

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effects of stimulating motor and cognitive cortex by transcranial direct current stimulation on standing balance under dual-task condition in people with stroke

Protocol summary

Study aim

Determining the effects of stimulating motor and cognitive cortex by transcranial direct current stimulation (tDCS) on standing balance under dual-task condition in people with 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

Initially, a neurologist was asked to refer stroke patients with inclusion criteria and without exclusion criteria to the physiotherapy clinic of Tabriz

Participants/Inclusion and exclusion criteria

Stroke patients under 80 years of age without any other neurological and psychological problems and tDCS contraindications.

Intervention groups

Motor cortex stimulation group Cognitive cortex stimulation group Placebo group

Main outcome variables

Sway area; Sway path length, Cognitive task performance score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190922044839N1**

Registration date: **2019-10-13, 1398/07/21**

Registration timing: **prospective**

Last update: **2019-10-13, 1398/07/21**

Update count: **0**

Registration date

2019-10-13, 1398/07/21

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

2020-01-21, 1398/11/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of stimulating motor and cognitive cortex by transcranial direct current stimulation on standing balance under dual-task condition in people with stroke

Public title

Effects of transcranial direct current stimulation on balance in stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Knee extensor strength equal or more than 3 in manual muscle test Mini-Mental State Examination score equal or more than 21 First stroke At least 4 weeks after stroke Fugl-Mayer test score less than 18 Less than 80 years of age

Exclusion criteria:
 History of seizure or epilepsy Existence of metal in skull Using pace-maker Neurological problems Skull fracture History of brain surgery Psychological impairments Sensitive head skin Using cortical facilitating medications such as Antidepressants, Antiepileptics, Neuroleptics and Benzodiazepines Using medications with facilitating of inhibiting effects on brain plasticity such as Dopamine, Fluoxetine and D-Amphetamine

Age
 To 80 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 RANDBETWEEN function in Excel 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
 2019-09-16, 1398/06/25

Ethics committee reference number
 IR.TBZMED.REC.1398.62

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

Sway area

Timepoint

Before intervention and immediately after intervention

Method of measurement

Force plate apparatus

2

Description

Sway path length

Timepoint

Before intervention and immediately after intervention

Method of measurement

Force plate apparatus

3

Description

Cognitive performance score

Timepoint

Before intervention and immediately after intervention

Method of measurement

Recording and calculation by a special equation

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Motor cortex stimulation

Category

Rehabilitation

2

Description

Second intervention group: Cognitive cortex stimulation

Category

Rehabilitation

3

Description

Control group: Placebo

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

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Email

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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iro@tbzmed.ac.ir

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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Person responsible for scientific inquiries

Contact

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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