Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Mahdieh 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

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
+98 26 3355 5670
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

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- permoted 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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45 metri golshahr- saffarian street- school of health

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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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45 metri golshahr- saffarian street- school of health
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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
Assisstance professor- Alborz university of medical scinces
Latest degree
Ph.D.
Other areas of specialty/work
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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
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