Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of repeated transcranial electrical stimulation with direct current (tDCS) on the improvement of emotional distress and love trauma syndrome in students with romantic relationship breakup: a randomized clinical trial study with sham group

Protocol summary

Study aim
Determining the effectiveness of electrical stimulation with tdcs method on improving love shock and emotional disturbance in students with emotional breakdown.

Design
The present study is a clinical trial with pre-test, post-test and follow-up design with control group.

Settings and conduct
This study will be conducted in the city of Zanjan (Zanjan University) and will be selected from among the students who experienced emotional failure and suffered low trauma in the last year and will be randomly replaced in treatment groups.

Participants/Inclusion and exclusion criteria
Eligibility criteria: having love shock syndrome; experiencing failure in an emotional relationship within the last year. Exclusion criteria: previous history of neurological diseases; brain surgery; epilepsy, seizures, brain injury, head injury or metal brain implantation; diagnosis of depression disorder; bipolar, psychotic disorder or other psychiatric disorder according to DSM5 criteria.

Intervention groups
Two intervention groups and one control group: 1- Intervention group one: stimulating the DLPFC area for ten sessions, two sessions every day, and the duration of each session is 20 minutes. 2-Intervention group two: Stimulation of the VLPFC area for ten sessions, two sessions every day, and the duration of each session is 20 minutes. 3- Control group: Stimulation of the DLPFC area for ten sessions, two sessions every day, and the duration of fake stimulation is 20 minutes per session.

Main outcome variables
Love trauma syndrome; emotional dysregulation; depression; anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181013041327N3**
Registration date: **2023-04-13, 1402/01/24**
Registration timing: **prospective**

Last update: **2023-04-13, 1402/01/24**
Update count: **0**

Registration date
2023-04-13, 1402/01/24

Registrant information
Name
jaber Alizadehgoradel
Name of organization / entity
The University of shahid beheshti
Country
Iran (Islamic Republic of)
Phone
+98 45 3325 0055
Email address
j.alizadeh45@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2023-06-15, 1402/03/25
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of repeated transcranial electrical stimulation with direct current (tDCS) on the improvement of emotional distress and love trauma syndrome in students with romantic relationship breakup: a randomized clinical trial study with sham group

Public title
Brain electrical stimulation and romantic relationship breakup

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having love trauma syndrome The experience of failure in an emotional relationship during the last year Absence of psychiatric disorders

Exclusion criteria:
No previous history of neurological diseases, brain surgery, epilepsy, seizures, brain injury, head trauma or metal brain implants Diagnosis of depressive disorder, bipolar disorder, psychotic disorder or other psychiatric disorders based on DSM5 criteria

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
For small studies, random numbers can be used to sort individuals into groups. Persons participating in the research will be given a code or machine number in order to use the random or random numbers table. Since the number of people we want will be selected from 45 people, so the assigned codes and numbers will be double digits. To select sample people from the table, it will randomly start from a table point in the row or column direction. Subjects are then randomly assigned to one of tree study groups using the random number table and receive intervention in the same group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants will be blind to the type of stimulation received (fake or real).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zanjan University

Street address
Zanjan, University Blvd, University of Zanjan

City
Zanjan

Province
Zanjan

Postal code
3879145371

Approval date
2023-03-13, 1401/12/22

Ethics committee reference number
IR.ZNU.REC.1401.039

Health conditions studied

1

Description of health condition studied
love trauma syndrome

ICD-10 code
F43.10

ICD-10 code description
Post-traumatic stress disorder, unspecified

Primary outcomes

1

Description
Love trauma syndrome

Timepoint
Before the intervention, after the intervention and one months after the intervention

Method of measurement
Love trauma syndrome Questionnaire

2

Description
Emotion regulation

Timepoint
Before the intervention, after the intervention and one months after the intervention

Method of measurement
CANTAB Tset

3

Description
Quality of Life

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Quality of Life Questionnaire

4

Description

Depression

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Beck Depression Inventory

5

Description

Anxiety

Timepoint

Before the intervention, after the intervention and one months after the intervention

Method of measurement

Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Electrical stimulation of the dorsolateral prefrontal cortex (DLPFC) area with an intensity of 2 mA- 10 sessions, two sessions every day and the duration of providing stimulation for each session is 20 minutes

Category

Treatment - Other

2

Description

Intervention group: Electrical stimulation of the Ventrolateral Prefrontal Cortex (VLPFC) area with an intensity of 2 mA- 0 sessions, two sessions every day and the duration of providing stimulation for each session is 20 minutes

Category

Treatment - Other

3

Description

Control group: Mock stimulation of orsolateral prefrontal cortex (DLPFC)- 10 sessions, two sessions every day and duration of sham stimulation for each session is 20 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Zanjan

Full name of responsible person

Jaber Alizadehgoradel

Street address

University of Zanjan, University Blvd., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4537138791

Phone

+98 24 3305 2441

Email

j.alizadeh45@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research and Technology of Zanjan University

Full name of responsible person

Omid Rahmani

Street address

Kilometer 5 of Tabriz Road, Zanjan University, Central Building, Research and Technology Vice-Chancellor

City

Zanjan

Province

Zanjan

Postal code

4537138791

Phone

+98 24 3305 2441

Email

omid.rahmani@znu.ac.ir

Web page address

https://www.znu.ac.ir/research/tel

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice President of Research and Technology of Zanjan University

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

The University of Zanjan

Full name of responsible person

Jaber Alizadehgoradel

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

University of Zanjan, University Blvd., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4537138791

Phone

098243352441

Email

j.alizadeh45@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Zanjan

Full name of responsible person

Jaber Alizadehgoradel

Position

Assistant Professor

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Street address

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City

Zanjan

Province

Zanjan

Postal code

3879145371

Phone

0098243354124

Email

j.alizadeh45@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Zanjan

Full name of responsible person

Jaber Alizadehgoradel

Position

Assistant Professor

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4537138791

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j.alizadeh45@gmail.com

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

Behavioral data files, study protocols, informed consent forms, and clinical trial reports after identifiable individuals are shared.

When the data will become available and for how long

The access period starts 5 years after the results are published.

To whom data/document is available

Behavioral data for this study will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

En Use of data is permitted only for articles related to the field of emotion.

From where data/document is obtainable

Jaber Alizadehgoradel - j.alizadeh45@gmail.com

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

Researchers who want to access the data should receive a letter from their workplace university and send it to the responsible person's email address, and the data will be available in less than 1 month.

Comments