Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy on self-care activities, practice and acceptance of diabetes, fear of hypoglycemia, and quality of life in patients with type 2 diabetes

Protocol summary

Study aim
Comparing the effectiveness of cognitive therapy based on mindfulness and acceptance and commitment therapy on self-care activities, practice and acceptance of diabetes, fear of hypoglycemia and quality of life in patients with type 2 diabetes

Design
A clinical trial with two intervention groups and one control group, with parallel groups, no blinding, randomized, on 45 patients with type 2 diabetes, was used for randomization by lottery.

Settings and conduct
After obtaining code of ethics and permission from Azad University of Neishabur, he will refer to Parsian Diabetes Clinic in Mashhad. In the following, 45 people will be selected from the mentioned statistical population using the available sampling method and will be randomly divided into three groups of 15 people, the experimental group and the control group. Then pre-test, treatment sessions and post-test and two-month follow-up will be done.

Participants/Inclusion and exclusion criteria
Entry criteria - Age between 30 and 50 years - Having a minimum cycle degree - Not suffering from psychiatric diseases (based on the patient's records that are asked about the person himself, as well as consultation by a specialist psychologist and review of the patient's medical record in the clinic) - Not using psychiatric drugs - Failure to receive any similar training programs before and during interventions - Having informed consent to participate in the study Exit criteria - Voluntary withdrawal from the research - Absence of more than two sessions in training sessions - Lack of proper cooperation

Intervention groups
mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy

Main outcome variables
Improving self-care activities, improving the practice and acceptance of diabetes, reducing the fear of hypoglycemia and improving the quality of life in patients with type 2 diabetes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240211060960N1**
Registration date: **2025-02-08, 1403/11/20**
Registration timing: **retrospective**

Last update: **2025-02-08, 1403/11/20**
Update count: **0**

Registration date
2025-02-08, 1403/11/20

Registrant information

Name
Tina Karbasi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3604 4326

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karbasit2017@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-07-01, 1403/04/11

Expected recruitment end date

2024-08-01, 1403/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy on self-care activities, practice and acceptance of diabetes, fear of hypoglycemia, and quality of life in patients with type 2 diabetes

Public title

Comparing the effectiveness of mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy on self-care activities, practice and acceptance of diabetes, fear of hypoglycemia, and quality of life in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Age between 30 and 50 years - having a minimum cycle degree - Lack of psychiatric diseases (patients' records questioned by the person as well as consultation by a specialist psychologist and reviewing the patient's medical record at the clinic) - Failure to use psychiatric drugs - No drug abuse Failure to receive any similar training programs before and during interference - Regular participation in therapeutic sessions (cognitive therapy based on mentality and admission and commitment treatment) according to the therapy - Having informed consent to participate in the study

Exclusion criteria:

Voluntary withdrawal from research Absence of more than two sessions in training sessions Lack of proper cooperation

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be done through simple randomization. According to this method, the names of each selected member are written on the paper as an example of the research. They are thrown into a box for drawing, then picking the paper pieces one by one and the first 15 (1-15) part of the Cognitive Therapy Experimental Group. On the consciousness, 15 seconds (16 to 30) of the Acceptance and commitment Experimental group and the last 15 (31 to 45) whose names come out of the lottery box will be members of the control group.

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

Ethical Committee of Azad University of Neyshabur branch

Street address

Pazhoohesh Blvd

City

Neyshabur

Province

Razavi Khorasan

Postal code

۹۳۱۹۹۷۵۸۵۳

Approval date

2024-04-03, 1403/01/15

Ethics committee reference number

IR.IAU.Neyshabur.REC.1403.001

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

The score of self-care activities in the self-care questionnaire

Timepoint

At the beginning of the study, after treatment sessions and follow-up two months after treatment

Method of measurement

Self-care: In this research, the state of self-care is the score that the subject will get from the self-care questionnaire of patients with diabetes Tobert et al.

(2000).

2

Description
the score of diabetes practice and acceptance in the diabetes practice and acceptance questionnaire
Timepoint
At the beginning of the study, after treatment sessions and follow-up two months after treatment
Method of measurement
Acceptance and Action: In this research, acceptance and action are the scores that the subject will get from the Acceptance and Action Questionnaire AAQ-R Bund et al. (2007).

3

Description
the fear of hypoglycemia score in the hypoglycemia questionnaire
Timepoint
At the beginning of the study, after treatment sessions and follow-up two months after treatment
Method of measurement
Quality of life: In this research, quality of life is the score that the subject will get from the questionnaire on the quality of life of diabetic patients by Broth et al. (2004).

4

Description
the quality of life score in the quality of life questionnaire of patients with diabetes
Timepoint
At the beginning of the study, after treatment sessions and follow-up two months after treatment
Method of measurement
Fear of hypoglycemia: In this research, fear of hypoglycemia is the score that the subject will get from the fear of hypoglycemia questionnaire or HFS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Cognitive therapy based on mindfulness: Cognitive therapy based on mindfulness or MBCT is one of the types of therapy based on cognition and behavior. This therapy integrates presence of mind as a treatment goal with exercises such as conscious thought cessation and non-judgmental observation of one's own thoughts. Mindfulness emerges through purposeful and non-judgmental attention to the present moment and situation in a specific way. In this research, the experimental group of 8 sessions of 60 minutes each week are treated based on cognitive-behavioral protocol interventions based on mindfulness. This training program is based on Crane's book on cognitive therapy based on mindfulness.
Category
Treatment - Other

2

Description
Intervention group 2: Treatment based on commitment and acceptance: therapy based on commitment and acceptance is a mixture of 4 approaches: awareness, acceptance, commitment and behavior change. The basis of treatment is based on the acceptance and commitment of Relational Frame Theory (RFT). which is a result of the third wave of psychotherapy introduced by Steven Hayes and his colleagues in 1982. The word ACT is actually derived from: A: accepting thoughts and feelings and being in the present, C: choosing a valuable direction and T: acting. Treatment sessions will be held in the form of 8 sessions of 60 minutes each week.
Category
Treatment - Other

3

Description
Control group: The control group will not receive treatment, but after a two-month follow-up, it will undergo treatment sessions chosen by the members.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Parsian diabetes clinic
Full name of responsible person
AliAkbar Raouf Saeb
Street address
No. 222, between lashgar Cross and bisim Cross, Bahar Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University

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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
Islamic Azad University

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data will be published in the student's article and thesis, and the identity information of the participants will be preserved.

When the data will become available and for how long

Since 1404

To whom data/document is available

Academic and scientific researchers

Under which criteria data/document could be used

After completing the treatment and follow-up sessions, writing a doctoral thesis, defending the thesis and research articles will be published in reputable scientific journals.

From where data/document is obtainable

Tina karbasi

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

A message containing the request for research documents should be sent to the email of the author of the article.

Comments