Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, Fluoxetin and D-Amphetamin

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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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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Email
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
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Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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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