Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of 12 week of Aerobic Exercise Combined with a Low-Sodium Diet on Blood Pressure and Pulmonary Function in Obese Elderly Individuals with Hypertension

Protocol summary

Study aim

To investigate the effect of a 12-week combined aerobic exercise and low-sodium diet program on blood pressure levels and pulmonary function in obese elderly individuals with hypertension

Design

This research is a parallel-group, randomized controlled trial where participants are randomly allocated into four groups (combined, exercise, diet, control). The study design is single-blind.

Settings and conduct

Sampling Method: Convenience Sampling will be employed. Study Setting: The study will be conducted at the Mehr-e Nikān Elderly Center and the Specialized Clinic of Samen al-A'emmeh (AS) in Kermanshah, Iran.

Participants/Inclusion and exclusion criteria

Inclusion: Elderly (≥60 years) with obesity (BMI≥30) and mild-moderate hypertension on stable treatment, medically cleared for exercise, and no recent regular exercise/special diet. Exclusion: Significant acute/uncontrolled comorbidities, use of medications affecting metabolism/weight, severe physical limitations, or confounding behavioral factors (smoking/alcohol use).

Intervention groups

Combined Group: Aerobic exercise + Low-sodium diet. Exercise Group: Aerobic exercise only. Diet Group: Low-sodium diet only. Control Group: Usual care (no exercise or dietary intervention of the study).

Main outcome variables

Blood Pressure (measured with a digital sphygmomanometer) Pulmonary Function including: Forced Expiratory Volume in 1 second (FEV1) Forced Vital Capacity (FVC) FEV1/FVC Ratio (measured by spirometry)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260125068657N1**
Registration date: **2026-02-27, 1404/12/08**
Registration timing: **prospective**

Last update: **2026-02-27, 1404/12/08**
Update count: **0**

Registration date

2026-02-27, 1404/12/08

Registrant information

Name
Sahel Veiskarami
Name of organization / entity
Razi University
Country
Iran (Islamic Republic of)
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+98 83 3429 1980
Email address
sahelveiskarami93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-11, 1404/12/20

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of 12 week of Aerobic Exercise Combined with a Low-Sodium Diet on Blood Pressure and Pulmonary Function in Obese Elderly Individuals with Hypertension

Public title
The Effect of 12-Week Aerobic Training Combined with a Low-Sodium Diet on Blood Pressure and Pulmonary Function in Obese Elderly Adults with Hypertension

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥ 60 years, and provision of informed consent. Obesity (BMI ≥ 30 kg/m²) stage 1 or 2 hypertension on stable pharmacological treatment Medical clearance for moderate-intensity exercise Absence of acute cardio-pulmonary diseases No regular participation in structured exercise programs or a low-sodium diet in the past 6 months

Exclusion criteria:
Serious or uncontrolled comorbidities (e.g., cardiovascular, pulmonary, renal, or diabetes). Use of medications affecting blood pressure or body weight (other than stable antihypertensive therapy) Having severe orthopedic limitations Active smoking within the past year

Age
From **60 years** old to **75 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants, after completing the baseline assessment, will be randomly assigned to either the "intervention" or "control" group. The randomization process will be performed using a **block randomization** method with blocks of four, and will be stratified based on **treatment center** and **disease severity** (stratified randomization). The unit of randomization in this study is the individual. The random allocation sequence will be generated by an individual not involved in the trial's execution, using SAS statistical software (version 9.4). To ensure allocation concealment, the group assignment for each participant will be placed inside sequentially numbered, opaque, sealed envelopes. These envelopes will only be opened by the researcher after a participant's final eligibility is confirmed and at the moment of enrollment in the study. The detailed procedure for randomization is as follows: first, the list of eligible participants will be categorized based on the strata (center and disease severity). Then, for each stratum separately, blocks of four with a specific random sequence (maintaining a 1:1 ratio for intervention and control groups) will be generated by the software. These assignments will be placed in the numbered envelopes and distributed to the centers. Using this method, both the researcher and the participant remain unaware of the next group assignment until after the allocation is finalized, thereby minimizing selection bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will employ a single-blind design. The participants will be blinded to their group allocation (intervention or control). Exercise trainers and clinical assessors will not be blinded to the intervention type, but all efforts will be made to standardize interactions with both groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Kermanshah Razi University

Street address
No. 8, Razi University, Daneshgah Boulevard, Taq Bostan Street, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Approval date
2025-12-29, 1404/10/08

Ethics committee reference number
IR.RAZI.REC.1404.045

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I27.2

ICD-10 code description
Other secondary pulmonary hypertension

Primary outcomes

1

Description
Systolic and Diastolic Blood Pressure
Timepoint
Study baseline, Week 6, and post-intervention at Week 12.
Method of measurement
Measured using a calibrated digital sphygmomanometer after 5 minutes of seated rest.

2

Description
Forced Expiratory Volume in 1 second (FEV1).
Timepoint
Study baseline and post-intervention at Week 12.
Method of measurement
Measured using a spirometer according to standard ATS/ERS guidelines

3

Description
Forced Vital Capacity (FVC).
Timepoint
Study baseline and post-intervention at Week 12.
Method of measurement
Measured using a spirometer according to standard ATS/ERS guidelines

4

Description
FEV1/FVC Ratio.
Timepoint
Study baseline and post-intervention at Week 12.
Method of measurement
Measured using a spirometer according to standard ATS/ERS guidelines

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Combined Group; Receives aerobic exercise (3 sessions/week, 12 weeks) combined with a low-sodium diet (<2g sodium/day)
Category
Prevention

2

Description
Intervention group: Exercise Group; Receives only the aerobic exercise program.
Category
Prevention

3

Description
Intervention group: Diet Group; Receives only the low-sodium diet.
Category
Prevention

4

Description
Control group: Receives usual care without the specific exercise or dietary intervention of this study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehr Nikān Elderly Center
Full name of responsible person
Sahel Viskaremi
Street address
No. 20, Mehr Nikān Welfare Center (Rehabilitation Center), Banafsheh Street, Masaken Neighborhood, Kermanshah.
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6748959686
Phone
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Meharnikan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi University
Full name of responsible person
Kivan Amini
Street address
No. 9, Razi University, Daneshgah Boulevard, Taq Bostan Street, Kermanshah City
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Email

Keyvan.Amini@Gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi University

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

Razi University

Full name of responsible person

Rastegar Hoseini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Exercise Physiology

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Person responsible for scientific inquiries

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Exercise Physiology

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Person responsible for updating data

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Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be recorded in the SPSS software and will be available

When the data will become available and for how

long

Availability will start nine months after publishing all papers

To whom data/document is available

Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used

All data can be used as a reference

From where data/document is obtainable

sahelveiskarami93@gmail.com

What processes are involved for a request to access data/document

If the explanation for the data request would be convincing it will be given in 3 days.

Comments