

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Impact of Mindfulness-Based Stress Reduction in Emotional and Glycemic Regulation of Type-2 Diabetes Mellitus Outpatients

#### Protocol summary

##### Summary

The aim of the current research is to determine the effect of mindfulness-based stress reduction (MBSR) intervention on glycemic and Hemoglobin A1c level; general health improvement; and a decrease in anxiety and depressive symptoms. The study group is type-2 diabetes mellitus outpatients who are referred to Emam Khomani hospital of Tehran. 60 diabetic patients who have Hemoglobin A1c higher than 7 and not suffering from other chronic diseases are selected. this study is a randomized, controlled trial. Half of the selected group(30 patients) are referred to receive 8 sessions of mindfulness-based stress reduction that is conducted weekly for 8 weeks. An assessment of fasting blood sugar, Hemoglobin A1c, general health questionnaire, using the Hamilton rating scale for depression and anxiety, will be conducted at baseline, week 8 and after 3 months as follow up. Half of the selected group(30 patients) are in control group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017050925812N2**

Registration date: **2017-07-17, 1396/04/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-17, 1396/04/26

##### Registrant information

##### Name

Bitva Vahdani

##### Name of organization / entity

Zanjan University of Medical Sciences, Shahid

Beheshti Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3354 4000

##### Email address

bt\_vahdani@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2017-10-22, 1396/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Impact of Mindfulness-Based Stress Reduction in Emotional and Glycemic Regulation of Type-2 Diabetes Mellitus Outpatients

##### Public title

The Impact of Mindfulness-Based Stress Reduction in Emotional and Glycemic Regulation of Type-2 Diabetes Mellitus Outpatients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Included criteria: Hemoglobin A1c higher than 7; having of type-2 diabetes mellitus Exclusion criteria: suffering from other chronic diseases; history of neurological and psychiatric disorders; drug abuse; being in other psychological programs; more than two session absences in experimental group

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

The sampling method is available through the referral's referral center to Imam Khomeini Hospital's Endocrine Clinic, which is blind assigned to two experimental and control groups by coding and randomizing the patients

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

##### Street address

Azadi Boulevard

##### City

Zanjan

##### Postal code

15788-45136

#### Approval date

2016-06-02, 1395/03/13

#### Ethics committee reference number

Zums.rec.1396.41

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 Diabetes Melitus

#### ICD-10 code

E11

#### ICD-10 code description

Chronic type 2 Diabetes

## Primary outcomes

### 1

#### Description

Fasting Blood Sugar

#### Timepoint

Before intervention - after intervention - 3 months after intervention

#### Method of measurement

Photometric

### 2

#### Description

Hemoglobin A1c

#### Timepoint

Before intervention - after intervention - 3 months after intervention

#### Method of measurement

HPLC

## Secondary outcomes

### 1

#### Description

Anxiety

#### Timepoint

Before intervention - after intervention - 3 months after intervention

#### Method of measurement

patients score in Hamilton Anxiety Rating Scale questionnaire

### 2

#### Description

depression

#### Timepoint

Before intervention - after intervention - 3 months after intervention

#### Method of measurement

patients score in Hamilton Depression Rating Scale questionnaire

### 3

#### Description

General Health

#### Timepoint

Before intervention - after intervention - 3 months after intervention

#### Method of measurement

patients score in General Health Questionnaire-28

## Intervention groups

### 1

#### Description

control( without psychological intervention)

**Category**

Treatment - Drugs

**2****Description**

Mindfulness based stress reduction intervention

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Endocrinology clinic, Emam khomeini hospital

**Full name of responsible person**

Dr. Bita Vahdani. Bita Vahdani

**Street address**

tehran, emam hospital

**City**

tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences, Endocrinology clinic of Imam Khomeini Hospital

**Full name of responsible person**

Finance and Administration Affairs

**Street address**

tehran

**City**

tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences, Endocrinology clinic of Imam Khomeini Hospital

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Bita Vahdani

**Position**

psychiatry Resident

**Other areas of specialty/work****Street address**

zanjan University of Medical Sciences, Psychiatry Department

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran university of medical sciences

**Full name of responsible person**

Alireza Armani kian

**Position**

psychiatrist- Psychosomatic Fellowship

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Tehran, Emam Khomeini hospital, Psychosomatic ward

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Tehran

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

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psychiatry Resident

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Zanjan, Beheshti hospital

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**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*