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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

Registration date
22/06/2018

Overall study status
Completed

Last Edited
20/11/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number

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

Study type(s)
Treatment

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(s)
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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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
United Kingdom

Northern Ireland

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
United Kingdom
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Sponsor information

Organisation
UKIERI

ROR
https://ror.org/037dz3r63

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

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, Department of Science & Technology (DST), DST,

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes