Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of transcranial magnetic stimulation (TMS) therapy with and without computer-based cognitive rehabilitation (CCR) in the brain signal of patients with bipolar disorder

Protocol summary

Study aim

The main aim of the present study is to investigate the effectiveness of computer based cognitive rehabilitation treatment with transcranial magnetic stimulation on cognitive functions, brain signals and symptoms of bipolar disorder.

Design

Clinical trial without control group, with two non-randomized groups and evaluation before and after treatment in 30 patients.

Settings and conduct

30 patients in Atieh Clinic in Tehran will be assigned to two groups. The first group receives bilateral rTMS for 20 sessions on right and left DLPFC; the second group receives the same rTMS protocol with 14 sessions of cognitive rehabilitation after that.

Participants/Inclusion and exclusion criteria

Outpatients male and female with the range of 18-65 years of age; the diagnosis of bipolar disorder according to DSM-V; having stable symptoms; completion of the consent form. Exclusion Criteria: The history of rTMS treatment; cardiac pacemaker; the risk of seizure with any reasons; pregnancy; intracranial implant.

Intervention groups

Two intervention groups; The first group will be treated with TMS and the second group will be treated with TMS and Computer based cognitive rehabilitation (TMS+CCR) at the same time

Main outcome variables

The Bipolar Depression Rating Scale (BDRS) score, Cognitive function (Assessment by Cantab Test), and The power of frequency bands in resting conditions and Changes in the P300 components in the Go-NoGo task (Brain signal recording with Mitsar device)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220321054335N1**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **retrospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

Name

Haniyeh Ahmadi Segazi

Name of organization / entity

The University Of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 6519 7187

Email address

ahmadi.hanie@alumni.ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of transcranial magnetic stimulation (TMS) therapy with and without computer-based cognitive rehabilitation (CCR) in the brain signal of patients with bipolar disorder

Public title
Effect of rTMS with and without CCR in treatment of the bipolar disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All adults diagnosed with bipolar disorder by psychologists and psychiatrists Minimum education in reading and writing

Exclusion criteria:
History of epilepsy or convulsions in the person or first degree relatives Having acute heart disease No history of drug use and head trauma Pregnant or breastfeeding women The presence of intracranial implants (such as shunts, electrodes) or any other metal object in or near the head (such as the mouth) Having a pacemaker

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study,psychologists (evaluators), technicians, therapists (Health care personnel), and psychometricians will be blinded to the research design. In other words, the people referred to the evaluator or for treatment will be completely unaware that this person is part of a research project or a regular clinic patient.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Faculty of Psychology and Education

Street address
Dr. Kardan St., in front of Nasr Koi, Faculty of Psychology, University of Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۵۹۸۳۸۶۱

Approval date
2022-05-11, 1401/02/21

Ethics committee reference number
IR.UT.PSYEDU.REC.1401.026

Health conditions studied

1

Description of health condition studied
Bipolar Disorder

ICD-10 code
F31

ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
The score of Bipolar Depression Rating Scale (BDRS)

Timepoint
Evaluation of mood symptoms before the start of the intervention and after the last session of TMS and CCR treatment.

Method of measurement
Bipolar Depression Rating Scale (BDRS)

2

Description
Evaluation of cognitive functions by Cantab

Timepoint
Evaluation of cognitive functions before the start of the intervention and after the last session of TMS and CCR treatment.

Method of measurement
the Cambridge Neuropsychological Test Automated Battery (CANTAB) will be used.

3

Description
Power of frequency bands in rest condition and changes

of P300 component during Go-NoGo task (using Mitsar EEG recording device).

Timepoint

Evaluation of brain signal before the start of the intervention and after the last session of TMS and CCR treatment.

Method of measurement

by 19-channel EEG device during rest and Go-NoGo task

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bilateral rTMS; The coil will locate on F3 and F4 in accordance with the 10-20 international system. Bilateral rTMS include stimulate the right DLPFC at 1 Hz for a 10 seconds train of stimulation, and a total of 900 pulse trains. Immediately after that, the stimulation was carried out on the left DLPFC at 10 Hz, 5 seconds of stimulation, with 10 second inter-train interval and 75 pulse trains

Category

Treatment - Other

2

Description

Intervention group: Bilateral rTMS with Cognitive rehabilitation therapy; In this group, the same TMS protocol as the first group will be used, and after a short break from the end of the TMS session, they will receive attention and memory exercises according to their level in about 45 minutes for 14 sessions using Rahacom rehabilitation software.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Atieh Clinical Neuroscience Center (ACNC)

Full name of responsible person

Reza Rostami

Street address

No. 23, Valinezhad St., Vanak Square,. Tehran.

City

Tehran

Province

Tehran

Postal code

۱۹۶۹۷۱۳۶۶۳

Phone

+98 21 8401 2000

Email

Info@atiehclinic.com

Web page address

https://atiehclinic.com/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Atieh Clinical Neuroscience Center (ACNC)

Full name of responsible person

Reza Rostami

Street address

No. 23, Mostafa Valinejad St., Valiasr St., above Vanak Square, Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۶۹۷۱۳۶۶۳

Phone

+98 21 8401 2000

Email

info@atiehclinic.com

Web page address

https://atiehclinic.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Atieh Clinical Neuroscience Center (ACNC)

Proportion provided by this source

5

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

University of Tehran

Full name of responsible person

Reza Rostami

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

No. 23, Vali Nejad St., above Vanak Square, Valiasr

St., Tehran
City
Tehran
Province
Tehran
Postal code
3169467471
Phone
+98 21 8401 2000
Email
rezaros@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Atieh Clinical Neuroscience Center (ACNC)
Full name of responsible person
Haniyeh Ahmadi Segazi
Position
Psychologist
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 628, Khazaei Alley, Shahid Sadoughi Street, Mallard Road, Tehran
City
Tehran
Province
Tehran
Postal code
3169467471
Phone
+98 21 6519 7187
Email
ahmadi.hanie123@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Atieh Clinical Neuroscience Center (ACNC)
Full name of responsible person
Haniyeh Ahmadi Segazi
Position
psychologist
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 628, Khazaei Alley, Shahid Sadoughi Street, Mallard Road, Tehran
City
Malard
Province
Tehran
Postal code
3169467471
Phone
+98 21 6519 7187
Email
ahmadi.hanie123@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 the initial and final evaluations of the treatment will be stored in Excel without the names of the participants.
When the data will become available and for how long
After the end of the study and the analysis of the results and the publication of the preliminary results (assuming about 6 months after the end of the study), it will be possible to request access to the data.
To whom data/document is available
Researchers in line with the research topic without restrictions
Under which criteria data/document could be used
In order to improve the treatment and the scientific field in question, all researchers can apply with a guarantee of trustworthiness.
From where data/document is obtainable
ahmadi.hanie@gmail.com
What processes are involved for a request to access data/document
In the form of an email, the type of data and documents expected and the reason for the request will be sent, and the researcher will send the information format.
Comments