Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Body-Oriented Mentalization-Based Therapy on Quality of Life, Worry, Body Awareness, and Psychological Distress in Patients with Asthma

Protocol summary

Study aim

To determine the effectiveness of body-oriented mentalization-based treatment on quality of life, worry, body awareness, and psychological distress in patients with asthma.

Design

A quasi-experimental study with a control group, pre-test, post-test, and three-month follow-up design will be conducted on 36 patients randomly allocated to two parallel groups using computer-based randomization. No blinding will be applied.

Settings and conduct

The study will be conducted in healthcare centers in Isfahan, Iran. A total of 36 participants will be recruited through convenience sampling and randomly assigned to intervention and control groups (18 per group). The intervention group will receive a 12-session Body-Oriented Mentalization program, while the control group will receive no intervention. Both groups will complete pre- and post-intervention assessments. No blinding will be applied.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Confirmed asthma diagnosis, age over 18, basic literacy, willingness to participate, ability to attend sessions, and no concurrent psychological treatment. Exclusion Criteria: Development of a new significant chronic illness or a history of medical conditions requiring specific medications or dietary restrictions.

Intervention groups

Intervention Group: Participants will receive a 12-session body-oriented mentalization program focusing on bodily awareness, mindfulness, emotion regulation, attachment, interpersonal skills, personal boundaries, and social support, including experiential exercises and homework. Control Group: Participants in the control group will receive no intervention during the study period and will continue their usual care.

Main outcome variables

Quality of life, worry, body awareness, psychological distress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251129068145N10**
Registration date: **2026-11-08, 1405/08/17**
Registration timing: **prospective**

Last update: **2026-11-08, 1405/08/17**
Update count: **0**

Registration date

2026-11-08, 1405/08/17

Registrant information

Name

Mohammadreza Gorji Azghandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3872 0567

Email address

gorji@article-lab.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Body-Oriented Mentalization-Based Therapy on Quality of Life, Worry, Body Awareness, and Psychological Distress in Patients with Asthma

Public title

The Effectiveness of Body-Oriented Mentalization-Based Therapy on Quality of Life, Worry, Body Awareness, and Psychological Distress in Patients with Asthma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed diagnosis of asthma. Age over 18. Physical ability to attend the scheduled sessions. Willingness to participate in the study and provide written informed consent. Basic literacy (ability to read and write). Not receiving any other psychological treatment during the study.

Exclusion criteria:

Occurrence of a significant medical event during the study, such as the development of another chronic physical illness. History of physical conditions requiring specific medications or dietary regimens.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will initially be recruited using convenience sampling based on the study’s eligibility criteria. After obtaining informed consent and completing the baseline assessments, eligible participants will be randomly allocated to either the experimental group or the control group in a 1:1 ratio. The random allocation sequence will be generated using computer-based random number generation software to ensure an unpredictable assignment process. Each participant will be assigned a unique study identification number, and group allocation will be determined according to the pre-generated randomization sequence. This procedure will help minimize selection bias and ensure an unbiased allocation of participants to the study groups.

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

Research Ethics Committee of Islamic Azad University- Najafaba Branch

Street address

Islamic Azad University, Najafabad Branch, University Boulevard, Najafabad, Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

۸۵۱۴۱۴۳۱۳۱

Approval date

2026-10-22, 1405/07/30

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1405.282

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Quality of Life

Timepoint

Quality of life will be assessed at baseline (pre-intervention) and immediately after completion of the 12-session intervention (post-intervention).

Method of measurement

Quality of life will be assessed using the 26-item World Health Organization Quality of Life Questionnaire (WHOQOL-BREF). The questionnaire evaluates four domains: physical health, psychological health, social relationships, and environmental health. Responses are rated on a 5-point Likert scale. Items 3, 4, and 26 are reverse-scored. Domain scores are calculated according to the standardized scoring guidelines, with higher scores indicating better quality of life.

2

Description
Worry
Timepoint
Worry will be assessed at baseline (pre-intervention) and immediately after completion of the 12-session intervention (post-intervention).
Method of measurement
Worry will be assessed using the 16-item Penn State Worry Questionnaire (PSWQ). This self-report questionnaire measures the severity, frequency, and uncontrollability of excessive and persistent worry. Items are rated on a 5-point Likert scale, ranging from 1 (not at all typical of me) to 5 (very typical of me). Five items are reverse-scored, and total scores range from 16 to 80, with higher scores indicating greater levels of worry.

3

Description
Body Awareness
Timepoint
Body awareness will be assessed at baseline (pre-intervention) and immediately after completion of the 12-session intervention (post-intervention).
Method of measurement
Body awareness will be assessed using the 18-item Body Awareness Questionnaire (BAQ), developed by Shields et al. (1989). The questionnaire measures individuals' awareness of normal bodily processes, changes in bodily sensations, and physiological responses. Items are rated on a 9-point Likert scale, ranging from 1 (does not apply to me at all) to 9 (applies to me completely). The total score is calculated according to the instrument's scoring guidelines, with higher scores indicating greater body awareness.

4

Description
Psychological distress is defined as a general negative emotional state associated with symptoms of depression, anxiety, and stress.
Timepoint
Depression, anxiety, and stress will be assessed at baseline (pre-intervention) and immediately after completion of the 12-session intervention (post-intervention).
Method of measurement
Depression, anxiety, and stress will be assessed using the 21-item Depression, Anxiety, and Stress Scale (DASS-21), developed by Lovibond and Lovibond (1995). The questionnaire consists of three 7-item subscales measuring depression, anxiety, and stress. Items are rated on a 4-point Likert scale, ranging from 0 (did not apply to me at all) to 3 (applied to me very much or most of the time). Subscale scores are calculated by summing the relevant items and multiplying the results by two, with higher scores indicating greater symptom severity.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will take part in a 12-session body-oriented mentalization-based educational and therapeutic program. The sessions will focus on developing skills in bodily awareness, mindfulness, emotion recognition and regulation, identifying and understanding the window of tolerance, body-oriented mentalization, recognizing attachment patterns and interpersonal interaction styles, establishing personal boundaries, engaging in committed action, and effectively utilizing social support systems. Each session will include experiential exercises and homework assignments tailored to its specific content.
Category
Treatment - Other

2

Description
Control group: Participants in the control group will receive no intervention during the study period and will continue their usual care.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Ebrahim Abbasi Monjezi’s Private Practice
Full name of responsible person
Dr. Ebrahim Abbasi Monjezi
Street address
Shahid Mohammadi Alley, Next to Dr. Kazemi Pharmacy, Past Shahrdari Intersection, Najafabad, Isfahan Province, Iran.
City
Isfahan
Province
Isfehan
Postal code
8163713111
Phone
+98 937 048 7432
Email
eamonjezi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University, Najafabad Branch
Full name of responsible person
Dr. Iman Sadeghkhani
Street address
Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.
City
Najafabad
Province
Isfehan
Postal code
8514143131
Phone
+98 31 4229 3086
Email
sadeghkhani@pel.iaun.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University, Najafabad Branch

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
Islamic Azad University, Najafabad Branch
Full name of responsible person
Dr. Gholamreza Talebi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.
City
Najafabad
Province
Isfehan
Postal code
8135866531
Phone
+98 31 3237 1841
Fax
Email
rezatalebi@iau.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University, Najafabad Branch
Full name of responsible person
Dr. Gholamreza Talebi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.
City
Najafabad
Province
Isfehan
Postal code
8135866531
Phone
+98 31 3237 1841
Fax
Email
rezatalebi@iau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University, Najafabad Branch
Full name of responsible person
Maryam Khadem
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
Islamic Azad University Najafabad Branch, Daneshgah Blvd., Najafabad, Isfahan Province.
City
Najafabad
Province
Isfehan
Postal code
8135866531
Phone
+98 31 3666 0169
Fax
Email
1273441729@iau.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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