

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effectiveness of Cognitive-Behavioral Therapy Based on Mindfulness and Education on Health Promoting Lifestyle on Psychological Well-being, Hope and Quality of Life in Patients with Diabetes

Protocol summary

Study aim

Comparison of the Effectiveness of Cognitive-Behavioral Therapy Based on Mindfulness and Education on Health Promoting Lifestyle on Psychological Well-being, Hope and Quality of Life in Patients with Diabetes

Design

A randomized controlled clinical trial with parallel groups, Randomized block, sample size 45 (15 persons per group)

Settings and conduct

Both groups completed psychological well-being, hope and quality of life questionnaires before beginning the sessions. Experimental group A (Cognitive-behavioral therapy based on mindfulness) and experimental group B (health-promoting lifestyle education) were trained weekly in diabetic patients in diabetes centers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetes with physician-approved for at least one year, hemoglobin A1c levels above 7%, having a minimum age of 20 and a maximum of 50 years, having a minimum secondary education, not receiving psychological treatment. Since diagnosis, acute or chronic medical illnesses such as epilepsy, skeletal diseases, heart, and respiratory failure, etc. which can cause problems in blood sampling and long sessions, lack of severe mental illnesses such as disorders Psychotic and non-use of psychotropic drugs or substance abuse at present. Exclusion criteria: Severe complications of diabetes that lead to hospitalization, absence of more than two sessions in treatment sessions and major stress due to unforeseen events.

Intervention groups

In the first group, there will be no mindfulness-based cognitive-behavioral therapy, in the second group health-promoting lifestyle training and in the third group, there will be no intervention control.

Main outcome variables

Psychological well-being, hopefulness, and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200226046625N1**

Registration date: **2020-03-15, 1398/12/25**

Registration timing: **retrospective**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

Maryam Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 9783

Email address

m.ghorbani@iaukishint.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-15, 1398/09/24

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Cognitive-Behavioral Therapy Based on Mindfulness and Education on Health Promoting Lifestyle on Psychological Well-being, Hope and Quality of Life in Patients with Diabetes

Public title
Comparison of the Effectiveness of Cognitive-Behavioral Therapy Based on Mindfulness and Education on Health Promoting Lifestyle in In treatment of diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having type 2 diabetes with a doctor's approval for at least one year Hemoglobin A1c levels above 7%
Minimum age of 20 and maximum of 50 years Minimum secondary education equivalent Lack of psychological treatment since diagnosis Lack of acute or chronic medical illnesses such as epilepsy, skeletal diseases, heart and respiratory failure, etc. which can cause problems in blood sampling and long sessions Lack of severe mental illness such as psychotic disorders No psychotropic drugs or substance abuse at present
Exclusion criteria:
Severe complications of diabetes that lead to hospitalization absence of more than two sessions in treatment sessions major stress due to unforeseen events

Age
From **20 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
The block randomization method is performed by the statistical consultant as follows: Randomization is performed in 3 groups of Cognitive-Behavioral Therapy based on mindfulness, health-promoting lifestyle training and control group: First, the list of eligible people is provided and coded. Be. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = Mindfulness-based Cognitive-Behavioral Therapy, B = Health-Promoting Lifestyle Training, and C Control Group In this study with three groups A, B and C we create the following six

groups and assign 1 to 6 each: ABC-ACB-BAC-BCA-CAB-CBA Then we use a random number table to select one of these blocks whenever the numbers 1, 2, 3, 4, 5, 6 appear, and if the other number appears, consider null and go to the next choice. In fact, we have obtained a random sequence of numbers with a random number table that we consider the order of assignment for each number. This way the number of people in the groups will be approximately equal.

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 Hormozgan University Of Medical Sciences

Street address

No. 64, Janbazan Ave., North Karegar Street

City

Tehran

Province

Tehran

Postal code

2245986743

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.HUMS.REC.1398.325

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Psychological Well-being

Timepoint

Measurement will be done in pre-test, post-test and

follow-up three months after post-test

Method of measurement

Ryff Psychological Well-being Scale

2

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

The World Health Organization Quality of Life Questionnaire

3

Description

Hopefulness

Timepoint

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

Method of measurement

Snyder hope scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the present study, the goal of mindfulness-based cognitive-behavioral therapy is 8 sessions of mindfulness-based cognitive-behavioral therapy that were held two sessions per week (one month) and each session 60 minutes.

Category

Treatment - Other

2

Description

Intervention group 2: In this study, the purpose of health promoting lifestyle training is 10 sessions of health promoting lifestyle training that were held two sessions per week (one and a half months) and each session 60 minutes.

Category

Treatment - Other

3

Description

Control group: No Intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers and Diabetes Association of Tehran

Full name of responsible person

Maryam Ghorbani

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No. 64, Janbazan Ave., North Karegar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Islamic Azad University of Kish International Branch, Free Zone Organization Square, Sana'i Boulevard, Kish Island.

City

Kish

Province

Hormozgan

Postal code

7941775883

Phone

+98 76 4442 2720

Email

Info@iaukishint.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

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

Maryam Ghorbani

Position

Ph. D student

Latest degree

Master

Other areas of specialty/work

Psychology

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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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Maryam Ghorbani Sattarkhan St., Khosrow South, Atabaki Mehr Ave.

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

The request will be sent by email to:
m.ghorbani@iaukishint.ac.ir

Comments