# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 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)

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+98 45 3325 0055

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**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

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## 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

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**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**