

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Aug 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 Khomeini 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 centers1**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 sources1**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 sourceTehran 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**City**

zanjan

Postal code**Phone**

+98 24 3354 4001

Fax**Email**

bt_vahdani@zums.ac.ir

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

Other areas of specialty/work**Street address**Tehran, Emam Khomeini hospital, Psychosomatic
ward**City**

Tehran

Postal code**Phone**

+98 21 6658 1420

Fax**Email**

dr.armmani@gmail.com

Web page address**Person responsible for updating data****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, Beheshti hospital

City

Zanjan

Postal code**Phone**

+98 243344001

Fax**Email**

bt_vahdani@zums.ac.ir

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