

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the efficacy of schema therapy with mentalization in patients with borderline personality disorder

Protocol summary

Study aim

Comparison of the efficacy of schema therapy with mentalization in patients with borderline personality disorder

Design

Clinical trial, parallel groups, phase three, unblinded, randomized, which will be conducted on 40 patients.

Settings and conduct

The studied population is 40-18 years old patients with borderline personality disorder referring to affiliated clinics of the University of Medical Sciences. The patients will be randomly entered into the study by the random number table method by the computer and the intervention will be performed on them.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: patients with borderline personality disorder; At least sixth grade education; Age 18 to 40 years Exclusion Criteria: patients with psychotic and organic brain disorders; participation in other psychotherapy programs; intellectual disability; Cognitive disorders; Bipolar disorder; Drug use during intercourse

Intervention groups

Mentalization based treatment (MBT) group: treatment sessions according to the treatment protocol of Batman and Fonagy to 12 sessions of preliminary mindfulness-based therapy (MBT-I) and then 8 sessions of group mindfulness-based therapy (MBT-G) on a weekly basis Each session will last 75 minutes. Group therapy based on schema therapy (ST): according to the protocol, 15 sessions of 60-120 minutes will be conducted weekly.

Main outcome variables

Total score of borderline personality disorder index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230130057281N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Alireza Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 4719

Email address

a.azizi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of schema therapy with mentalization in patients with borderline personality disorder

Public title

Effectiveness of schema therapy with mentalization in patients with borderline personality disorder

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with borderline personality disorder At least sixth grade education Age 18 to 40 years

Exclusion criteria:

Patients with psychotic and organic brain disorders
Participation in other psychotherapy programs
Intellectual disability Cognitive disorders Bipolar disorder
Drug use at the time of the interview

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using permutation blocks of size 4. Patients will be randomly assigned to two groups of 15 using 10 blocks of size 4 and 1:1 ratio. Creation of random allocation sequence in blocks will be done by statistician.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-06-12, 1402/03/22

Ethics committee reference number

IR.MUBABOL.REC.1402.027

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

Total score of borderline personality disorder index

Timepoint

Before starting the treatment, immediately after the end of the sessions and 2 months after the end of the sessions

Method of measurement

Borderline personality disorder questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mentalization based treatment (MBT) group treatment sessions according to the treatment protocol of Batman and Fonagy to 12 sessions of preliminary mindfulness-based therapy (MBT-I) and then 8 sessions of group mindfulness-based therapy (MBT-G) on a weekly basis Each session will last 75 minutes.

Category

Treatment - Other

2

Description

Intervention group: Group therapy based on schema therapy (ST) according to the protocol, 15 sessions of 60-120 minutes will be conducted weekly..

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Alireza Azizi
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Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue
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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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m.rajabnia@mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Alireza Azizi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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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

There is still no plan for its publish.

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available