

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the efficacy of repeated transcranial magnetic stimulation (rTMS) and cognitive behavioral therapy (CBT) on depression, anxiety, emotion regulation and working memory in adolescents with major depressive disorder

Protocol summary

Study aim

Comparison of the efficacy of repeated transcranial magnetic stimulation and cognitive behavioral therapy on depression, anxiety, emotion regulation and working memory in adolescents with depressive disorder

Design

A clinical trial with 2 parallel intervention groups, double blinded is performed on 30 patients who were randomly distributed between 2 groups of 15 people.

Settings and conduct

Among the adolescents with depression who will refer to the psychiatric clinic of Shahid Beheshti Educational and Medical Center in Zanjan, 30 patients are selected and randomly divided into two groups. After obtaining informed consent to participate in the study, the CADS Depression and Anxiety Inventory, the Derman & Carpenter Working Memory Test, and the CERQ Cognitive Emotion Regulation Questionnaire are presented. After the implementation and completion of the treatment intervention, questionnaires and evaluation tests will be repeated in the form of post-test and one-month follow-up. Patients will be evaluated by someone other than the therapist.

Participants/Inclusion and exclusion criteria

Adolescents 12-19 years with major depression according to the psychiatrist and in accordance with DSM-5; no previous psychological treatment; no previous transcranial direct current stimulation and neurofeedback. Exclusion criteria: psychotic disorders; past history of seizures and epilepsy; electrical or metal object in the body.

Intervention groups

Intervention Group 1: Cognitive-Behavioral Therapy: Treatment sessions are performed in 12-16 sessions (each session approximately 45-60minutes twice a week). Intervention group2: Each person receives repetitive

transcranial magnetic stimulation with a frequency of 2 Hz, over the left dorsolateral prefrontal cortex five times a week for two weeks.

Main outcome variables

Symptoms of depressive disorder; anxiety; emotion regulation; working memory

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200824048497N1**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Maryam mohammad ali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7628 0897

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-28, 1399/08/07
Expected recruitment end date
 2021-06-20, 1400/03/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of the efficacy of repeated transcranial magnetic stimulation (rTMS) and cognitive behavioral therapy (CBT) on depression, anxiety, emotion regulation and working memory in adolescents with major depressive disorder

Public title
 Comparison of the efficacy of Repeated Transcranial Magnetic Stimulation and Cognitive Behavioral Therapy in adolescents with major Depressive Disorder

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a major depressive disorder diagnosed by a psychiatrist Age range 12-19 years old
Exclusion criteria:
 Infection severe psychiatric disorders such as psychotic spectrum disorders and bipolar disorder history of epilepsy, seizures and history of head injury Use drugs and alcohol Receiving psychological therapies and therapies such as neurofeedback, tDCS and ECT at least one month before entering the study

Age
 From **12 years** old to **19 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random assignment to intervention and control groups First of all each sample is given a specific code, then each code is written on a piece of paper and the papers are poured into a container. According to the sample size in each groups, a few papers will be randomly drawn.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Participants and evaluators are not aware of the intervention groups.

Placebo
 Not used

Assignment
 Parallel
Other design features

Secondary Ids
 empty

Ethics committees

1
Ethics committee
Name of ethics committee
 Ethics committe of Zanjan University of Medical Sciences
Street address
 Zanjan University of Medical Sciences, Azadi Square, Zanjan, Iran
City
 Zanjan
Province
 Zanjan
Postal code
 45156-13191
Approval date
 2020-08-19, 1399/05/29
Ethics committee reference number
 IR.ZUMS.REC. 1399. 181

Health conditions studied

1
Description of health condition studied
 Mjor depression
ICD-10 code
 F32.2
ICD-10 code description
 Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1
Description
 Symptoms of depressive
Timepoint
 Before intervention, After the intervention, One month after the intervention
Method of measurement
 Child and Adolescent Depression Inventory (CADS)

Secondary outcomes

1
Description
 Symptoms of anxiety
Timepoint

Before intervention, After the intervention, One month after the intervention
Method of measurement
Child and Adolescent Anxiety Inventory CADS

2

Description
Working memory
Timepoint
Before intervention, After the intervention, One month after the intervention
Method of measurement
Daneman, carpenter working memory test

3

Description
Emotion regulation
Timepoint
Before intervention, After the intervention, One month after the intervention
Method of measurement
Emotion Regulation Questionnaire CERQ

Intervention groups

1

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

2

Description
Intervention group: each person receives repetitive transcranial magnetic stimulation (rTMS) with a frequency of 2 Hz, over the left dorsolateral prefrontal cortex (IDL PFC). The sessions will be performed five times a week for two weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Mohsen Dadashi
Street address
Beheshti hospital, Ark sq.

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Zanjan
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Zanjan
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4513615788
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Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=29

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
Street address
Zanjan University of Medical Sciences, Azadi BLVD, Zanjan, Iran
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Fax
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Email
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Web page address
http://zums.ac.ir/index.php?slc_lang=fa&sid=1
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
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

Zanjan University of Medical Sciences

Full name of responsible person

Mohsen Dadashi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Department of Clinical Psychology, Beheshti Hospital,
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Maryam mohammadali

Position

student

Latest degree

Bachelor

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Total data after unidentifiable people as SPSS can be shared.

When the data will become available and for how long

Six months later print the results.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions

From where data/document is obtainable

DR. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr Mohsen Dadashi, Mobile: 0098 9127433559. Dr. Beheshti Hospital, Zanjan, Department of Clinical Psychology, Maryam Mohammadali, Mobile: +989127959756

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

Documents will be shared only when the reason for the request is announced by phone or e-mail

Comments