

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effectiveness of mindfulness based stress reduction on quality of life of patients with type 2 diabetes mellitus

Protocol summary

Summary

Objectives: Diabetes is a chronic and lifelong disease and have many physical and psychological complications that affect the quality of life. This study aimed to determine the effectiveness of Mindfulness based stress reduction on quality of life in patients with type 2 diabetes. Design: This quasi-experimental study has a pretest-posttest design with control group. Participants including major eligibility criteria: The study population include 30 diabetic patients, randomly divided into two, the study and control groups. Type 2 diabetes was the main criterion for entering this study. Setting and conduct: We used Ware & Sherbourne quality of life questionnaire (SF-36). Eight sessions of Mindfulness based stress reduction group training conducted in eight weeks for study group while the control group received no intervention. Both groups completed the (SF-36) before and after the intervention. Intervention: Eight sessions of Mindfulness based stress reduction group training were conducted in eight weeks for study group while the control group received no intervention. Measures: Quality of life was the main variable in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100736572N2**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-16, 1396/07/24

Registrant information

Name

Hamid Kharatzadeh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1548

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of mindfulness based stress reduction on quality of life of patients with type 2 diabetes mellitus

Public title

Effect of mindfulness on quality of life of diabetic patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Having type 2 diabetes; More than 18 years old; No psychological intervention has been received since the diagnosis of the disease; The absence of an acute or chronic medical condition that causes problems in tolerating long sessions; No severe

psychiatric illnesses, such as psychotic disorders; No substance abuse or addiction. Exclusion criteria: Severe complications of diabetes leading to hospitalization; Missing more than two sessions; The occurrence of major stresses due to unforeseen events.

Age

From **18 years** old to **110 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Koodakyar St, Tehran

City

Tehran

Postal code**Approval date**

2016-08-16, 1395/05/26

Ethics committee reference number

IR.SBMU.MSP.REC.1395.184

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E-10,E-11,

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Quality of life

Timepoint

Pre and post test.

Method of measurement

Waren & Sherbourne quality of life questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Experimental group: Mindfulness based stress reduction. Mindfulness based stress reduction is a training program using a variety of mindfulness practices, both formal and informal. Participants are required to practice mindfulness as homework for a total 45 minutes, 6 days each week during the course of the program.

Category

Other

2**Description**

Control group: No action.

Category

N/A

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

Isfahan Diabetes Charity Center

Full name of responsible person

Mr. Ahmad Nilforoushan

Street address

Isfahan Diabetes Charity Center, Lahore Street, Isfahan

City

Isfahan

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

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mrs. Memar

Street address

Shahid Beheshti University of Medical Sciences,
Koodakyar St, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamid Kharatzadeh

Position

MSc

Other areas of specialty/work

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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