Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aerobic training and DASH diet on insulin resistance and sex hormones in women with polycystic ovary syndrome

Protocol summary

Study aim
Determining the effect of aerobic exercise and DASH diet on insulin and Resistance to insulin and sex hormones in women with polycystic ovary syndrome

Design
A randomized controlled clinical trial on 60 patients who used a random number table for randomization.

Settings and conduct
60 women aged 20 to 40 years with polycystic ovary syndrome who are invited to participate in the study by a voluntary sports club.

Participants/Inclusion and exclusion criteria
1- Having at least two of the three criteria: a) low ovulation or no ovulation (which usually appears as algomenorrhea, amenorrhea, polymenorrhea) b) increase in circulating androgens, hirsutism and ratio LH / FSH> 2 and c) polycystic ovaries (seen on ultrasonography) 2- Being healthy based on health questionnaire 3- Do not take medicine 2- Not being older than 40 years and less than 20 years 3- No bmi less than ..... 4- Not having more bmi than ..... 5- Do not smoke 8- Do not suffer from muscle weakness related to known disorders such as stroke, cancer and cardiovascular diseases 9 - Do not use hormones and supplements as treatment 10 - Not participating in regular sports activities for at least the past year 12- Not having a separate diet outside the research program 14- Having a certificate from a doctor to perform sports exercises without hindrance

Intervention groups
Aerobic exercise (running) for 12 weeks and 3 sessions per week for 25-30 minutes and an intensity of 60-85% of maximum heart rate is observed in accordance with the principle of extra load in the gym. DASH diet pattern: DASH diet was used for 8 weeks and the DASH diet consisted of 52% carbohydrates, 18% protein, 30, is full fat. This diet includes a high proportion of fruits and vegetables and a minimum of fat and sugar. The recommended amount of sodium in this diet is less than 2400 mg per day.

Main outcome variables
Resistance to insulin and sex hormones

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211106052979N1**
Registration date: **2021-12-08, 1400/09/17**
Registration timing: **retrospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **0**

Registration date
2021-12-08, 1400/09/17

Registrant information

Name
Niusha Tajbakhsh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2276 1466

Email address
niusha.tajbakhsh.nt@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-17, 1400/07/25

Expected recruitment end date
2021-11-16, 1400/08/25

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aerobic training and DASH diet on insulin resistance and sex hormones in women with polycystic ovary syndrome

Public title

The effect of aerobic training and DASH diet on insulin resistance and sex hormones in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

with polycystic ovary syndrome Age 20 to 40 years

Exclusion criteria:

Doing regular exercise in the past year Not being healthy based on a health questionnaire

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 participants are randomly divided into 4 groups using a table of random numbers. In the present study, the restricted randomization method was used, which will be performed in a block randomization method.The size of four blocks is equal and we will have four groups of 60 blocks (including 15 people participating in each group). Randomization tool also uses software random allocation software (Random allocation software). In addition to simple randomization, these random sequence generation software are able to generate random sequences by block generation method.For concealment, we use concealment allocation, so that the assigned group is not known before the individual is assigned.Using opaque envelopes sealed with random sequences (envelopes opaque, sealed, numbered sequentially), in which each random sequence is recorded on a card. And the cards are placed in the envelopes of the letter, respectively.In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface.Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

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

Islamic Azad University, Science and Research Branch

Street address

Tehran - End of Shahid Sattari Highway - University Square - Shohada Hesarak Boulevard - Islamic Azad University, Science and Research Branch

City

tehran

Province

Tehran

Postal code

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Approval date

2021-11-02, 1400/08/11

Ethics committee reference number

ir.iau.srb.rec.1400.179

Health conditions studied

1

Description of health condition studied

insulin resistance

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2

Description of health condition studied

sex hormones

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum levels of sex hormones

Timepoint

24 hours before the intervention and 48 hours after the last session

Method of measurement

Measurement of serum LH, TSH, FSH and serum prolactin

by quantitative luminescence method

2

Description
Insulin resistance
Timepoint
24 hours before the intervention and 48 hours after the last session
Method of measurement
Insulin resistance using IR-HOMA index and based on Equation * = HOMA-IR = Fasting glucose(L / mmol)* Fasting (ml / L)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Aerobic exercise (running) for 12 weeks and 3 sessions per week for 25-30 minutes and an intensity of 60-85% of maximum heart rate with the principle of extra load in the gym
Category
Treatment - Other

2

Description
Intervention group2: use of DASH diet for 8 weeks
Category
Treatment - Other

3

Description
Intervention group3: Intervention group:Aerobic exercise (running) for 12 weeks and 3 sessions per week for 25-30 minutes and an intensity of 60-85% of maximum heart rate with the principle of extra load in the gym and use of DASH diet for 8 weeks
Category
Treatment - Other

4

Description
Control group: Do not receive intervention or treatment to eliminate insulin resistance or change sex hormones
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sport Club
Full name of responsible person
Nniusha Tajbakhsh
Street address
End of Shahid Sattari Highway - University Square - Shohada Hesarak Boulevard - Islamic Azad University, Science and Research Branch
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Mozafari@srbiau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
50
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
Islamic Azad University
Full name of responsible person
Nniusha Tajbakhsh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Sport Medicine
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Tehran - Pasdaran Crossroads - Dolat St. - Between Ekhtiarieh and Dibaji - Shahid Jafarin Abadi St. - Red Dead End Alley - Sepehr Building - Unit A51
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Person responsible for updating data

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable