Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of cognitive-behavioral therapy and mindfulness-based cognitive therapy on cognitive emotion regulation, psychological well-being, diabetes-related distress, and self-care in patients with type 2 diabetes

Protocol summary

Study aim
Comparison of the effectiveness of cognitive-behavioral therapy and cognitive therapy based on mindfulness on cognitive regulation of emotion, psychological well-being, distress related to diabetes and self-care of patients with type 2 diabetes

Design
Quasi-experimental with pre-test and post-test design with control group

Settings and conduct
we will be randomly placed in two experimental groups, CBT and MBCT, and a control group. Statistical sample: 30 patients will be selected as experimental group 1 and experimental group 2, and 15 patients will be selected as control group (the method of assignment to three random groups will be simple). Kalinzo and Ongbazi, 2007; Quoting Delavar and Kushki (2012), they mentioned the same number of samples required for experimental designs.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the sample are: Received a diagnosis of type 2 diabetes by an endocrinologist Age between 25 and 45 years Has not taken any neuropsychiatric medication in the past three months Not suffering from a serious physical illness such as cancer, MS, Alzheimer's, etc. Not suffering from a serious psychiatric illness such as psychosis or the like (based on the initial clinical interview) Have at least a high school diploma. Complete an informed consent agreement regarding participation in the research project Not undergoing treatment or other psychological interventions during the research. Exclusion criteria for the sample group are: Absent more than two sessions in treatment It is known that the patient has taken neuropsychiatric medication or substances in the past 5 months Suffering from mania or a psychotic disorder

Intervention groups
CBT MBCT

Main outcome variables
Self-care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260719070251N1**
Registration date: **2026-08-17, 1405/05/26**
Registration timing: **prospective**

Last update: **2026-08-17, 1405/05/26**
Update count: **0**

Registration date
2026-08-17, 1405/05/26

Registrant information

Name
Bahram Mirzaian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3325 9528

Email address
bahrammirzaian@iau.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01

Expected recruitment end date

2027-03-16, 1405/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of cognitive-behavioral therapy and mindfulness-based cognitive therapy on cognitive emotion regulation, psychological well-being, diabetes-related distress, and self-care in patients with type 2 diabetes

Public title

Comparing the effectiveness of cognitive-behavioral therapy and cognitive therapy based on mindfulness in patients with type 2 diabetes

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Getting a diagnosis of type 2 diabetes from an endocrinologist Age between 25 and 45 years She has not taken any psychiatric medication in the past three months. Not have a terminal physical illness such as cancer, MS, Alzheimer's, etc. Do not suffer from a serious psychiatric illness such as psychosis or the like (based on the initial clinical interview) They must have at least a high school diploma. Complete an informed consent agreement regarding participation in the research project. Do not undergo treatment or other psychological interventions during the research.

Exclusion criteria:

Presence of a severe and active psychiatric disorder, including psychotic disorders or a manic episode, based on the initial clinical interview.

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Islamic Azad University, Sari Branch

Street address

7th km of Darya Road (Farahabad), Azad University

City

Sari

Province

Mazandaran

Postal code

48164-194

Approval date

2026-05-25, 1405/03/04

Ethics committee reference number

IR.IAU.SARI.REC.1405.086

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Cognitive emotion regulation

Timepoint

Before intervention

Method of measurement

After intervention

2

Description

: Psychological well-being

Timepoint

before intervention

Method of measurement

after intervention

3

Description

Diabetes distress

Timepoint

before intervention

Method of measurement
after intervention

4

Description
Self-care
Timepoint
before intervention
Method of measurement
after intervention

Secondary outcomes

1

Description
Self-care
Timepoint
Before intervention
Method of measurement
After intervention

Intervention groups

1

Description
Intervention Group 1:Patients with type 2 diabetes who are assigned to this group will receive Mindfulness-Based Cognitive Therapy (MBCT) over 8 weekly sessions. The sessions will include mindfulness training and exercises, body scan, focused breathing, awareness of thoughts and emotions, acceptance, seated meditation, and other exercises specified in the treatment protocol.
Category
Other

2

Description
Intervention group: Intervention Group 2:Patients with type 2 diabetes who are assigned to this group will receive Cognitive Behavioral Therapy (CBT) over 12 weekly sessions. The sessions will include education about diabetes and psychological factors, identification of automatic thoughts, behavioral activation, goal setting, identification of cognitive distortions, cognitive restructuring, and relapse prevention.
Category
Other

3

Description
Control group: Control Group:Patients with type 2 diabetes who are assigned to the control group will not receive any psychological intervention during the intervention period and will be placed on a waiting list. After completion of the study, the intended treatment will be provided to this group
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Toba clinic
Full name of responsible person
Zahra Zamanpoor
Street address
Khazar Sq
City
Sari
Province
Mazandaran
Postal code
48164-194
Phone
+98 11 3303 2891
Email
Rohaaam2018@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Ghahraman Mahmoodi
Street address
Khzar Sq
City
Sari
Province
Mazandaran
Postal code
48164-194
Phone
+98 11 3303 3751
Email
Rohaaam2018@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
100
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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Zahra Zamanpoor

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Khazar Sq

City
Sari

Province
Mazandaran

Postal code
48164-194

Phone
+98 11 3303 2891

Email
Rohaaam2018@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Bahram Mirzaian

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Khazar Sq

City
Sari

Province
Mazandaran

Postal code
48164-194

Phone
+98 11 3303 2891

Email
Bahrammirzaian@iau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Zahra Zamanpoor

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Khazar Sq

City
Sari

Province
Mazandaran

Postal code
48164-194

Phone
+98 11 3303 2891

Email
Rohaaam2018@gmail.com

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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable