

# 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

#### City

Isfahan

#### Province

Isfahan

#### Postal code

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

#### Street address

Isfahan University of Medical Sciences , Hezar Jerib  
street, Isfahan, Iran

#### City

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#### Province

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8174673461

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#### Email

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## Person responsible for scientific 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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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

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Dr Anahita Babak

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Assistant Professor

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Specialist

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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**