

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

Name

Davar Khodadadi

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

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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 (Metrln)

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

Heidar Sajedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data**Contact****Name of organization / entity**

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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