

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison of two insomnia treatment protocols using transcranial direct current stimulation And its effects on cognitive functions and mood in women with chronic insomnia disorder

Protocol summary

Study aim

compare the effectiveness of two treatment protocols based on direct transcranial electrical stimulation in the treatment of insomnia and its effect on cognitive functions and mood of women with chronic insomnia

Design

Pre-test-post-test with control group, parallel groups, one-way blind and randomized with 6 blocks. The statistical sample will include 48 female patients with chronic insomnia.

Settings and conduct

In order to treat insomnia, direct electric current with a intensity of 2 mA for 20 to 30 minutes will be performed during 12 sessions. Two different protocols of direct transcranial electrical stimulation include 1) anodal stimulation on the primary motor cortex and cathodal stimulation on the dorsal-lateral frontal cortex; 2) Upper temporal anodal stimulation and cathodal stimulation of the dorsal-lateral prefrontal cortex and secondary motor cortex in two experimental groups and artificial stimulation in the control group are performed in the sleep clinic of Imam Khomeini Hospital in Tehran. Participants are not aware of what type of stimulation they received.

Participants/Inclusion and exclusion criteria

The women aged 18 to 55 years with chronic insomnia

Intervention groups

Two experimental groups that each received one type of stimulation protocol and one control group that received mock stimulation.

Main outcome variables

The primary outcome of the intervention is the treatment of insomnia, which is measured according to the difference of at least 10% between the pre-test and post-test scores of the participants on the Insomnia severity index. Also, the evaluation of this outcome in the implementation of two different treatment protocols is

evaluated according to the difference of at least 10% of the post-test scores of insomnia severity index of the three intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190620043954N2**

Registration date: **2022-01-23, 1400/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-23, 1400/11/03**

Update count: **0**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

Khosroo sadeghniaat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5546 0184

Email address

sadeghniaat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-05-15, 1401/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of two insomnia treatment protocols using transcranial direct current stimulation And its effects on cognitive functions and mood in women with chronic insomnia disorder

Public title

comparison of two insomnia treatment protocols using transcranial direct current stimulation And its effects on cognitive functions and mood in women with chronic insomnia disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

female Ages 18 to 55 years Get a score of 15 to 28 in the Insomnia severity index Do not take sleeping pills or resist drug treatment despite taking the medication

Exclusion criteria:

Having a history of psychiatric neurological diseases (Alzheimer's, epilepsy, Parkinson's, mental retardation, etc.) and brain damage Drug abuse, alcohol or caffeine according to DSM5 diagnostic criteria Existence of bioelectric devices implanted in the body, such as a heart rate monitor Being pregnant Level of education less than diploma

AgeFrom **18 years** old to **55 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **48****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to randomly assign the subjects in the experimental and control groups and also to create a balance in the number of samples assigned to each group, the method of 6 random blocks will be used. The size of all blocks is equal and in each block 2 people in the first intervention group (group A), 2 people in the second intervention group (group B) and 2 people in the control group (group C) will be randomly placed. Random allocation software will also be random generation software. In this way, the software output includes different modes of AABBC random order, which for each block, a different order is applied to assign participants to study groups. In this process, the order of the participants based on the blocks is not predictable.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this clinical trial, the assignment of participants to experimental groups 1 and 2 and the control group is random. In the present study, a one-way blind method is used to reduce bias or bias related to the intervention and evaluate the consequences. In this way, none of the participants knew which of the two intervention groups and the control group were assigned. In all three groups, the transcranial electrical stimulation device is used for the same duration and number of sessions, but participants do not know which treatment protocol or artificial stimulation they received, but the researcher and evaluator are aware of this. Participants agree to this type of blindness before conducting research in the consent form

Placebo

Used

Assignment

Parallel

Other design features

The treatment protocols mentioned in this study have not been used independently and specifically for the treatment of chronic insomnia.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of School of Nursing and Midwifery & Rehabilitation - Tehran University of

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Tehran

Province

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13467-78486

Approval date

2021-12-20, 1400/09/29

Ethics committee reference number

IR.TUMS.FNM.REC.1400.165

Health conditions studied**1****Description of health condition studied**

insomnia

ICD-10 code

G47.0

ICD-10 code description

Insomnia

Primary outcomes

1

Description

In the present study, the primary outcome of the intervention is insomnia treatment, which is measured according to the difference of at least 10% between the pre-test and post-test scores of the participants in the scale of insomnia severity. Also, the evaluation of this outcome in the implementation of two different treatment protocols is evaluated according to the difference of at least 10% of the post-test scores of the participants' insomnia severity index.

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Insomnia Severity Index

Secondary outcomes

1

Description

Memory

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

N-back Test

2

Description

Attention

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Stroop Test

3

Description

Problem Solving

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Wisconsin Card Sorting Test

4

Description

Mood

Timepoint

1 to 5 days before the intervention and 1 to 5 days after the intervention

Method of measurement

Positive and Negative Affection Scale

Intervention groups

1

Description

Intervention group 1: Direct current of 2 mA will be applied for 20 to 30 minutes in 12 sessions (3 times a week). In this group, direct transcranial electrical excitation includes anodal excitation on the primary motor cortex (M1) and cathodal excitation on the dorsal-lateral pre-frontal cortex (DLPFC), that electric current is induced by a transcranial electrical excitation device

Category

Treatment - Devices

2

Description

Intervention group 2: Direct current of 2 mA will run for 20 to 30 minutes in 12 sessions (3 times a week). In this group, direct transcranial electrical stimulation includes anodal stimulation of the supper temporal region (STG), cathodal stimulation of the dorsal-lateral pre-frontal cortex (DLPFC), and secondary motor area (SMA), that electric current is induced by a transcranial electrical stimulation device.

Category

Treatment - Devices

3

Description

Control group: In the sham control group, it is performed during 12 sessions and three sessions per week and each session for 20 to 30 minutes using a transcranial electrical stimulation device.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Occupational Sleep Disorders Research Center

Full name of responsible person

Dr. Khosrow Sadegh Niiat Haghighi

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2nd floor, No. 16, Between Nawab and Roudaki, 10 Meter Golkar, Imam Khomeini Ave.

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Email

tt.motevalli@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Sleep Clinic of Imam Khomeini Hospital

Full name of responsible person

Dr. Khosrow Sadegh Niiat

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

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?**

No

Title of funding source

Occupational Sleep Disorders Research Center of
Baharloo Hospital

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**

Tehran University of Medical Sciences

Full name of responsible person

Tahereh Motevalizadeh

Position

researcher

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Tahereh Motevalizadeh

Position

Researcher

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Tahereh Motevalizadeh

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Latest degree

Master

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publication of study protocol in the form of a scientific-
research article

When the data will become available and for how long

6 months after the end of the study

To whom data/document is available

Scientific researchers and therapists

Under which criteria data/document could be used

Use the results of this study in other scientific studies
and therapy

From where data/document is obtainable

Tahereh Motevalizadeh 00989363726007
tt.motevalli@gmail.com Occupational Sleep Research
Center sadeghniat@yahoo.com

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

Send the request by e-mail, then the documents will be
sent.

Comments