

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Investigating the effect of ventromedial prefrontal transcranial direct current stimulation on empathy, resilience, decision-making and electroencephalography in nursing students

Protocol summary

resilience, decision-making, and QEEG of nursing students

Study aim

Investigating the effect of TDCS over vmPFC on empathy, resilience, decision-making, and QEEG of nursing students

Design

This is a double-blind parallel-group randomized clinical trial.

Settings and conduct

This study will be conducted in the community-based psychiatric care research center and the faculty of advanced medical sciences and technologies of SUMS. eligible candidate will be evaluated for resilience and empathy. Then, resting-stage EEG is recorded for 5 minutes in eyes open and eyes closed conditions. Then the person performs the Iowa decision-making task and the brain signal is recorded simultaneously. participants receive 6 sessions of TDCS with Neurostim-2 device.

Participants/Inclusion and exclusion criteria

Undergraduate and postgraduate nursing students in the age range of 18 to 40 years who do not have a history of neurological or neuropsychiatric diseases.

Intervention groups

Individuals in the intervention group will receive real stimulation. these participants will receive 20 minutes of TDCS with an intensity of 2 mA. Subjects in the control (sham) group will receive sham stimulation. For these people, stimulation with a current intensity of 2 mA is applied in the first 30 seconds of the session, but after 30 seconds, the device will be automatically turned off. The device will be placed in a space out of sight of the participants and they will not know that the device is turned off. The device will remain on people's heads for 20 minutes. Participants of both intervention and control groups will receive 6 stimulation sessions, three sessions per week for two weeks

Main outcome variables

Investigating the effect of TDCS on vmPFC on empathy,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048893N8**

Registration date: **2023-09-17, 1402/06/26**

Registration timing: **prospective**

Last update: **2023-09-17, 1402/06/26**

Update count: **0**

Registration date

2023-09-17, 1402/06/26

Registrant information

Name

Maryam Shaygan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 7345

Email address

m2620.shaygan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of ventromedial prefrontal transcranial direct current stimulation on empathy, resilience, decision-making and electroencephalography in nursing students

Public title
Investigating the effect of transcranial direct current stimulation on empathy, resilience, decision-making, and electroencephalography in nursing students

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 18-40 years old Unfamiliarity with cognitive test and transcranial direct current stimulation Not using drugs, psychedelics and cigarettes No history of neurological diseases or psychiatric disorders No history of brain surgery and brain tumor Absence of metallic implants in the head Being right-handed Willingness to participate in the study
Exclusion criteria:
Failure to complete the treatment course Withdrawing from the study

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be allocated to the intervention or control (sham) group randomly using randomization computer software. In this randomization method, first, a number is assigned to each patient, and then the patients' numbers will be entered into the randomization software, and this software will completely randomize the samples into one of the two groups. The randomization process will be done by someone who is not involved in the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the volunteers, none of the volunteers will be aware of their allocated group (whether the real transcranial direct electrical stimulation or sham stimulation). Collecting and interpreting the questionnaire, entering and interpreting the data, and analyzing the information in statistical software will be

done by a research assistant and statisticians not involved in the study.

Placebo
Used

Assignment
Parallel

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
Community Based Psychiatric Care Research Center, School of Nursing and Midwifery, Zand street, Namazi square
City
Shiraz
Province
Fars
Postal code
7193613119

Approval date
2023-05-28, 1402/03/07

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1402.061

Health conditions studied

1

Description of health condition studied
healthy subjects

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Resilience

Timepoint
Before and after six sessions of tdcS

Method of measurement
Connor-Davidson Resilience Scale

2

Description
Empathy

Timepoint
Before and after six sessions of tdcS

Method of measurement

Jefferson Scale of Empathy Health Profession Students' version (JSPE-HPS)

3

Description

Decision making

Timepoint

Before and after six sessions of tdcs

Method of measurement

Iowa gambling task

4

Description

Electroencephalography

Timepoint

Before and after six sessions of tdcs

Method of measurement

Nr sign EEG amplifier

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving transcranial direct electrical stimulation for 20 minutes with an intensity of 2 mA per session, three sessions per week, and for two weeks, a total of 6 sessions.

Category

Rehabilitation

2

Description

Control group: People in this group will receive sham stimulation. For these people, stimulation with a current intensity of 2 milliamps is applied in the first 30 seconds of the session, but after 30 seconds, the device will be automatically turned off. The device will be placed in a space out of sight of the participants and they will not know that the device is turned off. The device will remain on people's heads for 20 minutes. Three sessions per week, and for two weeks, a total of 6 sessions

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Community Based Psychiatric Care Research Center, School of Nursing and Midwifery, Shiraz University

Full name of responsible person

Dr. Maryam Shaygan

Street address

Zand street, Namazi square

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Phone

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cbpcrc@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempour

Street address

Zand St., Central Building of Shiraz University of Medical Sciences, 7th floor, Vice Chancellor for Research and Technology

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7134814336

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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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Maryam Shaygan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Community Based Psychiatric Care Research Center,
School of Nursing and Midwifery, Zand street, Namazi
square

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Maryam Shaygan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Maryam Shaygan

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Anonymous study data will be shared in correspondence
with the project manager

When the data will become available and for how long

Access period starts 6 months after the results are
published.

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

For including in systematic reviews only

From where data/document is obtainable

Contact via email

What processes are involved for a request to access data/document

After obtaining permission from the security unit and the
university's vice chancellor for research, the data will be
made available to the individual.

Comments