

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The Effectiveness of Group Therapy Based on Mindfulness and cognitive-behavioral therapy (CBT) in the anxiety, metabolic control and quality of life in type 2 diabetic patients

Protocol summary

Study aim

The Effectiveness of Group Therapy Based on Mindfulness and cognitive-behavioral therapy (CBT) in the anxiety, metabolic control and quality of life in type 2 diabetic patients

Design

A randomized clinical trial with parallel groups

Settings and conduct

In order to conduct research, by attending the Diabetes Association of Tehran, while explaining the nature and objectives of the research and obtaining patients' consent, individually from each case, first the initial evaluation in terms of anxiety, metabolic control and pre-test quality of life will be performed. The mindfulness test group will be in 2 sessions of 90 minutes per week for 8 sessions, the cognitive-behavioral group will be in the form of 2 sessions per week for 8 sessions of 90 minutes after the sessions both groups will be anxious again. , Metabolic control and quality of life will respond.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age range 25 to 45 years, having type 2 diabetes, a sense of cooperation and a willingness to participate in medical intervention and being literate was at least a diploma (for reading and writing). Exclusion criteria included chronic mental disorders, severe depression, chronic physical illness with diabetes such as blindness and amputation.

Intervention groups

For the first group of mindfulness cognitive group psychotherapy, For the second group, cognitive behavioral therapy will be performed.

Main outcome variables

anxiety, metabolic control and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046699N1**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Fatemeh Rezaei kookhdan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-07, 1398/10/17

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Group Therapy Based on

Mindfulness and cognitive-behavioral therapy (CBT) in the anxiety, metabolic control and quality of life in type 2 diabetic patients Public title The Effectiveness of Group Therapy Based on Mindfulness and cognitive-behavioral therapy (CBT) in the anxiety, metabolic control and quality of life in type 2 diabetic patients Purpose Supportive Inclusion/Exclusion criteria Inclusion criteria: Age range 25 to 45 years Having type 2 diabetes Having a sense of cooperation and satisfaction in participating in therapeutic intervention Have at least a diploma literacy (to read and write) Exclusion criteria: Having chronic mental disorders Having severe depression Having a chronic physical illness with diabetes, such as blindness Amputation Age From 25 years old to 45 years old Gender Both Phase 2 Groups that have been masked <i>No information</i> Sample size Target sample size: 45 Randomization (investigator's opinion) Randomized Randomization description Using the block randomization method by the statistical consultant, the following randomization is done in 3 groups of mindfulness-based cognitive therapy, cognitive-behavioral therapy, and control: First, the list of names of qualified people is provided and coded. In block randomization, the number of participants in all groups will be very close, this is done by building blocks of sequences and intersections so that the same number of participants are allocated to study groups within each group. First, we encode the groups based on the Latin letters as follows: A = mindfulness-based cognitive therapy, B = cognitive-behavioral therapy and C control group In this study, with three groups A, B, and C, we create the following six groups and assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, 6, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be null and void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups will be almost equal. Blinding (investigator's opinion) Not blinded Blinding description Placebo	Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Hormozgan University of Medical Sciences Street address No.2, Shahid Karami Alley, North Allameh, Sa'adatabad City Tehran Province Tehran Postal code 2255689744 Approval date 2019-12-07, 1398/09/16 Ethics committee reference number IR.HUMS.REC.1398.317 Health conditions studied <u>1</u> Description of health condition studied Diabetes Type II ICD-10 code E08 ICD-10 code description Diabetes mellitus due to underlying condition Primary outcomes <u>1</u> Description Anxiety Timepoint Measurement will be done in pre-test, post-test and follow-up three months after post-test Method of measurement Spielberger State-Trait Anxiety Inventory <u>2</u> Description Metabolic control Timepoint Measurement will be done in pre-test, post-test and follow-up three months after post-test Method of measurement
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Blood glucose test

3

Description

Quality of Life

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: It is a collection of training and treatment instructions and homework that will be presented to people during 8 sessions of one and a half hours. The Practical Guide to Mindfulness Therapy will be used to help people (Kabat-Zinn, 2012), and the Personalized Mindfulness Therapy Handbook will be used as the main source of therapeutic techniques.

Mindfulness-based cognitive therapy was taught to participants based on Kabat-Zinn (2012) in 8 sessions (two sessions per week, each session for 90 minutes) and during one month.

Category

Treatment - Other

2

Description

Second Intervention Group: It is a collection of training and treatment instructions and homework that will be presented to people during 8 sessions of one and a half hours. The Practical Guide to Cognitive-Behavioral Therapy will be used to help people take control of their lives (Lam, 2008), and the Individual Guide to Cognitive Behavioral Therapy and the Guide to Group Cognitive Behavioral Therapy will be used as the main source of therapeutic techniques. But there is no limit to the use of other cognitive-behavioral techniques. In this study, cognitive-behavioral intervention with the help of Lam Training Package (2008) was taught to participants in 8 sessions (one session per week and 90 minutes per session) for one and a half months.

Category

Treatment - Other

3

Description

Control group: No Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Association of Tehran

Full name of responsible person

Fatemeh Rezaei Kookhdan

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No. 2, Shahid Karami Alley, North Allameh, Sa'adatabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

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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

Fax**Email**

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Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Fatemeh Rezaei kookhdan

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Psychology

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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