

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Transcranial Direct Current Stimulation (tDCS) Treatment on Processing Speed, Life Satisfaction, Negative Emotional States in Students With Poor Sleep Quality

Protocol summary

Study aim

The aim of this Study is to determine how effective the use of tDCS can be in Improving Processing Speed: life Satisfaction: Depression: Anxiety: Stress and Sleep Quality in Students.

Design

This trial has a control group, double-blind, randomized, on 30 students per day with sleep problems, and SPSS-24 software is used for analysis.

Settings and conduct

This work was done in the cognitive science lab of the university and for 10 sessions (20min) in two experimental and control groups, and the participants and the clinical supervisor did not know about the type of intervention.

Participants/Inclusion and exclusion criteria

The research population is all students of Shahid Bahonar uk , who are at a low level in terms of sleep quality, and the Entry criteria are as follows: Having Problems With the Quality of Sleep and Being Dissatisfied With Its Quality in the Last Month: Having Sleep Mode While Driving and Daily Tasks: The Sample Must be From The Student Community: Having Depression, Anxiety, Stress: Having Problems in Some Executive Functions, Including Processing Speed.The exit criteria are as follows: Having a History of Brain Injury or Seizures:Having a History of Bipolar Disorders or Psychotic Disorders: Having Acute Suicidal Thoughts: Taking Psychiatric Drugs at The Time of The Study:: Being Pregnant: Having Metal, Prostheses,Implants and The Presence of Batteries in the Heart: History of Neurological Diseases: Serious Medical Diseases (Heart Problems, Respiratory Failure): Attention Problems: Memory Problems

Intervention groups

The Intervention in the Experimental Group was applied in the form of 20 min of Stimulation of the F3 and F4

area, but in the control group, in the form of 30 seconds of stimulation from 20 min of stimulation and the rest of the time the device was turned off.

Main outcome variables

Processing Speed: life Satisfaction: Depression: Anxiety: Stress: Sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056780N1**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **retrospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Hamid Reza Dehghan

Name of organization / entity

Shahid Bahonar University of Kerman

Country

Iran (Islamic Republic of)

Phone

+98 31 3274 1025

Email address

h.dehghan@ens.uk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-14, 1401/11/25

Expected recruitment end date

2023-05-15, 1402/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Transcranial Direct Current Stimulation (tDCS) Treatment on Processing Speed, Life Satisfaction, Negative Emotional States in Students With Poor Sleep Quality

Public title

The Effect of Transcranial Direct Current Stimulation (tDCS) Treatment on Processing Speed, Life Satisfaction, Negative Emotional States in Students With Poor Sleep Quality

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Problems With the Quality of Sleep and Being Dissatisfied With Its Quality in the Last Month Having Sleep Mode While Driving and Daily Tasks The Sample Must be From The Student Community Having Depression, Anxiety, Stress Having Problems in Some Executive Functions, Including Processing Speed

Exclusion criteria:

Having a History of Brain Injury or Seizures Having a History of Bipolar Disorders or Psychotic Disorders Having Acute Suicidal Thoughts Taking Psychiatric Drugs at The Time of The Study (Anti -Depressants, Anti-Psychotics, Anti-Anxiety Drugs, Sedatives and Benzodiazepines) Dependence on Alcohol or Drugs or Psychoactive Substances Being Pregnant Having Metal, Prostheses, Implants and The Presence of Batteries in the Heart History of Neurological Diseases (Stroke, etc.) Serious Medical Diseases (Heart Problems, Respiratory Failure, Various Malignancies) Attention Problems Memory Problems

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the simple randomization method is used to implement the randomization method, and the randomization was done individually, and it is in this way that for the implementation of simple randomization, a

table of random numbers is used, and the subjects must be a similar pair. Use in groups. In contrast, according to the score they get from the Pittsburgh Sleep Quality Questionnaire, they can't. After that, the subjects are placed in a table of random numbers from 1 to 30, so any test that can be chosen randomly. The control group is placed. Also, the method of concealment is such that, as an important clinical activity in the laboratory, it can determine which of these subjects are in the intervention group and which are in the control group, and each subject who is in the control group is known. Is. with the subject who is in the experimental group under the same conditions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering that there are two groups (Experimental Group and Control Group) in this study, the participants in the experimental or control group were kept blind, so that they were treated with direct electrical stimulation for 20 minutes, but in the group Placebo is a fake treatment, that is, only 30 seconds of electrical stimulation is done in 20 minutes to get a feeling similar to the real treatment, and also both groups are intervened in exactly the same conditions so that the clinical supervisor does not realize that the subject in which group (Intervention or Placebo) and only the researcher and project implementers are aware of this issue, but all participants are fully aware that they are participating in a study and have been fully informed of this type of treatment and its conditions and have expressed their satisfaction.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics committees of Kerman University of Medical Sciences

Street address

Shahid Bahonar University of Kerman, Pajoohesh Sq, Imam Khomeni Highway, Kerman, I.R Iran

City

kerman

Province

Kerman

Postal code

7616913439

Approval date

2023-06-06, 1402/03/16

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Poor Sleep Quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Processing Speed

Timepoint

Before an Intervention and Ten Days After an Intervention.

Method of measurement

Wechsler Coding Test of Adult Intelligence (Revised)

2

Description

Life Satisfaction

Timepoint

Before an Intervention and Ten Days After an Intervention.

Method of measurement

Diener Life Satisfaction Scale

3

Description

Negative Emotional States

Timepoint

Before an Intervention and Ten Days After an Intervention

Method of measurement

Depression, Anxiety, Stress Scale _ 21 Question

4

Description

Sleep

Timepoint

Before an Intervention and Ten Days After an Intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this Group, Subjects were Subjected to Transcranial Direct Current Stimulation of the Brain (tDCS). In this Study, Electrical Stimulation With Direct Electric Current was used based on the F3/F4 Protocol, According to the System of 10-20 Brain Regions, the F3 Region was Anodically Stimulated and the F4 Region was Cathodically Inhibited. Stimulation was done up to 2 mA and automatically turned off after 20 minutes.

Category

Treatment - Devices

2

Description

Control group: In this Group, Subjects were subjected to Transcranial Direct Current Stimulation. In this Study, stimulation with Direct Electric Current was used based on the F3 and F4 protocol, According to the System of 10-20 brain regions, the F3 region was Anodically stimulated and the F4 region was Cathodically inhibited, and the stimulation was performed up to 2 mA and then It was automatically turned off after 30 seconds.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar University of Kerman

Full name of responsible person

Hamid Reza Dehghan

Street address

Shahid Bahonar University of Kerman, Pajooheh Sq, Imam Khomeni Highway, Kerman, I.R Iran

City

kerman

Province

Kerman

Postal code

7616913439

Phone

+98 913 025 6226

Email

h.dehghan@ens.uk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Bahonar University of Kerman

Full name of responsible person

Ali Reza Saidi

Street address

Shahid Bahonar University of Kerman, Pajooresh Sq,
Imam Khomeni Highway,Kerman,I.R Iran

City

kerman

Province

Kerman

Postal code

7616913439

Phone

+98 913 025 6226

Email

h.dehghan@ens.uk.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Bahonar University of Kerman

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

Shahid Bahonar University of Kerman

Full name of responsible person

Sayyed Mohammad Hossein Mousavi Nasab

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Shahid Bahonar University of Kerman, Pajooresh Sq,
Imam Khomeni Highway,Kerman,I.R Iran

City

kerman

Province

Kerman

Postal code

7616913439

Phone

+98 34 3132 2425

Email

hossein.mousavi-nasab@uk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Bahonar University of Kerman

Full name of responsible person

Hamid Reza Dehghan

Position

Master student of clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Shahid Bahonar University of Kerman, Pajooresh Sq,
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kerman

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Postal code

7616913439

Phone

+98 31 3274 1025

Email

h.dehghan@ens.uk.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Bahonar University of Kerman

Full name of responsible person

Hamid Reza Dehghan

Position

Master student of clinical psychology

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

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Province

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Postal code

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Phone

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Email

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only documents related to the main variables of the study are shared. The personal information of the participants is confidential.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

After printing the results of all researchers in educational sciences and psychology, psychiatrists and neuroscience

researchers and other fields can use the documents.

Under which criteria data/document could be used

Any analysis of the data is allowed only with the permission of the organizers of the project and Shahid Bahonar University of Kerman, Faculty of Humanities, Department of Psychology.

From where data/document is obtainable

Shahid Bahonar University of Kerman, postal code 7616913439 Respondents: 1- Dr. Seyyed Mohammad Hossein Mousavi Nesab, Head of Psychology Department Contact number: 03431322425 Email: hossein.mousavi-nasab@uk.ac.ir 2- Dr. Mahshid, experience, vice-chancellor of the faculty Email: m.tajrobehkar@uk.ac.ir Contact number: 09193207522 3- Hamid Reza Dehghan Email: h.dehghan@ens.uk.ac.ir Contact number: 09130256226

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

6 months after the results are published

Comments