ISRCTN88026375 https://doi.org/10.1186/ISRCTN88026375

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

Submission date	Recruitment status	[ ] Prospectively registered
20/11/2020	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/11/2020	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/12/2024	Nervous System Diseases	[X] 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

Study website
https://www.ulster.ac.uk/research/topic/computer-science/intelligent-systems-research-centre/projects

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

266827

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional file ISRCTN88026375_PIS_v2.0_19May2020 (added 02/12/2020)

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 measure
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

Secondary outcome measures
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

Overall study start date
01/04/2017

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants

30

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
Ireland

Northern Ireland

United Kingdom

Study participating centre
Ulster University
Northern Ireland Functional Brain Mapping Facility
MS229
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ROR
https://ror.org/01yp9g959

Funder(s)

Funder type
Government

Funder Name
UK-India Education and Research Initiative

Alternative Name(s)
UKIERI

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The dissemination of the findings is done by publishing the outcomes of the study in various internationally reported scientific journals and conferences.

Intention to publish date
31/12/2027

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?
Participant information sheet	version v2.0	19/05/2020	02/12/2020	No	Yes
HRA research summary			28/06/2023	No	No