

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of time-restricted eating (TRE) or modified alternate day fasting (MADF) diet in comparison with calorie-restricted balanced diet on metabolic and hormonal indices in overweight/obese women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the effect of time-restricted diet (TRE) and modified intermittent fasting (MADF) diet compared to a balanced diet with calorie restriction on metabolic and hormonal indicators in overweight and obese women with polycystic ovary syndrome

Design

Randomized controlled clinical trial, with parallel groups

Settings and conduct

In this 14-week clinical trial, 216 obese and overweight women referred to the Nutrition and Diet Therapy Clinic of Imam Reza Hospital with a diagnosis of polycystic ovary syndrome will be included in the study using a convenience sampling method and randomly assigned to three groups with an allocation ratio of 1:1:1. This will be done using opaque sealed envelopes to conceal the allocation process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Body mass index of 25 kg/m² and above
Diagnosis of polycystic ovary syndrome by a gynecologist
Age of 18 to 40 years
Exclusion criteria: Pregnancy and breastfeeding
Menopause
Use of dietary supplements, diuretics, or laxatives during the intervention period
Participation in sports programs or changes in physical activity
Use of weight-affecting medications

Intervention groups

Time-restricted eating group: Participants are instructed to consume their diet ad libitum over 8 hours, and they are allowed to consume only calorie-free foods, non-starchy vegetables, and sugar-free gum from 7 p.m. to 11 a.m.
Modified intermittent fasting diet group: Participants are asked to consume a very low-calorie diet for 3 days and can eat ad libitum on the remaining days.
Control group: Participants consume their energy intake (500 kcal less than resting energy) according to a

traditional substitution-based meal-list pattern, with breakfast, lunch, dinner, and two snacks.

Main outcome variables

Anthropometric indices and body composition analysis, hormonal indices, and glucose metabolism indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N14**

Registration date: **2025-06-14, 1404/03/24**

Registration timing: **prospective**

Last update: **2025-06-14, 1404/03/24**

Update count: **0**

Registration date

2025-06-14, 1404/03/24

Registrant information

Name

Neda Dolatkhan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-07-21, 1404/04/30

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of time-restricted eating (TRE) or modified alternate day fasting (MADF) diet in comparison with calorie-restricted balanced diet on metabolic and hormonal indices in overweight/obese women with polycystic ovary syndrome

Public title

Time-restricted eating (TRE) or modified alternate day fasting (MADF) diet in polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index of 25 kg/m² and above Diagnosis of polycystic ovary syndrome by a gynecologist Age between 18 to 40 years

Exclusion criteria:

Pregnancy and breastfeeding Menopause Daily calorie intake of less than 800 and more than 4200 kcal Use of dietary supplements, diuretics, or laxatives during the intervention period Participation in sports programs or changes in physical activity Use of weight-affecting medications A deviation from a specific eating pattern due to medical or other reasons

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **216**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use a stratified block randomization method for allocation. The computer-generated code generated using SAS software version 8.01 will be used to create a randomized sequence by a statistician outside the project's research team. Randomization will be stratified based on age and body mass index. Serially numbered opaque sealed packets will be used to ensure allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding the patients is not feasible in this trial. A trained

nutritionist will ban diet-related conversations between assessors and patients during the study. Outcome assessors and the person responsible for statistical analysis will be blinded to the type of interventions received until the end of the study

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

Vice Chancellor for Research and Technology, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5456787654

Approval date

2025-05-24, 1404/03/03

Ethics committee reference number

IR.TBZMED.REC.1404.218

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

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

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

Free androgen index (FAI)

Timepoint

Measurement of Free androgen index (FAI) at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

It is calculated by dividing the numerical value of serum

free testosterone by the value of sex hormone-binding globulin.

Secondary outcomes

1

Description

Weight

Timepoint

Weight measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Seca digital scale

2

Description

Body fat mass

Timepoint

Body fat mass measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Body analyzer

3

Description

Prolactin levels

Timepoint

Prolactin level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

4

Description

Total testosterone level

Timepoint

Total testosterone level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

5

Description

luteinizing hormone level

Timepoint

luteinizing hormone level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

6

Description

Follicle-stimulating hormone level

Timepoint

Follicle-stimulating hormone level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

7

Description

Sex hormone-binding globulin level

Timepoint

Sex hormone-binding globulin level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

8

Description

Serum indicators of glucose metabolism

Timepoint

Serum indicators of glucose metabolism measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

9

Description

Progesterone levels

Timepoint

Progesterone level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

10

Description

Estrogen levels

Timepoint

Estrogen level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the intervention

Method of measurement

Biochemical analysis

11

Description

Dehydroepiandrosterone sulfate level

Timepoint

Dehydroepiandrosterone sulfate level measurement at the beginning of the study (before the start of the intervention) and 14 weeks after the start of the

intervention
Method of measurement
Biochemical analysis

Intervention groups

1

Description

Time-restricted eating group: Participants are instructed to consume their diet ad libitum over 8 hours, and they are allowed to consume only calorie-free foods, non-starchy vegetables, and sugar-free gum from 7 p.m. to 11 a.m.

Category

Treatment - Other

2

Description

Modified intermittent fasting diet group: Participants are asked to consume a very low-calorie diet for 3 days and can eat ad libitum on the remaining days.

Category

Treatment - Other

3

Description

Control group: Participants consume their energy intake (500 kcal less than resting energy) according to a traditional substitution-based meal-list pattern, with breakfast, lunch, dinner, and two snacks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational and Medical Center

Full name of responsible person

Neda Dolatkah

Street address

Imam Reza Educational and Medical Center, opposite the Central Organization of the University, Golgasht Street

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

75863

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

Neda Dolatkah

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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