

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of a low-calorie, high-protein diet on anthropometric measurements, body composition, and sleep quantity and quality in obese individuals; a randomized clinical trial

Protocol summary

Study aim

Determining the effects of low-calorie, high-protein diet on anthropometric measurements, body composition, amount and quality of sleep in obese people.

Design

A clinical trial with a control group, with a randomized parallel group, 30 people are given a diet in each group. The SEALDEVENLOPE standard website was used for randomization and blocking.

Settings and conduct

The present study is an open-label randomized clinical trial (RCT) with the target population of adults and diagnosed with obesity (BMI>29.9, confirmed by a nutritionist) of the city. Mashhad, who went to the nutrition clinic of Qaim Hospital to receive a diet and the presence of low sleep quality was confirmed by a sleep medicine specialist.

Participants/Inclusion and exclusion criteria

Study inclusion Body mass index higher than 29.9 kg/m²
Disturbed sleep quality by PSQI questionnaire with a higher score equal to 6 and stop bang higher equal to 3
Non-entry Having underlying diseases such as: heart diseases, low blood pressure, diabetes, cancer, autoimmune diseases
Overweight people

Intervention groups

In the intervention group, caloric restriction was applied and the protein percentage was increased to achieve the mentioned goals, and to obtain 60% of the required proteins, HBV high protein and 40% of vegetable proteins will be used.

Main outcome variables

Based on the studies, we know that weight loss improves the quality of sleep and improves the indices related to it, but the lack of a study that has the right sample size, the right distribution of the sample in two groups, the minimal effect of confounders to investigate the effect
The ratio of protein in the diet is important, especially

with accurate tools for its evaluation, such as polysomnography, especially in the environment of Iranian society.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056371N1**

Registration date: **2022-11-08, 1401/08/17**

Registration timing: **prospective**

Last update: **2022-11-08, 1401/08/17**

Update count: **0**

Registration date

2022-11-08, 1401/08/17

Registrant information

Name

Fatemeh Sadat Hashemi Javaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3608 2257

Email address

fatemeh.hjavaheri76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a low-calorie, high-protein diet on anthropometric measurements, body composition, and sleep quantity and quality in obese individuals; a randomized clinical trial

Public title

effect of high protein diet on sleep quality in obese people

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults 18-65 years old At least in the last 3 months, they have not been subjected to any nutrition and diet intervention. Do not have unwanted weight loss. Do not be treated with any nutritional supplements or herbal medicine. Disturbed sleep quality by PSQI questionnaire with a higher score equal to 6 and stop bang higher equal to 3 Body mass index (BMI) more than 29.9 kg/m2

Exclusion criteria:

Having underlying diseases such as: heart diseases, low blood pressure, diabetes, cancer, autoimmune diseases Overweight people pregnant women Lactating women Having psychological diseases or disorders in the mental health screening questionnaire

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent and checking the enter criteria, we will divided study population, randomly, by using the block classification method, based on the body mass index (30-35 and more than 35), age (18 up to 45 years and more than 45 years), and gender (male and female) into two groups: intervention and control groups through the closed-door envelope method. All the steps of randomization and blocking will be done by the dedicated standard website of SEALDEVENLOPE by one of the collaborators of the project who is not involved in the implementation process of the clinical phase of the study. Through the analytic calculation, the target sample size for each group should be 30 people. 5 individuals whose poor quality of sleep has been determined by a sleep medicine specialist and also, have the indication and compliance for further investigation of sleep apnea through polysomnography, will be randomly selected. Those people, should sleep two nights (8 hours

on each night) on days 0 and 90 of study, in Imam Reza Hospital in the department of sleep disorders for further investigations.

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 Tabriz University of Medical Sciences

Street address

No. 105.2, Jalal Al Ahmad 26, Vakil Abad blvd, Mashhad, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

9165617178

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.TBZMED.REC.1401.688

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

Obesity- Sleep disorders

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

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

Comparing the effects of diets on sleep quality in obese people, the primary outcome can be "quality score and sleep apnea in Saint Petersburg and Stop Bang questionnaires and polysomnography test report"

Timepoint

Investigating the quality of sleep before the intervention and 90 days after the intervention

Method of measurement

St.Petersburg questionnaire, stop bang and polysomnography test

2

Description

Comparing the effects of diets on anthropometric measurements, body composition

Timepoint

Body composition measurement (before the intervention), 15, 30, 60 and 90 days after following the diet

Method of measurement

Body analysis device Tanita MC780

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People in both control and intervention groups are given a diet with required calories and with a calorie deficit equivalent to 750 kcal. People in both the control and intervention groups are given a diet with required calories and with a calorie deficit equal to 750 kcal, with the difference that the diet in the intervention group is a diet with an increased protein ratio (30% protein). The intervention is limited Applied calories and increased protein percentage to achieve the mentioned goals and to obtain 60% of the needed proteins, HBV high protein and 40% of vegetable proteins will be used. The composition of the participants' diet, including micronutrients and macronutrients, is confirmed by N4 software in order to match the designed diet with food intake standards.

Category

Treatment - Other

2

Description

Control group: People in both control and intervention groups are given a diet with required calories and with a calorie deficit equivalent to 750 kcal. Diet in the control group is prescribed with a standard protein percentage based on table food (12% protein).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital, Mashhad

Full name of responsible person

Fatemeh Sadat Hashemi Javaheri

Street address

No. 105.2, Jalal Al Ahmad 26, Vakil Abad blvd, Mashhad, Iran

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fatemeh.hjavaheri76@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

دکتر پرویز شهابی

Street address

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Hashemi Javaheri

Position

Master's student in clinical nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Hashemi Javaheri

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

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Still undecided - no release schedule yet

When the data will become available and for how long

Still undecided - no release schedule yet

To whom data/document is available

Still undecided - no release schedule yet

Under which criteria data/document could be used

Still undecided - no release schedule yet

From where data/document is obtainable

Still undecided - no release schedule yet

What processes are involved for a request to access data/document

Still undecided - no release schedule yet

Comments