

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effects of mindfulness meditation on glycemic control and mental health in patients with diabetes type II , Imam Ali City Comprehensive Health Center , 2018

Protocol summary

Study aim

The Effect of Mindfulness Based Stress Management on Glycemic Control and Mental Health in Patients with type 2 Diabetes Mellitus

Design

randomized controlled clinical trial

Settings and conduct

This study will be carried out on patients with diabetes mellitus type 2 referred to Imam Ali's comprehensive health care center (Isfahan city) in 2019

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetes Mellitus with the approval of a physician, having a health record in the health center, Age between 30-59 years, HbA1c ranged between 7-9%, History of diabetes for at least 6 months, informed consent. Exclusion criteria: acute psychological disorders, Chronic diseases such as cancer or any other serious medical condition, pregnancy and lactation, alcohol and substance abuse, end organ damage caused by diabetes, psychological treatment in the past year.

Intervention groups

The intervention group will be taught 8 sessions (each session 2 hours) once a week, by an expert psychologist and will then perform home exercises for 4 weeks and report the homework weekly. The control group is under the routine care of the health system.

Main outcome variables

Anxiety, Depression and Stress score Glycemic indexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190813044527N1**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **retrospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

omid nikkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3833 2114

Email address

omid.nik71@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2019-04-19, 1398/01/30

Scientific title

Evaluation of the effects of mindfulness meditation on glycemic control and mental health in patients with diabetes type II , Imam Ali City Comprehensive Health Center , 2018

Public title

The Effect of Mindfulness Based Stress Management on Glycemic Control and Mental Health in Patients with

Diabetes Mellitus

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetes Mellitus with the approval of a physician having a health record in the health center Age between 30-59 years HbA1c ranged between 7-9% History of diabetes for at least 6 months informed consent

Exclusion criteria:

acute psychological disorders Chronic diseases such as cancer or any other serious medical condition pregnancy and lactation alcohol and substance abuse end organ damage caused by diabetes psychological treatment in the past year

Age

From **30 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 108 diabetic patients with inclusion criteria will be selected by convenient sampling from the Imam Ali Comprehensive Health care Center in Isfahan. All participants will be invited to an introduction session, and a code will be assigned to each patient in front of their name and contact number. These codes will be randomly divided into two groups of 54 people using random allocation software v. 2.0 developed by Mahmood Saghaei and downloaded for free from Google. Then, based on the resulting list and contact numbers provided during the introduction session, we will contact with the intervention group patients, and the necessary coordination will be done.

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 Isfahan University of Medical

Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.MUI.MED.REC.1397.165

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

Anxiety, Depression and Stress

Timepoint

Beginning of the study and 13 weeks after the intervention

Method of measurement

DASS21 questionnaire

2

Description

Fasting Blood Sugar

Timepoint

Beginning of the study and 13 weeks after the intervention

Method of measurement

fasting venous blood sample

3

Description

HbA1c

Timepoint

Beginning of the study and 13 weeks after the intervention

Method of measurement

fasting venous blood sample

Secondary outcomes

1

Description

sleep quality

Timepoint

before and 13 weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality questionnaire

Intervention groups

1

Description

Intervention group: Eight 2-hour sessions once a week are taught by an expert psychologist, followed by 4 weeks homework which will be weekly reported by the patient. The topics of these sessions include explanations of mindfulness, physical activity and yoga exercises, receiving feedback and answering the questions, breathing exercises, and sleep hygiene education.

Category

Other

2

Description

Control group: This group is under routine care based on national guidelines for diabetes mellitus management

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Urban Comprehensive Health Care Center

Full name of responsible person

Dr Anahita Babak

Street address

West Toosi St, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81649 69459

Phone

+98 31 3661 7371

Email

babakanahita@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

Street address

Vice-Chancellery for Research and Technology,
Isfahan University of Medical Sciences, Hezar Jerib
street, Isfahan, Iran

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8174673461

Phone

+98 31 3792 8092

Fax

+98 31 3669 2174

Email

sh.haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Anahita Babak

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Isfahan University of Medical Sciences , Hezar Jerib
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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

Whole data will be available

When the data will become available and for how long

Immediately after publishing manuscript

To whom data/document is available

To whom is in need to this data

Under which criteria data/document could be used

Email to Dr Anahita Babak, Email:

babakanahita@yahoo.com

From where data/document is obtainable

Dr Anahita Babak Email: babakanahita@yahoo.com

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

Send an Email to Dr Anahita Babak

Comments