Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of combined exercises on the levels of some factors related to muscle hypertrophy in elderly women

Protocol summary

Study aim
The effect of combined exercises on the levels of some factors related to muscle hypertrophy in elderly women

Design
A randomized, parallel-group, open-label, controlled clinical trial involving 30 patients. The Excel `rand` function will be used for randomization.

Settings and conduct
The statistical population for this study consists of elderly women residing in Ahvaz who visit the Pardis Center for the Elderly during the designated research period. A convenience sampling method is employed for sample selection. Following the selection of 30 participants based on the study's inclusion and exclusion criteria, they will be randomly assigned to two groups: "combined exercises" (intervention group) and "waiting list" (control group).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women over the age of 60 with a sedentary lifestyle and no regular physical activity; achieving a normal score on a cognitive screening test to ensure comprehension of exercise instructions. Exclusion criteria: Use of medications directly affecting muscle metabolism or muscle growth; presence of progressive neurological diseases.

Intervention groups
Intervention group: All older adults who will receive the combined exercise intervention. Control group: All older adults who will not receive any intervention.

Main outcome variables
Body Mass Index, Body Fat Percentage, Myostatin, Follistatin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261005071304N1**
Registration date: **2026-10-08, 1405/07/16**
Registration timing: **prospective**

Last update: **2026-10-08, 1405/07/16**
Update count: **0**

Registration date
2026-10-08, 1405/07/16

Registrant information

Name
Samaneh Fazilat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3333 3333

Email address
fazilatsamane1@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

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
The effect of combined exercises on the levels of some factors related to muscle hypertrophy in elderly women

Public title
The Effect of Combined Training on Muscular Changes in Older Women

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women over the age of 60instructions Sedentary lifestyle and lack of regular physical activity Absence of musculoskeletal disorders Achieving a normal score on a cognitive screening test to ensure comprehension of exercise
Exclusion criteria:
A history of heart attack, heart failure, or uncontrolled high blood pressure Acute or chronic joint or spinal injuries that prevent the performance of resistance or combined exercises Use of medications that directly affect muscle metabolism or muscle growth Presence of progressive neurological disorders
Age
From **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The study population consists of elderly women who visit the elderly care center during the designated research period. A convenience sampling method is employed for participant selection. Following the selection of 30 participants based on the study's inclusion and exclusion criteria, they will be randomly assigned to either the "combined exercises" group (intervention group) or the "waiting list" group (control group). Randomization will be performed using a block randomization method with variable block sizes (4 and 6) by an independent statistician who is not involved in the study's implementation. The randomization schedule will be generated using the RAND function in Excel and subsequently placed in numbered, opaque, sealed envelopes to ensure that neither the researcher nor the participants are aware of the allocation sequence (allocation concealment). The envelopes will be opened—and the assigned group revealed—only at the time each participant enters the study. To ensure the comparability of baseline variables (such as age), their distribution across the two groups will be assessed during the statistical analysis phase.
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 Islamic Azad University, Ahvaz Branch
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Approval date
2024-04-27, 1403/02/08
Ethics committee reference number
IR.IAU.AHVAZ.REC.1403.123

Health conditions studied

1

Description of health condition studied
Physiological changes in aging
ICD-10 code
Z00.6
ICD-10 code description
Encounter for examination for normal comparison and control in clinical research program

Primary outcomes

1

Description
Body Mass Index
Timepoint
Phase 1: 48 hours prior to the start of the intervention. Phase 2: 72 hours after the final training session, to avoid the acute effects of exercise on the variables.
Method of measurement
By means of a calculation involving dividing weight in kilograms by the square of height in meters.

2

Description
Body Fat Percentage
Timepoint
Phase 1: 48 hours prior to the start of the intervention. Phase 2: 72 hours after the final training session, to avoid the acute effects of exercise on the variables.
Method of measurement
Using the bioimpedance method

3

Description
Myostatin
Timepoint
Phase 1: 48 hours prior to the start of the intervention. Phase 2: 72 hours after the final training session, to avoid the acute effects of exercise on the variables.
Method of measurement
Using an ELISA kit

4

Description
Follistatin
Timepoint
Phase 1: 48 hours prior to the start of the intervention. Phase 2: 72 hours after the final training session, to avoid the acute effects of exercise on the variables.
Method of measurement
Using an ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention consists of an 8-week combined exercise program (Pilates and fitness). Each session begins with a 10-minute warm-up (comprising preparatory movements, breathing exercises, and spinal mobility drills). This is followed by 30 minutes of Pilates exercises performed in standing, seated, and supine positions, aimed at improving flexibility, balance, and neuromuscular coordination. The intensity of the Pilates exercises is gradually increased based on heart rate reserve (Karvonen method), rising from 50–55% in the first week to 65–70% by the eighth week. After a 5-minute rest, fitness (resistance) exercises are performed to enhance physical fitness and promote hypertrophy. Adhering to the principle of progressive overload, exercise intensity is gradually increased from a 20-repetition maximum (RM) load during the first two weeks to a 10-RM load by the seventh and eighth weeks. All exercises are performed to the point of voluntary exhaustion, and participants' heart rates are monitored using an electronic heart rate monitor to ensure precise control of exercise intensity.
Category
Prevention

2

Description
Control group: The control group will not receive any type of intervention during the implementation of the research, but to avoid factors that threaten the internal validity of the research, such as compensatory competition of the control group or demoralization, they will receive the intervention after data collection.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Pardis Nursing Home, Ahvaz
Full name of responsible person
Samaneh Fazilat
Street address
Saba Street, Pardis
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6139758185
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Fazilatsamane1@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aslan Egdarnezhad
Street address
Opposite Keshavarz Street, Farhang Shahr, Golestan Highway
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Ahvaz
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6134937333
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+98 61 3334 8421
Email
a_eigder@ymail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad 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

Islamic Azad University

Full name of responsible person

Samaneh Fazilat

Position

Master’s Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Full name of responsible person

Samaneh Fazilat

Position

Master’s Student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable