Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Synergistic effect of repeated transcranial magnetic stimulation with cognitive behavioral therapy in patients with panic disorder

Protocol summary

Study aim
Combined effect of recurrent transcranial magnetic stimulation of the brain With cognitive-behavioral therapy in patients with panic disorder

Design
A randomized, double-blind, randomized controlled clinical trial of 45 patients

Settings and conduct
This study will be performed in Beheshti hospital clinic with repeated transcranial magnetic stimulation for 20 session and cognitive-behavioral therapy for 12 sessions.

Participants/Inclusion and exclusion criteria
Having complete diagnostic criteria for panic disorder at the discretion of a Psychiatrist and psychologist based on diagnostic and statistical manual of Mental disorder , being 18 to 65 years old, the participants needed to Complete the written consent form, Do not use alcohol and substances during The last month. Exclusion criteria: Inclusion complete criteria for personality Disorder, Existence of psychotic disorders, bipolar, history of epilepsy and Seizures, Use of tricyclic antidepressants (TCAs).

Intervention groups
The first intervention group will receive a combination of repetitive transcranial magnetic stimulation of the brain(rTMS) and cognitive-behavioral therapy(CBT). The second intervention group will receive only rTMS, and finally the control group will receive sham rTMS with CBT.

Main outcome variables
Clinical signs of panic disorder, emotional regulation, attention bias, depression, amplitude and coherence, and asymmetry in the frontal cortex of people with panic.

General information

Reason for update
Due to the registration of the project with the following scientific title in Zanjan University of Medical Sciences, the title was changed

Acronym

IRCT registration information
IRCT registration number: **IRCT20210611051543N1**
Registration date: **2021-08-05, 1400/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-07, 1400/05/16**
Update count: **1**

Registration date
2021-08-05, 1400/05/14

Registrant information

Name
Maryam Habibi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 45 3368 8209

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-13, 1400/04/22

Expected recruitment end date
2022-01-12, 1400/10/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Synergistic effect of repeated transcranial magnetic stimulation with cognitive behavioral therapy in patients with panic disorder

Public title
The synergistic effect of repeated transcranial magnetic stimulation of the brain with cognitive behavior therapy in patients with panic disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having diagnostic criteria for Panic disorder based on psychiatrist diagnosis and clinical interview Having at least a third secondary education Experience at least 3 panic attacks per week Being 18 to 65 years old Signing the written consent form Not to be exposed to any psychological Therapies for at least 1 month before entering the research Not using alcohol and substances during the last month

Exclusion criteria:
Inclusion complete criteria for personality disorder Existence of psychotic disorders, bipolar History of epilepsy and seizures No contraindications to repeated transcranial magnetic Stimulation, such as metal in the head or implanted brain medical Devices Diagnosis of any neurological conditions affecting central Nervous system(e.g. Parkinson's disease) Pregnancy Use of tricyclic antidepressants (TCAs)

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the finite randomization method of block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all blocks is equal and in this three-group experiment we will have 15 blocks (including 5 people in the first intervention group, 5 people in the second intervention group and 5 people in the control group). Randomization tool also uses random sequence generation software that these random sequence generation software in addition to simple structural randomization are able to generate random sequence by blocking method. For concealment, we use random allocation concealment, which is the method used to execute random sequences on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants to the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The subjects do not know the type of intervention. The patient receives the intervention in separate coded treatment rooms. No mirrors are installed on the patient's entrance and exit. Coding is done by one of the design partners. Patients do not see each other during the intervention. People who analyze the results do not know the nature of the study groups. The evaluation is done by someone other than the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences

Street address
Azadegan Square

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Zanjan

Province
Zanjan

Postal code
45136-15788

Approval date
2021-05-25, 1400/03/04

Ethics committee reference number
IR.ZUMS.REC.1400.060

Health conditions studied

1

Description of health condition studied
Panic disorder

ICD-10 code
F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

Primary outcomes

1

Description
Percentage of people whose Panic Disorder Severity Scale score is above 4
Timepoint
Measurement of panic before intervention, in the tenth session of the intervention, after the intervention, follow-up for two months after the intervention
Method of measurement
Panic Disorder Severity Scale

2

Description
Percentage of people whose Beck questionnaire score is above 20
Timepoint
Measurement of depression before the intervention, after intervention, tow-month follow-up intervention
Method of measurement
Beck Questionnaire

3

Description
Percentage of people whose Hamilton questionnaire score is above 17
Timepoint
Measurement of depression before the intervention, after intervention and tow-month follow-up intervention
Method of measurement
Hamilton Depression Test

4

Description
Cognitive test score in Stroop test
Timepoint
Measurement of attention bias before intervention, after intervention and tow-month follow-up after intervention
Method of measurement
Stroop test

5

Description
Analyze the electroencephalography results
Timepoint
Measurements before the intervention, after the intervention
Method of measurement
Electroencephalography

Secondary outcomes

1

Description
The higher the score, the higher the emotion regulation
Timepoint
Measuring emotion regulation strategies before intervention, after intervention and follow-up for tow months after intervention
Method of measurement
Gross and John Emotion Regulation Questionnaire

Intervention groups

1

Description
Intervention group: The combination of repetitive transcranial magnetic stimulation of the brain and cognitive-behavioral therapy: The first session of cognitive-behavioral therapy, includes assessment and homework; session 2: assessment, socialization to treatment, medication and homework, session 3: assessment, interventions, medication and homework, session 4 includes assessment, behavioral interventions, medication and homework; sessions 5-8 include assessment, cognitive interventions, other interventions, medication and homework, sessions 9-10 include assessment, cognitive interventions, behavioral interventions, medication, and homework; sessions 11-12 include assessment, cognitive interventions, behavioral interventions, other interventions, and homework. Repetitive transcranial magnetic stimulation protocol: 1 Hz transcranial magnetic stimulation to stimulate the right dorsolateral prefrontal cortex, 110% resting motor threshold, 1800 pulses (lasting for 30 minutes) in each session, and one session per day. Performed for 20 sessions (5 sessions per week for 4 weeks).
Category
Treatment - Devices

2

Description
Intervention group: Repetitive transcranial magnetic stimulation: 1 Hz transcranial magnetic stimulation to stimulate the right dorsolateral prefrontal cortex, 110% resting motor threshold, 1800 pulses (lasting for 30 minutes) in each session, and one session per day. Performed for 20 sessions (5 sessions per week for 4 weeks).
Category
Treatment - Devices

3

Description
Control group: The control group received sham repetitive transcranial magnetic stimulation. Most of the parameters of the sham stimulation (frequency, pulses, stimulation site and intensity) were the same as for active stimulation. The sham stimulation was defined with a coil diverted by90 degrees over the same area

and same intensity and design as real repetitive transcranial magnetic stimulation. An also cognitive-behavioral therapy applied in this group.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Beheshti Hospital Clinic
Full name of responsible person
Maryam Habibi
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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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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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Full name of responsible person
Maryam Habibi
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Outcomes and results are published in the form of statistics

When the data will become available and for how long

After publishing the article

To whom data/document is available

The data will be available to researchers

Under which criteria data/document could be used

Can be used for secondary studies

From where data/document is obtainable

93Ma.hbi@zums.ac.ir 09147432754

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

Will be sent after receiving the email

Comments