Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 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 Ghanaei 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
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Ferdowsi University of Mashhad, Azadi Square, Razavi Khorasan Province, Mashhad, Iran
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Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IR.UM.REC.1402.119

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

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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
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Doctoral student of cognitive sciences

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Master

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Cognitive science - cognitive psychology

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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 (Fatemeh Ghanaei Chamanabad) to receive the desired documents or data. Email address:fa.ghanaeechamanabad@um.ac.ir Farnoosh.ghanaee91@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