

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of QEEG indicators, neuropsychological characteristics and theory of mind in subjects with depressive symptoms: comparing the effectiveness of transcranial direct current stimulation (tDCS) and transcranial pulsed current stimulation (tPCS) with cognitive rehabilitation.

Protocol summary

Study aim

Evaluation of QEEG indicators, neuropsychological characteristics and theory of mind of people with depressive symptoms in terms of severity. Comparing the effectiveness of tDCS and tPCS with cognitive rehabilitation.

Design

Practical and a clinical trial with a parallel group design, including 60 participants, who are randomly assigned to three experimental groups.

Settings and conduct

Subjects are diagnosed with symptoms of depression by a clinical psychologist and are referred to the research process. They are randomly replaced in 3 experimental groups, and they are blinded in the research, and until the end of the research period, no explanation is given as to which type of intervention they received. The participants declare their agreement and satisfaction in writing.

Participants/Inclusion and exclusion criteria

Entry conditions No history of hospitalization and mood disorder Not having anxiety disorders No psychotic symptoms Being right-handed Exit conditions The person's unwillingness to continue cooperation Absence of more than three consecutive sessions Taking antidepressants Occurrence of psychotic symptoms

Intervention groups

Experimental group 1: tDCS is combined with cognitive rehabilitation. Experimental group 2: tPCS is combined with cognitive rehabilitation. Experiment group 3: cognitive rehabilitation alone. Stimulation is applied in 10 sessions and each session lasts for 20 minutes with a current intensity of 2 milliamps. Cognitive rehabilitation in the form of 10 consecutive sessions for 45 minutes.

Main outcome variables

What is the difference between QEEG indices, neuropsychological characteristics and theory of mind of people with depressive symptoms? What is the level of effect of each intervention on QEEG indicators and neuropsychological features of theory of mind of people with depressive symptoms?

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230922059489N1**

Registration date: **2023-10-05, 1402/07/13**

Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**

Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

Fatemeh Ghanaee Chamanabad

Name of organization / entity

Ferdowsi University of Mashhad

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of QEEG indicators, neuropsychological characteristics and theory of mind in subjects with depressive symptoms: comparing the effectiveness of transcranial direct current stimulation (tDCS) and transcranial pulsed current stimulation (tPCS) with cognitive rehabilitation.

Public title

Brain function of people with depressive symptoms before and after tDCS, tPCS and cognitive rehabilitation interventions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from depression based on; Clinical interview and psychologist's diagnosis as well as Beck Depression Inventory Not starting to take antidepressants No history of hospitalization and mood disorder Not having anxiety disorders No psychotic symptoms Not having a history of seizures and epilepsy being right-handed Age ranges from 18 to 40 years Have at least a high school diploma The person's agreement to participate in the research based on completing the informed consent form

Exclusion criteria:

The person's unwillingness to continue cooperation Absence of more than three consecutive sessions Taking antidepressants during the research process Occurrence of psychotic symptoms Occurrence of seizures and epilepsy History of hospitalization in a psychiatric hospital, psychiatric and psychological treatment at the same time as conducting research

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the randomization of the participants, in order to balance the overall sample size and homogeneity of the

main characteristics in the groups (gender and severity of depression), the minimization or matching randomization method is used based on auxiliary variables. In this method, the first participant is randomly assigned to one of the groups, and the next participants are assigned to a group with the least predetermined characteristic in that group. Randomization is done using sealed and waxed opaque envelopes. Based on the size of the research sample, a number of envelopes with aluminum foil (in order to make the contents of the envelopes unclear), preparation, and each of the random sequences created on a card are recorded and the cards are placed inside the envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order.

Blinding (investigator's opinion)

Single blinded

Blinding description

Before starting the research process, all three intervention methods (tDCS + cognitive rehabilitation), (tPCS + cognitive rehabilitation) and (cognitive rehabilitation) and their role in reducing depression symptoms are to be explained to the participants based on past articles and researches. The purpose of this explanation is to increase the level of awareness of the participants regarding the desired interventions. Finally, after increasing the level of awareness of the participants, they are informed that one of the interventions will be applicable for them by chance, but an explanation regarding which intervention is being implemented is not given until the end of the research process. Therefore, the participants will enter the study process with their written consent.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ferdowsi University of Mashhad

Street address

Ferdowsi University of Mashhad, Azadi Square, Razavi Khorasan Province, Mashhad, Iran

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9117948974

Approval date

Health conditions studied

1

Description of health condition studied

The participants in this research are people who are diagnosed with symptoms of depression after conducting clinical interviews and initial evaluations by a clinical psychologist. Also, the severity of depression symptoms will be based on the Beck Depression Inventory in three ranges (minimum depression, weak depression and moderate depression).

ICD-10 code

F06.30

ICD-10 code description

Mood disorder due to known physiological condition, unspecified

Primary outcomes

1

Description

In this research, in order to measure the symptoms of depression and better understand the changes in the level of depression symptoms before and after the desired interventions, the scores obtained in the Beck Depression Inventory (based on the severity of depression) are used.

Timepoint

Evaluation and measurement of depression symptoms will be done at the beginning of the study (before the start of the intervention) and after 10 intervention sessions.

Method of measurement

Beck Depression Inventory

2

Description

In the present study, in order to record brain waves and better understand the changes made in QEEG indicators (three-dimensional intra-brain distributions of current density for frequency bands, power changes, frequency bandwidth and brain wave asymmetry) of people with depression symptoms, Before and after the desired interventions, visible changes in Quantitative Electroencephalography recording are used.

Timepoint

QEEG indicators will be evaluated at the beginning of the study (before the intervention) and after 10 intervention sessions.

Method of measurement

Quantitative Electroencephalography(QEEG)

3

Description

In this research, in order to measure and better understand the changes in neuropsychological characteristics (verbal working memory, visuospatial working memory, planning, set shifting (mental flexibility), inhibition and sustained attention) of people with symptoms Depression, before and after the desired interventions, the scores obtained in the computerized cognitive tests and Barkley Deficits in Executive Functioning Scale are used.

Timepoint

Evaluation of neuropsychological characteristics will be done at the beginning of the study (before the start of the intervention) and after 10 intervention sessions.

Method of measurement

Digit Span, Corsi Blocks Test, Tower of London Test, Wisconsin Card Sorting Test, Go/No-Go, Continuous Performance Test and Barkley Deficits in Executive Functioning Scale.

4

Description

In this research, in order to measure and better understand the changes made in the theory of mind of people suffering from depression symptoms, before and after the desired interventions, the scores obtained in Reading the Mind in the Eyes Test will be used.

Timepoint

Theory of mind evaluation and measurement will be done at the beginning of the study (before the intervention) and after 10 intervention sessions.

Method of measurement

Reading the Mind in the Eyes Test

Secondary outcomes

1

Description

In the present study, in order to measure and better understand the changes in the level of emotional problems of people with depressive symptoms before and after the desired interventions, from the scores obtained in Positive Affect and Negative Affect Scales(PANAS)and Multidimensional Emotional Disorder Inventory (MEDI) is used.

Timepoint

Evaluation and measurement of emotional problems is done at the beginning of the study (before the start of the intervention) and after 10 sessions of the intervention.

Method of measurement

Positive Affect and Negative Affect Scales(PANAS), Multidimensional Emotional Disorder Inventory (MEDI).

Intervention groups

1

Description

Intervention group: (Experimental group 1): tDCS is combined with cognitive rehabilitation. In this research,

stimulation using the SegalStim device, through two positive and negative electrodes that are placed on the head through sponge pads soaked with conductive solution (normal saline) — in 10 consecutive sessions and each session It is applied for 20 minutes with a current of 2 milliamps. In this group, as mentioned, cognitive rehabilitation(Captain Log's) is used in the form of 10 consecutive sessions for 45 minutes in each session together with tDCS.

Category

Treatment - Devices

2

Description

Intervention group: (Experiment group 2): tPCS is combined with cognitive rehabilitation. In this research, transcranial pulsed current stimulation is applied in 10 consecutive sessions (2 weeks) and each session lasts for 20 minutes with a current intensity of 2 milliamps with a randomly generated frequency between 6 and 10 Hz. In this group, cognitive rehabilitation (Captain Log's) is also used in 10 consecutive sessions for 45 minutes in each session along with tPCS.

Category

Treatment - Devices

3

Description

Intervention group:(Experimental group 3): Cognitive rehabilitation (Captain Log's) alone. In this group, cognitive rehabilitation (Captain Log's) is used in 10 consecutive sessions for 45 minutes in each session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ferdowsi University of Mashhad

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ferdowsi University of Mashhad

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

Ferdowsi University of Mashhad

Full name of responsible person

Fatemeh Ghanaei Chamanabad

Position

Doctoral student of cognitive sciences

Latest degree

Master

Other areas of specialty/work

Cognitive science - cognitive psychology

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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

At the end of the research process and statistical analysis of the data obtained from the evaluations performed for each participant, all the data without the names of the people and their personal characteristics are unidentifiable, and the data related to the main results of the study in theses and articles will be shared.

When the data will become available and for how long

Access to the data of this research will begin 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions as well as people working in an industry can send request to receive data and other study documents.

Under which criteria data/document could be used

The request to receive personal non-identifiable data should be aimed at expanding the current research and advancing scientific issues.

From where data/document is obtainable

Applicants can refer to the researcher of this study (Fateme Ghanaei Chamanabad) to receive the desired documents or data. Email address: fa.ghanaeechamanabad@um.ac.ir Farnoosh.ghanae91@gmail.com Phone number: 0098-9150528381

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

6 months after printing the results, the request to receive documents or data files must be made. Applicants must introduce themselves and provide the necessary documents to introduce themselves as researchers working in academic and scientific institutions or industrial units. The purpose of receiving this data should also be mentioned.

Comments