Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Mindfulness-Based Cognitive Therapy on Anxiety,Irrational Beliefs, quality of life and Self- compassion in patients with functional dyspepsiain

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based cognitive therapy on anxiety, irrational beliefs, quality of life, and self-compassion in patients with functional dyspepsia.

Design
Clinical trial with control group, parallel, randomized, unblinded, single-phase, on 30 patients (15 in experimental group, 15 in control group). Simple randomization using Random Allocation Software and allocation concealment using sealed envelopes.

Settings and conduct
Quasi-experimental study with pretest-posttest and control group. Sample: 30 patients with functional dyspepsia in Ahvaz (15 experimental, 15 control), selected purposively and randomly assigned. Experimental group receives 8 weekly 90-minute MBCT sessions; control group receives no intervention. No blinding.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Definitive diagnosis of functional dyspepsia based on Rome IV criteria, age 20 to 55 years, minimum high school diploma, residence in Ahvaz city, signed informed consent. **Exclusion Criteria:** Use of psychiatric medications, concurrent use of other treatment methods, refusal to complete questionnaires, absence of two or more sessions, incomplete questionnaires, occurrence of stressful events in the past three months (divorce, death of close relatives or close friends).

Intervention groups
Experimental Group: 8 sessions of 90-minute group MBCT (once weekly for 8 weeks) based on the protocol by Segal et al. (2002). Content: mindfulness, body focus, identifying negative thoughts, emotional acceptance, mind-body connection, self-compassion, consolidation of changes, and summary. **Control Group:** No intervention during the study (waiting list). Treatment offered after study completion upon request.

Main outcome variables
Anxiety; irrational beliefs; quality of life; self-compassion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260509069319N1**
Registration date: **2026-06-02, 1405/03/12**
Registration timing: **prospective**

Last update: **2026-06-02, 1405/03/12**
Update count: **0**

Registration date
2026-06-02, 1405/03/12

Registrant information

Name
Sajjad Pousti zade dezfuli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 4252 2665

Email address
poustizades@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-10, 1405/03/20

Expected recruitment end date
2026-07-16, 1405/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mindfulness-Based Cognitive Therapy on Anxiety,Irrational Beliefs, quality of life and Self- compassion in patients with functional dyspepsiain

Public title

Effectiveness of Mindfulness-Based Cognitive Therapy on Functional Dyspepsia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of functional dyspepsia by a gastroenterologist based on Rome IV criteria Age between 20 and 55 years Having at least a high school diploma Residing in Ahvaz city during the study period Signing the informed consent form to participate in the study

Exclusion criteria:

Use of psychiatric medications Concurrent use of other treatment methods Refusal of participants to complete the questionnaires Absence from two or more treatment sessions Submission of incomplete questionnaires Occurrence of stressful events such as divorce or death of relatives or close friends in the past three months

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization. Randomization unit: Individual. Stratification factors: None. Randomization tool: Random Allocation Software. Method of generating random sequence: The random sequence will be generated by a person outside the research team (research assistant) using Random Allocation Software. The software will generate a random list of 30 numbers consisting of 1 and 2 (corresponding to the experimental group and the control group, respectively) with an equal allocation ratio (1:1). This generated random sequence will be the basis for assigning participants to the groups. Allocation concealment: All allocation procedures will be performed by the research assistant who will have no role in the subsequent intervention and assessment phases. The final allocation results will be recorded and stored in sealed envelopes to ensure allocation concealment. Participants will be assigned to one of the two groups based on the generated random sequence in order of entry into the study.

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 Committees of Islamic Azad University - Ahvaz Branch

Street address

Islamic Azad University of Ahvaz, Farhangshahr, Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61349- 37333

Approval date

2026-01-07, 1404/10/17

Ethics committee reference number

IR.IAU.AHVAZ.REC.1404.596

Health conditions studied

1

Description of health condition studied

Functional Dyspepsia

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

Primary outcomes

1

Description

Anxiety

Timepoint

It is measured at two time points: 1- Pretest (one week before the start of the intervention) 2- Posttest (one week after the completion of the last intervention session).

Method of measurement

Using the Beck Anxiety Inventory.

2

Description
Irrational Beliefs
Timepoint
It is measured at two time points: 1- Pretest (one week before the start of the intervention) 2- Posttest (one week after the completion of the last intervention session).
Method of measurement
Using the Jones Irrational Beliefs Questionnaire.

3

Description
Quality of Life
Timepoint
It is measured at two time points: 1- Pretest (one week before the start of the intervention) 2- Posttest (one week after the completion of the last intervention session).
Method of measurement
Using the World Health Organization Quality of Life Questionnaire (WHOQOL).

4

Description
Self-Compassion
Timepoint
It is measured at two time points: 1- Pretest (one week before the start of the intervention) 2- Posttest (one week after the completion of the last intervention session).
Method of measurement
Using the Neff Self-Compassion Scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness-Based Cognitive Therapy (MBCT) was first developed by Segal, Williams, and Teasdale (2002). In this study, the intervention will be delivered based on the standard 8-session MBCT protocol, with each session lasting 90 minutes and held weekly. The sessions include training in mindfulness practices (focusing on breath, body scan, awareness of thoughts and feelings), reviewing negative thought patterns, practicing acceptance and self-compassion, and teaching emotion regulation skills. This intervention will be delivered in a group format over 8 weeks (one session per week).
Category
Treatment - Other

2

Description
Control group: Without receiving any intervention during the study (waiting list group)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Great Oil hospital
Full name of responsible person
Sajjad Poosti Zadeh Dezfoli.
Street address
Oil Hospital, Beginning of Naft Town Road, Airport Intersection, Ahvaz, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan eigder nejad.
Street address
Islamic Azad University, Ahvaz Branch, Farhangshahr, Golestan Highway, Ahvaz, Iran.
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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
Islamic Azad University, Ahvaz 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
Full name of responsible person
Sajjad Pousti Zadeh Dezfoli.
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Latest degree
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6461855993
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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 data can be shared after the participants have been de-identified.
When the data will become available and for how long
Access begins 6 months after final publication.
To whom data/document is available
Families, stakeholders, and officials of counseling and psychotherapy centers, hospitals, and other mental health professionals can have access to the general results of this study. Raw and identifiable data of participants are confidential and are only available to the research team.
Under which criteria data/document could be used
Data may only be used for research, educational, and therapeutic development purposes related to

Mindfulness-Based Cognitive Therapy (MBCT). Conditions of use: Approval of the research proposal by the principal investigator, anonymity of data, confidentiality, prohibition of commercial use, citation of the source, and no transfer to third parties. Conditions for submitting a request: Submit a written request along with a research proposal to the principal investigator's email, provide a written confidentiality commitment, and obtain ethics committee approval if required.

From where data/document is obtainable

Send an email to: poustizades@gmail.com

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

The applicant first submits a written request along with a research proposal to the principal investigator's email address (poustizades@gmail.com). After receiving the request, the research team will review the proposal for scientific merit and alignment with the objectives of the original study within a maximum of two weeks. If approved, the applicant must provide a written commitment to adhere to confidentiality regulations (data anonymization and non-disclosure of participant identities) and to refrain from commercial use of the data. Upon receipt of the commitment letter, the anonymized data will be made available to the applicant within a maximum of one week via email or a download link. If the request is rejected, the reason will be communicated to the applicant. The entire process will take a maximum of 3 weeks.

Comments