Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Investigating the effect of two types of time restricted eating on glycemic, lipid indices, appetite, and sleep quality of women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the effect of two types of time restricted eating on glycemic, lipid indices, appetite, and sleep quality of women with polycystic ovary

Design

The parallel randomized controlled clinical trial without blinding will be performed on 75 patients for 6 weeks, in which sufficient information about the objectives of the study and the type of intervention will be explained to all those who qualify for the study. Individuals enter 3 groups of study using the Block Randomization program and randomly allocated.

Settings and conduct

Patients are randomly selected from among those who refer to Kosar Women's Hospital in Urmia. At the beginning and end of the study, the main outcome variables are measured and compared to determine the impact of the intervention.

Participants/Inclusion and exclusion criteria

Age 18 - 40 years; 25 ≤ body mass index(BMI) ≤ 34.9; PCOS diagnosed by the Rotterdam criteria. Exclusion criteria: pregnant or lactating; night-shift workers; hypotension; use of medication therapy that impacts carbohydrate or lipid metabolism in the recent 3 months; body weight fluctuations for more than 5% in the past 3 months; Taking drugs that affect appetite; fasting for more than 14 h per day; Other chronic diseases.

Intervention groups

In the intervention groups will have a time-restricted diet of the type (14:10), in which the individuals of the early time restricted eating (eTRE) group will eat from 8:00 to 18:00 and the group Mid-day time restricted eating (mTRE) are placed in a state of free consumption of food from 11:00 to 21:00. These individuals are in a fasting state for 14 hours and are only allowed to receive water and tea without sweets. In the control group, individuals will continue the usual diet and there will be no time limit.

Main outcome variables

Blood glycemic index; lipid profile; weight; appetite; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221122056575N1**
Registration date: **2022-12-24, 1401/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-24, 1401/10/03**
Update count: **0**

Registration date

2022-12-24, 1401/10/03

Registrant information

Name

Maryam Aminian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 0153

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aminian.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-10, 1401/08/19

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of two types of time restricted eating on glycemic, lipid indices, appetite, and sleep quality of women with polycystic ovary syndrome

Public title

Investigating the effect of two types of time restricted eating on glycemic, lipid indices, appetite, and sleep quality of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 - 40 years 25 ≤ body mass index(BMI) ≤ 34.9 Women with PCOS diagnosed by the Rotterdam criteria

Exclusion criteria:

pregnant or lactating night-shift workers, hypotension use of medication therapy that impacts carbohydrate or lipid metabolism (oral contraceptive pills, insulin-sensitizers, antiepileptics, statins, fish oil and ...) in the recent 3 months body weight fluctuations for more than 5% in the past 3 months Medicines that affect body weight Regular use of any drug or supplement that affects sleep Taking drugs that affect appetite at the time of entering the study Having a special diet Eating disorders or mental disorders night eating syndrome fasting for more than 14 h per day Congenital adrenal hyperplasia, androgen-secreting tumor, Cushing's syndrome, diabetes, thyroid dysfunction and hyperprolactinemia Cardiovascular, kidney, liver, lung and nervous diseases, digestive system surgery or food absorption disorders professional athlete perimenopausal Tobacco history Taking food supplements Sarcopenia

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is used to equalize the sample size in the group step by step and in intervals called defined blocks, because in the simple randomization method, when the sample size is small, the sample is not balanced in the study arms. For this purpose, the online software for this type of randomization was used in the following link: https://www.sealedenvelope.com/simple-randomiser/v1/lists In this multimeter online software, including a total sample of 75 people, the number of groups (the names of the groups with capital letters A, B, C) and the number of blocks (the number of 3 blocks in the sizes of 3 and 6) were defined. Finally, by running the program, it gave us a random output list in which the sequence of people entering the study is shown. Because in the present study, the samples are gradually entered into the study, determining the sequence and the order of people's entry into the groups is carried out with this method, and the researcher performs the random allocation sequence of this list. In other words, each new person enters the study without research and is selected from his place in the target group, and according to this list, he places his samples in the target group.

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

Research ethics committee of Urmia University of Medical Sciences

Street address

Boostan dormitory, Zaker St, Apadana Crossroad, Urmia City, West Azarbaijan

City

Urmia

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West Azarbaijan

Postal code

5714783734

Approval date

2022-11-16, 1401/08/25

Ethics committee reference number

IR.UMSU.REC.1401.318

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
Fasting Blood Sugar
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

2

Description
Fasting Insulin
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

3

Description
Insulin resistance
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Calculation of Homeostatic Model Assessment (HOMA)

4

Description
Total cholesterol
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

5

Description
Triglyceride
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

6

Description
High-density lipoprotein (HDL)
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

7

Description
Low-density lipoprotein (LDL)
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Biochemical analysis of blood sample

8

Description
Appetite
Timepoint
beginning, middle and end of study (every two weeks)
Method of measurement
Visual Analog Scale (VAS) questionnaire

9

Description
Sleep quality
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Petersburg’s sleep quality questionnaire

10

Description
Body weight
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
scale

11

Description
Waist circumference
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Meter

12

Description
Body mass index (BMI)
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Weight in kilograms divided by height squared in meters

Secondary outcomes

1

Description
Body composition
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement
Bioelectric Impedance Analysis (BIA) device

2

Description
Eating behavior
Timepoint
At the beginning and end of the study (after 6 weeks)
Method of measurement

The Three-Factor Eating Questionnaire

3

Description
Energy intake
Timepoint
beginning, middle and end of study (every two weeks)
Method of measurement
24-hour Dietary Recall

4

Description
Carbohydrate intake
Timepoint
beginning, middle and end of study (every two weeks)
Method of measurement
24-hour Dietary Recall

5

Description
Protein intake
Timepoint
beginning, middle and end of study (every two weeks)
Method of measurement
24-hour Dietary Recall

6

Description
Fat intake
Timepoint
beginning, middle and end of study (every two weeks)
Method of measurement
24-hour Dietary Recall

Intervention groups

1

Description
Intervention group: People in the intervention groups will have a time-restricted eating of the type (14:10), in which people in the early time restricted eating (eTRE) group will be in a state of free consumption of food from 8:00 to 18:00. These people have been fasting for 14 hours and are only allowed to receive water and tea without sweets.
Category
Treatment - Other

2

Description
Intervention group: People in the intervention groups will have a time-restricted eating (14:10), in which the people in the mid-day time restricted eating (mTRE) group will eat freely from 11:00 to 21:00. Food is placed. These people have been fasting for 14 hours and are only allowed to receive water and tea without sweets.
Category
Treatment - Other

3

Description
Control group: People will continue their usual diet and there will be no time limit.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Women's Hospital
Full name of responsible person
Sevana Daneghian
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Kosar Hospital, Hasani St., Urmia,
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source

Urmia 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
Oroumia University of Medical Sciences

Full name of responsible person
Sevana Daneghian

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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to confidentiality of participant information, it is not possible to publish it

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

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable