

# 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)

##### Phone

+98 21 7628 0897

##### Email address

mohammadali.maryam20@zums.ac.ir

##### 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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4513615788  
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[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=29](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  
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Zanjan University of Medical Sciences, Azadi BLVD, Zanjan, Iran  
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**Web page address**  
[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=1](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

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Department of Clinical Psychology, Beheshti Hospital,  
Besat Ave, Ark Square

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Maryam mohammadali

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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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**