Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of a self-management program based on the 5A model on improving lifestyle and self-efficacy in older adults with metabolic syndrome: a randomized controlled trial

Protocol summary

Study aim
Determining the effect of a 5A-based self-management program on improving lifestyle and self-efficacy in older adults with metabolic syndrome

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

Settings and conduct
Older adults attending the health centers of Meyami 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: Age 60 years or older; diagnosis of metabolic syndrome according to the IDF criteria; ability and willingness to participate in educational sessions; provision of informed consent; and a score of 7 or higher on the Abbreviated Mental Test (AMT). Exclusion criteria: Presence of an acute or unstable medical condition, acute psychiatric disorders, or any condition that would make participation unsafe or impossible.

Intervention groups
Intervention group: Following the needs assessment, participants will attend eight weekly 60-minute sessions based on the 5A model. They will perform daily home-based activities (15–30 minutes) and receive weekly telephone or text-message follow-up. Self-efficacy will be enhanced using Bandura-based strategies, and adherence will be monitored through attendance, home activity completion, and follow-up responses. Control group: Participants will receive routine care only, with no educational intervention.

Main outcome variables
Health-Promoting Lifestyle, Self-Efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260413069068N1**
Registration date: **2026-06-18, 1405/03/28**
Registration timing: **prospective**

Last update: **2026-06-18, 1405/03/28**
Update count: **0**

Registration date
2026-06-18, 1405/03/28

Registrant information

Name
Elahe Bahrami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

Expected recruitment end date
2026-12-06, 1405/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of a self-management program based on the 5A model on improving lifestyle and self-efficacy in older adults with metabolic syndrome: a randomized controlled trial

Public title
Effect of a self-management program on improving lifestyle and self-efficacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Metabolic syndrome according to IDF criteria Age 60 and above Having the ability and willingness to participate in training sessions Obtaining a score of 7 or higher on the short cognitive status test Informed consent to participate in research

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 allocated to the intervention (A) and comparison (B) groups using the permuted block randomization method. In this approach, six possible arrangements of blocks with a block size of four (AABB, BBAA, ABBA, BAAB, ABAB, and BABA) will be generated and predefined. Using a random number table, numbers 1 to 6 will correspond to one of the six block arrangements, whereas 0 and 7 to 9 will be discarded. Participants will then be sequentially assigned to groups A and B according to the order of the selected blocks.

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

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Province
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Approval date
2026-05-21, 1405/02/31

Ethics committee reference number
IR.SEMUMS.REC.1405.021

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary 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-Efficacy

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

Method of measurement
Self-Efficacy Questionnaire SRAHPS

Secondary outcomes

1

Description
Waist Circumference
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Non-stretchable Cloth Measuring Tape (cm)

2

Description
Fasting Blood Sugar (FBS)
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Blood Test (Glucose Oxidase Enzymatic Method)

3

Description
Triglycerides (TG)
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Blood Test

4

Description
High-Density Lipoprotein (HDL)
Timepoint
Before, immediately after, 3 months after the educational intervention
Method of measurement
Blood Test

5

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

6

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

7

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

Intervention groups

1

Description
Based on the pretest results and needs assessment, educational content and materials (booklets, pamphlets, and educational files) will be developed. The intervention group will participate in eight weekly 60-minute sessions based on the 5A self-management model. Educational sessions will be delivered through lectures, group discussions, question-and-answer activities, practical exercises, and written materials. To accommodate participants with limited literacy, the content will be presented in simple language, primarily through verbal and practical methods. For illiterate participants, questionnaires will be completed through interviewer administration. Each session will incorporate the five components of the 5A model (Assess, Advise, Agree, Assist, and Arrange). Participants will be asked to perform daily home-based exercises (15–30 minutes), and weekly telephone or text-message follow-ups will be conducted to monitor adherence, provide feedback, and address potential barriers. Self-efficacy will be enhanced using Bandura's strategies, including mastery experiences, vicarious learning, and verbal persuasion. The control group will receive routine care only. Intervention adherence will be assessed based on session attendance, completion of home exercises, and responsiveness to follow-up contacts, with adherence above 75% considered satisfactory. All screening, data collection, physical measurements, and follow-up procedures will be thoroughly documented.
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
Meyami County Health and Treatment Network
Full name of responsible person
Dr. Alireza Mesri Pour Alavijeh
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1

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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

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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