

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the Effect of Education Based on Theory of Planned Behavior on Eating Behaviors In Adolescent Girls with Polycystic Ovarian Syndrome (PCOS)

Protocol summary

Study aim

Determination of the effect of education based on the theory of planned behavior on eating behaviors In adolescent girls with polycystic ovarian syndrome(PCOS)

Design

This clinical trial has an intervention group and a control group. Each group will be selected randomly based on their admission to the clinic from 4 gynecologic clinics. Sample size for each group is 32 persons but considering the chance of sample loss, sample size will be increased to 72.

Settings and conduct

In this study the research environment is 4 selected educational clinics affiliated to Shiraz University of Medical Sciences. Initially, through health records, the list of adolescent girls aged 15 to 21 with polycystic ovary syndrome is extracted and invite them to participate in the research by telephone. Training for intervention group is conducted in 4 sessions of 60 to 90 minutes during two weeks (two sessions a week). Also, in the intervention group, follow-up training and sharing experiences of adolescent girls with PCOS will be conducted through the social media messaging network .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight, obese and single adolescent girls with PCOS, Not having any chronic diseases which requires special diet. Exclusion criteria: Absence of more than 2 sessions of training course

Intervention groups

This study is a clinical trial that will be conducted on two groups. In the intervention group education will be done by lecture, group discussion and role playing. The control group will not receive training, .

Main outcome variables

Knowledge; attitude; subjective norms; perceived behavioral control; Intention and eating practice in 2 groups will be measured before and 3 months after the

intervention through researcher-made questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160224026756N6**

Registration date: **2018-08-18, 1397/05/27**

Registration timing: **prospective**

Last update: **2018-08-18, 1397/05/27**

Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

Name

Mahnaz Noroozi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3441 1421

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noroozi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Education Based on Theory of Planned Behavior on Eating Behaviors In Adolescent Girls with Polycystic Ovarian Syndrome (PCOS)

Public title
Effect of education on eating behaviors In adolescent girls with polycystic ovarian syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Willingness to participate in the study and obtaining informed consent from the adolescent and her parents (in cases of younger than 18 years old) Overweight, obese, and single adolescent girls with PCOS Diagnosis of PCOS has been confirmed by a gynecologist Not having a history of diagnosed major mental problems undergoing drug treatments Not having any chronic diseases (cardiovascular diseases, diabetes, renal diseases etc.), which requires special diet prescribed by a physician Not attending a clinical trial simultaneously Possibility of participation in training course
Exclusion criteria:
 Use of certain dietary patterns during study Absence of more than 2 sessions of training course

Age
From **15 years** old to **21 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Isfahan University of Medical Sciences

Street address

School of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2016-12-19, 1395/09/29

Ethics committee reference number

IR.MUI.Rec.1395.3.885

Health conditions studied

1

Description of health condition studied

Eating behaviors in adolescent girls with polycystic ovarian syndrome

ICD-10 code

E00-E90

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Knowledge

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Knowledge Questionnaire

2

Description

Attitude

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Attitude Questionnaire

3

Description

Subjective norms

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Subjective norms Questionnaire

4

Description

Perceived behavioral control

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Perceived behavioral control Questionnaire

5

Description

Behavioral intention

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Behavioral intention Questionnaire

6

Description

Eating practice

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Food frequency Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group training (groups of 12 people) will be conducted in four sessions of 60 to 90 minutes during two weeks.

Category

Other

2

Description

Control group: No intervention will be received

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

Dr Hossein Jamali

Street address

Shahid Motahari Clinic, Namazi Square, Shiraz

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71348714658

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2

Recruitment center

Name of recruitment center

Hazrat Zeynab Medical and Training Center

Full name of responsible person

Dr Navid Omidifar

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Hazrat Zeynab Medical and Training Center, Holy Defense Square, Shiraz

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3

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Dr Mohammad Rafati

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Hafez Hospital, Chamran Blvd, Shiraz

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4

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Dr Hossein Jamali

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Imam Reza Clinic, West Blood Transfusion, Namazi Square, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjouy Javanmard
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Research & Technology Dept, Isfahan University of
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319-81745
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Research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

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

2

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
Street address
Research Department, Seven Floor, Central
Construction of Shiraz University of Medical Sciences,
Zand Avenue ,Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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
Esfahan University of Medical Sciences
Full name of responsible person
Mahnaz Noroozi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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School of Nursing and Midwifery, Isfahan University of
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Noroozi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Leila Hajivandi

Position

Phd candidate

Latest degree

Master

Other areas of specialty/work

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leila.hajivandi@gmail.com

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

Data of participants are privacy

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

Email: noroozi@nm.mui.ac.ir

What processes are involved for a request to access data/document

Maximum one week after the communication by email

Comments