

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Evaluation of Transcranial Direct Current Stimulation (TDCS) effect on the cognitive symptoms of patients with frontotemporal dementia: a randomized double blind trial

Protocol summary

Study aim

Considering the lack of effective drug treatment for the cognitive symptoms of frontotemporal dementia, by determining the effect of transcranial direct current stimulation on the cognitive symptoms of these patients, a suitable treatment method can be provided to improve the cognitive symptoms.

Design

A crossed study, double-blinded, randomised, 30 patients

Settings and conduct

The study is conducted on patients at the Faculty of Modern Medical Sciences and Technologies, which is done in the form of 5 consecutive intervention sessions and again two months later, 5 consecutive sham sessions for each patient. The study is double-blind, in which the patients and the person conducting the psychological tests are blind.

Participants/Inclusion and exclusion criteria

Mini-Mental State Examination more than 11 Exclusion criteria: epilepsy/major depression/scalp lesions/presence of ferromagnetic device

Intervention groups

5 session of anodal tdc for frontotemporal patients
5 sessions of sham tdc for frontotemporal patients

Main outcome variables

language; executive function; behavior; impulsivity;
Inhibition of response; psychological manifestations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231016059737N1**

Registration date: **2024-02-20, 1402/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-20, 1402/12/01**

Update count: **0**

Registration date

2024-02-20, 1402/12/01

Registrant information

Name

Vahid Reza Ostovan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-09, 1402/11/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Transcranial Direct Current Stimulation (TDCS) effect on the cognitive symptoms of patients with frontotemporal dementia: a randomized double blind trial

Public title

Tdcs in frontotemporal dementia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Frontotemporal dementia MMSE more than 11

Exclusion criteria:

Psychiatric or neurologic disorders except FTD Epilepsy
MDD Scalp or skull lesions Contraindications for mri and
tdcs like such as ferromagnetic devices in skull

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization A randomized block design is a design, in which experimental units are first organized into homogeneous blocks and then the treatments are assigned at random to these units within these blocks. The main advantage of this design is, if done properly, it provides more precise results.

Blinding (investigator's opinion)

Double blinded

Blinding description

The control and intervention group patients are both blinded and none of them are told which group they are in. The intervention patients are placed with the tdcs device and have electrical activity, but for the control group, the device is placed but the electric current is not active. The clinical caregiver who is responsible for placing tdcs on the patients is also blind. The settings of the device are applied by the relevant doctor.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Street

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Postal code

7134814336

Approval date

2023-05-03, 1402/02/13

Ethics committee reference number

IR.SUMS.MED.REC.1402.078

Health conditions studied

1

Description of health condition studied

Frontotemporal dementia

ICD-10 code

G31.0

ICD-10 code description

Frontotemporal dementia

Primary outcomes

1

Description

language

Timepoint

The beginning of the study / after 5 tdcs sessions / one month later / the end of the study

Method of measurement

verbal fluency test questionnaire /frontal assesment
battery questionnaire/ picture naming task questionnaire
/neuropsychiatric inventory questionnaire

Secondary outcomes

1

Description

psychiatric manifestation

Timepoint

The beginning of the study / after 5 tdcs sessions / one month later / the end of the study

Method of measurement

neuropsychiatricinventory-questionnaire

2

Description

behavior

Timepoint

The beginning of the study / after 5 tdcs sessions / one month later / the end of the study

Method of measurement

neuropsychiatricinventory-questionnaire

3

Description

executive function

Timepoint

The beginning of the study / after 5 tDCS sessions / one month later / the end of the study

Method of measurement

frontal assessment battery/ trail making test/ behavior rating inventory of executive function

4

Description

response inhibition

Timepoint

The beginning of the study / after 5 tDCS sessions / one month later / the end of the study

Method of measurement

go /no go task interview

5

Description

impulsiveness

Timepoint

The beginning of the study / after 5 tDCS sessions / one month later / the end of the study

Method of measurement

go /no go task interview

Intervention groups

1

Description

Intervention group: After confirming the diagnosis of the patients, the MMSE Mini-Mental State Examination test is taken from the people. The short mental state test is a test to evaluate the quality of consciousness with the diagnosis and screening of dementia, the maximum score of which is 30. People whose MMSE score is higher than 20 will enter the study. Patients are treated with anodal tDCS. In the anodal tDCS group, anodal stimulation depolarizes neurons and increases the probability of action potentials. Stimulation is done unilaterally on the dorsolateral prefrontal cortex and tDCS will be done for the patients during 5 consecutive days, before tDCS, neuropsychiatric tests including frontal assessment battery, trail making test, verbal fluency (PFT), Picture naming task (PNT), Go no-GO task (GGT), Brief test and NPI (Neuropsychiatric inventory) are performed for patients immediately after tDCS and again 1 month after tDCS. Patients will undergo a second round 2 months after the first tDCS, and those who received anodal at the beginning will now receive sham and vice versa.

Category

Treatment - Devices

2

Description

Control group: After confirming the diagnosis of the patients, the MMSE Mental State Examination-Mini test is taken from the people. The short MMSE mental state test is a test to evaluate the quality of consciousness with the diagnosis and screening of dementia, the maximum

score of which is 30. People whose MMSE score is above 20 are included in the study. Patients are treated with anodal tDCS and sham tDCS. The sham group is a general term to indicate a passive form of stimulation (eg, very brief or weak) that is used in research to control the placebo effect. Stimulation is performed unilaterally on the dorsolateral prefrontal cortex and tDCS will be performed for 5 consecutive days for the patients. Before performing tDCS, neuropsychiatric tests including frontal battery assessment, trail making test, phonemic verbal fluency (PFT), Picture naming task (PNT), Go no-GO task (GGT), Brief test and NPI (Neuropsychiatric inventory) are performed for patients immediately after tDCS and again 1 month after tDCS. Patients will undergo a second round 2 months after the first tDCS, and those who received anodal at the beginning will now receive sham and vice versa.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Specialty and Subspecialty Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Shiraz 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
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Vahid Reza Ostovan
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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

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

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