Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

The Effectiveness of Dialectical Behavior Therapy and repetitive Transcranial Magnetic Stimulation of the Dorsolateral Prefrontal Cortex on Symptoms of Borderline Personality Disorder: A Single blind randomized controlled clinical trial

Protocol summary

Study aim
The Effectiveness of Dialectical Behavior Therapy and repetitive Transcranial Magnetic Stimulation of the Dorsolateral Prefrontal Cortex on Symptoms of Borderline Personality Disorder: A Single blind randomized controlled clinical trial

Design
Limited randomization, block randomization (quadruple random blocks) with sealedenvelop.com online system; Assignment concealment; Sample size: 50

Settings and conduct
Project location: Imam Hossein Hospital and 505 Hospital
Blinding: Single blind

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of an experienced psychiatrist based on DSM-5 and SCID-5-PD; Minimum diploma education; Age range between 18 and 45 years; Not receiving psychological treatment in the past; At least five times of self-harm (self-injury) in the past.
Exclusion criteria: Having prominent psychotic symptoms and uncontrollable suicidal thoughts; Having delusional disorders; Patients who have been undergoing psychotherapy at the time of selection.

Intervention groups
1) The first group (positive control) includes healthy people who do not have any psychological or neurological problems. 2) The second group (negative control or waiting list) includes people with BPD who do not receive any intervention but all questionnaires are run on them (waiting list). 3) The third group (DBT group) includes people with BPD who receive only DBT. 4) The fourth group (rTMS group) includes people with BPD who receive only rTMS. 5) The fifth group (DBT + rTMS group) includes people with BPD who enter DBT treatment immediately after receiving and completing rTMS sessions.

Main outcome variables
Borderline Personality Disorder Severity Index (BPDSI), Distress Tolerance Scale (DTS), Barratt Impulsiveness Scale, Difficulties in Emotion Regulation Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170417033485N1**
Registration date: **2021-07-20, 1400/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-20, 1400/04/29**
Update count: **0**

Registration date
2021-07-20, 1400/04/29

Registrant information

Name
Dr. Alireza Mohammadi

Name of organization / entity
Neuroscience Research Center, Baqiyatallah University of Medical Science, Tehran, Iran.

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-05-26, 1400/03/05

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Dialectical Behavior Therapy and repetitive Transcranial Magnetic Stimulation of the Dorsolateral Prefrontal Cortex on Symptoms of Borderline Personality Disorder: A Single blind randomized controlled clinical trial

Public title

The Effectiveness of Dialectical Behavior Therapy and repetitive Transcranial Magnetic Stimulation of the Dorsolateral Prefrontal Cortex on Symptoms of Borderline Personality Disorder: A Single blind randomized controlled clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of an experienced psychiatrist and possession of diagnostic properties of borderline personality disorder based on DSM-5 and SCID-5-PD Minimum diploma education Age range between 18 and 45 years Failure to receive psychological treatment in the past with the aim of treating borderline personality disorder At least five times self injury (self-harm) in the past

Exclusion criteria:

Having prominent psychotic symptoms and uncontrollable suicidal thoughts Having delusional disorders Patients undergoing psychotherapy at the time of selection

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the restricted randomization method of the type of permuted block randomization (Random quadruple blocks) will be used and for this purpose, the online system sealedenvelop.com will be used, which randomly divides the four main intervention groups (D, C, B, E, ...). Then the first patient enters group D, the second patient in group C, etc. until the groups are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Once the relevant groups have been identified, the study is designed in such a way that, except for the lead researcher, none of the subjects and all those who come into contact with them unaware of the assignment of the study groups. For this purpose, first of all, all patients have the idea that each of them receives the intervention and are also unaware of the type of intervention. Second, other colleagues who are in contact with patients along the study path do not know the study group and its type.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Ethics Committee of Baqiyatallah Hospital

Street address

Vanak Square, Mulla Sadra Street, Sheikh Baha'i Intersection

City

Tehran

Province

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Postal code

1435916471

Approval date

2021-05-25, 1400/03/04

Ethics committee reference number

IR.BMSU.BAQ.REC.1400.007

Health conditions studied

1

Description of health condition studied

Borderline Personality Disorder

ICD-10 code

F60.3

ICD-10 code description

Borderline personality disorder

Primary outcomes

1

Description

The score of Borderline Personality Disorder Severity Index (BPDSI)

Timepoint
Before the intervention (Pre-test), after the intervention (Post-test) and one month after the intervention (Following)
Method of measurement
Borderline Personality Disorder Severity Index (BPDSI)

Secondary outcomes

1

Description
Distress Tolerance Scale (DTS)
Timepoint
Before the intervention (Pre-test), after the intervention (Post-test) and one month after the intervention (Following)
Method of measurement
Distress Tolerance Scale (DTS) Questionnaire

2

Description
Barratt Impulsiveness Scale
Timepoint
Before the intervention (Pre-test), after the intervention (Post-test) and one month after the intervention (Following)
Method of measurement
Barratt Impulsiveness Scale Questionnaire

3

Description
Difficulties in Emotion Regulation Scale
Timepoint
Before the intervention (Pre-test), after the intervention (Post-test) and one month after the intervention (Following)
Method of measurement
Difficulties in Emotion Regulation Scale Questionnaire

Intervention groups

1

Description
Dialectical Behavior Therapy: Dialectical behavioral therapy is a special type of cognitive behavioral therapy which developed in the late of 1980s by Marsha Linhan to help better treatment of borderline personality disorder; But it is currently used to treat a variety of psychological disorders. In this study, two groups will receive dialectical behavior therapy (DBT). The first is the group that receives DBT alone, and the group that receives it after receiving repetitive Transcranial Magnetic Stimulation (rTMS) sessions. DBT will be performed as group psychotherapy for 8 to 12 sessions (Linhan, 1993). After the intervention, questionnaires and Flanker test will be taken immediately after and one month later.
Category
Treatment - Other

2

Description
repetitive Transcranial Magnetic Stimulation (rTMS): rTMS is a noninvasive form of brain stimulation in which a changing magnetic field is used to cause electric current at a specific area of the brain through electromagnetic induction. In this study, a group will receive real rTMS and a placebo group received it artificially. In the rTMS group, rTMS will be performed with the device of Magstim Company under the supervision of a psychiatrist and a physiologist of the psychiatry center located in Imam Hossein (AS) Hospital. As mentioned, according to previous studies, the target area for this purpose will be right dorsolateral prefrontal cortex (right DLPFC) with a frequency of 10 Hz for 8 to 10 sessions of 20 minutes per day for two weeks. The placebo group will lie on the device but will not recieve any stimuluatin. After the intervention, questionnaires and Flanker test will be taken immediately after and one month later.
Category
Treatment - Devices

3

Description
Dialectical Behavior Therapy + repetitive Transcranial Magnetic Stimulation: This group receives two interventions and after performing and completing rTMS sessions (10 Hz for 8 to 10 sessions for 20 minutes per day for two weeks on DLPFC right hemisphere), 8 to 12 DBT sessions (Linhan, 1993) will be done. After the intervention, questionnaires and Flanker test will be taken immediately after and one month later.
Category
Treatment - Other

4

Description
Negative control group (waiting list) with sham brain stimulation: This group includes borderline patients who do not receive any intervention and whose brain stimulation is artificial. Sham rTMS stimulation was delivered using the same stimulation parameters and at the same site; however, a sham coil was used.
Category
Placebo

5

Description
Positive control group includes healthy people: Healthy people who do not receive any intervention.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
505 Psychiatric Hospital

Full name of responsible person
Dr. Alireza Mohammadi

Street address
Arteh Highway - End of Shahid Mozhdi Boulevard (Oshan) - 505 Hospital

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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
does not have

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
does not have

Proportion provided by this source
1

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Alirza Mohammadi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuropsychiatry

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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 personal data of the study participants can be shared after encoding individuals.
When the data will become available and for how long
Data release time will be available after the relevant articles are published.
To whom data/document is available
All researchers
Under which criteria data/document could be used
If the articles of this project are cited to.
From where data/document is obtainable
Alireza Mohammadi
What processes are involved for a request to access data/document
By sending an email to the project manager
Comments