Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Immediate effects of transcranial direct current stimulation of motor and cognitive cortex on upper extremity performance under dual-task condition in people with subacute stroke

Protocol summary

Study aim

Immediate effects of transcranial direct current stimulation of motor and cognitive cortex on upper extremity performance under dual-task condition in people with subacute stroke

Design

This study is a parallel double-blinded randomized clinical controlled trial. The referred people will be randomly allocated to one of the three groups of motor cortex stimulation, cognitive cortex stimulation and placebo

Settings and conduct

Initialy, patients with stroke were refered by a neurologist based on inclusion and exclusion criteria, fulfilling a written informed consent form. Then they were randomly allocated into three groups of motor, cognition and control. After baseline assessment of outcomes, participants in motor group will receive bilateral tDCS of 1 miliamper on primary motor cortex area (M1) for 20 minutes (with cathode electrode on intact M1 and anode electrode on involed M1). Participants in cognitive group will receive bilateral tDCS of 1 miliamper on dorsolateral prefrontal cortex area (DLPFC) for 20 minutes minutes (with cathode electrode on intact M1 and anode electrode on involed M1). Participants in control group will receive bilateral tDCS of 1 miliamper for only the initial and final 30 sendonds while during the rest of the time there will be no current. The electrode placement will be similar to either of motor or cognitive group. The secondary assessment of outcomes will be performed immidiately after tDCS treatment.

Participants/Inclusion and exclusion criteria

Patients with the first stroke who are at least 18 years old and have no other neurological or psychiatric problems and contraindications to the use of tDCS

Intervention groups

1.Motor cortex stimulation 2.Cognitive cortex stimulation 3.Placebo

Main outcome variables

Cognitive score, motor score, motor dual task difference, cognitive dual task difference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190922044839N2**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Tabassom Ghanavati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 2072

Email address

ghanavatit@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Immediate effects of transcranial direct current stimulation of motor and cognitive cortex on upper extremity performance under dual-task condition in people with subacute stroke

Public title
Immediate effects of transcranial direct current stimulation on upper extremity performance under dual-task condition in stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Physical ability to complete the motor activities required in examine by the examiner (ability to tap with the finger and perform a Purdepeg board test) Awareness and ability to communicate with the examiner and therapist Level of cognition enough to understand the test (score 22 or higher on the short test of mental state by the examiner) Score less than 18 upper limbs in the Fugel_Meyer test The first unilateral stroke that is at least 4 weeks old Confirmation of a stroke by one of the methods of brain imaging by a doctor
Exclusion criteria:
Contraindications to tDCS include: having a pacemaker, metal implants, a history of seizures, a skin rash, allergies or sores where the electrodes are placed, and cranial skin sensitivity. Severe upper limb pain (visual pain scale greater than 5) speech problem Existence of orthopedic or neurological disorder in the upper limb involved Upper extremity spasticity of less than 2 or more than 15 on the modified Ashworth scale
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple individual randomization via a statistical software will be performed. We will use the Win Pepi for making randomization order. Allocation concealment will be performed by the secretary of the assessment center
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants in this study will be blind to their allocation to study groups (motor cortex stimulation, cognitive cortex stimulation and placebo). The outcome assessor, before and after intervention, will be blind to the allocation as well. However, the physiotherapist, study designer, statistical analyst and the committee of safety and data supervision will not be blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
29th Bahman Blvd, Tabriz University, Faculty of Rehabilitation Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2020-11-01, 1399/08/11
Ethics committee reference number
IR.TBZMED.REC.1399.740

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
Cognitive test score of Auditory Stroop test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Software

2

Description
Motion test score of unilateral simple Fugl_meyer test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Software

3

Description
Motion test score of Purdue Pegboard board test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Examiner

4

Description
Cost of cognitive dual task conditions for combining Purdue Pegboard board test and Auditory Stroop test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Voice recording and calculation

5

Description
Cost of cognitive dual-task conditions for combining unilateral simple Fugl_meyer test and Auditory Stroop test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Voice recording and calculation

6

Description
Cost of dual task conditions for combining Purdue Pegboard board test and Auditory Stroop test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Calculation

7

Description
Cost of dual task conditions to combine unilateral simple Fugl_meyer test and Auditory Stroop test
Timepoint
Before intervention and immediately after intervention
Method of measurement
Voice recording and calculation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Motor cortex stimulation: The participants in the motor cortex intervention group will receive one bilateral tDCS treatment session with the intensity of 1 milliamperes for 20 minutes in the primary motor area (M1). In this group, the anode electrode will be placed on the M1 area of the involved hemisphere and the cathode electrode will be placed on the M1 area of the intact hemisphere. It should be noted that the tDCS device is a nerve modulator device that includes a battery and at least two electrodes. The battery has a resistance of 9 volts. Each device must have only one anode source and one cathode evolution, one of which must be located on the head. The changes are covered with a sponge soaked in saline or other semiconductor material. The size of the changes varies between 16, 25, 35, 36 square centimeters. 2mA is the highest current strongest tested by experience, but powerful devices have increased dramatically (3-4mA). The most used current density is in the range of 0.028-0.06 current per square centimeter.
Category
Rehabilitation

2

Description
Intervention group 2: Cognitive cortex stimulation: The participants in the motor cortex intervention group will receive one bilateral tDCS treatment session with the intensity of 1 milliamperes for 20 minutes in the dorsolateral prefrontal cortex (DLPFC). In this group, the anode electrode will be placed on the DLPFC area of the involved hemisphere and the cathode electrode will be placed on the DLPFC area of the intact hemisphere. It should be noted that the tDCS device is a nerve modulator device that includes a battery and at least two electrodes. The battery has a resistance of 9 volts. Each device must have only one anode source and one cathode evolution, one of which must be located on the head. The changes are covered with a sponge soaked in saline or other semiconductor material. The size of the changes varies between 16, 25, 35, 36 square centimeters. 2mA is the highest current strongest tested by experience, but powerful devices have increased dramatically (3-4mA). The most used current density is in the range of 0.028-0.06 current per square centimeter.
Category
Rehabilitation

3

Description
Control group: Placebo: Cognitive cortex stimulation: The participants in the control group will receive a tDCS session with an elctrode placement similar to either of motor intervention group or cognitive intervention group, however they will receive tDCS only for the first 30 seconds and the rest of the time will be currentless. It

should be noted that the tDCS device is a nerve modulator device that includes a battery and at least two electrodes. The battery has a resistance of 9 volts. Each device must have only one anode source and one cathode evolution, one of which must be located on the head. The changes are covered with a sponge soaked in saline or other semiconductor material. The size of the changes varies between 16, 25, 35, 36 square centimeters. 2mA is the highest current strongest tested by experience, but powerful devices have increased dramatically (3-4mA). The most used current density is in the range of 0.028-0.06 current per square centimeter.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy Clinic of Tabriz Rehabilitation Faculty

Full name of responsible person
Tabassom Ghanavati

Street address
29 Bahman Blvd, Tabriz University, Faculty of Rehabilitation Sciences

City
Tabriz

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East Azarbaijan

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5166616471

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+98 41 3337 2072

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ghanavatit@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Sami'ei

Street address
No. 2 Central Building, Tabriz University of Medical Sciences, University Street

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Web page address
http://portal-en.tbzmed.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

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
Tabriz University of Medical Sciences

Full name of responsible person
Tabassom Ghanavati

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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29 Bahman Blvd, Tabriz University, Faculty of Rehabilitation Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Tabassom Ghanavati

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Tabassom Ghanavati
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable