

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### 7 Effect of Repetitive Transcranial Magnetic Stimulation (rTMS) on depression severity, response inhibition, cognitive flexibility and visuo-spatial memory in patients with Depressive Disorder

#### Protocol summary

##### Study aim

investigating the effect of two types of repetitive transcranial magnetic stimulation protocols in the severity of depression, cognitive flexibility, response inhibition, and visual-spatial memory in patients with depressive disorder.

##### Design

A) Before presenting the independent variable, 55 patients will be selected in the available method. They will then be initially assessed by the Beck Scoring Index and the Wisconsin, Corsi, and Go-Nogo Cognitive Tasks. B) In the Independent variable implementation stage, the subject will receive 10 sessions of treatment during 2 weeks. Sham's group will receive only artificial stimuli.

##### Settings and conduct

This study will be performed at the Azarbaijan Shahid Madani University. The subjects will not be explained whether they will be in the stimulus or sham group, and the individuals and their type of stimulus will be defined with a specific code.

##### Participants/Inclusion and exclusion criteria

Being right-hand Having physical health No trauma or seizures in the individual or family Not having other psychological disorders No dependence on psychotropic substances Not being pregnant No metal, prosthesis, implant, or pacemaker

##### Intervention groups

The first group with unilateral stimulation of DLPFC in patients with depressive disorder The second group with bilateral stimulation of DLPFC in patients with depressive disorder The third group with sham stimulation in patients with depressive disorder

##### Main outcome variables

Reducing the severity of depression; Improving patients' cognitive functions (improving cognitive flexibility; improving visual-spatial memory; improving response inhibition)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210211050329N1**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

##### Registration date

2021-03-02, 1399/12/12

##### Registrant information

##### Name

Fatemeh Asgharian asl

##### Name of organization / entity

Azarbaijan Shahid Madani University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3145 2406

##### Email address

fatemeh.asgharian@azaruniv.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-05, 1399/12/15

##### Expected recruitment end date

2021-04-04, 1400/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

7 Effect of Repetitive Transcranial Magnetic Stimulation (rTMS) on depression severity, response inhibition, cognitive flexibility and visuo-spatial memory in patients with Depressive Disorder

### Public title

Effect of rTMS on Cognitive Function of Depressive Disorder

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Being right-hand Age between 25-45 Having physical health

#### Exclusion criteria:

Being pregnant Having metal, prosthesis, implant or pacemaker Dependence on psychotropic substances History of Trauma or seizures in the individual or family Having other psychological disorders

### Age

From **25 years** old to **45 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization method: simple Randomization unit: individual Randomization tool: In separate sheets, we will write the names of all the participants in the study and will put them in a container, and then randomly will pick the names and will add the first one to the list of the unilateral stimulation group, the second to the list of the bilateral stimulation group, and the third to the control group list. We will continue this until the last person.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Participants will not be explained whether they are in the intervention group or in the control group (blinding takes place), but due to the difference in stimulation areas in the two intervention groups, blinding between intervention groups is not possible for participants. Due to the difference in stimulation areas in the intervention groups and the difference in the stimulation angle in the control group and the intervention groups, blinding is impossible for the researcher. However, the data analyzer will be blind because he will receive only the list of data specified by a different code. And the person does not know which code is for which group—for example, the number 25 for a unilateral group. The number 35 will be assigned to the control group and the

number 15 to the bilateral group, which in data analysis, the analyst will not be aware of the allocation of these numbers to the groups.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Abresan. Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

#### Approval date

2020-02-17, 1398/11/28

#### Ethics committee reference number

IR.TBZMED.REC.1398.1248

## Health conditions studied

### 1

#### Description of health condition studied

Depressive Disorder

#### ICD-10 code

F32.2

#### ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

## Primary outcomes

### 1

#### Description

Depression score in Beck questionnaire and clients' performance in cognitive functions of response inhibition, cognitive flexibility, and visual-spatial memory

#### Timepoint

Before the intervention and after two weeks

#### Method of measurement

By Beck Depression questionnaire and Clients' Performance in Cognitive Tasks of Go-Go, Corsi, and Wisconsin

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Stimulation will be performed by using a Magstim super-rapid magnetic stimulator (Wales, UK). The unilateral group will receive stimulation of Left DLPFC (20Hz, 5s in each train, 2100 pulses, and 85% of Motor Threshold) for 10 sessions during 2 weeks( 5 sessions each week). The coil will be placed at a 45-degree angle on the patient's scalp.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: Stimulation will be performed by using a Magstim super-rapid magnetic stimulator (Wales, UK). The bilateral group will receive stimulation of left DLPFC (20Hz, 5s in each train, 1400 pulses, and 85% of Motor Threshold), followed by Right DLPFC stimulation (1Hz, 10s in each train, 700 pulses, and 110% of Motor Threshold) for 10 sessions during 2 weeks( 5 sessions each week). The coil will be placed at a 45-degree angle on the patient's scalp.

#### Category

Treatment - Other

### 3

#### Description

Control group: In the control group, we will perform artificial stimulation and for 10 sessions for 2 weeks( 5 sessions each week), but the coil will be placed at a 90-degree angle on the patient's scalp. So they will not receive any stimulation.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Azərbaycan Şahid Madani University

##### Full name of responsible person

Ladan Vaghef

##### Street address

Tabriz, East Azarbaijan Province 35 km. of. Maragheh Hwy

##### City

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

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##### Full name of responsible person

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<http://research.azaruniv.ac.ir/Page/33/%D9%85%D8%B9%D8%A7%D9%88%D9%86-%D9%BE%DA%98%D9%88%D9%87%D8%B4-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%D9%8A.html>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Azərbaycan Şahid Madani 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

Azərbaycan Şahid Madani University

##### Full name of responsible person

Fatemeh Asgharian Asl

##### Position

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**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