

# 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

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Dr. Ali Hamzehei

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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  
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Ahad Shafiei  
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Assistant Professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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

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**