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 sadeghniiat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5546 0184

Email address

sadeghniiat@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
Age
From **18 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target 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 AABBCC 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
Street address
2 th, No. 16, Between Nawab and Roudaki, 10 Meter Golkar, Imam Khomeini Ave.
City
Tehran
Province
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Postal code
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
Street address
2nd floor, No. 16, Between Nawab and Roudaki, 10 Meter Golkar, Imam Khomeini Ave.
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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

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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

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Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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 sadeghniiat@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