Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Assessing the Impact of Modified Intermittent Fasting and Daily Calorie Restriction on Appetite, Food Cravings, and Eating Habits of Overweight and Obese Women Aged 18 to 50 Years

Protocol summary

Study aim

To determine the effect of Modified Intermittent Fasting on Appetite, Food Craving and Eating Behavior of adult obese and/or overweight women aged 18 to 50 years old

Design

A randomized, controlled clinical trial has been designed with two parallel groups of 54 patients. Individuals will be recruited utilizing a simple random sampling technique. Then, they are assigned to control (daily calorie restriction diet) and intervention (fasting diet) groups by simple randomization method and using a table of random numbers. Because there is diet intervention, blinding and the trial phase are not applicable.

Settings and conduct

54 obese or overweight women will be selected by a simple random sampling technique based on the inclusion and exclusion criteria of the study from Kashan health centers. Individuals are randomly assigned to one of the two groups of control and intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women in the age range of 18 to 50 years and their body mass index is more than or equal to 25 and less than 40 exclusion criteria: Pregnancy, Breastfeeding, chronic diseases such as high blood pressure, heart disease, diabetes, and gastrointestinal disorders , the habit of smoking, alcohol abuse, recent weight loss of at least 1 kg within the past three months, following a specific diet or taking a specific medication, taking dietary supplements.

Intervention groups

The intervention group: After calculating the daily energy requirement of a person, 25% of the energy is alternately provided one day and 100% of the required energy the next day and follows this diet for 8 weeks. The control group: After calculating the daily energy requirement of a person, 63% of the total energy requirement is provided each day and follows this diet for 8 weeks.

Main outcome variables

Appetite index, Food Craving, Eating Behavior

General information

Reason for update

Due to problems encountered during sampling and conducting the study, we are requesting changes to some parts of the protocol. Because the patient recruitment has not yet begun, we are requesting a change in the recruitment dates. We also request changes to a number of variables and sample size due to further review of past studies.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220522054958N2**
Registration date: **2022-05-30, 1401/03/09**
Registration timing: **prospective**

Last update: **2025-03-16, 1403/12/26**
Update count: **4**

Registration date

2022-05-30, 1401/03/09

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
2025-04-30, 1404/02/10
Expected recruitment end date
2025-08-30, 1404/06/08
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the Impact of Modified Intermittent Fasting and Daily Calorie Restriction on Appetite, Food Cravings, and Eating Habits of Overweight and Obese Women Aged 18 to 50 Years

Public title
Comparison the effect of Modified Intermittent Fasting and Daily Calorie Restriction on Appetite, Food Craving and Eating Behavior
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women in the age range of 18 to 50 years Their body mass index is between 25 and 40.
Exclusion criteria:
Pregnancy Breastfeeding The presence of chronic metabolic conditions like diabetes The existence of cardiovascular disorders such as coronary heart disease and hypertension Gastrointestinal disorders Recent weight loss of at least 1 kg within the past three months Smoking or alcohol abuse Adherence to a specific diet or use of specific medications that may interfere with the trial process The presence of mental or psychological disorders Calorie intake that fall below 80% or exceed 110% of the recommended caloric intake Experiencing severe emotional distress throughout the course of the study Participant unwillingness to continue cooperation or non-adherence to the prescribed diet
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: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be recruited from the Health Centers affiliated with Kashan University of Medical Sciences, utilizing a Simple Random Sampling method that adheres to the predefined inclusion and exclusion criteria. Then, participants are divided into control and intervention groups by simple randomization and using the table of random numbers. 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 table of random numbers.
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 Kashan University of Medical Sciences
Street address
5 km Ghotbravandi Blvd, Kashan
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
obese, overweight
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Appetite index
Timepoint
Beginning and end of the study
Method of measurement
Visual Analog Scale

2

Description
Food Craving

Timepoint
Beginning and end of the study
Method of measurement
Food Craving Questionnaire

3

Description
Duch Eating Behavior questionnaire
Timepoint
Beginning and end of the study
Method of measurement
Eating Behavior questionnaire

4

Description
BMI
Timepoint
Beginning and end of the study
Method of measurement
Height: Stadiometer and weight: scales

5

Description
percentage of body fat
Timepoint
Beginning and end of the study
Method of measurement
Inbody device

6

Description
Skeletal muscle mass
Timepoint
Beginning and end of the study
Method of measurement
Inbody device

7

Description
waist-to-hip circumference ratio
Timepoint
Beginning and end of the study
Method of measurement
Inbody device

Secondary outcomes

1

Description
Waist circumference
Timepoint
Beginning and end of the study
Method of measurement
a non-stretchable measuring tape

Intervention groups

1

Description
The intervention group: For calculating the energy requirement, first, the amount of basal metabolic rate is calculated using the Mifflin and then by applying the level of physical activity and the thermic effect of food, the total energy requirement is calculated. 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
The control group: For calculating the energy requirement, first, the amount of basal metabolic rate is calculated using the Mifflin and then by applying the level of physical activity and the thermic effect of food, the total energy requirement is calculated. Then 63% of the calculated energy is provided daily. This diet is followed for 8 weeks.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Health Center of Kashan
Full name of responsible person
Saeedeh Hosseini Hooshiar
Street address
Niloufar 4th Street, Phase 2, Najiabad Town
City
Kashan
Province
Isfehan
Postal code
8715973474
Phone
+98 31 5544 3022
Fax
Email
health_at_kaums@gmail.com
Web page address
http://kaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr. Hamidreza Banafsheh
Street address
5 km Qotb –e Ravandi Blvd., Kashan
City
kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5554 2999
Email
banafshe57@hotmail.com
Web page address
http://en.kaums.ac.ir

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
Saeedeh Hosseini Hooshiar
Position
MS
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Qutb Ravandi Boulevard, Kashan
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Saeedeh Hosseini Hooshiar
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
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Web page address
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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
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Email
shoseinih3322@gmail.com
Web page address
http://kaums.ac.ir/

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 on Appetite, Food Craving and Eating Behavior ''. 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