

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Efficacy of Mindfulness-Based Intervention and Transcranial Direct Current Stimulation (TDCS) on Cognitive Disorders, and emotional problems in patients with stroke: a randomized clinical trial

Protocol summary

Study aim

To investigate the efficacy of Mindfulness-Based intervention and TDCS on cognitive and emotional problems in stroke patients

Design

A randomized, blinded, controlled clinical trial with a parallel group design of a total of 72 patients (4 groups of about 18 stroke cases)

Settings and conduct

This project will be performed in Imam Reza Hospital, Tabriz, Iran. In electrical stimulation by TDCS, the anodal electrode will be placed in the left dorsolateral prefrontal cortex (F3) and the cathodal electrode in the contralateral right dorsolateral prefrontal cortex (F4) and 2 mA electricity flows is passed from participants' skull directly for 20 minutes during 10 sessions. In the mindfulness intervention group, participants will be trained by Kabat-Zinn mindfulness-based stress reduction treatment program (2003) during eight sessions for 2.5 hours. Data will be analyzed by Multivariate Analysis of Variance (MANCOVA).

Participants/Inclusion and exclusion criteria

Inclusion/ Exclusion criteria: age of 30-70 years, educated, acceptance of informed consent, the possibility to follow up and no involvement of the language area in the brain, no history of past stroke or psychiatric disease

Intervention groups

Mindfulness group, TDCS group, both mindfulness and TDCS group, and control group taking standard treatment without the interventions.

Main outcome variables

Changes of cognitive scores will be assessed by Eden Brook cognitive examination and emotional impairments scores by Beck anxiety and depression questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090716002195N3**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Mehdi Farhoudi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-06, 1398/04/15

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of Mindfulness-Based Intervention and Transcranial Direct Current Stimulation (TDCS) on Cognitive Disorders, and emotional problems in patients with stroke: a randomized clinical trial

Public title
Efficacy of Mindfulness and TDCS on patients with stroke

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
No involvement of language area in left hemisphere
Unilateral brain involvement After 3 months of recent stroke Possibility to write and read Signing of the informed consent Available and possible to follow-up
Exclusion criteria:
Language area involvement (aphasia) Past history of stroke Past history of psychiatric disease

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization and explanation, block

Blinding (investigator's opinion)
Double blinded

Blinding description
The person performing mindfulness and TDCS will be separate from persons working on outcome and analysis of data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Ethic Committee of Tabriz University of Medical Sciences

Street address

Neurosciences Research Center, Imam Reza Hospital, Gholghast Street

City
Tabriz

Province
East Azarbaijan

Postal code
51566614756

Approval date
2018-08-06, 1397/05/15

Ethics committee reference number
IR.TBZMED.REC.1397.430

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

I63.3, I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Change of cognitive scale

Timepoint

Before intervention and after 10 sessions of TDCS therapy and after 8 sessions of Kabat-Zinn mindfulness-based stress reduction treatment program

Method of measurement

Addenbrooke's Cognitive Examinations

2

Description

Change of emotional scale

Timepoint

before intervention and after 10 sessions of TDCS therapy and after 8 sessions of Kabat-Zinn mindfulness-based stress reduction treatment program

Method of measurement

Beck's depression and anxiety inventories

Secondary outcomes

empty

Intervention groups

1

Description

First group: TDCS intervention, for this purpose, 2 mA electricity flows is passed from participants' skull directly for 20 minutes during 10 sessions.

Category

Rehabilitation

2

Description

Second Group: mindfulness intervention, participants will be trained by Kabat-Zinn mindfulness-based stress reduction treatment program (2003) during eight sessions for two and a half hours.

Category

Rehabilitation

3

Description

Third Group: intervention by TDCS + Mindfulness, for this purpose, 2 mA electricity flows is passed from participants' skull directly for 20 minutes during 10 sessions and after that participants will be trained by Kabat-Zinn mindfulness-based stress reduction treatment program (2003) during eight sessions for two and a half hours.

Category

Rehabilitation

4

Description

Fourth group: control group, will not receive any of the interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza medical research and training hospital

Full name of responsible person

Mehdi Farhoudi

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Golgasht street , Imam Reza hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cognitive Sciences and Technologies Council

Full name of responsible person

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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

Cognitive Sciences and Technologies Council

Proportion provided by this source

100

Public or private sector

Private

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

Mehdi Farhoudi

Position

Professor of Neurology

Latest degree

Specialist

Other areas of specialty/work

Neurology

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available