Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Possiblity 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 psyciatric 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 ofTDCS 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