

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of ten weeks of Tabata resistance training on structural and functional changes in the heart of obese elderly women

Protocol summary

Study aim

Determining the effect of 10 weeks of Tabata resistance training on structural and functional indices of the heart

Design

A controlled clinical trial with parallel groups, double-blind, randomized, on 36 patients. SPSS software was used for randomization.

Settings and conduct

The intervention group will perform 10 weeks of Tabata resistance training (3 sessions per week, including 8 sets of 20 seconds of maximum with 10 seconds of rest) and the control group will have their usual activity. The exercises will be performed in a gym under the supervision of a trainer. Cardiac variables will be measured before and after the intervention period.

Double-blinding: Participants are unaware of the main hypotheses of the study and the type of group allocation. The doctor does not know which subject is in the Tabata training group and which is in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female gender; age 55 to 65 years, body mass index in the overweight or obese range, physical activity less than 150 minutes of exercise per week in the past 6 months, physical and mental health confirmed by a specialist physician. Inclusion criteria: Use of sports supplements or steroid drugs, smoking, history of pain or surgery in musculoskeletal areas, cardiovascular disease or limiting systemic diseases.

Intervention groups

The intervention group will perform 10 weeks of Tabata resistance training (3 sessions per week, including 8 sets of 20 seconds max with 10 seconds rest), and the control group will have their normal activity.

Main outcome variables

Significant reduction in left ventricular mass; improvement in left ventricular internal diameter at end-diastole; reduction in left ventricular internal diameter at end-systole; increase in cardiac ejection fraction; modification of left ventricular posterior wall thickness

and interventricular septal thickness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260520069464N1**

Registration date: **2026-05-25, 1405/03/04**

Registration timing: **prospective**

Last update: **2026-05-25, 1405/03/04**

Update count: **0**

Registration date

2026-05-25, 1405/03/04

Registrant information

Name

Amineh Razazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4431 3611

Email address

am.razazi79@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-28, 1405/03/07

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ten weeks of Tabata resistance training on structural and functional changes in the heart of obese elderly women

Public title

The effect of ten weeks of intense and short-term exercise on the heart health of obese elderly women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index in the overweight or obese range
Physical activity less than 150 minutes of exercise per week in the past 6 months
Physical and mental health certified by a medical professional

Exclusion criteria:

Participation in regular exercise or resistance training in the past year
Use of sports supplements or steroid medications
Smoking
History of pain or surgery in the musculoskeletal area
Suffering from cardiovascular disease or limiting systemic diseases

Age

From **55 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization unit in this study is the individual. After being called and screened based on the inclusion criteria, volunteers are individually assigned to the allocation process. Simple randomization will be used to divide the subjects into two groups: Tabata and control. The sequence of this allocation will be generated by a statistician using SPSS statistical software so that each individual has an equal chance of being placed in each group. Stratification will not be used in this study. To conceal allocation and prevent bias, opaque, sealed, serially numbered envelopes are used. The names of the groups are placed on cards in the software sequence and placed inside these envelopes. These envelopes are opened by someone outside the implementation team only after initial measurements, including weight and body composition indices, have been taken. This process ensures that neither the researcher nor the subject is aware of the type of group assigned until the exercises begin.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to comply with the principles of

double blinding, participants and the outcome assessor (echocardiography specialist) will be unaware of the type of group assignment. Participants are not aware of the main hypotheses of the study and the type of group division. Also, the specialist physician responsible for performing echocardiography will not be aware of which subject is in the Tabata exercise group and which is in the control group. For this purpose, subjects are referred to the physician without mentioning the group name and only with a protocolized identification code to prevent bias in the evaluation and interpretation of the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Kerman branch

Street address

No. 5, Alley 21., Emam Khomeini Blvd., Bam Town

City

Bam

Province

Kerman

Postal code

7661715678

Approval date

2026-05-06, 1405/02/16

Ethics committee reference number

IR.IAU.KERMAN.REC.1405.035

Health conditions studied

1

Description of health condition studied

Structural and functional cardiac changes in obese elderly women.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Left Ventricular Mass (LVM) measured by 2D echocardiography in grams.

Timepoint

Measurement at the beginning of the study (baseline), at the end of the 10th week (24 hours after the last session)

of the meeting), and 4 weeks after the end of the intervention (follow-up phase).

Method of measurement

Using a two-dimensional echocardiography device based on the American Society of Echocardiography standard formulas by a cardiologist.

Secondary outcomes

1

Description

Left Ventricular End-Systolic Dimension (LVESD)

Timepoint

Measurement at the beginning of the study (before starting the exercises), at the end of the tenth week (24 hours after the last session of the meeting), and four weeks after the completion of the training period (follow-up phase).

Method of measurement

2D Echocardiography

2

Description

Left Ventricular End-Diastolic Dimension (LVEDD)

Timepoint

Measurement at the beginning of the study (before starting the exercises), at the end of the tenth week (24 hours after the last session of the meeting), and four weeks after the completion of the training period (follow-up phase).

Method of measurement

2D Echocardiography

Intervention groups

1

Description

Intervention group: Performing high-intensity interval training based on the Tabata protocol for ten weeks and three sessions per week. Each training session includes six minutes of warm-up with stretching exercises, Twenty to thirty minutes of the main exercise block (consisting of eight rounds of twenty seconds of activity at ninety to ninety-five percent of maximum heart rate and ten seconds of active rest between each round), and finally, six minutes of cool-down. The exercises include functional movements tailored to the ability of elderly women (such as half-squats, fast marching, and knee-ups) conducted under the supervision of an exercise physiologist.

Category

Lifestyle

2

Description

Control group: Subjects in this group do not receive any exercise intervention or organized training program during the ten-week study period. These individuals are

requested to maintain their usual level of daily activities and lifestyle habits throughout the research period and not to participate in any organized physical activity program.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Kerman Branch

Full name of responsible person

Amineh Razazi

Street address

Department of Physical Education and Sport Sciences, Islamic Azad University, Kerman Branch., Emam ali Blvd., kerman Town

City

Kerman

Province

Kerman

Postal code

7635168111

Phone

+98 34 3321 0043

Fax

+98 34 3321 0051

Email

info@iauk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Ali Hamzehei

Street address

Department of Physical Education and Sport Sciences, Islamic Azad University, Kerman Branch., Emam ali Blvd., kerman Town

City

Kerman

Province

Kerman

Postal code

7635168111

Phone

+98 34 3321 0043

Fax

+98 34 3321 0051

Email

research@iauk.ac.ir

Grant name

Grant code / Reference number

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

No
Title of funding source
Islamic Azad University, Kerman Branch
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ahad Shafiei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Department of Physical Education and Sport Sciences,
Islamic Azad University, Kerman Branch., Emam ali
Blvd., kerman Town
City
Kerman
Province
Kerman
Postal code
7635168111
Phone
+98 34 3321 0043
Fax
+98 34 3321 0051
Email
Shafiee.sport@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ahad Shafiei
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Department of Physical Education and Sport Sciences,
Islamic Azad University, Kerman Branch., Emam ali

Blvd., kerman Town
City
Kerman
Province
Kerman
Postal code
7635168111
Phone
+98 34 3321 0043
Fax
+98 34 3321 0051
Email
Shafiee.sport@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Ahad Shafiei
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Department of Physical Education and Sport Sciences,
Islamic Azad University, Kerman Branch., Emam ali
Blvd., kerman Town
City
Kerman
Province
Kerman
Postal code
7635168111
Phone
+98 34 3321 0043
Fax
+98 34 3321 0051
Email
Shafiee.sport@gmail.com

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

De-identified Individual Participant Dataset and Study

Documents for the Trial: Effects of 10-Week Tabata Resistance Training on Left Ventricular Mass and Cardiac Dimensions in Obese Older Women. All individual participant data (IPD) related to primary outcomes and secondary outcomes will be available for sharing after the completion of the study and publication of the main manuscript. To adhere to ethical principles, all personal identifiers (such as names, national IDs, and contact information) will be completely removed, and the data will be shared in a de-identified Excel format to ensure participant confidentiality.

When the data will become available and for how long

Data and document access will begin 6 months after the publication of the final results and the main manuscript, and will be available for a period of 2 years.

To whom data/document is available

Access to the data and documents of this study will be granted only to researchers and investigators affiliated with academic and scientific institutions, as well as graduate students conducting related research in sports science or cardiovascular fields.

Under which criteria data/document could be used

The data and documents of this study are available solely for secondary statistical analysis, systematic reviews, and meta-analyses to advance knowledge in sports science and cardiovascular physiology. Any commercial use or advertising purposes are strictly prohibited. Applicants are required to provide a formal citation to the original study in any resulting scientific work. Furthermore, the data must not be shared with third parties. Requirements for submitting a request include an official letter of introduction from the affiliated university or institution, a brief proposal outlining the intended use of the data, and a commitment to

maintaining confidentiality and avoiding any attempts at participant re-identification.

From where data/document is obtainable

Applicants should submit their requests for data or documents through the following channels in order of priority: First Priority (Email): Send the request to the Corresponding Author's email at info@iauk.ac.ir (or the specific academic email provided in the final published paper). The subject line must include "Request for IPD - Tabata Training Clinical Trial". Second Priority (In-person or Postal Mail): Department of Physical Education and Sport Sciences, Islamic Azad University of Kerman, Imam Ali Boulevard, Kerman, Iran. Contact Person: Corresponding Author and Head of the Department of Physical Education and Sport Sciences, Islamic Azad University of Kerman.

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

Applicants must follow the process below to access the data or documents: 1. Formal Request Submission: The applicant must send an email containing a valid letter of introduction from their university or institution, along with a brief proposal (purpose of use), to the corresponding author. 2. Initial Review: The corresponding author will review the request for ethical and scientific compliance within 7 working days and provide an initial response. 3. Signing the Agreement: If approved, a Non-Disclosure Agreement (NDA) and confidentiality form will be sent to the applicant, which must be signed and returned (approximately 3 to 5 days). 4. Preparation and Delivery: After receiving the signed agreement, the anonymized data and requested documents will be sent to the applicant as encrypted files within 7 days.

Comments