

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effectiveness of Self-management program on Quality of life and Self efficacy in women with Polycystic ovary syndrome

#### Protocol summary

##### Study aim

Determining the effectiveness of the self-management program on the quality of life and self efficacy of women with polycystic ovary syndrome

##### Design

The study is a parallel clinical trial with a control group, randomized and without blinding, on 64 eligible women with low quality of life and low self-efficacy. The available sampling method is by using a sequence of random numbers and through the online software, 32 people are assigned to two intervention groups (presentation of 5A self-management program) and 32 people control group (presentation of educational booklets).

##### Settings and conduct

Baghaeipour Clinic of Shahid Sadoughi Hospital in Yazd, Invitation to study, sampling, random allocation and psychological intervention will conduct by the second investigator under the supervision of the first, third and fourth investigators.

##### Participants/Inclusion and exclusion criteria

Inclusion: Diagnosis of polycystic ovary syndrome based on doctor's approval; At least one year has passed since the diagnosis of the disease; Age 15-49 years; Being Iranian; Being literate in reading and writing; Having an Android or iOS smart phone; The possibility of participating in training sessions; Being the only wife of her husband Exclusion: Participation in consulting studies; The presence of various types of severe mental disorders under drug treatment; Smoking, drugs and alcohol; Existence of stressful events during the last 6 months; Treated with assisted reproductive methods; limitation in physical activity; Getting diseases with a special diet;

##### Intervention groups

For the intervention group, the self-management program based on the 5A model is provided weekly for 8 weeks on the authorized virtual network. For the control group, routine trainings and educational booklets are given regarding polycystic ovary syndrome.

#### Main outcome variables

Change in the mean quality of life and self-efficacy scores

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230307057652N1**

Registration date: **2023-03-24, 1402/01/04**

Registration timing: **prospective**

Last update: **2023-03-24, 1402/01/04**

Update count: **0**

##### Registration date

2023-03-24, 1402/01/04

##### Registrant information

##### Name

Shahnaz Mojahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 1754

##### Email address

f.goodarzi@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-09, 1402/01/20

##### Expected recruitment end date

2023-10-12, 1402/07/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effectiveness of Self-management program on Quality of life and Self efficacy in women with Polycystic ovary syndrome

**Public title**  
Effect of self-management program on Quality of life and Self efficacy in women with Polycystic ovary syndrome

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diagnosis of polycystic ovary syndrome based on the confirmation of a specialist doctor or recorded in the medical record At least one year has passed since the diagnosis of the disease Being literate in reading and writing Having an Android or iOS smart phone Ability to participate in training sessions Women who live with their husbands and are the only wives of their husbands Being Iranian Age (15-49)  
**Exclusion criteria:**  
Participation in consulting studies Existence of various types of severe mental disorders (psychosis, schizophrenia, etc.) under medical treatment based on medical record information or statements Smoking, drugs and alcohol Existence of stressful events during the last 6 months such as immigration, death of relatives, divorce Treated with assisted reproductive methods Restrictions on physical activity Having diseases that require following a special diet (such as phenylketonuria)

**Age**  
From **15 years** old to **49 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible women are selected by available sampling method and using random number sequence and through online software ([www.Random.org/sequences](http://www.Random.org/sequences)), patients are divided into two intervention groups (providing self-management program 5A) and control group. (presentation of educational booklets) (32 people each) are allocated. Again, the research units in the intervention group are divided into two subgroups by a simple random method.

**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 Shahid Sadoughi University of Medical Sciences

##### Street address

Bahonar Square, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8916189165

#### Approval date

2023-03-01, 1401/12/10

#### Ethics committee reference number

IR.SSU.REC.1401.111

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

Measuring the average quality of life scores in women with polycystic ovary syndrome

#### Timepoint

At the baseline and completion of the intervention at week 12

#### Method of measurement

Quality of life questionnaire for women with polycystic ovary syndrome(Cornin and et al.)

### 2

#### Description

Measuring mean self-efficacy scores in women with polycystic ovary syndrome

#### Timepoint

At the baseline and completion of the intervention at week 12

**Method of measurement**

General Self-Efficacy Scale(Scherer)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The intervention group receives the self-management program based on the 5A model in the virtual network. In the Assess stage, after effective communication, height, weight and body mass index are measured. In the Advise stage, Information is given about the abnormal cases obtained from the first stage and the disadvantages of low self-efficacy, low quality of life, disadvantages of increasing body mass index, stress management, adherence to treatment, adoption of a healthy lifestyle, appropriate physical activity and proper diet will be explained. In the Agree stage, suitable and agreed behavioral goals will be adjusted. In the Assist stage, 5 training sessions of 45 to 60 minutes (1 session per week) are offered. In training sessions, about polycystic ovary syndrome, importance of healthy fertility, definition of stress, stress coping techniques, importance of self-care, importance of healthy lifestyle, how to calculate daily calories, how to calculate body mass index and its interpretation, how to measure circumference The waist and its interpretation, the role of nutrition in the treatment and control of disease, the pyramid of food groups, how to read food labels, correct diet recommendations, recommendations for weight loss and appropriate physical activity are given. Also, the checklist related to physical activity or the form to complete the meal plan or the daily checklist of practicing the relaxation technique is recorded by the patient on a daily basis. In the Arrange stage, In the first two weeks, by sending a daily SMS, after two weeks, the practical plan will be reminded twice a week, and then once a week for a month, follow-up will be done to remind the implementation of the practical plan.

**Category**

Behavior

**2****Description**

Control group: Self-management routine training is done in the control group. Also, after completing the study, an educational booklet related to polycystic ovary syndrome will be provided to them.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Baghaeipour Clinic of Shahid Sadoughi Hospital

**Full name of responsible person**

Shahnaz mojahed

**Street address**

Bouali ave

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877443

**Phone**

+98 35 3824 1754

**Email**

sh\_mojahed@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amin Salehi Abargouei

**Street address**

Medical sciences Campus, Alam Square

**City**

Yazd

**Province**

Yazd

**Postal code**

8916978477

**Phone**

+98 35 3149 2229

**Email**

abargouei@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Shahnaz Mojahed

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Shahnaz Mojahed

**Position**

Assistant Professor

**Latest degree**

Master

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

Yazd University of Medical Sciences

**Full name of responsible person**

Shahnaz Mojahed

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

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

Yes - There is 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

All personal data of study participants can be shared after un identifying

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

After results publication

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions, and people working in industry can also apply to receive it.

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

Scientific usage

**From where data/document is obtainable**

sh\_mojahed@yahoo.com

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

One week after receiving the requested email

**Comments**