Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of transcranial direct current stimulation (tDCS) and high definition stimulation (HD-tDCS) on cognitive-psychological symptoms in adults with restless leg syndrome (RLS)

Protocol summary

Study aim

The present study seeks to investigate transcranial direct-current stimulation (tDCS) and compare it with High definition- tDCS (HD-tDCS) to evaluate their effect on symptoms of restless legs syndrome.

Design

This is a clinical trial research include pre-test, post-test, one-month follow-up and control group. There are parallel groups of 45 subjects which randomly divide into three groups (two experimental and one control group).

Settings and conduct

This is a randomized clinical trial study in which the double blind method will be used. Therefore we refer to consulting Centers of Yazd and by using the convenience sampling method, people with discomfort and complaints of restless legs syndrome are suggested to participate in the study. We offer neurotherapy to satisfy the clients to participate in the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of the disorder by a psychiatrist, Rejecting differential diagnosis by a neurologist, Aged between 18 to 75 years, Not suffering from cardiovascular disease and diabetes, Not Smoking, Non-pregnancy. Exclusion criteria: Dissatisfaction to participate in the research, Having a type of motor or cognitive disabilities, Receiving simultaneous psychiatric treatment, History of seizure disorders, Having a pacemaker

Intervention groups

The first intervention group received transcranial direct-current stimulation (tDCS) at 4 mA (positive stimulation) over 10 consecutive sessions. The second intervention group received High definition-tDCS (HD-tDCS) at 2 mA (positive stimulation) over 10 consecutive sessions. Ten sessions of HD-tDCS without electricity flow (sham mode) will be used for the control group.

Main outcome variables

Cognitive Symptoms, Depression, Severity of restless legs syndrome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044138N1**
Registration date: **2020-05-07, 1399/02/18**
Registration timing: **retrospective**

Last update: **2020-05-07, 1399/02/18**
Update count: **0**

Registration date

2020-05-07, 1399/02/18

Registrant information

Name

Mohammad Hossein Sorbi

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

2019-07-23, 1398/05/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of transcranial direct current stimulation (tDCS) and high definition stimulation (HD-tDCS) on cognitive-psychological symptoms in adults with restless leg syndrome (RLS)

Public title

Effect of transcranial direct current stimulation and high definition stimulation on restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of restless legs syndrome by a psychiatrist or psychologist Gaining moderate to high score in severity of the syndrome (scores of 5 to 12) in the international restless legs syndrome questionnaire Rejecting differential diagnosis of neuro-motor disorder by a neurologist and absence of neurological disorder Aged between 18 to 75 years Not suffering from cardiovascular disease, kidney disease and diabetes (getting information by asking from participants and get help from a physician) Not Smoking and not taking painkillers, sedatives and hypnotics Non-pregnancy in women

Exclusion criteria:

Dissatisfaction to participate in the research Having a type of motor or cognitive disabilities that interferes working with computer Receiving simultaneous psychiatric treatment or other psychotherapies to relieve RLS symptoms History of seizure disorders in individuals, having a pacemaker, having a metal object in the head and neck or any other obstacle to do electrical stimulation

Age

From **18 years** old to **75 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using www.randomization.com to assign equal participants in each group (1:1 allocation). An independent researcher will make random allocation cards using computer-generated random numbers. he will keep the original random allocation sequences until analysis time. Another independent researcher will measure the patients outcome and she will not know the allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The neuroscientist of Yazd Psychological Center will be aware of the research topic and will perform therapeutic interventions. He codes the patients and refers them to a psychologist to check the patient's mental state and record the relevant criteria based on the same code. The patients will be tested in the same condition in the neurotherapy room and the electrodes of the device will be connected to them, but they will not be aware of the real or sham stimulation. Accordingly, this study will be a double-blind study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences

Street address

Central Administration, Bahonar Sq., Yazd

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Yazd

Province

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Postal code

8916978477

Approval date

2019-06-25, 1398/04/04

Ethics committee reference number

IR.SSU.REC.1398.051

Health conditions studied

1

Description of health condition studied

restless legs syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Cognitive Symptoms

Timepoint

Cognitive Symptoms was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

Method of measurement

The Integrated Visual and Auditory (IVA-2)

2

Description

Depression

Timepoint

Depression was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

Method of measurement

beck depression inventory (BDI-II)

3

Description

Severity of Restless Legs Syndrome

Timepoint

Severity of Restless Legs Syndrome was measured at the beginning of the study (before the intervention), after the last treatment session, and 30 days (one month) after the last treatment session.

Method of measurement

International Restless Legs Syndrome Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group received transcranial direct current stimulation (HD-tDCS) at 4 mA (positive or anode stimulation) over 10 consecutive sessions (25 minutes per session).

Category

Treatment - Devices

2

Description

The second intervention group received high definition-transcranial direct current stimulation (HD-tDCS) at 2 mA (positive or anode stimulation) over 10 consecutive sessions (25 minutes per session).

Category

Treatment - Devices

3

Description

The first control group received high definition-transcranial direct current stimulation (HD-tDCS) with Sham over 10 consecutive sessions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling Center and Psychological Services of Imam Hossein

Full name of responsible person

Dr. Hamid Mirhosseini

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University

Full name of responsible person

Dr. Bahram Dalir Naghdeh

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eleven kilometers of University Boulevard- Iran-Urmia,

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Web page address
http://www.urmia.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Urmia University

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
Urmia University
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not 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

Participant Data File: Because the individual data of the study participants are considered, this study shares some of the data such as information about the main outcomes of the study.

When the data will become available and for how long

The access period starts 9 months after the results are published.

To whom data/document is available

The data obtained from this study are only available to researchers working at Urmia University snd Shahid Sadoughi University of Medical Sciences.

Under which criteria data/document could be used

The data of this study are only permitted for correlation analysis and independent t-test.

From where data/document is obtainable

Visit Mr. Mohammad Hossein Sorbi from Urmia University, or contact him by email or phone. Phone: 09131560290, Email: Sorbih@gmail.com

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

Applicants are required to notify Mr. Sorbi by phone or email 9 months after the results of the study are published. Next, the data will be delivered in person.

Comments