

# Post-stroke hand rehabilitation with MEG-based brain-robot interface

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<b>Registration date</b> 24/11/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off.

Over 20M people suffer from stroke annually worldwide and up to 40% of stroke survivors may suffer from permanent upper limb paralysis. Unfortunately, despite undergoing a range of therapeutic treatments, many people with upper limb impairments (arising from a stroke & other nervous system disorders) fail to make full functional recovery adversely affecting their quality of life and employability.

It is possible to control an external robotic device using electrical signals generated from brain activity (known as a brain-robot interface [BRI]).

Magnetoencephalography (MEG) is a functional neuroimaging technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain, using very sensitive magnetometers.

The study aims to look into the connection between brain activity measured using MEG and muscle activity.

### Who can participate?

Post-stroke volunteers aged 18 - 80 years, who had a stroke between 6 months and 2 years previously.

### What does the study involve?

Experiments will take place in ISRC's Northern Ireland Functional Brain Mapping (NIFBM) facility where EEG/MEG will be recorded while undertaking physical practice and/or mental practice of left or right-hand movements. This will involve some preparation consisting of attaching a few electrodes and head digitisation following a standard operating procedure. Once ready, participants will wear a robotic exoskeleton on their impaired hand and be seated in an armchair in front of a projector or computer screen. Arrows on the screen will guide participants about the hand (either left or right) to be used for performing or imagining the experimental task. A typical experimental task may consist of clenching a softball in one of the hands at a time. Thus, participants have to either perform the task or imagine to perform it. During and after the session participants will complete some brief questionnaires.

What are the possible benefits and risks of participating?

Benefits include the validation of a novel post-stroke rehabilitation therapy capable of motor recovery from chronic upper limb impairments. There are no expected risks.

Where is the study run from?

Ulster University (UK)

When is the study starting and how long is it expected to run for?

April 2017 to December 2026

Who is funding the study?

UK-India Education and Research Initiative

Ulster University (UK)

Who is the main contact?

Prof. Girijesh Prasad, g.prasad@ulster.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

266827

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Protocol number 19/0103, IRAS 266827

## **Study information**

**Scientific Title**

M/EEG based Post-stroke Neurorehabilitation with Brain-Robot Interface

**Acronym**

MEPSeN-BRI

**Study objectives**

1. Evaluate the effectiveness of the BCI algorithms developed in non-disabled adults for people with stroke. Evaluate whether MEG/EEG-EMG based BCI algorithm is able to function correctly under different levels of impairments and MEG/EEG signal variability is appropriately accounted for so that motor tasks detection accuracy does not deteriorate over time. MEG, EEG and EMG will be acquired concurrently
2. Conduct pilot trials over multiple sessions to monitor the effect of learning over time in terms of progression in BCI task detection accuracy as well as functional recovery. Also, analyze EEG and/or MEG data along with rehabilitation outcomes (or recovery measures) to estimate neuro-markers as a relationship between cortical connectivity measures and motor deficits
3. Compare the contributions of different interventions by creating control groups for post-stroke hand functional recovery such as i) Manual Physical Practice without robot, ii) Physical Practice with Robot without BCI, iii) Only BCI based Mental Practice without robot, iv) Combined BCI based Mental and Robot based Physical Practice

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 09/06/2020, Office for Research Ethics Committees Northern Ireland (ORECNI) (Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 9536 1400; info.orecni@hscni.net), ref: 20/NI/0034

**Study design**

Interventional non-randomized

**Primary study design**

Interventional

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Neurorehabilitation of chronic stroke patients

**Interventions**

A therapy session normally consists of approximately half an hour of physical (i.e. motor execution (ME)) practice followed by half an hour of motor imagery (MI) practice. This amounts to 4 runs of PP followed by 4 runs of MI practice, each run consisting of 40 trials of

approximately 10 seconds duration. Thus each run lasts between 6 and 7 minutes. There will be a resting period of approximately 5 minutes between two consecutive runs. An additional time of up to 1 hour will be required in subject preparation and thus total time required for one session will be about 2.5 hours.

#### **Background:**

The project involves development of a robotic hand exoskeleton and MEG/EEG-EMG based BCI algorithms, experimentation over a maximum of twenty sessions for motor execution and/or imagery tasks related MEG/EEG-EMG data acquisition, and extensive performance evaluation with stroke participants on a state-of-the-art BCI system at Northern Ireland Functional Brain Mapping (NIFBM) at Intelligent Systems research Centre(ISRC), Ulster University, Magee campus. Experimental trials are being conducted in two phases. The ethical approval for phase-1 has already been obtained and trials on sixteen healthy and nine stroke participants have been completed and the data analysis is underway. All the three components MEG/EEG-EMG based BCI algorithm, visual neurofeedback, and robotic exoskeleton have been found to work very satisfactorily on healthy individuals. An experimental session normally consists of approximately half an hour of physical (i.e. motor execution (ME)) practice followed by half an hour of motor imagery (MI) practice. This amounts to 4 runs of PP followed by 4 runs of MI practice, each run consisting of 40 trials of approximately 10 seconds duration. Thus each run lasts between 6 and 7 minutes. There will be a resting period of approximately 5 minutes between two consecutive runs. An additional time of up to 1 hour will be required in subject preparation and thus total time required for one session will be about 2.5 hours. In particular, this phase-2 trial will meet the above three aims in the following ways:

1. Some stroke survivors may have none or very weak EMG activation, while some may suffer from hand spasticity resulting from involuntary excitation of multiple muscles (i.e. EMG). It will be investigated whether the MEG/EEG-EMG based BCI algorithms can effectively account for these issues, while controlling hand exoskeleton motion and providing appropriate neurofeedback for enhancing post-stroke rehabilitation. Neurofeedback will be a visual representation of the task completed.
2. Functional recovery outcomes using Action Research Arm Test (ARAT) and grip strength will be measured on a weekly basis during the trial period. At the same time, functional connectivities among activated brain regions will be computed using activation related MEG /EEG-EMG data. Using these two sets of measures, a correlation between motor deficit and functional connectivity will be established.
3. As part of acceptability and usability study, participants' mood, motivation, and fatigue level will be continuously monitored using appropriate visual analog scales. To monitor the sustained effect of using the system, mood will also be assessed on a weekly basis, using the Centre for Epidemiologic Studies-Depression Scale.

#### **Intervention Type**

Behavioural

#### **Primary outcome(s)**

1. Functional recovery measured using the Action Research Arm Test (ARAT) and grip strength on a weekly basis during the trial period
2. Functional connectivity among activated brain regions will be computed using activation related MEG/EEG-EMG data on a weekly basis during the trial period

#### **Key secondary outcome(s)**

1. Participants' mood, motivation, and fatigue levels will be continuously monitored during sessions using appropriate methods including visual analog scales
2. Mood will be assessed weekly, using the Centre for Epidemiologic Studies-Depression Scale

**Completion date**

31/12/2026

## Eligibility

**Key inclusion criteria**

1. Post-stroke volunteers aged 18 - 80 years with normal or corrected to normal vision (e.g. normal vision by using glasses)
2. 6 months - 2 years post-stroke since first episode of stroke
3. Able to follow two-part spoken or written commands
4. Have movement disability in at least one of their hands due to stroke
5. Able to get in and out of a low seat unassisted
6. Prepared to remove all body piercings

**Participant type(s)**

Healthy volunteer, Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Key exclusion criteria**

1. Known to have a progressive neurological condition
2. Have metal or active implants in their body (excluding dental fillings or crowns)
3. Known to suffer from claustrophobia
4. Pregnant or breast feeding
5. Gross cognitive impairment or disorientation, evidenced by a Hodgkinson mini-mental test score (HMMS) (Hodgkinson, 1972) of less than 21/30

**Date of first enrolment**

07/10/2020

**Date of final enrolment**

31/10/2026

# Locations

## Countries of recruitment

United Kingdom

Northern Ireland

Ireland

## Study participating centre

### Ulster University

Northern Ireland Functional Brain Mapping Facility

MS229

Intelligent Systems Research Centre

Magee Campus

Derry-Londonderry

United Kingdom

BT48 7JL

# Sponsor information

## Organisation

University of Ulster

## ROR

<https://ror.org/01yp9g959>

# Funder(s)

## Funder type

Government

## Funder Name

UK-India Education and Research Initiative

## Alternative Name(s)

UKIERI UK India Education and Research Initiative, UK India Education & Research Initiative, UKIERI

## 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

The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version v2.0	19/05/2020	02/12/2020	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes