

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 Siences
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

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

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2

Recruitment center

Name of recruitment center

Shahid Yahyanezhad Hospital

Full name of responsible person

Alireza Azizi

Street address

Shahid Yaheinejad Hospital, Shahid Mustafa Khomeini Street, Modares Street

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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

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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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 scientific inquiries

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Full name of responsible person

Alireza Azizi

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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