Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness of repeated transcranial magnetic stimulation on sleep quality, emotional disturbance and severity of disorder symptoms in patients with emotional disorders

Protocol summary

Study aim

Determining the effectiveness of transcranial magnetic stimulation on sleep quality, emotional disturbances and the severity of symptoms of emotional disorders in patients with emotional disorders

Design

A placebo-controlled, single-blind, randomized clinical trial of 60 patients with mood disorders. Randomized block method was used for randomization.

Settings and conduct

This study is conducted in a private clinic of psychological services in Tehran. 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 two groups of 30 people randomly. The experimental group will be affected by repeated transcranial magnetic stimulation and the control group will receive rTMS in silence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of emotional disorders in patients based on diagnostic criteria, age range of participants between 18 and 65 years, patients with moderate to severe symptoms, willingness to participate in research, patients with agitation Emotional and significant problems in sleep quality. Exclusion criteria: presence of coexisting psychiatric disorders, use of interfering drugs, presence of serious physical problems, presence of metal implants, pregnancy or breastfeeding, non-cooperation and unwillingness to continue the research.

Intervention groups

60 patients with emotional disorder received repetitive transcranial magnetic stimulation (rTMS) in 20 sessions, which included frequency of 10 Hz, stimulation duration of 5 seconds, interval between each stimulation of 25 seconds, 120% movement threshold, stimulation location equal to f3 area in They receive a 10-20 system or LDLPFC and a 20-minute stimulation duration.

Main outcome variables

Sleep quality, emotional disturbances and severity of symptoms of emotional disorders in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240713062416N1**
Registration date: **2024-07-18, 1403/04/28**
Registration timing: **prospective**

Last update: **2024-07-18, 1403/04/28**
Update count: **0**

Registration date

2024-07-18, 1403/04/28

Registrant information

Name

Fatemeh Sohrabi

Name of organization / entity

Islamic Azad University Semnan branch

Country

Iran (Islamic Republic of)

Phone

+98 21 3364 5489

Email address

fsohrabi.master@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-24, 1403/05/03

Expected recruitment end date

2024-08-24, 1403/06/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of repeated transcranial magnetic stimulation on sleep quality, emotional disturbance and severity of disorder symptoms in patients with emotional disorders

Public title
Effectiveness of repeated transcranial magnetic stimulation on sleep quality, emotional disturbance and severity of disorder symptoms in patients with emotional disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients must be certified by a psychiatrist or psychologist based on DSM-5 or ICD-10 diagnostic criteria. The age range of participants should be between 18 and 65 years. Patients must have moderate to severe symptom severity as assessed using validated instruments such as the Beck Depression Scale (BDI), Hamilton Anxiety Scale (HAM-A), or similar instruments. Patients must sign informed consent and be willing to participate in all repeated transcranial magnetic stimulation sessions and related assessments. Patients who are currently receiving medication or psychotherapy should have stable treatment and not have any major changes in their treatment for at least 4 weeks before the start of the study. Patients must have significant problems in sleep quality and emotional disturbances that affect their quality of life and daily performance.
Exclusion criteria:
Patients diagnosed with other psychiatric disorders such as psychotic disorders, bipolar disorders or substance abuse disorders in the period of 6 months before the start of the study. Taking medications that may interfere with transcranial magnetic stimulation, such as anticonvulsants or antipsychotics. Patients with serious physical problems such as cardiovascular disease, renal or hepatic failure, or serious neurological disease that may interfere with the treatment protocol. Patients with metal implants in the head or neck area (such as implanted hearing aids) that may be stimulated by magnetic fields. Pregnant or lactating women due to unknown risks to the fetus or infant. Patients who do not attend or follow instructions for repeated transcranial magnetic stimulation sessions or follow-up assessments. Patients who decide to withdraw from the study at any stage of the research and do not want to continue.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are randomly assigned to intervention and control groups using the random block method. First, a number is assigned to each sample person. Then the numbers are written on paper, folded and thrown into a container. The papers are thoroughly mixed and removed one by one. Accordingly, one number is assigned to the first group and one number to the second group. For randomized use, one group is known as the "control group" and the other group is known as the "intervention group" by drawing lots. To randomly determine "control group" and "intervention group", we put the set of numbers of each group in two separate envelopes and put these envelopes 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". This method ensures that the allocation of patients to groups is done completely randomly and without bias.
Blinding (investigator's opinion)
Single blinded
Blinding description
Because the patients do not know about the group assignment, the study is performed in a blinded manner.
Placebo
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
2024-05-21, 1403/03/01
Ethics committee reference number
IR.IAU.SEMNAN.REC.1403.055

Health conditions studied

1

Description of health condition studied
Behavioral and emotional disorders
ICD-10 code
F98
ICD-10 code description
Other behavioral and emotional disorders with onset usually occurring in childhood and adolescence

Primary outcomes

1

Description
Sleep quality
Timepoint
Before intervention and after 20 intervention sessions.
Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI)

2

Description
Emotional disturbance
Timepoint
Before intervention and after 20 intervention sessions.
Method of measurement
Emotional disturbance questionnaire (DASS21)

3

Description
Severity of disorder symptoms
Timepoint
Before intervention and after 20 intervention sessions.
Method of measurement
Clinical General Impression Questionnaire (CGI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This research will be conducted on patients with emotional disorders and the intervention will include 20 sessions (regularly on 5 days of the week). The experimental group was treated with transcranial magnetic stimulation from the usual protocol used in clinics, which includes a frequency of 10 Hz, a duration of stimulation of 5 seconds, an interval between each stimulation of 25 seconds, 120% movement threshold, and a stimulation location equal to f3 area in the 10-20 system. or LDLPFC and the duration of stimulation is 20 minutes.
Category
Treatment - Devices

2

Description
Control group: They will receive rTMS in a silent mode.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Key Consultants Group
Full name of responsible person
Amir Mohammad Pakrah
Street address
4th floor, Omid Doctors Building, in front of Baqiyatullah Hospital, Mulla Sadra, Tehran
City
Tehran
Province
Tehran
Postal code
1344653816
Phone
+98 21 6605 0191
Email
info@yourkilid.com
Web page address
https://yourkilid.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University Semnan branch
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?
Yes
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
Fatemeh Sohrabi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
5th floor, No. 5, East Second Alley, Akakia Street, Mobarez East Street, Abu Dharr Blvd
City
Tehran
Province
Tehran
Postal code
1778833386
Phone
+98 21 3364 5489
Email
fsohrabi.master@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University Semnan branch
Full name of responsible person
Maryam Izadi Mazidi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University, University Town, Semnan
City
Semnan
Province
Semnan
Postal code
3513137111
Phone
+98 23 3365 4040
Email
maryam.izadi.psy@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University Semnan branch
Full name of responsible person
Fatemeh Sohrabi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
5th floor, No. 5, East Second Alley, Akakia Street, Mobarez East Street, Abu Dharr Blvd
City
Tehran
Province
Tehran
Postal code
1778833386
Phone
+98 21 3364 5489
Email
fsohrabi.master@gmail.com

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
Since the research plan is related to a thesis, only the study protocol, clinical study report, and study results will be published. The participant data file contains information about the participants, and due to the preservation of individuals' privacy it cannot be published.
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The steps of the clinical study, such as the number of participants, the inclusion and exclusion criteria for the research plan, the sampling method, the therapeutic protocol, and the study results, will be detailed in the thesis and article.
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

In order to study or conduct research by mentioning the source.

From where data/document is obtainable

If you need the data, write to fsohrabi.master@gmail.com.

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

After receiving the request and reviewing it by the main researcher, the data will be sent to the requester within a week along with an undertaking that the data will not be published without the name of the main researcher.

Comments