

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of high protein snack replacement by low protein snack in regulating dietary intake, appetite, body composition and anthropometric indices of normal weight obese female

Protocol summary

Study aim

The aim of the present study is to compare the effect of high protein to low protein snack meals on appetite, anthropometry indices, body composition and dietary intake in normal weight obese women.

Design

A randomized, double-blinded clinical trial with a parallel group design of 120 participants, enrolled between October 2018 and September 2019, and followed for 6 months

Settings and conduct

The participants who met the inclusion and exclusion criteria were randomly assigned to either the high protein content snacks or low protein content snacks group, using a convenience allocation. The participants and researchers were unaware of the allocation of the two meal plan.

Participants/Inclusion and exclusion criteria

healthy, none-menopause female, having a body mass index (BMI) <25 and >18.5, body fat > 30 %

Intervention groups

high protein snack group: an instruction with a high protein content snacks (50 grams of soybeans) low protein content snacks: an instruction with a low protein content snacks (fruits from the exchange list)

Main outcome variables

Body weight percentage of body fat Fat mass Lean mass Waist circumference waist to hip ratio (WC/hip) appetite dietary intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170412033393N3**
Registration date: **2019-10-31, 1398/08/09**

Registration timing: **retrospective**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

Neda Haghighat

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-21, 1397/06/30

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-10-22, 1397/07/30

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2019-03-18, 1397/12/27

Scientific title

The effect of high protein snack replacement by low protein snack in regulating dietary intake, appetite, body composition and anthropometric indices of normal weight obese female

Public title

The effect of high protein snack replacement by low protein snack in nutritional status of normal weight obese female

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

healthy, none-menopause female body fat > 30 % aged between 20 to 60 years having a BMI (in kg/m²) <25 and >18.5

Exclusion criteria:

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Actual sample size reached: **112**

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 snack group or low protein snack group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants were unaware of the allocation of the two meal plan. The researchers were not aware of the type of meal plans and they delivered the instruction in sealed envelopes to participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.SUMS.REC.1398.776

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

before and 6 months after intervention

Method of measurement

mechanical scale

2

Description

Fat body mass

Timepoint

before and 6 months after intervention

Method of measurement

BIA machine

3

Description

lean body mass

Timepoint

before and 6 months after intervention

Method of measurement

BIA machine

4

Description

calorie intake

Timepoint

before and 6 months after intervention

Method of measurement

24-hour dietary recall questionnaire

Secondary outcomes

1

Description

appetite score

Timepoint

before and after 6 months intervention

Method of measurement

Visual analogue scale questionnaire

Intervention groups

1

Description

Intervention group: high protein snack group; an instruction with a high protein content snacks (50 grams of soybeans)

Category

Prevention

2

Description

Control group: low protein content snacks; an instruction with a low protein content snacks (fruits from the exchange list)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Neda Haghighat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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Central buliding of Shiraz University of Medical

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

neda Haghighat

Position

Ph.D of Nutrition Science

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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)**

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