# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 2026

## Evaluation the effectiveness of interventions based on life style modification in women with polycystic ovarian syndrom

## Protocol summary

**Study aim**

The aims of this interventional study are to examine the effects of energy restricted low glycemic diet on the health-related quality of life questionnaire for women with PCOS (PCOSQ), hirsutism, frequency of menstrual cycles and to compare the effects of energy restricted diet on anthropometric and general Health related quality of life, depression and anexiety, Rosenberg's Self-Esteem Scale , Body Image, Binge eating scale, female sexual disorder between women with or without PCOS.

**Design**

A clinical trial with parallel groups in 101 women with polycystic ovary syndrome and 101 healthy control who were matched for body mass index and age and were selected by convenience sampling.

**Settings and conduct**

The case group will be recruited from PCOS women , attending Reproductive Endocrinology Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences. Healthy controls recruited from women attending for their annual visit to the health care center affiliated to Shahid Beheshti University of Medical Sciences.

**Participants/Inclusion and exclusion criteria**

1-Diagnosis of PCOS according to Rotterdam criteria 2-Age between 18-40 years old 3- BMI > 25 kg / m² and < 38 kg / m² Exclusion criteria 1-Chronic disease 2- Using any hormonal drugs 3-Being pregnant and Lactation 4-Mental disorders

**Intervention groups**

The intervention includes a restricted energy low glycemic index diet of 500 kcal per day for 6 months to reduce weight by 5 - 10% in women with polycystic ovary syndrome and healthy control.

**Main outcome variables**

General Health related quality of life, depression, Rosenberg's Self-Esteem Scale , Body Image, Binge eating scale, female sexual disorder, hirsutism, frequency of menstrual cycles, Health-related quality of life questionnaire for women with PCOS (PCOSQ), Anthropometric variables.

## General information

**Reason for update**

Due to executive problems, the start of sampling was postponed and ethical approval was acquired from the ethics committee of the Research Institute of Endocrine Sciences.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016092129909N1**
Registration date: **2016-12-08, 1395/09/18**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **2**

**Registration date**

2016-12-08, 1395/09/18

**Registrant information**

**Name**

Farnaz Shishehgar

**Name of organization / entity**

Reproductive Endocrinology Research Center of Shahid Beheshti University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 4464 4017

**Email address**

fshishehgar@iautmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

**Expected recruitment start date**
2019-01-04, 1397/10/14
**Expected recruitment end date**
2020-02-16, 1398/11/27
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation the effectiveness of interventions based on life style modification in women with polycystic ovarian syndrom

**Public title**
interventions based on lifestyle modification
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of PCOS according to Rotterdam criteria All participants are Iranian speakers and have the ability to read and write Age between 18-40 years old BMI > 25 kg / m² and < 38 kg / m²
**Exclusion criteria:**
chronic disease Using insulin-sensitizing drugs; Using contraceptive drugs Using antihypertensive drugs Using lipid lowering drugs Using any hormonal drugs Using any antidepressants Special diets or exercise for weight loss in past 6 months Participating in previous similar studies Ovulation induction in the past year Smoking or using alcohol Mental disorders History of any type of malignancy Being pregnant Lactation in the past year Bleeding of unknown cause
**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: **220**
**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 research institute for endocrine sciences, Shahid Beheshti Universityof Medical
**Street address**
24 Parvaneh, Yaman Street, Velenjak, Tehran, I.R.Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1985717413
**Approval date**
2016-11-15, 1395/08/25
**Ethics committee reference number**
IR.SBMU.ENDOCRINE.REC.1395.276

## Health conditions studied

**1**

**Description of health condition studied**
Polycystic ovary syndrome
**ICD-10 code**
E20-E35
**ICD-10 code description**
Disorders of other endocrine glands

## Primary outcomes

**1**

**Description**
Quality of Life Score in the Health Short Form Questionnaire (SF-36)
**Timepoint**
0-24 weeks
**Method of measurement**
The Short Form Health Survey(SF-36)

**2**

**Description**
Quality of Life Score in Polycystic Ovary Syndrome Questionnaire (PCOSQ)
**Timepoint**
0--24 weeks
**Method of measurement**
Polycystic Ovary Syndrome Questionnaire (PCOSQ)

## Secondary outcomes

**1**

**Description**
Hirsutism
**Timepoint**

0-12-24 weeks

**Method of measurement**

Ferriman-Gallwey scoring

**2**

**Description**

Menstural Cyclicity

**Timepoint**

0-12-24 weeks

**Method of measurement**

Questionnare

**3**

**Description**

Waist Circumference

**Timepoint**

0-12-24 weeks

**Method of measurement**

non flexible tape measure

**4**

**Description**

Hip circumference

**Timepoint**

0-12-24 weeks

**Method of measurement**

non flexible tape measure

**5**

**Description**

Weight

**Timepoint**

0-12-24 weeks

**Method of measurement**

digital scale

**6**

**Description**

Hospital Depression and Anxiety Scale

**Timepoint**

0-24 weeks

**Method of measurement**

Hospital Depression and Anxiety Scale

**7**

**Description**

Self-esteem

**Timepoint**

0-24 weeks

**Method of measurement**

Rosenberg Self-esteem Scale (RSES)

**8**

**Description**

Ṡexual function

**Timepoint**

Female Sexual Function Index (FSFI)

**Method of measurement**

0-24 weeks

**9**

**Description**

Body Shape Questionnaire

**Timepoint**

0-24 weeks

**Method of measurement**

Body Shape Questionnaire

**10**

**Description**

Multidimensional Body-self Relations Questionnaire (MBSRQ)

**Timepoint**

0-24 weeks

**Method of measurement**

Multidimensional Body-self Relations Questionnaire (MBSRQ)

**11**

**Description**

Binge Eating Scale (BES)

**Timepoint**

0-24 weeks

**Method of measurement**

Binge Eating Scale (BES)

## Intervention groups

**1**

**Description**

energy restricted low glycemic lindex diet

**Category**

Lifestyle

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Reproductive Endocrinology Research Center, Research Institute for Endocrine Sciences, Shahid Behesh

**Full name of responsible person**

Farnaz Shishehgar ( PhD in reproductive health)

**Street address**

NO. 24 Parvaneh, Yaman Street, Velenjak, Tehran, I.R.Iran.

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info@endocrine.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Health centers depended to the municipality( velenjak-bime- zaferanieh)

**Full name of responsible person**

Farnaz Shishehgar ( PhD in reproductive health)

**Street address**

Floor 5, block 1, Islamic Azad University, Science and Research Branch, University Square, Shohada Hesarak Boulevard, Shahid Sattari Highway, Tehran, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Doctor Shahram alamdari

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**Email**

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**Grant name**

not applicable

**Grant code / Reference number**

ندارد

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Islamic Azad University

**Full name of responsible person**

Farnaz Shishehgar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

Main consequences, statistical analysis

**When the data will become available and for how long**

The access period will start 6 months after the results are published.

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Use of statistical tests in the present research in similar studies, Use the main results of current research by citing references to the main authors to compare the results of the current research with the studies of others.

**From where data/document is obtainable**

Email address shishehgarf@yahoo.com

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

6 months after the publication of the current research results, the information requested by the academic persons will be sent to their e-mail.

**Comments**