

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of high protein diet in regulating appetite, anthropometric indices, and body composition of Normal Weight Obese women

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effect of high protein diet and standard protein on appetite status, body weight, body mass index (BMI), fat mass (FM) and lean body mass (LBM) in normal obese women.

##### Design

Design: In this randomized controlled trial, the participants randomly will be assigned to 2 groups. 25 women will be allocated in the control group to receive a diet regimen with a standard protein content (standard protein (SP); providing 0.8 g/kg body weight/day), and 25 women will be allocated in the intervention group to receive a diet regimen with a higher protein content (high protein (HP); providing 1.2 g/kg body weight/day) for 12 weeks. The diet regimens have an equal amount of calories in both groups according to the resting metabolic rate (BMR) based on the Harris-Benedict predictive formula.

##### Settings and conduct

The participants will not know whether they are a member of the HP group or the SP group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria into the study are for healthy women, aged between 30 to 60 years having a BMI (in kg/m<sup>2</sup>) <25 and >18.5, body fat >30 %. Exclusion criteria include: smoking, pregnancy, lactation, history or presence of kidney, gastrointestinal, liver, or thyroid disease, gout, certain cancers, or type 2 diabetes, severe weight changes within the last 3 months and bariatric surgery; recently following a high-protein diet or using anti-obesity medications or supplements; and consuming protein supplement and high amounts of caffeine (>250-300 mg/d).

##### Intervention groups

high protein diet and standard protein

##### Main outcome variables

The weight, body composition including fat body mass and lean body mass by BIA machine and appetite level by visual analogue scale questionnaire will be measured

before and after the trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170412033393N2**

Registration date: **2019-04-06, 1398/01/17**

Registration timing: **retrospective**

Last update: **2019-04-06, 1398/01/17**

Update count: **0**

##### Registration date

2019-04-06, 1398/01/17

##### Registrant information

##### Name

Neda Haghghat

##### Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 705 0021

##### Email address

haghghat.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-21, 1397/02/31

##### Expected recruitment end date

2018-11-21, 1397/08/30

##### Actual recruitment start date

2018-05-21, 1397/02/31

##### Actual recruitment end date

2019-01-20, 1397/10/30

**Trial completion date**

2019-02-03, 1397/11/14

**Scientific title**

The effect of high protein diet in regulating appetite, anthropometric indices, and body composition of Normal Weight Obese women

**Public title**

High protein diet in normal weight obese women

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

healthy women having a body mass index (kg/m<sup>2</sup>) <25 and >18.5 body fat>30 % aged between 30 to 60 years

**Exclusion criteria:****Age**

From **30 years** old to **60 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

Actual sample size reached: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants divide into two groups randomly. Randomization will be carried out by means of a random number table; for this, an independent coordinator creates the randomization list assigning participants to the high protein diet group or standard protein diet 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 Ahvaz university of medical sciences

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Ethics Committee

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2017-03-13, 1395/12/23

**Ethics committee reference number**

IR.AJUMS.REC.1395.55

**Health conditions studied****1****Description of health condition studied**

normal weight obesity

**ICD-10 code**

E66.8

**ICD-10 code description**

Other obesity

**Primary outcomes****1****Description**

weight

**Timepoint**

6 months

**Method of measurement**

mechanical scale

**2****Description**

Fat body mass

**Timepoint**

Before and after intervention

**Method of measurement**

BIA machine

**3****Description**

Lean body mass

**Timepoint**

Before and after intervention

**Method of measurement**

BIA machine

**Secondary outcomes****1****Description**

appetite score

**Timepoint**

before and after intervention

**Method of measurement**

Visual analogue scale questionnaire

## Intervention groups

### 1

#### Description

Intervention group: high protein diet [high protein (HP); protein amount of 1.2 grams per kilogram body weight (gr/kg)]

#### Category

Lifestyle

### 2

#### Description

Control group: standard protein diet high protein diet [standard protein (SP); protein amount of 0.8 grams per kilogram body weight (gr/kg)]

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Obesity clinic

##### Full name of responsible person

Meysam Alipour

##### Street address

Golestan hospital

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

3311861357

##### Phone

+98 61 3374 1047

##### Email

Golestanhospital@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Badavi

##### Street address

Vice chancellor for research, Ahvaz Jundishapur University of Medical Science, Ahvaz, Khuzestan

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##### Province

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##### Postal code

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##### Phone

+98 61 3336 2414

#### Email

itc@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz University of Medical Sciences

#### 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Neda Haghghat

##### Position

Ph.D of Nutrition Science

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

Dept of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz, Khuzestan

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## Person responsible for scientific inquiries

#### Contact

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Ahvaz University of Medical Sciences

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PhD in nutrition

##### Latest degree

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Neda Haghighat

**Position**

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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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable