Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the effectiveness of adding transcranial direct current stimulation to resistance exercise on function, quality of life, and movement smoothness of the upper limbs in individuals with stroke

Protocol summary

Study aim

The main objective is to investigate the effectiveness of adding tDCS to resistance training on upper-limb QoL, performance, and movement smoothness in stroke patients.

Design

A clinical trial with a placebo-controlled parallel-group, double-blind, randomized design, using sealed opaque envelopes for randomization

Settings and conduct

Patients from neuro-rehabilitation clinics who meet the inclusion and exclusion criteria after signing informed consent will be allocated, using sealed, opaque envelopes, into two groups: resistance training placebo and resistance training with tDCS. Assessments will be performed by a physiotherapist blinded to treatment. It will be noted that tDCS sensation may be absent, but stimulation will be delivered, and patients will be blinded to group allocation. tDCS and therapeutic training will be performed by different therapists. The statistician will be blinded to group allocation, and the study will be double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 45–75; Ischemic hemiplegia; Stroke in MCA territory; ≥3 months since event; Upper-limb 18–48 on Fugl-Meyer; Shoulder pain <3 on VAS; MAS score for biceps = 2; No cognitive/perceptual impairments preventing regimen (MMSE ≥18); Written informed consent approved for participation in the study Exclusion criteria Complex regional pain ; Depression preventing participation; CVD; Other neuro, ortho, rheumatological issues; Severe comorbid conditions; Contracture

Intervention groups

Resistance training with tDCS Resistance training with tDCS in a placebo form

Main outcome variables

Fugl-Meyer Test ; Modified Ashworth Scale; Stroke Impact Scale ; Maximum muscle strength: flexors, extensors, adductors, abductors, and internal and external rotators of the shoulder; Maximum ROM for shoulder flexion and abduction; Kinematics : calculation of movement smoothness in flexion and abduction

General information

Reason for update

Acronym

transcranial direct current stimulation(tDCS)

IRCT registration information

IRCT registration number: **IRCT20251006067516N1**
Registration date: **2025-12-09, 1404/09/18**
Registration timing: **prospective**

Last update: **2025-12-09, 1404/09/18**
Update count: **0**

Registration date

2025-12-09, 1404/09/18

Registrant information

Name

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Name of organization / entity

تربیت مدرس

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-21, 1404/09/30

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness of adding transcranial direct current stimulation to resistance exercise on function, quality of life, and movement smoothness of the upper limbs in individuals with stroke

Public title

Effect of resistance training with and without transcranial direct current stimulation on upper limb recovery after stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ischemic hemiplegia Stroke in the territory of the middle cerebral artery At least three months since the event Fugl-Meyer Assessment upper-extremity score between 18 and 48 Shoulder pain with a Visual Analog Scale (VAS) score less than 3 Modified Ashworth Scale score for the biceps muscle of 2 No cognitive or perceptual impairments that would hinder following the treatment process (MMSE score at least 18) Written informed consent form confirmed for participation in the study

Exclusion criteria:

Complex Regional Pain Syndrome Patients with depression who are unable to participate in treatment Cardiovascular problems Other problems in neurology, orthopedics, and rheumatology Presence of severe comorbidities Presence of contracture

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

After becoming aware of the aims and steps of the plan, participants will read and sign the consent form. The randomization method in this trial is simple randomization. Upon entry into the study, participants will be divided into two groups—resistance training and resistance training combined with tDCS—using sealed, opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

During the tDCS procedure, some patients may not feel any sensation, but the stimulation is still applied. As a result, the patient does not know which group they are assigned to. The tDCS is administered by a different clinician, and the clinician is blinded to group assignment (they do not know which treatment the patient receives). Additionally, the analyst who processes the data is blinded to the groupings (the grouping is masked from them as well). Therefore, this study is double-blinded (or double-masked): both the clinician delivering the treatment and the person analyzing the data do not know the group assignments.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Modares University

Street address

No. 30, Shahrivar Ave., North Kargar Blvd

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Province

Tehran

Postal code

1411956511

Approval date

2025-04-25, 1404/02/05

Ethics committee reference number

IR.MODARES.REC.1404.013

Health conditions studied

1

Description of health condition studied

Upper limb of patients with stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fugl-Meyer Assessment

Timepoint

Before and after six weeks of treatment

Method of measurement

Thirty-three items pertain to the upper limb, including the shoulder, elbow, forearm, and wrist. The test is scored based on direct observation of performance, with each item scored from 0 to 2. If a person cannot perform the movement, the score is 0; if the movement is performed partially, the score is 1; if the movement is performed fully, the score is 2

2

Description

Modified Ashworth Scale: It is a ranked scale for measuring spasticity.

Timepoint

Before and after six weeks of treatment

Method of measurement

t is rated on a scale from zero to four. Grade 2 indicates a clear increase in muscle tone that is evident when the joint is held in a specified range, but the limb(s) can be moved easily.

3

Description

Maximum muscular power: For measuring the strength (in kilograms) of the muscles of the upper limb, including flexors, extensors, abductors, adductors, internal and external rotators of the shoulder, flexors and extensors of the elbow, using a nerve stimulator (Lafayette Company

Timepoint

Before and after six weeks of treatment

Method of measurement

Each test will be performed three times: once by the examiner for training, once by the patient to learn how to perform it, and once again by the patient to perform it. Muscle power measurements for two directions, flexion and abduction, will be carried out once in the lower position and once in the upper position using a nerve stimulator (Lafayette Company).

4

Description

Maximum range of motion for shoulder flexion and abduction

Timepoint

Before and after six weeks of treatment

Method of measurement

For measuring the range of motion (ROM) of shoulder abduction, the patient sits on a chair and the examiner holds the fixed arm of the goniometer completely perpendicular to the trunk in the frontal plane, with the goniometer's axis centered on the acromion process. The movable arm of the goniometer follows the arm and runs along the lateral epicondyle of the elbow, parallel to the arm, as the shoulder moves toward abduction. To measure shoulder flexion, the goniometer's axis is placed 2.5 cm proximal to the acromion on the outer aspect of the shoulder, with the fixed arm in the midline of the trunk, the upper chest, and the movable arm along the lateral midline of the arm in line with the external epicondyle. The distance between the two arms is recorded as the ROM for shoulder flexion.

5

Description

Kinematic analysis for assessing the functional movement of the involved hand and also calculating movement smoothness

Timepoint

Before and after six weeks of treatment

Method of measurement

Marker placement will be on the radial groove of the radial/radius? (the radioulnar area seems intended: radial styloid, radius radial styloid and medial radial styloid) and the motion analysis device (VICON,) will record data at 120 Hz. The output of the kinetic model will be the sum of the movement of the upper limb when reaching an object in both the upward and downward directions in two motions: flexion and abduction. Movement smoothness will be based on the SPARC variable during four reaching movements, calculated from the arc length of the velocity signal spectrum (V).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention A-tDCS Initially, for 20 minutes, this protocol is applied to patients assigned to this group. Considering that previous studies have reported tDCS after-effects persisting up to 1.5 hours post-stimulation, conventional resistance training is performed after the stimulation period according to the intervention of the first group. The tDCS execution protocol is as follows: Neutral (reference) electrode: the midpoint of the forehead Active electrode: placed over points C3 and C4 according to the standard 10-20 EEG system Electrode size: 35 cm^2 (5 cm × 7 cm)Current intensity: 1 mA Stimulation duration: 20 minutes Number of treatment sessions: 6 weeks, every other day Device model: Segal Stim two-channel Pharmaceutical Medical Equipment Company FarmedBefore starting treatment, the electrode pads are moistened with normal saline solution, and the treatment area is cleaned with an alcohol pad to remove fat. Then the hair is moved aside as much as possible and the electrodes are fixed to the scalp and forehead using straps. The current intensity is set to 1 mA, and the patient is instructed to report any uncomfortable sensations such as burning as soon as they occur. If such sensations arise, the therapist reduces the current intensity until the patient again feels comfortable. All of these procedures are recorded.

Category

Rehabilitation

2

Description

Before the main intervention for both groups, participants perform a 10-minute warm-up. First, each joint is actively moved ten times through its maximum possible range of motion. After the active exercises, for the shorter muscles, a passive stretch is performed for three sets of 45 seconds. The stretches are performed so that the limb is placed at the target maximum range of motion in the resistance training that is not painful for the patient. In other words, the stretch corresponds to the maximum pain-free range for the spastic muscles. During stretching, the joints of the fingers and wrist are kept in a neutral position with a splint.In the resistance-training group, stroke patients perform movements using a calf weight and a pulley resistance system to flexion, abduction, external rotation, horizontal abduction and adduction of the shoulder, as well as flexion and extension of the elbow. To determine 1RM, the patient first performs the maximum range of motion. Then the patient starts with a weight that they believe they can lift with maximal effort for one repetition. The weight is then increased until the maximum load they can lift for one full range of motion is reached. If the participant cannot complete one repetition, 2.5% of the weight used in the test is reduced. The exercises are performed at 80% of 1RM. When the patient can perform 12 repetitions, the weight is increased so that 8 repetitions can be performed. Each exercise is performed in three sets of 8 repetitions.Before the main intervention for both groups, participants perform a 10-minute warm-up. First, each joint is actively moved ten times through its maximum possible range of motion. After the active exercises, for the shorter muscles, a passive stretch is performed for three sets of 45 seconds. The stretches are performed so that the limb is at the maximum pain-free range targeted in the resistance training that is not painful for the patient. The joints of the fingers and wrist are kept in a neutral position with a splint during stretching. In the resistance-training group, stroke patients perform movements with a calf weight and a pulley resistance system to move flexion, abduction, external rotation, horizontal abduction and adduction of the shoulder, and flexion and extension of the elbow. To determine 1RM, the patient first performs the maximum range of motion. Then the patient starts with a weight they believe they can lift with maximal effort for one repetition. The weight is increased until the maximum load that can be lifted for one full range of motion is reached. If the participant cannot perform one repetition, 2.5% of the load used in the test is subtracted. The training is performed at 80% of 1RM. When the patient can perform 12 repetitions, the weight is increased to perform 8 repetitions. Each exercise is performed as three sets of 8 repetitions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Pouria Moshayedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
The University of modares

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Information related to the results of the assessment of main outcomes will be published in the article and thesis. Access to the microdata will be allowed only with approval from the supervisors and on a restricted basis for the target journal, after de-identification, and in a resolvable Excel format.
When the data will become available and for how long
After the sampling is completed, in the article and thesis.
To whom data/document is available
All individuals with access to the thesis and article registry will have access to the study results. More detailed data will be available to the journal with the approval of the supervisors and on a restricted basis.
Under which criteria data/document could be used
Documented data may be used for review articles and clinical decision-making, and the granular details will be available only in a limited manner, with supervisor approval, to ensure the validity of the results for the target journal upon request.
From where data/document is obtainable
dpttehran@gmail.com 09377525456
What processes are involved for a request to access data/document
Initial contact will be made through the available communication channels. The request will be submitted to the supervisors. Any questions from the supervisors will be addressed to the individual, and, if approved, the

information will be provided to the individual on a restricted basis.

Comments