

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Modified Intermittent Fasting Diet and Daily Calorie Restriction Diet on sleep quality and anthropometric indices of obese and/or overweight adult women 18 to 50 years

Protocol summary

Study aim

Comparison of the effect of modified intermittent fasting diet and daily calorie restriction diet on sleep quality and anthropometric indices of obese or overweight adult women 18 to 50 years

Design

This is a randomized, controlled, parallel-group trial. Participants will be stratified using stratified randomization based on age and BMI. Then using the random numbers table are assigned to one of the two groups intervention and control. Because it is a diet intervention, it is not blinding. The trial phase is not applicable.

Settings and conduct

Participants are selected from the Health Centers of Kashan University of Medical Sciences by convenient sampling. Participants are randomly assigned into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women in the age range of 18 to 50 years and body mass index greater than or equal to 25 and less than 40. Exclusion criteria: pregnancy, lactation, chronic diseases such as hypertension, heart disease, diabetes, gastrointestinal disorders such as gastritis, gastric and duodenal ulcers, Smoking habits, alcoholism, weight loss of 1 to 2 kg in the past month, following a special diet or taking certain medications, taking dietary supplements, having a mental disorder

Intervention groups

Intervention: The energy requirements for the individuals calculate using the Mifflin equation. It involves alternating periods of feeding and fasting, on an every-other-day basis. Fasting day only comprises 25% of the recommended calorie intake. On feeding days, the participants are provided foods at 100% of calculated daily energy requirements. control: The energy requirements for the individuals calculate using the

Mifflin equation. subjects consume 63% of their energy requirement each day.

Main outcome variables

The sleep quality, daytime sleepiness, insomnia, BMI, FFM, and the body fat mass

General information

Reason for update

Due to the delay in the recruitment dates, we request to change the expected recruitment start date.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220522054958N3**

Registration date: **2022-07-08, 1401/04/17**

Registration timing: **prospective**

Last update: **2023-02-16, 1401/11/27**

Update count: **4**

Registration date

2022-07-08, 1401/04/17

Registrant information

Name

Saeedeh Hosseini hooshir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 9024

Email address

shoseinih3322@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-01, 1401/06/10

Expected recruitment end date

2022-12-30, 1401/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Modified Intermittent Fasting Diet and Daily Calorie Restriction Diet on sleep quality and anthropometric indices of obese and/or overweight adult women 18 to 50 years

Public title

The effect of Modified Intermittent Fasting Diet on sleep quality and anthropometric indices of obese and/or overweight adult women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

women in the age range of 18 to 50 years BMI more than or equal to 25 and less than 40

Exclusion criteria:

pregnancy breastfeeding Chronic diseases such as high blood pressure, heart disease, diabetes, gastrointestinal disorders such as gastritis, peptic ulcer and duodenal ulcer the habit of smoking alcohol abuse weight loss of 1 to 2 kg in the past month following a specific diet or taking a specific medication taking dietary supplements Having mental disorders Having overnight shifts

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects are selected by a convenient sampling method. Then, participants are divided into groups of control and intervention by simple randomization and using the random numbers table. The randomization method is that at the beginning, it is agreed to give the intervention group the odd number and the control group the even number. Therefore, participants are assigned to the control or intervention group depending on whether we reach the odd or even number in the random numbers table. Randomization is individual.

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**

Faculty of Medicine and Dentistry - Kashan University of Medical Sciences (Research Ethics Committee)

Street address

5 km Qutb Ravandi Boulevard, Kashan University of Medical Sciences, Vice Chancellor for Research

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2022-04-17, 1401/01/28

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.002

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

overweight

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Obesity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Sleep quality

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality questionnaire

2**Description**

daytime sleepiness

Timepoint

The beginning and end of the study

Method of measurement

Epworth Sleepiness questionnaire

3**Description**

Insomnia

Timepoint

The beginning and end of the study

Method of measurement

Insomnia Severity questionnaire

4**Description**

BMI

Timepoint

The beginning and end of the study

Method of measurement

Height: stadiometer, Weight: scale

5**Description**

Free fat mass FM and the body fat mass

Timepoint

The beginning and end of the study

Method of measurement

Inbody Device

6**Description**

The body fat mass

Timepoint

The beginning and end of the study

Method of measurement

Inbody Device

7**Description**

waist circumference

Timepoint

The beginning and end of the study

Method of measurement

non-stretchable measuring tape

8**Description**

The waist-to-hip ratio

Timepoint

The beginning and end of the study

Method of measurement

by dividing the waist circumference by the hip circumference

9**Description**

weight

Timepoint

The beginning and end of the study

Method of measurement

scales

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

The hip circumference

Timepoint

The beginning and end of the study

Method of measurement

non-stretchable measuring tape

2**Description**

visceral fat area

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

3**Description**

The percent body fat

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

4**Description**

The soft lean mass

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

5**Description**

The skeletal muscle mass

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

6**Description**

the extracellular water ratio

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

7**Description**

The total body water

Timepoint

The beginning and end of the study

Method of measurement

Inbody device

8**Description**

Subjective sleep quality (SSQ)

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

9**Description**

Sleep latency

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

10**Description**

Sleep duration

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

11**Description**

Habitual sleep efficiency

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

12**Description**

Sleep disturbances

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

13**Description**

use of sleeping medication

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

14**Description**

daytime dysfunction

Timepoint

The beginning and end of the study

Method of measurement

Pittsburgh Sleep Quality Index (PSQI) questionnaire

Intervention groups**1****Description**

Intervention group: The energy requirements for the individuals calculate using the Mifflin equation. Then, alternately, one day 25% of the energy and the next day 100% of the required energy is provided. On fasting days, one can get 25% of the daily calories needed from 12 noon to 2 pm. This diet is followed for 8 weeks.

Category

Prevention

2**Description**

Control group: The energy requirements for the individuals calculate using the Mifflin equation. subjects consume 63% of their energy requirement each day. This diet is followed for 8 weeks.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kashan Health Centers

Full name of responsible person

Saeede Hoseini

Street address

5th of Qotb -e Ravandi Blvd.

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 21 5544 7275

Fax

+98 21 5544 2061

Email

darman@at_kaums.ac.ir

Web page address

<http://contact.kaums.ac.ir/Default.aspx?PageID=161&Action=ViewReport&ReportID=28>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

5th of Qotb -e Ravandi Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 1112

Fax

+98 31 5554 1112

Email

banafshe57@hotmail.com

Web page address<http://en.kaums.ac.ir/Default.aspx?PageID=199>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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

Email

shoseinih3322@gmail.com

Web page address<http://en.kaums.ac.ir/Default.aspx?PageID=199>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Saeede Hoseini

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

5th of Qotb -e Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 1112

Fax

+98 31 5554 1112

Email

shoseinih3322@gmail.com

Web page address<http://en.kaums.ac.ir/Default.aspx?PageID=199>**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Saeedeh Hosseini hooshir

Position

Ms

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Kashan university of medical science

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9024

Fax**Email**

shoseinih3322@gmail.com

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

Kashan University of Medical Sciences

Full name of responsible person

Saeede Hoseini

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

5th of Qotb -e Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 1112

Fax

+98 31 5554 1112

Web page address

<http://en.kaums.ac.ir/Default.aspx?PageID=199>

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The title of the data will be "the effect of Modified intermittent Fasting Diet on sleep quality and anthropometric indices ". All data can be shared after

making participants anonymous.

When the data will become available and for how long

Six months after publishing results, everything will be accessible.

To whom data/document is available

The data from this research will be accessible only to health researchers and those who are working in academic and scientific institutions

Under which criteria data/document could be used

With respect to ethical considerations, the data from this research can be used for other research purposes. It is also possible to conduct any statistical analyses. All these processes require correspondence and coordination.

From where data/document is obtainable

All applicants can contact Dr. Sadegh Jafarnejad through e-mail drsadegh2008@gmail.com

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

Within 10 working days after correspondence or a phone call, your request will be answered and the data will be sent to a valid email submitted by the applicant.

Comments