

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Aug 2026

Effect of Health-Promoting Lifestyle and Positive Mindfulness Training on Reducing Self-Neglect in Older Adults with Type 2 Diabetes: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of health-promoting lifestyle education and positive mindfulness on reducing self-neglect in older adults with type 2 diabetes

Design

This is a non-blinded randomized controlled trial with two parallel groups (intervention and control) including 60 older adults with type 2 diabetes mellitus. Participants will be allocated using permuted block randomization.

Settings and conduct

Older adults attending the health centers of Mobarakeh County who meet the eligibility criteria will be enrolled in the study and randomly assigned to either the intervention or control group. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Older adults aged 60 years and above with a confirmed diagnosis of type 2 diabetes who are able to perform daily activities and understand the educational intervention. Exclusion Criteria: Acute or unstable medical conditions, acute psychiatric disorders, or any condition that would make participation unsafe or not feasible.

Intervention groups

Intervention Group: A group-based education program will be delivered to older adults with type 2 diabetes, focusing on health-promoting lifestyle and positive mindfulness. It will include 8 weekly sessions (45–60 minutes) covering diabetes self-care, healthy behaviors, and mindfulness practices, supported by educational materials. Participants will perform daily home exercises (15–30 minutes) with weekly phone or text follow-ups. Control Group: The control group will receive routine care only without any educational intervention.

Main outcome variables

Self-Neglect, Health-Promoting Lifestyle, Self-Compassion, Fasting Blood Glucose (FBG), Glycated

Hemoglobin (HbA1c), Systolic Blood Pressure, Diastolic Blood Pressure, and Body Mass Index (BMI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260213068844N1**

Registration date: **2026-06-25, 1405/04/04**

Registration timing: **prospective**

Last update: **2026-06-25, 1405/04/04**

Update count: **0**

Registration date

2026-06-25, 1405/04/04

Registrant information

Name

Akram Esrafilii Bishe

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Health-Promoting Lifestyle and Positive Mindfulness Training on Reducing Self-Neglect in Older Adults with Type 2 Diabetes: A Randomized Controlled Trial

Public title
Effect of Lifestyle Education and Mindfulness on Self-Neglect

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Being +60 years old At least elementary literacy or presence of a literate caregiver to complete questionnaires and follow up on exercises Definite medical diagnosis of type 2 diabetes based on medical records Having moderate to severe self-neglect based on a standardized questionnaire or primary caregiver report Score 7 or higher on the Abbreviated Mental Test (AMT) Ability to perform basic activities of daily living Ability to understand and implement educational intervention instructions
Exclusion criteria:
 Presence of an acute illness or clinical instability at the time of enrollment Presence of an acute psychiatric disorder Severe hearing or visual impairment that prevents participation in educational sessions Any medical condition that makes participation in the study inappropriate or unsafe

Age
From **60 years** old to **90 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
Participants will be randomly assigned to either the intervention group (A) or the comparison group (B) using the permuted block randomization method. The randomization procedure will be conducted using six predefined four-person blocks, including AABB, BBAA, ABBA, BAAB, ABAB, and BABA. A random number table will be used to select the corresponding block arrangements for numbers 1 to 6, while numbers 0 and 7-9 will be disregarded. Participants will subsequently be assigned sequentially to groups A and B according to the order of the selected block sequences.

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 Semnan University of Medical Sciences
Street address
 Research and Technology Deputy, Central Headquarters Building, Semnan University of Medical Sciences, Basij Service Road, Basij Blvd., Modiran Town, Semnan, Iran
City
 Semnan
Province
 Semnan
Postal code
 3514799442
Approval date
 2026-02-16, 1404/11/27
Ethics committee reference number
 IR.SEMUMS.REC.1404.322

Health conditions studied

1

Description of health condition studied
Diabetes mellitus due to underlying condition

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Self-neglect

Timepoint
Before, immediately after, 3 months after the educational intervention

Method of measurement
Elder Self-Neglect Scale

Secondary outcomes

1

Description

Health-Promoting Lifestyle
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Walker's Health-Promoting Lifestyle Profile (HPLP-II)

2

Description
Self-Compassion
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Self-Compassion Scale Short Form (SCS-SF)

3

Description
Fasting Blood Sugar
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
CareSens Glucometer

4

Description
Glycated Hemoglobin (HbA1c)
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Infopia HbA1c Analyzer

5

Description
Systolic blood pressure
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
OMRON Blood Pressure Monitor

6

Description
Body Mass Index (BMI)
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
SECA Calibrated Scale and Stadiometer

7

Description
Diastolic blood pressure
Timepoint
Before, immediately after, 3 months after the

educational intervention
Method of measurement
OMRON Blood Pressure Monitor

Intervention groups

1

Description
Intervention Group: The intervention will be delivered as a group-based healthy lifestyle and positive mindfulness training program for older adults with type 2 diabetes. The educational content will be developed based on needs assessment findings, diabetes self-care principles, healthy lifestyle recommendations, and mindfulness and positive psychology approaches. Participants will attend eight weekly sessions lasting 45–60 minutes each. Session contents include: (1) introduction to the program, goal setting, and education on diabetes and self-care; (2) healthy nutrition and basic mindfulness training; (3) physical activity and self-compassion; (4) sleep hygiene, positive emotions, and gratitude practice; (5) social skills and autonomy; (6) stress management, acceptance, and mindful breathing; (7) values, positive relationships, and meaning in later life; and (8) review and consolidation of learned skills and development of a home follow-up plan. Sessions will be conducted using lectures, group discussions, question-and-answer activities, and practical exercises. Educational materials include booklets, pamphlets, guided meditation audio/video files, and home practice logs. Participants will be asked to perform mindfulness and healthy lifestyle-related home exercises for 15–30 minutes daily. Weekly follow-up will be conducted through telephone calls or text messages. Adherence to the intervention will be assessed based on session attendance, completion of home exercises, and responsiveness to follow-up contacts. Adherence rates above 75% will be considered satisfactory.

Category
Lifestyle

2

Description
Control Group: No educational intervention will be performed for the control group, and they will only receive routine health care.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobarakeh County Health and Treatment Network
Full name of responsible person
Dr. Ali Parsa
Street address
Central Headquarters Building, Mobarakeh County

Health and Treatment Network, Adjacent to Hazrat
Mohammad Rasool Allah Hospital, Parastar Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid Eslami

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Akram Esrafil Bisheh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Geriatrics

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Geriatric Health Department, School of Rehabilitation
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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