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Transcranial direct current stimulation (tDCS) combined with robotic rehabilitation for upper limbs in stroke

Submission date
07/10/2021

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
03/09/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A stroke is a serious life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. According to the World Health Organization, cerebrovascular accidents (stroke) are the second leading cause of death and the third leading cause of disability. One of the most frequent problems after stroke is upper limb (UL) impairments such as muscle weakness, contractures, changes in muscle tone, and other problems related to coordination of arms, hands, or fingers. These impairments induce disabilities in common movements such as reaching, picking up, or holding objects and difficult activities of daily living (ADLs) such as washing, eating, or dressing, their participation in society, and their professional activities. Most people experiencing this upper limb impairment will still have problems chronically several years after the stroke. Impairment in the upper limbs is one of the most prevalent consequences of stroke. For this reason, rehabilitation is an essential step towards clinical recovery, patient empowerment, and improvement of their quality of life.
Rehabilitation-based robotics have shown moderate efficacy for rehabilitating upper limbs. Noninvasive brain stimulation is a method for modulating electrical activity of the brain. Specifically, transcranial direct current stimulation (tDCS) is useful in the rehabilitation process. The aim of the project is to evaluate the efficacy of combined tDCS with robotic training for motor recovery of the upper limb after stroke.

Who can participate?
Adults diagnosed with stroke (18-85 years old).

What does the study involve?
Rehabilitation programs using tDCS combined with robotic training.
Participants were randomly assigned to the experimental group (EG) or control group (CG).
EG participants received 20 individual training sessions with tDCS and robotic training. Each session lasted 20-30 minutes.
CG is a similar protocol but they received sham stimulation, for only 30 seconds.

What are the possible benefits and risks of participating?
The possible benefits of using tDCS combined with robotic treatment in rehabilitation processes with stroke adults include improvement of upper limb mobility and function and improvement in the performance of daily life activities.
The possible adverse effects include fatigue, muscle pain, and headaches.

Where is the study run from?
The study was designed at the University of Castilla La Mancha (Spain) and rehabilitation sessions with technology based on virtual reality were developed in the Neuron Center of Madrid (Spain).

When is the study starting and how long is it expected to run for?
July 2020 to August 2022.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
1. Juan Bernal Jiménez, Juanjose.Bernal@uclm.es (primary contact)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Randomized clinical trial of tDCS combined with robotic rehabilitation for upper limbs in stroke

Study objectives
Robotic therapy combined with tDCS enhances motor recovery in stroke patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2020, Clinical Research Ethical Committee of the Talavera de la Reina Integrated Management Area (CEIC del AGI de Talavera de la Reina, Hospital Nuestra Señora del Prado. Ctra. Nacional V, km. 114, 45600, Talavera de la Reina (Toledo), Spain; +34 (0)925 80 36 00 Ext. 86.316; varroyo@sescam.org), ref: 12/2018

Study design
Transversal prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Motor injuries of the upper limb and functional dependence in adults with stroke

Interventions
Rehabilitation programs using robotic treatment combined with tDCS.
The robot device is Amadeo, Tyromotion.
The assignment to each of the groups was parallel. Participants were randomly assigned to the experimental group (EG) or control group (CG). Participants and therapists were blinded.

Experimental group: participants received 20 sessions of robotic combined with tDCS. Robotic training lasted 20-30 minutes and it was specific finger training. tDCS was applied online with robotic treatment. tDCS lasted 20 minutes.

Control group: participants received a similar robotic protocol but tDCS lasted 30 seconds, and it was a sham intervention. The rest of the protocol was the same as in the experimental group.

Intervention Type
Behavioural

Primary outcome(s)
1. The impact of stroke on daily life was measured using the Functional Independence Measure at baseline, at the end of the study (20 sessions), and at 3 months.
2. Body functions (International Coaching Federation domains) were measured using the Fugl Meyer Motor Assessment at the end of the study (20 sessions) and at 3 months.
3. Activities (International Coaching Federation domains) were measured using ARA-T at the end of the study (20 sessions) and at 3 months.
4. Perceived quality of life was measured using the EuroQool-5 L test at baseline, at the end of the study (20 sessions), and at 3 months.
5. Satisfaction with the robot device and treatment was measured using the USEQ at baseline, at the end of the study (20 sessions), and at 3 months.

Key secondary outcome(s))
1. Muscle tone assessment using modified Ashworth Test at baseline, the end of study (20 sessions), and 3 months.
2. Hand strength measured using dynamometer (using robot device) at baseline, the end of study (20 sessions), and 3 months.
3. Range of Motion (ROM) measured using goniometry (using robot device) at baseline, the end of study (20 sessions), and 3 months.

Completion date
09/08/2022

Eligibility

Key inclusion criteria
1. Age between 18 and 85 years old
2. Diagnosed stroke
3. Difficulties motor skills of the upper limb
4. Dependence in daily life activities
5. No other disabling pathology prior to the injury
6. Acceptance and signature of the informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
21

Key exclusion criteria
1. Cognitive impairment (<24 in Mini-mental state exam)
2. Severe Aphasia
3. Upper limb fractures
4. Unresolved vascular problem
5. tDCS contraindications such as epilepsy
6. No signing informed consent

Date of first enrolment
28/03/2022

Date of final enrolment
04/04/2022

Locations

Countries of recruitment
Spain

Study participating centre
University of Castilla La Mancha
Faculty of Science Health
Avenida Real Fábrica de Sedas s/n
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Study participating centre

Neuron Center
C/ Modesto Lafuente, 45
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Sponsor information

Organisation
University of Castile-La Mancha

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Juan Bernal Jiménez (JuanJose.Bernal@uclm.es).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/02/2024	03/09/2024	Yes	No
Participant information sheet	in Spanish		07/10/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes