

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational intervention based on PRECEDE model on Increasing physical activity among women with polycystic ovarian syndrome

Protocol summary

Study aim

The effect of the theory-based educational intervention on improving mental and objective physical activity and loss weight and BMI in women with polycystic ovary syndrome

Design

parallel controlled trial study

Settings and conduct

Mahdiah hospital in Tehran

Participants/Inclusion and exclusion criteria

inclusion: Women aged 18-40 years with polycystic ovary syndrome exclusion; Pregnancy and lactation, smokers

Intervention groups

Educational intervention and pedometer

Main outcome variables

physical activity - steps-weight-BMI

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Email address

l.sabzmakan@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2016-11-20, 1395/08/30

Actual recruitment end date

2017-02-18, 1395/11/30

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161116030923N3**

Registration date: **2018-01-24, 1396/11/04**

Registration timing: **retrospective**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

Scientific title

The effect of educational intervention based on PRECEDE model on Increasing physical activity among women with polycystic ovarian syndrome

Public title

Increasing physical activity among women with polycystic ovarian syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

women with polycystic ovarian syndrome age 18-40
Declaration of written and oral consent for participation in the study
Reading and writing at least elementary
Lack of disability and motor limitation
Not having a known mental disorder
Patients under the supervision of the physician should have physical activity, such as cardiovascular disease, advanced diabetes

Exclusion criteria:

Pregnancy and lactation
Taking hormonal medications

Use of infertility treatment methods smokers

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: **68**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

random allocation- permuted block randomization- stratified (age)-

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 Alborz University of Medical Sciences

Street address

45 metri golshahr- saffarian street- school of health-

City

karaj

Province

Alborz

Postal code

3183744439

Approval date

2016-06-12, 1395/03/23

Ethics committee reference number

Abzums.Rec.1395.23

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E35.8

ICD-10 code description

Disorders of other endocrine glands in diseases classified

elsewhere

Primary outcomes

1

Description

physical activity- steps- weight- BMI

Timepoint

Three months

Method of measurement

IPAC questionnaire- pedometer- scale- meter

Secondary outcomes

1

Description

knowledge- attitude- self efficacy- skill- social support

Timepoint

three months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh hospital

Full name of responsible person

leila sabzmakan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad norisepehr

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

25

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

Karaj University of Medical Sciences

Full name of responsible person

leila sabzmakan

Position

Assistance professor- Alborz university of medical sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Lelia sabzmakan

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

leila sabzmakan

Position

faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable