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Use of neuromodulation system and assistive devices for rehabilitation of upper limb motor function after stroke

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
23/03/2017

Overall study status
Completed

Last Edited
16/10/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Strokes are caused by a bleed in the brain and can be life threatening. One common consequence is upper limb impairment. This causes stroke patients to be unable to use their arms and upper body to do simple tasks such as reaching or grasping. Currently, people with stroke undergo rehabilitation, which is usually done through a physical and occupational (daily living skills) therapies to improve their mobility (movement) with their upper limbs. However, this kind of treatment has limitations and often cannot help patients regain total mobility. There are alternative rehabilitation treatments that use new methods and technologies that may be able to help patients with stroke. Neuromodulaton therapies using brain-computer interfaces (BCI), which connects brain signals directly to a computer, have the potential to help patients. This type of therapy uses assistive devices such as electrical stimulation (electrical shocks or waves) and robots to help restore function to the areas affected by stroke. The aim of this study is to evaluate and the potential benefits that can be achieved by using assistive devices in rehabilitation sessions with stroke patients.

Who can participate?
Adult subjects aged 18-65 who have had a stroke and healthy adults aged 18-65

What does the study involve?
This study involves three phases. The first phase examines the technical feasibility of the study to see how well the technology systems work. This is done using healthy participants and only a small number of participants who have had a stroke. This phase involves one to three one hour sessions that require participants to do a number of tasks such as reaching or grasping with the help of assisted devices. The second phase of this study aims to verify the cortical (a part of the brain) changes. This involves both healthy participants and a small number of participants who have had a stroke carry out tasks using a BCI to trigger the action of assistive devices or robots. This involves one to three one hour sessions. The final phase is the evaluation and it involves only participants who have had a stroke. Participants are randomly allocated to one of two groups. Those in the first group attend 12 treatment sessions that requires them to use BCI and assistive devices to help them perform tasks such as reaching or grasping. These types of tasks

are repeated many times. Those in the second group receive 12 traditional physical therapy sessions as per the standard level of care. Participants are followed up at the end of the session to assess their mobility.

What are the possible benefits and risks of participating?
Participants with stroke may benefit from undergoing this rehabilitation programme. There are no notable risks with participating.

Where is the study run from?
1. Cajal Institute of the Spanish National Research Council (CSIC) (Spain)
2. Centro de Referencia Estatal de Atención al Daño Cerebral (CEADAC) (Spain)

When is the study starting and how long is it expected to run for?
January 2016 to December 2019

Who is funding the study?
Spanish National Research Council (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CSEULS-PI-106/2016

Study information

Scientific Title
Validation and evaluation of using functional electrical stimulation techniques, robotic devices and brain-computer interfaces for rehabilitation upper limbs motor functions in people with stroke

Study objectives
The aim of this study is to evaluate the rehabilitation effects, at cortical and functional level, when using a brain-machine interface to trigger the action of assistive devices (like functional electrical stimulation -FES- and robotic devices) during the execution of functional upper limbs tasks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Ethics Committee of the Centro Superior de Estudios Universitarios La Salle, Universidad Autónoma de Madrid, 01/02/2016, ref: CSEULS-PI-106/2016

Study design
Phase One: initial feasibility study
Phase Two and Three: multi-session balanced experimental and controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
The protocol of the study comprises of three phases.

Phase 1 Technical feasibility and usability verification: This phase includes experimentation with healthy volunteers and with a small cohort of subjects with a stroke. The intervention at this stage relies on the execution of a predefined number of a functional upper limb tasks (e.g. reaching and/or grasping) led by the assisted devices (FES and/or robots). Healthy subjects participate in a single evaluation session, while stroke subjects participate in a few evaluation

sessions (no more than three). The duration of each session of either group (healthy or stroke patients) is less than 1 hour.

Phase 2 Verification of cortical changes: This stage also includes healthy participants and a small cohort of subjects with stroke. In this phase, the participants carry out a predefined number of a functional upper limb tasks (e.g. reaching and/or grasping) in which a brain-computer interfaces (BCI) trigger the action of assistive devices (FES and/or robots). Again, healthy subjects participate in a single evaluation session, while stroke subjects participate in a few evaluation sessions (no more than three). The maximum duration of each session for either group (healthy or stroke patients) is 1 hour.

Phase 3 Pre-clinical evaluation: This phase includes a multi-session pilot intervention with one experimental and one control group. For this intervention, only subjects who has suffered a stroke are recruited. Both groups participate in 12 consecutive sessions, distributed 3 sessions per week. Participants are randomly allocated to the experimental or to the control group.

Experimental group: BCI and assistive devices (FES and/or robots) are used to assist the execution of upper limb tasks. On each session, the participants are asked to perform a functional upper limb tasks (e.g. reaching and/or grasping) in which a BCI trigger the action of assistive devices (FES and/or robots). At least 50 repetitions must be accomplished in each session.

Control group: is based on traditional physical therapy. The provided therapy is matched with the provided in the experimental group in physical (muscles and joints exercised) and doze terms (same number of sessions and repetitions per session). The type of physical therapy is defined by professional experts in this field.

Intervention Type
Device

Primary outcome measure
Phase 1:
Arm joints kinematics are measured using kinematic sensors at sessions one, two and three (healthy volunteers only attend session one and are therefore only assessed at session one).

Phase 2:
1. Arm joints kinematics are measured using kinematic sensors at sessions one, two and three (healthy volunteers only attend session one and are therefore only assessed at session one)
2. Motor evoked potential (MEP) induced by Transcranial magnetic stimulation is measured using the Electromyography (EMG) signal of the arm's muscles both before and after intervention at sessions one, two and three (healthy volunteers only attend session one and are therefore only assessed at session one)

Phase 3:
1. Arm joints kinematics are measured using kinematic sensors at session one, two, three, four, five, six, seven, eight, nine, ten, 11, and 12
2. Kinetics data of the arm joints under isometric condition are measured using torque sensors at session one, two, three, four, five, six, seven, eight, nine, ten, 11, and 12
3. Co-contraction index of target muscles of the arm are measured using EMG signals at session one, two, three, four, five, six, seven, eight, nine, ten, 11, and 12

4. Clinical outcomes are measured using the Box and block test, the Modified Answorth scale for the upper limbs and the Medical Research Council scale for upper limbs at baseline (before session one) and after the intervention (after session 12)

Secondary outcome measures
Phase 1:
User satisfaction is measured using the Quebec User Evaluation of satisfaction with Assistive Technology 2.0 (QUEST) and Self-Assessment Manikin (SAM) at the end of the intervention (after session three).Healthy volunteers only attend session one and are therefore only assessed at the end of the session one.

Phase 2:
1. User satisfaction is measured using the Quebec User Evaluation of satisfaction with Assistive Technology 2.0 (QUEST) and Self-Assessment Manikin (SAM) at the end of the intervention (after session three). Healthy volunteers only attend session one and are therefore only assessed at the end of the session one.
2. Analysis of cortical pattern is measured using the recorded EEG signals at sessions one, two and three. Healthy volunteers only attend session one and are therefore only assessed at session one.

Phase 3:
1. User satisfaction is measured using the Quebec User Evaluation of satisfaction with Assistive Technology 2.0 (QUEST) and Self-Assessment Manikin (SAM) at the end of the intervention (after session 12)
2. Cognitive tests are assessed using the Mini-Mental State Examination at baseline, session (before session one) and at the end of the intervention (after session 12)
3. Analysis of cortical pattern is assessed using the recorded EEG signals at session one, two, three, four, five, six, seven, eight, nine, ten, 11, and 12

Overall study start date
01/01/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Inclusion criteria for Healthy subjects:
1. Age between 18 and 65
2. Not pregnant
4. Tolerance to functional electrical stimulation of the upper limbs muscle
5. Absence of neurological lesion
6. Availability to participate to the study

Inclusion criteria for subjects with stroke:
1. Aged between 18 and 65 years old
2. Not pregnant
3. Subject with a chronic or subacute stroke
4. Without prior neurological lesion to stroke
5. With cognitive capabilities to follow instruction

6. Tolerance to functional electrical stimulation of the upper limbs muscle
7. With motor response to functional electrical stimulation
8. Availability to participate to the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Evidence or known history of epilepsy
2. Pregnancy
3. With implanted devices
4. Reject to sign the informed consent

Date of first enrolment
01/02/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Spain

Study participating centre
Centro de Referencia Estatal de Atención Al Daño Cerebral (CEADAC)
Calle Río Bullaque 1
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Study participating centre
Instituto de Rehabilitación Funcional (IRF) La Salle
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Study participating centre
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Sponsor information

Organisation
Spanish National Research Council (CSIC)

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Sponsor type
Research council

ROR
https://ror.org/02gfc7t72

Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Innovation (Ministerio de Ciencia e Innovación)

Results and Publications

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

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Francisco Resquín at franresquin@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2017		Yes	No