

Effect of EEG-EMG based hybrid brain-computer interface operated hand exoskeleton for poststroke hand functional recovery

Submission date 15/05/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/11/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This Physical Practice (PP) and Mental Practice (PP) based neurorehabilitation protocol was inspired by the researchers' earlier works on BCI based hand rehabilitation producing effective motor recovery. In their first clinical trial the PP part was manual and the MP part was based on a BCI based computer game-play, although there was no exoskeleton assistance in either stage. The study established the feasibility of the PP+MP strategy, improving motor recovery, but there was no significant improvement in the BCI performance. In the second clinical trial the hand exoskeleton was introduced in both the PP and MP stage. The exoskeleton was driven in assist-as-needed mode although the difficulty level of PP was set to a fixed level. In the MP stage the exoskeleton provided proprioceptive neurofeedback. This led to improvement in BCI performance and motor recovery. Recent findings suggest that the performance-based challenge level adjustment during PP has a positive impact on motor recovery. Moreover, the hybrid-BCI (h-BCI) approaches are found to be more reliable as compared to the conventional BCI systems. Therefore, in this study the difficulty level of the PP stage was adjusted according to the performance of the participants and the MP stage was driven by an EEG-EMG correlation based h-BCI system with a hand exoskeleton based proprioceptive neurofeedback.

Who can participate?

Patients aged 18-80, 6 months to 2 years after a stroke

What does the study involve?

All participants undergo the same intervention for 6-8 weeks. The intervention is given 1-3 times per week and consists of two stages. The first stage is the Physical Practice (PP) stage of 30 min followed by a Mental Practice (MP) stage of almost an hour including the BCI calibration time of around 16 min. The PP stage is of 30 min duration during which a hand exoskeleton device provides repetitive finger grasping and extension exercise in assist-as-needed mode. The difficulty level of the PP is adjusted according to the ability of the participant. In the MP stage the participants are given h-BCI based neurofeedback. In one particular session of the MP there are 5 runs of about 7 min 30 sec each consisting of 40 trials, in each of which the participants are asked to perform a left/right hand grasp attempt. The exoskeleton is worn in the impaired hand

of the participant, whereas the other hand is placed on a soft ball on top of the table. Among five runs, the first two are for calibrating the BCI system and the rest of the three are for giving online neurofeedback. Hand functional recovery is measured using once a week to investigate the effectiveness of the intervention. Motivation and fatigue are assessed before and after each therapy session to evaluate the usability of the intervention.

What are the possible benefits and risks of participating?

After the end of the clinical trial the participants are expected to gain the motor functionality of their impaired hand motions such as grasping, gripping, pinching or overall hand movements, which could also be reflected in carrying out their daily living activities. The devices used for brain signal acquisition (EEG electrodes) and the physical practice (the hand exoskeleton device) are all non-invasive and the therapy was also designed in consultation with the occupational therapist to keep the therapeutic task within the tolerable limits. Hence, there are no risks associated with the intervention.

Where is the study run from?

Ulster University (UK)

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

March 2017 to March 2020

Who is funding the study?

1. UK-India Education and Research Initiative
2. Department of Science and Technology, Ministry of Science and Technology (India)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC/16/0089

Study information

Scientific Title

A BCI operated hand exoskeleton based neuro-rehabilitation system for movement restoration in paralysis

Acronym

hBCI-hEXO

Study objectives

The study hypothesis is that if there is a neurorehabilitation protocol involving physical and mental practice, where the physical practice is mediated by a hand exoskeleton in assist-as-needed mode and the mental practice is mediated by an EEG-EMG band power correlation based BCI operated hand exoskeleton with visual and proprioceptive neurofeedback, then the proposed neurorehabilitation protocol would be a clinically effective and usable solution for hand functional recovery of the chronic stroke patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ulster University Research Ethics Committee, 31/03/2017, ref: REC/16/0089

Study design

Non-randomised uncontrolled study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Chronic stroke patients suffering from post-stroke hand plegia on either side of the body (left /right)

Interventions

Participants underwent hand therapy sessions with a frequency of 1-3 times/week, for a period of 6-8 weeks. Each therapy session consists of a 30 min long Physical Practice (PP) mediated by a hand exoskeleton in assist-as-needed mode. This is followed by a Mental Practice (MP) session of 1 hour long, mediated by a brain-computer interface operated hand exoskeleton with visual and proprioceptive neurofeedback. The resting state MEG was also recorded once a week to investigate the brain-connectivity related changes during the rehabilitation process. The motivation and the fatigue measurements were taken both before and after each session using visual analog scale (VAS) based assessment. Once a week, the motor recovery assessments were taken using Action Research Arm Test (ARAT) and by measuring the grip-strength (GS) of the participants.

Intervention Type

Device

Primary outcome measure

Hand functional recovery measured using action research arm test (ARAT) and the grip-strength (GS) measurement on a weekly basis for a period of 6-8 weeks

Secondary outcome measures

Motivation and fatigue measured using the visual analog scale (0-10 cm) before and after each therapy session

Overall study start date

31/03/2017

Completion date

30/03/2020

Eligibility

Key inclusion criteria

1. Male and female post-stroke volunteers, in the age group of 18-80 years and have normal or corrected to normal vision (e.g. normal vision by using glasses)
2. Six months – two years post-stroke since the first episode of stroke: this is to capture stroke survivors within the chronic stage and also to ensure the stage of fast spontaneous recovery has finished
3. Able to follow two-part spoken or written commands: this is to ensure stroke survivors can provide informed consent and also to ensure they will be able to comply with therapy
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. Ready to remove all body piercings

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Aged less than 18 years or above 80 years
2. Known to have a progressive neurological condition, any serious medical or psychological diseases which are likely to seriously affect their ability to continue with experimentation
3. Have metal or active implants in their body (excluding dental fillings or crowns)
4. Known to suffer from claustrophobia
5. Pregnant or breastfeeding
6. Gross cognitive impairment or disorientation, evidenced by a score of <21 in the Mini-Mental State Examination (MMSE); the MMSE is an 11-item reliable and valid measure of cognitive function (Folstein, Folstein & McHugh 1975), such that they are unable to follow verbal or written instruction

Date of first enrolment

12/04/2017

Date of final enrolment

24/04/2017

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre**Ulster University**

Intelligent Systems Research Centre
School of Computing and Intelligent Systems
Faculty of Computing and Engineering
Magee campus
Northland Road

Derry~Londonderry
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Sponsor information

Organisation

UKIERI

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Sponsor type

Government

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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

Funder Name

Department of Science and Technology, Ministry of Science and Technology

Alternative Name(s)

Department Of Science & Technology | , Department of Science and Technology, , , , ,
Department of Science & Technology, Ministry of Science and Technology, India, Department of
Science & Technology, Department of Science and Technology (India), DSTIndia, IndiaDST,
Department of Science and Technology, Government of India, DST,

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

India

Results and Publications

Publication and dissemination plan

One conference paper (Rathee et al. 2018) regarding this study has already been accepted in 21st International Conference on Biomagnetism (BIOMAG2018), to be held in Philadelphia, PA, USA, from August 26th-30th of 2018. A journal paper is currently under construction on the extended version of the conference paper, which expected to be submitted to the "IEEE Transactions on Neural Systems and Rehabilitation" by the end of June 2018). After that the trialists are planning to write another paper covering the detail analysis of the outcomes of the study, intended for submission in the journal "Stroke".

Intention to publish date

01/08/2018

Individual participant data (IPD) sharing plan

Data will be available indefinitely at Dryad Digital Repository and in the University Data Repository of the Ulster University. All of the individual participant data collected during the trial will be shared after deidentification. Participant Information sheet, Study Protocol, Filter Form, Statistical Analysis Plan, Informed Consent Form, and Clinical Study Report will also be available. Data will be available immediately following publication with no end date for anyone who wishes to access the data for any purpose.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Results article	results	01/10/2018		Yes	No
Results article	results	01/11/2018	20/11/2020	Yes	No
Results article	results	01/01/2019	20/11/2020	Yes	No
Results article	results	01/05/2019	20/11/2020	Yes	No
Results article	results	01/01/2020	20/11/2020	Yes	No
Results article	results	26/10/2018	20/11/2020	Yes	No
Results article	results	01/12/2018	20/11/2020	Yes	No