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 Dolatkhah

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 tp 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 Dolatkhah

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

Name of organization / entity

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Full name of responsible person

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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 Dolatkhah

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