Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 reffered to Emam Khomaini 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

Bita 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 Suger
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
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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
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Person responsible for updating data

Contact
Name of organization / entity
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Position
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