Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of long-term intermittent fasting, with or without resistance training, on muscle mass, bone mineral density and biochemical measurements in postmenopausal women with obesity: a randomized clinical trial

Protocol summary

Study aim
To investigate the effect of long-term intermittent fasting, with or without resistance training, on muscle mass and bone mineral density in postmenopausal women with obesity

Design
A randomized, controlled, parallel-group clinical trial on 120 postmenopausal women with obesity. The RAND function of Excel software will be used for randomization.

Settings and conduct
Volunteers will undergo dietary and/or resistance exercise interventions for 6 months. Dependent variables will be assessed at baseline, and after 2-, 4-, and 6-month intervention as well as following a 6-month follow-up. This study will be conducted in Ankara, Turkey. Due to the type of interventions (exercise and fasting), blinding is not possible during the intervention phase. However, blinding will be performed during the data analysis phase, and by assigning abbreviations to the groups, the statistical analyst will be blinded to the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women over 50 years of age, with a BMI > 30 kg/m2, > 3 years after the final period, and no regular exercise in the past six months. Exclusion criteria: Suffering from chronic cardiovascular, hepatic, or renal disease, and having any pain or mobility limitations that prevent intervention.

Intervention groups
Daily intermittent fasting group (16:8, from 19 to 11 h), daily intermittent fasting with resistance training group (~1 h, from 16 to 17 h, 5 days/week), and control (no nutritional and exercise intervention). Both the intervention groups will also receive daily supplementation with whey and casein proteins, calcium, and vitamin D; the amounts will be determined by a nutritional specialist based on the daily needs of each subject.

Main outcome variables
Muscle mass; Bone mineral density

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231004059615N6**
Registration date: **2025-09-15, 1404/06/24**
Registration timing: **prospective**

Last update: **2025-09-15, 1404/06/24**
Update count: **0**

Registration date
2025-09-15, 1404/06/24

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-20, 1404/06/29

Expected recruitment end date

2025-09-30, 1404/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of long-term intermittent fasting, with or without resistance training, on muscle mass, bone mineral density and biochemical measurements in postmenopausal women with obesity: a randomized clinical trial

Public title

The effect of fasting and resistance training on sarcopenia in postmenopausal women with obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female Age > 50 years Body mass index > 30 kg/m2 > 3 years after the final period Not engaged in regular exercise activities over the last six months No smoking or alcohol consumption

Exclusion criteria:

Suffering from chronic cardiovascular, liver and kidney diseases Having any pain or mobility limitations that prevent interventions. Current treatment with medication or supplements that significantly affect the main study variables. Having a history of bariatric surgery Following a special diet, including strict vegetarian/vegan, within the past 6 months

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The names of the subjects will be entered in an Excel column. Using the RAND function (=RAND()), each subject will be randomly assigned a number. Then, the numbers will be sorted from smallest to largest. After that, every 40 subjects will be assigned to one of the study groups (numbers 1 to 40 to the first group, numbers 41 to 80 to the second group, and numbers 81 to 120 to the third group).

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 the International Science and Technology University

Street address

Tunahan Mah. Dumlupinar 30 Agustos Cad. No:2, Metromal Business F Blok Office

City

Ankara

Postal code

21,06824

Approval date

2025-09-03, 1404/06/12

Ethics committee reference number

202509-01

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Muscle mass

Timepoint

At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.

Method of measurement

By Dual-Energy X-ray Absorptiometry (DXA)

2

Description

Bone mineral density

Timepoint

At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.

Method of measurement

By Dual-Energy X-ray Absorptiometry (DXA)

Secondary outcomes

1

Description
Body weight
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
By digital scale

2

Description
body fat, visceral adipose tissue
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
By Dual-Energy X-ray Absorptiometry (DXA)

3

Description
Muscle strength
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using one repetition maximum test and digital strength measuring devices

4

Description
balance
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using the dynamic balance test

5

Description
Resting metabolic rate
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Indirect calorimetry

6

Description
Cognitive function
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using functional tests to assess executive function, memory, processing speed, and attention

7

Description
Mood
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using the Menopause-Specific Quality of Life Questionnaire, Patient Health Questionnaire-9, and Generalized Anxiety Disorder-7 questionnaire

8

Description
Plasma levels of irisin
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

9

Description
Insulin resistance
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using fasting glucose, HOMA-IR, and HbA1c measurements

10

Description
Lipid profile
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using cholesterol, triglycerides, HDL-C, and LDL-C measurements

11

Description
Plasma levels of brain-derived neurotrophic factor
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

12

Description
Plasma levels of beta-hydroxybutyrate
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

13

Description
Oxidative stress
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

14

Description
Inflammation
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

15

Description
Plasma levels of hormones
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

16

Description
Meteorin-like protein (Metrnl)
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

17

Description
Plasma levels of dehydroepiandrosterone-sulfate (DHEA-S)
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

18

Description
Plasma levels of FGF-21
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

19

Description
Plasma levels of sclerostin
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

20

Description
Plasma levels of C-terminal telopeptide (CTX)
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

21

Description
Plasma levels of Procollagen Type I N-Terminal Propeptide (P1NP)
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

22

Description
Plasma levels of fat browning factors
Timepoint
At baseline, and after 2-, 4-, and 6-month intervention as well as following 6-month follow-up.
Method of measurement
Using ELISA method

Intervention groups

1

Description
Intervention group 1: Daily intermittent fasting (16:8, from 19 to 11 h); these volunteers will also receive daily supplementation with whey and casein proteins, calcium, and vitamin D (the amounts will be determined by a nutritional specialist based on the daily needs of each subject).
Category
Lifestyle

2

Description
Intervention group 2: Daily intermittent fasting (16:8, from 19 to 11 h) with resistance training (~1 h, 16 to 17 h, 5 days/week); these volunteers will also receive daily supplementation with whey and casein proteins, calcium, and vitamin D (the amounts will be determined by a nutritional specialist based on the daily needs of each subject).
Category

Lifestyle

3

Description
Control group: Without nutritional and/or exercise intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
INTERNATIONAL SCIENCE AND TECHNOLOGY UNIVERSITY
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
INTERNATIONAL SCIENCE AND TECHNOLOGY UNIVERSITY
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
IR
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
Davar Khodadadi
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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
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
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 collected during the study will be shareable after de-identifying the subjects.
When the data will become available and for how long
The data will be published after the extracted articles are accepted.
To whom data/document is available
All people
Under which criteria data/document could be used
All data collected during the study will be shareable after de-identifying the subjects. The requester will only be permitted to use the data for meta-analysis reviews.
From where data/document is obtainable
Corresponding author: Davar Khodadadi, Faculty of Physical Education and Sports Sciences, Islamic Azad University Central Tehran Branch, Tehran, Iran Email: davar.khodadadi@yahoo.com
What processes are involved for a request to access data/document
Sending an email request to the corresponding author: Davar Khodadadi Email: davar.khodadadi@yahoo.com
Comments