, including the arm, start when the brain produces specific electrical signals. Sometimes after a stroke, even though the person intends to move the arm, the arm will not move or will only move partly. The brain continues to produce electrical signals after stroke, but when the signals are weak the arm does not move. Brain-computer interface (BCI), is a device that can detect these brain signals produced during the intention to move the weak arm. When BCI detects these specific brain signals, it triggers an electrical stimulator (FES). The electrical stimulator then stimulates the muscles in the weak arm to produce a grasp like movement. The currently available BCI-FES devices are bulky and patients need to come to the hospital to get the treatment. Our project aims to develop a BCI-FES device, called Tele BCI-FES that can be used at a patient's home.

Who can participate?
Stroke patients 18 years of age or older with one-handed weakness.

What does the study involve?
The following steps will be followed by all participants:
Visit-1: The participants will give consent to participate in the study and we will check their medical records. The participants will be examined by a medical doctor to determine whether they can take part in this study. After this, we will undergo an assessment of affected hand function and pain before the intervention
We will then start the intervention, during the intervention, the participant will wear a cap with electrodes, which will record the electrical activity of the brain. The electrodes will be filled with a salt-based gel, which can be easily washed out with shampoo or wiped out with a wet tissue. We will also attach two electrodes on the participant's forearm. These electrodes will be connected to a functional electrical stimulation (FES) device with wires. The intervention will include the participant being asked to try to grasp with his/her weak hand. The BCI will use the brain signals to operate this FES device. The FES device will generate small electrical pulses which will stimulate the muscles in the participant's forearm. This will make his/her fingers open and close. The participant will do this repeatedly for 45 minutes. The participant will be issued an

EEG cap and FES device. We will train the participant and his/her carer or family member to use the device at home. We will decide a mutually agreeable time to do the therapy at home.
Home sessions:
Session-1 at the agreed time, the participant will log into our safe and secure system. Our research therapist will meet the participant online. The therapist will monitor the session remotely and guide the participant. This session is for practicing and making sure the participant and his/her caregiver are comfortable in setting up and using the Tele BCI-FES.
Sessions 2-10: The next 9 sessions will be spread over 3 weeks. At the agreed time, participants will log into our safe and secure system. Our research therapist will meet participants online. Each session consists of 10 minutes of preparation, 40 minutes of Tele BCI-FES rehabilitation, and a10 minute interview about the participant experience with the session and any side effects.
Last visit: This visit takes place in the Northern General Hospital. During this visit, the participant will have a post-therapy assessment to see if any changes have occurred as well as to complete several questionnaires about his/her experience with BCI-FES device.
What are the possible benefits and risks of participating?
We do not know whether participation in this experiment will lead to improvement in the upper limb function. This experiment will help us advance the project in the future and design interventions that may help patients with stroke in the future. FES is a safe and well-tolerated procedure in patients with stroke and other neurological disorders. Possible side effects include a feeling of tightness over the arm, swelling, tingling, numbness, and, rarely pain. These effects last only for a few minutes.

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

When is the study starting and how long is it expected to run for?
July 2021 to 30 December 2022

Who is funding the study?
MRC Confidence in Concept Scheme and the NIHR Sheffield Biomedical Research Centre (UK)

Who is the main contact?
1. Dr Mahnaz Arvaneh (E-mail: m.arvaneh@sheffield.ac.uk )
2. Salem Mansour (E-mail: sslmansour1@sheffield.ac.uk)

### Study website
https://teleregain.com/

# Contact information

### Type(s)
Scientific

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
305929

### ClinicalTrials.gov number
NCT05215522

### Secondary identifying numbers
IRAS 305929, STH 21582, CPMS 51928

## Study information

### Scientific Title
Upper limb Telerehabilitation using Brain-Controlled Functional Electrical Stimulation (Tele BCI-FES)

### Acronym
Tele BCI-FES

### Study objectives
1. To develop a prototype of Tele brain-computer interface (BCI) coupled with functional electrical stimulation (FES)
2. To assess the ability of patients to control FES effectively using the Tele BCI system
3. To assess the acceptability and compliance of TeleBCI-FES by the participants
4. To assess the feasibility of using different upper limb outcome measures to capture the effect of TeleBCI-FES

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 02/03/2022, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE; +44 (0)224 558458; gram.nosres@nhs.scot), ref: 22/NS/0018

## Study design
Interventional non-randomized study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Home

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

## Health condition(s) or problem(s) studied
Upper limb stroke rehabilitation

## Interventions
Phase 1: In this phase, the researchers design and develop the hardware/software of their TeleBCI-FES system. The hardware includes a commercially available EEG cap, a commercially available FES system, and a laptop. The EEG cap, worn by the patient, will record EEG signals. The patient will use the EEG signals generated during attempted arm movements to operate the FES system. The FES, directed by the user's thoughts, will deliver the stimulation to activate upper limb muscles. The laptop communicates with the EEG device and FES devices via Bluetooth/WiFi and Arduino (an electronic board) respectively. The software consists of two parts, namely the BCI model and the remote telecommunication platform. The BCI model is a machine learning algorithm that reads, analyses and decodes the EEG signals. If the desired brain patterns were generated during the attempt of moving the weak arm, the BCI model activates the FES. The machine learning algorithm also includes a section that selects the minimum EEG electrodes for each BCI user without compromising the accuracy of the system. This will be done at Visit 1 when the calibration EEG data will be collected from the participant. The telecommunication platform makes the entire delivery of BCI rehabilitation over telecommunication networks and the internet. This allows patients to interact with the BCI therapist from home. The BCI therapist can remotely provide instruction to set up the system, monitor the rehabilitation remotely and troubleshoot the system if needed.

Phase 2: The researchers will assess the feasibility of using this BCI-FES device to deliver home-based upper limb rehabilitation in 10 stroke patients with arm weakness.

Participants' GPs will be informed of their participation and will be sent a letter outlining this. Any abnormal findings will be reported to their GP and appropriate actions taken.

The BCI-FES Intervention lasts three weeks and consists of three sessions each week. Each session will last around 50 minutes, including 10 minutes of preparation and 40 minutes of intervention.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
BCI-FES device

### Primary outcome measure
1. Brain-computer interface accuracy measured by percentage of successful movements achieved in each remote therapy session.
2. Safety assessed using Adverse Event questionnaire after each therapy session.
3. Improvement in upper extremity performance measured by Fugl-Meyer Assessment and Action Research Arm Test (ARAT) during the pre- and post- intervention.
4. Self-assessed health related, quality of life measured by European Quality of List 5D-5L (EQ-5D-5L) during the pre- and post- intervention.
5. Pain rate using Numerical Rating Scale (NRS) diary at the end of each therapy session

### Secondary outcome measures
1. The patient's participation effort and motivation measured by PITTSBURGH rehabilitation participation scale after each therapy session.
2. Muscle strength measured by Medical Research Council (MRC) grade during the pre- and post-intervention.
3. Muscle tone assessment using the modified Ashworth scale during the pre- and post-intervention.

4. Acceptability of the proposed technology using qualitative interview and questionnaire at the end of each therapy session.

### Overall study start date
15/07/2021

### Completion date
01/12/2022

## Eligibility

### Key inclusion criteria
1. Age 18 years and above
2. Experienced an ischaemic or haemorrhagic stroke over 6 months ago
3. Arm weakness interfering with activities of daily living
4. Fugl-Meyer score of upper limb <45
5. Caregiver is willing to assist with trial by helping to deliver intervention

6. Cognitive and language abilities to understand and participate in the study protocol
7. Can maintain sitting with or without support for 1 hour continuously
8. Able to give consent and understand instructions

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
10

### Total final enrolment
9

### Key exclusion criteria
1. Cognitive impairment that would interfere with their ability to comply with the experimental protocol or provide informed consent
2. Dermatological, rheumatologic or orthopaedic illnesses of the affected arm interfering with movement of the elbow
3. Pre-existing severe systemic disorders like cardiovascular disease; active cancer or renal disease; end-stage pulmonary or cardiovascular disease; psychiatric illness including severe alcohol or drug abuse
4. Inability to perform the baseline assessments
5. Severe tactile hypersensitivity
6. Participation in other, upper limb rehabilitation studies
7. Within 12 weeks of receiving Botulinum toxin injections
8. Uncontrolled epilepsy
9. Pacemaker or any other implanted devices
10. Pregnancy
11. Severe dystonia/spasm

### Date of first enrolment
01/01/2022

### Date of final enrolment
01/11/2022

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Northern General Hospital**
Herries Road
Sheffield
United Kingdom
S5 7AU

# Sponsor information

**Organisation**
Sheffield Teaching Hospitals NHS Foundation Trust

**Sponsor details**
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.sth.nhs.uk/

**ROR**
https://ror.org/018hjpz25

# Funder(s)

**Funder type**
Research council

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

### Funder Name
NIHR Sheffield Biomedical Research Centre

## Results and Publications

### Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

### Intention to publish date
30/12/2023

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
Data will be archived in line with the University of Sheffield’s Research Data Management Policy, which is a component of the University's Policy on Good R&I Practices (the 'GRIP' Policy). All the data will be collected in digital format, except signed consent forms. The signed consent forms will be deposited in a secure locked drawer which only the PI will have access to, and will be effectively destroyed at the end of the project. Research data selected for long-term preservation and sharing will be deposited on centrally provisioned University of Sheffield virtual servers and research storage infrastructure for at least ten years. Records of these data will be published in ORDA. ORDA is the University of Sheffield's data repository. It is enables University research data to be preserved, discovered and accessed.
Data collected through this proposal (EEG and questionnaire data) will be suitable to share in an anonymised format for other interested researchers. Any non-anonymised data which is participant-identifiable will not be shared. Importantly, EEG data can be analysed in multiple ways and it is beneficial to allow other research groups to apply various analytic techniques to understand the data and develop new methodologies. The data will be shared with other researchers free of charge upon request for non-commercial use.
The written consent for sharing the anonymised data will be obtained from the participant.

### IPD sharing plan summary
Stored in non-publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | | 21/08/2023 | No | No |
| HRA research summary | | | 20/09/2023 | No | No |

| | | | | |
|---|---|---|---|---|
| Results article | 24/04/2025 | 24/04/2025 | Yes | No |