Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of synergestic effectiveness between cognitive behavioral therapy (CBT) and repeated transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS) in cognitive flexibility, attention control, working memory and reducing signs and symptoms of MDD patients

Protocol summary

Study aim

Comparing the synergistic effectiveness of cognitive behavioral therapy (CBT) and repetitive transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS) on cognitive flexibility, attentional control, working memory, and reduction of depressive symptoms and signs in people with major depression.

Design

A controlled, parallel-group, single-blind, randomized, phase 2 clinical trial on 40 patients.

Settings and conduct

This research was conducted in the Beheshti Hospital Clinic of Zanjan using four methods: transcranial direct current electrical stimulation with medication, repetitive transcranial magnetic stimulation with medication, cognitive behavioral therapy with medication, and medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of major depressive disorder by a psychiatrist based on the HDRS (21) questionnaire (score greater than 17), minimum fifth grade education, no psychological treatment received at least one month before participating in the study, during the study and for the duration of the follow-up period, being 18 to 65 years old. Inclusion criteria:, history of epilepsy, history of seizures, history of previous head injury with anesthesia, or hearing impairment, diagnosis of any neurological condition affecting the central nervous system, presence of an electrical or metal object in the body

Intervention groups

1- Group receiving psychotherapy. 2- Group receiving tDCS treatment. 3- Group receiving rTMS. 4- Drug receiving group (control)

Main outcome variables

BDI, Hamilton, Asberg, Stroop congruent error, Stroop incongruent error, Stroop consonant deletion, Stroop interference time, Wisconsin response rate, Wisconsin error rate, go-no-go presentation error, go-no-go omission error, inhibition of outgoing response, outgoing response time, backtest response, backtest response time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240107060643N1**
Registration date: **2025-01-03, 1403/10/14**
Registration timing: **retrospective**

Last update: **2025-01-03, 1403/10/14**
Update count: **0**

Registration date

2025-01-03, 1403/10/14

Registrant information

Name

alireza atabakhsh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2024-03-12, 1402/12/22

Actual recruitment start date
2021-09-23, 1400/07/01

Actual recruitment end date
2024-03-12, 1402/12/22

Trial completion date
empty

Scientific title
Comparison of synergestic effectiveness between cognitive behavioral therapy (CBT) and repeated transcranial magnetic stimulation (rTMS) and transcranial direct current stimulation (tDCS) in cognitive flexibility, attention control, working memory and reducing signs and symptoms of MDD patients

Public title
Investigating the synergy of three cognitive behavioral therapy methods, repeated transcranial magnetic stimulation, and transcranial direct current stimulation on major depression patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All major depression patients Subjects had to show symptoms of major depressive disorder confirmed by a psychiatrist according to the HDRS (21). The participants had to complete a written consent form and were not exposed to any psychological or complementary treatment for at least one month before entering the study. Carrying metal or other electrical devices on the head or having wounds and scratches on the scalp. Absent contraindications to tDCS, such as metal in the head or medical devices implanted in the brain, experience at least Three AHs per week Age: 18 to 65 years old

Exclusion criteria:
Risk of suicide, History of epilepsy and seizures Presence of an electrical or metal object in the body Presence of any neurological disease that affects the central nervous system (such as Parkinson's) Pregnancy Co-occurring bipolar disorder Psychosis

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **65**
Actual sample size reached: **65**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are entered into four groups using simple randomization. Random assignment is done using Excel software. To do this, we enter sixteen numbers 1, sixteen numbers 2, sixteen numbers 3, and sixteen numbers 4 in the first column, which represent the three intervention groups and one control group, respectively. Then, we generate sixty-four random numbers in the second column using the (RAND) function. We sort the data (ascending or descending) based on the values of the column containing the random numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluator and data analyst are unaware of the type of intervention performed in the group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Islamic Azad University - Zanjan Branch (Research Ethics Committee)

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Approval date
2024-03-20, 1403/01/01

Ethics committee reference number
IR.IAU.Z.REC.1402.110

Health conditions studied

1

Description of health condition studied
Major depression

ICD-10 code
F33.2

ICD-10 code description
Major depressive disorder, recurrent severe without psychotic features

Primary outcomes

1

Description
The individual's score on Hamilton Depression Rating Scale (HDRS)
Timepoint
Measuring the severity of depressive symptoms before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
Hamiltonian measurement test

2

Description
Wisconsin Cognitive Flexibility Test (WCST) score
Timepoint
Measuring the individual's WCST score before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
Wisconsin Cognitive Task (WCST) by Sina Software

3

Description
Working memory score in the N-BACK test
Timepoint
Measuring the individual's N-BACK score before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
N-BACK working memory cognitive task by Sina Software

4

Description
Cognitive selective attention score in the simple Stroop test
Timepoint
Measuring the individual's score on the simple stroop task before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
Simple Stroop cognitive attention and concentration task by Sina Company software

5

Description
Cognitive attention inhibition score in the GONOGO test
Timepoint
Measuring the individual's score on the GONOGO task before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
Cognitive task of attention inhibition by Sina Company software

6

Description
The individual's score on the beck Depression Inventory(BDI)
Timepoint
Measuring the severity of depressive symptoms before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
he individual's score on Beck Depression Inventory (BDI)

7

Description
The individual's score on the Montgomery-Aasberg Depression Rating Scale (MADRS)
Timepoint
Measuring the severity of depressive symptoms before the intervention, immediately after the intervention, and one month after the intervention as a follow-up.
Method of measurement
Montgomery-Asberg Depression Scale (MADRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive behavioral therapy is performed in 12-16 sessions (45-60 minutes) according to the protocol (Leahy, 2012) twice a week. After the initial assessment and identification of the patient's problems, familiarization with the treatment begins. After that, intervention and training in cognitive and behavioral techniques are provided.
Category
Treatment - Other

2

Description
Intervention group: Each individual received repetitive transcranial magnetic stimulation (rTMS) at a frequency of 1 Hz, 20 minutes per session, 1200 pulses on the right dorsolateral prefrontal cortex (rDLPFC) and 10 Hz on the left dorsolateral prefrontal cortex (lDLPFC) for 20 minutes, 1600 pulses in total, 2800 pulses per session.
Category
Treatment - Devices

3

Description
Control group: Control group: The group that receives one of the SSRI drugs at an antidepressant dose.
Category
Treatment - Drugs

4

Description
Intervention group: Combination of tDCS and drug therapy: The tDCS treatment program was implemented for the experimental group for 10 20-minute sessions (F3) and (F4). In direct current cranial wall stimulation treatment, two electrodes, one positive and the other negative, are placed on the head through a sponge pad soaked in a conductive solution. After passing through different areas (scalp, skull, etc.), the electric current through these electrodes reaches the surface of the cerebral cortex. The current that reaches this area charges the neurons and creates positive and negative poles, which leads to a change in the activity of that area.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Beheshti Hospital of zanjan

Full name of responsible person
Dr. Mohsen Dadashi

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Sponsors / Funding sources

1

Sponsor

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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
Islamic Azad University

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
Islamic Azad University

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Position
student

Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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