

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Fasting and Ketogenic Diet Compared to Balanced Low-Calorie Diet on Weight among Obese Individuals with Eating Disorders: A Randomized Clinical Trial

Protocol summary

Study aim

Investigating the effect of two types of fasting diet, ketogenic and standard diet on anthropometric indicators, body composition, brain-derived neurotrophic factor (BDNF) and serotonin levels in obese people with eating disorders

Design

Allocation to 3 study groups is done randomly The study is of parallel type And the sample size is 75 people Blinding is not possible due to the type of intervention, which is a treatment regimen

Settings and conduct

Sampling will be done in Tehran and will be selected from among the patients referred to the obesity center of Hazrat Fatemeh Al-Zahra Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Body mass index between 30 and 39.9 kg/m² Willingness to participate in the study Being in the age range of 20-60 years Non-entry criteria: Suffering from any disease such as cancer, diagnosed diabetes, hypothyroidism, kidney or liver failure. Having a weight loss diet in the last 2 months Pregnancy and breastfeeding Menopause smoking Taking vitamin and mineral supplements Continuous use of any type of medicine Use of any type of antibiotic in the last three months Using probiotic products (probiotic supplement, yogurt and probiotic cheese) continuously (more than once a week) in the last month Use of weight loss and appetite suppressants Having a sports activity that has been more than 3 weeks since its start.

Intervention groups

Recipient of a balanced low-calorie diet Low calorie ketogenic diet recipient Recipient of low-calorie fasting diet

Main outcome variables

Weight BDNF serum level Serotonin serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240629062275N1**

Registration date: **2024-07-21, 1403/04/31**

Registration timing: **prospective**

Last update: **2024-07-21, 1403/04/31**

Update count: **0**

Registration date

2024-07-21, 1403/04/31

Registrant information

Name

maryam mohamadinarab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4416 2494

Email address

maryam.mohamadi.narab@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2025-10-02, 1404/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Fasting and Ketogenic Diet Compared to Balanced Low-Calorie Diet on Weight among Obese Individuals with Eating Disorders: A Randomized Clinical Trial

Public title
Effect of Different Types of Diet on Weight among Obese Individuals with Eating Disorders

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index between 30 and 39.9 kg/m2
Willingness to participate in the study Being in the age range of 20-60 years
Exclusion criteria:
Suffering from any Disease such as Cancer, Diabetes, Hypothyroidism, Kidney Failure or Liver Failure Having a weight loss diet in the last 2 months Pregnancy and breastfeeding Menopause Smoking Taking vitamin and mineral supplements Continuous use of any type of medicine Use of any type of antibiotic in the last three months Using probiotic products continuously (more than once a week) in the last month Use of weight loss and appetite suppressants Having a sports activity that has been more than 3 weeks since its start

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Stratified Blocked Randomization is used to randomly assign people to three groups.

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 Mashhad University of Medical

Science
Street address
Department of Nutrition, Faculty of Medicine, Ferdowsi University Campus, Azadi Square, Mashhad, Razavi Khorasan
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2024-01-02, 1402/10/12
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.480

Health conditions studied

1

Description of health condition studied
A broad group of psychological disorders with abnormal eating behaviors leading to physiological effects from overeating or insufficient food intake.
ICD-10 code
F50
ICD-10 code description
Eating disorders

Primary outcomes

1

Description
weight
Timepoint
The beginning and end of the study
Method of measurement
Using a scale

Secondary outcomes

1

Description
Serum level of BDNF, serotonin
Timepoint
The beginning and end of the study
Method of measurement
Using a blood test

Intervention groups

1

Description
Intervention group 1: Participants who Received Fasting Diet
Category
Lifestyle

2

Description

Intervention group 2: Participants who Received Ketogenic Diet

Category

Lifestyle

3

Description

Control group: Participants who Received Balanced Low-Calorie Diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatima Al-Zahra Hospital

Full name of responsible person

Somaye Mokhber

Street address

yousef Abad

City

Tehran

Province

Tehran

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1433933111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Safarian

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Department of Nutrition, Faculty of Medicine,
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mjms@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Safarian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data used in statistical analysis will be published without names of individuals

When the data will become available and for how long

Access will start from 2025

To whom data/document is available

All interested people

Under which criteria data/document could be used

Theses and articles are published in the form of files and printed copies

From where data/document is obtainable

Library of Mashhad University of Medical Sciences The site of the magazine where the article is published

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

After publishing the data in the appendix of the thesis and also the published articles, it will be accessible by applying to the university or visiting the journal website or even emailing the author responsible for the data.

Comments