Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) with and without Physical Activity on Depressive Symptoms, Brain Map , Physical Condition and Sleep Quality of Depressed Patients

Protocol summary

Study aim

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) with and without Physical Activity on Depressive Symptoms, Brain Map, Physical Condition and Sleep Quality of Depressed Patients.

Design

A controlled clinical trial with parallel groups, a blinded Single, phase 2-3 randomized, on 45 patients with depressive disorder. Random blocks were used for randomization.

Settings and conduct

This study is conducted in a private clinic of psychological services in Tehran, patients with depression disorder are included in the study. Due to the fact that the patients do not know about the group allocation, therefore, a blind strain study is performed. We will place the patients in three groups of 15 randomly. The first test group will be affected by repeated stimulation and the second test group will be affected by repeated transcranial magnetic stimulation along with physical activity. The third group of 15 people is the control group, which will not be affected by any experiment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: obtaining a score above 20 in the Beck depression Inventory, No history of seizures and epilepsy, no drug addiction, no history of seizures and epilepsy, aged 18 to 65 years. Exclusion criteria: not completing the questionnaires and having intracranial implants and any other metal object near the head.

Intervention groups

30 patients with depressive disorder received repetitive transcranial magnetic stimulation (rTMS) with and without physical activity in 25 sessions of 20 minutes with current in the left DLPFC area with a frequency of 10Hz.

Main outcome variables

Physical condition improvement questionnaire, brain map measurement scale, Beck depression inventory and Petersburg sleep quality questionnaire are compared in two intervention and control groups, before the intervention and after the 25th session.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240528061935N1**
Registration date: **2024-06-01, 1403/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-01, 1403/03/12**
Update count: **0**

Registration date

2024-06-01, 1403/03/12

Registrant information

Name

Firouze Fadaei Goke

Name of organization / entity

Islamic Azad University, Semnan branch

Country

Iran (Islamic Republic of)

Phone

+98 21 5649 3166

Email address

firoozefadaee1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-01, 1403/02/12

Expected recruitment end date

2024-09-02, 1403/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) with and without Physical Activity on Depressive Symptoms, Brain Map , Physical Condition and Sleep Quality of Depressed Patients

Public title

Effectiveness of Repetitive Transcranial Magnetic Stimulation (rTMS) with and without Physical Activity on Depressive Symptoms, Brain Map , Physical Condition and Sleep Quality of Depressed Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum literacy to read and write Completing the patients' consent form to participate in the experiment Getting a score above 20 in the Beck depression Inventory No history of special diseases and mental illnesses Not taking psychotropic drugs No drug addiction No history of seizures and epilepsy Have a minimum age of 18 and a maximum age of 65 years

Exclusion criteria:

Unwillingness to continue cooperation Failure to complete research questionnaires or filling them incompletely Having intracranial implants (shunts, stimulators, electrodes) and any other metal object near the head

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to the intervention and control groups using the random block method. Then random replacement is done by lottery method (one number will be assigned to each of the sampled people). We write down the numbers on paper, then fold them and put them in a container. We mix and stir the papers completely. Then we take out the papers one by one and place one number in the first group and one number in the second group, respectively. Then random application will be done. In this way, one group is known as "control group" and the other group is known as "intervention group". In this way, to randomly determine the "control group" and the "intervention group", we put the set of each group in two separate envelopes and put them in a container. Then we randomly take one envelope out of the container and assign it to the "intervention group" and the other envelope to the "control group".

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the patients do not know about the group assignment, a blind study is performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan Azad University

Street address

Islamic Azad University, University Town, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513137111

Approval date

2024-04-30, 1403/02/11

Ethics committee reference number

IR.IAU.SEMNAN.REC.1403.011

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Depression

Timepoint

Before and after 25 sessions of intervention.

Method of measurement

Beck depression questionnaire is used to check

depression.

2

Description
Quantitative electroencephalography
Timepoint
Before and after 25 sessions of intervention.
Method of measurement
Quantitative electroencephalography measurement scale

3

Description
Physical Condition
Timepoint
Before and after 25 sessions of intervention.
Method of measurement
Lindenberg Physical Status Improvement Questionnaire

4

Description
Sleep Quality
Timepoint
Before and after 25 sessions of intervention.
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description
CD3 and CD4 levels
Timepoint
In the intervals before and immediately after receiving repetitive brain magnetic stimulation (rTMS) treatment.
Method of measurement
Routine blood sample Test for CD3-CD4 level count.

Intervention groups

1

Description
Intervention group: They will receive the rTMS protocol in addition to the usual treatment. The research was conducted in such a way that the subjects will be evaluated by the Beck depression test one week before rTMS. Then they will be treated with rTMS for 25 sessions (regularly on 5 days of the week) and for 20 minutes of magnetic stimulation in the dorsolateral area of the prefrontal cortex of the left hemisphere (with the opinion of the attending physician). During the study, subjects will take their medicines without any changes. Checking the dose and the amount of medication and changing the drugs during the treatment period, if it occurs, will be excluded from the study.
Category
Treatment - Devices

2

Description
Control group: rTMS will be received off.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Key Consultants Group
Full name of responsible person
Firouze Fadaei Goke
Street address
Ground floor, No. 3, Dead end Hamid, Shahid Jamshid Zamani Alley, Azadi St., Tehran
City
Tehran
Province
Tehran
Postal code
1344653816
Phone
+98 21 6608 4345
Email
firoozefadaee1@gmail.com
Web page address
https://yourkilid.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Shahab Moradi
Street address
Islamic Azad University, University Town, Semnan
City
Semnan
Province
Semnan
Postal code
3513137111
Phone
+98 23 3365 4040
Email
shahabmoradi66@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Semnan Branch
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, Semnan branch
Full name of responsible person
Firouze Fadaei Goke
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Ali Mahmoudi Street, Qamiyeh Township
City
Eslamshahr
Province
Tehran
Postal code
3315865451
Phone
+98 21 5649 3166
Email
firoozefadaee1@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University, Semnan branch
Full name of responsible person
Firouze Fadaei Goke
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Ali Mahmoudi Street, Qamiyeh Township
City
Eslamshahr
Province
Tehran
Postal code
3315865451
Phone
+98 21 5649 3166
Email
firoozefadaee1@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University, Semnan branch
Full name of responsible person
Firouze Fadaei Goke
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Ali Mahmoudi Street, Qamiyeh Township
City
Eslamshahr
Province
Tehran
Postal code
3315865451
Phone
+98 21 5649 3166
Email
firoozefadaee1@gmail.com

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
All data can be shared after de-identification.
When the data will become available and for how long
Data can be made available 6 months after results are published.
To whom data/document is available
Researchers in scientific and academic centers can access the data.
Under which criteria data/document could be used
The data can be used in meta-analyses if the names of the main researchers are mentioned.
From where data/document is obtainable
If you need data, write to firoozefadaee1@gmail.com.
What processes are involved for a request to access data/document
After receiving the request and its review by the main researcher, the data will be sent to the applicant along with a letter of commitment stating that the data will not be published without the name of the main researcher

within one month.

Comments