# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 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**

omparison 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 hooshiar

**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**
Isfehan
**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**
K ashan
**Province**
Isfehan
**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**
Isfehan
**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

## 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
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**Postal code**
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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**
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**Street address**
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**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 hooshiar
**Position**
Ms
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nutrition
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Kashan university of medical science
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Kashan
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**Fax**
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shoseinih3322@gmail.com

**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**