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Self-directed upper limb rehabilitation following stroke

Submission date
27/12/2019

Recruitment status
No longer recruiting

Registration date
09/01/2020

Overall study status
Completed

Last Edited
08/01/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
In traditional motor rehabilitation training, patients practice repetitive limb movements aimed at improving motor function with the help of physical therapists. However, this training paradigm requires extensive training periods for patients and intensive labor for therapists. We aimed to build an EEG-based active engagement monitoring system that can be applied to various motor task of stroke patients.

Who can participate?
Patients aged 18 to 70 years old who have suffered their first stroke

What does the study involve?
Participants will be required to perform three simple motor tasks whilst brain activity is monitored using EEG equipment.

What are the possible benefits and risks of participating?
Benefit : contributing to research that may support the rehabilitation for the stroke in the future
Risk : No risks by executing three motor task(motor execution by themselves(Active task) or robot assist(Passive task)/ by imaging motor task (MI task)

Where is the study run from?
Samsung Medical Center, South Korea

When is the study starting and how long is it expected to run for?
January 2013 to August 2014

Who is funding the study?
The Korea Institute of Science and Technology (KIST), South Korea

Who is the main contact?
Dr Laehyun Kim
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Study website
http://www.kist.re.kr

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KIST 2013-009; SMC 2013-02-091

Study information

Scientific Title
Development of Robot-assisted Motor Rehabilitation of the Upper Limb Using Bio-signal Interface

Study objectives
The present study aimed to gauge patient engagement during rehabilitation training using an EEG-based BCI. We hypotheses that information related to motor task engagement can be extracted from distinct neural activity patterns associated with each motor task.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 17/10/2013, Institutional Review Board of both Korea Institute of Science and Technology (Hwarangno 14-gil 5, Seongbukgu, Seoul 02792, Republic of Korea; +82-2-958-6929; yeeun.lee@kist.re.kr), ref: KIST 2013-009

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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

Interventions
In order to obtain the characteristics of brain networks of chronic stroke patients during upper limb movements for rehabilitation, participants performed grasp movements with the affected hand by collecting their EEG signals. The haptic device in the experiment was controlled by a DSP processor, and it was synchronized with a stimulation program by FlashTM. This stimulus of haptic was connected to EEG System (sampling rate: 2048 Hz; Active-two, BiosemiTM, Amsterdam, Netherlands).

The experimental protocol included the following three motor tasks: an active task to be executed by a voluntary movement; a passive task to be executed using a robotic device; and a motor imagery task in which participants were instructed to imagine their movement without any physical movement. Each task involved 42 trials.

For each trial, participants fixed their gaze on the monitor for 2 or 3 s, after which they performed the motor task for 2 s after the visual and auditory cues. Participants maintained their grasping movement for 1 s, after which they were asked to release the handle while the robotic device returned it back to its starting position

Intervention Type
Behavioural

Primary outcome measure

1. Brain activity measured using EEG data collected at the time of participation
2. Device data measured using the device log data collected at the time of participation

Secondary outcome measures
1. Months after stroke onset at time of participation measured using patient records
2. Diagnosis at time of participation measured using patient records
3. Arm mobility measured using the upper-FMA score at time of participation

Overall study start date
05/12/2012

Completion date
13/08/2014

Eligibility

Key inclusion criteria
1. First ischemic or cerebral hemorrhagic stroke, which lasted over 3 months after onset
2. Between 18 and 70 years old

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
1. Intracranial metal insertion
2. Claustrophobia
3. Pacemakers
4. Prohibited from taking MRI

Date of first enrolment
04/01/2013

Date of final enrolment
13/08/2014

Locations

Countries of recruitment
Korea, South

Study participating centre
Samsung Medical Center
81 Irwon-Ro Gangnam-gu
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Sponsor information

Organisation
Korea Institute of Science and Technology

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Sponsor type
Research organisation

Website
http://eng.kist.re.kr/kist_eng/main/

ROR
https://ror.org/05kzfa883

Funder(s)

Funder type
Research organisation

Funder Name
Korea Institute of Science and Technology

Alternative Name(s)
KIST

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Korea, South

Results and Publications

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

Intention to publish date
30/01/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2015	08/01/2020	Yes	No
Results article	results	14/12/2015	08/01/2020	Yes	No
Results article	results	02/03/2016	08/01/2020	Yes	No
Results article	results	01/08/2017	08/01/2020	Yes	No