Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mindfulness on Body Shame and Self-Stigma in patients with type 1 Diabetes referred to the Healthcare Centers of Kerman University of Medical Sciences

Protocol summary

Study aim

To determine the effect of Mindfulness on Body Shame and Self-Stigma in patients with type 1 Diabetes referred to the Healthcare Centers of Kerman University of Medical Sciences

Design

This study is a single-blind, randomized controlled clinical trial with two groups (intervention and control), comprising 40 participants in each group. Simple randomization was performed using Open Epi software.

Settings and conduct

This study will be conducted at the healthcare centers affiliated with Kerman University of Medical Sciences, specifically the Besat and Afzali-Pour subspecialty clinics. Study outcomes will be assessed at two time points: baseline (before the intervention) and immediately after the intervention in both the intervention and control groups.

Participants/Inclusion and exclusion criteria

The study's inclusion criteria comprised patients aged 16–20 years with a definitive Type 1 diabetes diagnosis confirmed at least 6 months prior to enrollment, a score >17 on the Body Image Shame Scale, and a score >21 on the Diabetes Self-Stigma Scale; conversely, the exclusion criteria included the presence of severe psychiatric disorders or suicidal ideation, a history of substance abuse, or chronic comorbidities—excluding hypertension—that might interfere with diabetes management, such as cystic fibrosis or renal and liver diseases.

Intervention groups

Intervention Group: "The intervention group will receive an 8-week modified MBSR program (90–120 min weekly sessions) focusing on mindfulness practices and stress-coping concepts." Control Group: "The control group will receive treatment-as-usual only, receiving no additional psychological or educational interventions. Contact will be restricted to essential administrative tasks."

Main outcome variables

Mindfulness, Body Shame, Self-Stigma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N23**
Registration date: **2026-10-10, 1405/07/18**
Registration timing: **prospective**

Last update: **2026-10-10, 1405/07/18**
Update count: **0**

Registration date

2026-10-10, 1405/07/18

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5207

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Mindfulness on Body Shame and Self-Stigma in patients with type 1 Diabetes referred to the Healthcare Centers of Kerman University of Medical Sciences

Public title

The Effect of Mindfulness on Body Shame and Self-Stigma in patients with type 1 Diabetes referred to the Healthcare Centers of Kerman University of Medical Sciences

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 16 to 20 Definitive diagnosis of Type 1 diabetes by an endocrinologist At least 6 months since the diagnosis of Type 1 diabetes Ability to read and write and participate in group intervention sessions Scoring above 17 on the Body Image Shame Scale Scoring above 21 on the Diabetes Self-Stigma Scale

Exclusion criteria:

Diagnosis of severe psychiatric disorders such as psychosis, autism, developmental delay, or suicidal ideation Presence of comorbid physical or chronic conditions (excluding hypertension) that interfere with diabetes management, such as cystic fibrosis, or renal and liver diseases History of substance abuse

Age

From **16 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the researcher will visit the healthcare centers of Kerman University of Medical Sciences to recruit eligible individuals. Eligible patients will be selected via convenience sampling. To allocate participants to the control and intervention groups, stratified randomization based on gender will be employed. Participants will first be stratified by gender (male and female), and then within each stratum, they will be randomly assigned to either the control or intervention group using a simple randomization method with a 1:1 allocation ratio. The randomization sequence will be generated using Open Epi software. To ensure allocation concealment, the randomization list will be held by an individual independent of the research team. Allocation for each participant will be assigned by contacting this person, ensuring that the researcher remains blinded to the group assignment until the patient is officially enrolled in the study

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the educational nature of the intervention, blinding of participants and the researcher is not feasible. However, since the scoring is self-reported by the patients, the potential for researcher bias in the results is minimized. Furthermore, to control for bias during the data analysis phase, the data will be analyzed by an independent statistician who is blinded to group assignments. Data for both the intervention and control groups will be entered into SPSS and labeled as ‘Group 1’ and ‘Group 2.’ The analyst will remain unaware of which group corresponds to the intervention and which to the control throughout the analysis process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616910002

Approval date

2026-09-12, 1405/06/21

Ethics committee reference number

IR.KMU.REC.1405.346

Health conditions studied

1

Description of health condition studied

type 1 Diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

2

Description of health condition studied
Psychological factors associated with Type 1 diabetes
ICD-10 code
F54
ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Body Shamel
Timepoint
The effect of a mindfulness-based training program on body shame in patients with Type 1 diabetes is evaluated in two stages: pre-intervention and immediately post-intervention (at the end of week 8).
Method of measurement
BISS: Body Image Shame Scale

2

Description
Self-Stigma
Timepoint
The effect of a mindfulness-based training program on self-stigma in patients with Type 1 diabetes is evaluated in two stages: pre-intervention and immediately post-intervention (at the end of the 8th week).
Method of measurement
DSSS: Diabetes Self-Stigma Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention is based on a modified version of the Mindfulness-Based Stress Reduction (MBSR) program originally developed by Kabat-Zinn. It consists of eight weekly group sessions, each lasting approximately 90 to 120 minutes. The sessions incorporate various mindfulness practices, including sitting meditation, body scan, walking meditation, and mindful movement, alongside discussions on concepts related to present-moment awareness and mindful responding to stress. The researcher has completed the MBSR training under the supervision of the thesis advisor, who will verify the competence and adequacy of the instruction. Homework and exercises will be assigned at the end of each session for practice between meetings. Additionally, educational videos and supplementary explanations will be provided asynchronously via the 'Eitaa' messenger, which will also serve as a platform for participants to ask questions, receive answers, and resolve issues. The researcher will monitor the completion of practice assignments and provide necessary feedback. Each session will commence with a review of participants' experiences with the previous week's exercises, offering sufficient opportunity for Q&A, troubleshooting, feedback, and discussion regarding barriers to practice.
Category
Other

2

Description
Control group: Participants in the control group will not receive any educational content. Interaction with this group will be limited to necessary notifications regarding questionnaire completion schedules and routine clinical follow-ups, including reminders for medical appointments and the opportunity to ask general questions related to diabetes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Healthcare Centers of Kerman University of Medical Sciences
Full name of responsible person
Batool Tirgari
Street address
Shahid Dastgheib St, 22 Bahman Blvd, Kerman, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Batool Tirgari
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available