Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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), 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
Bouali ave
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1754
Email
sh_mojahed@yahoo.com

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
Other areas of specialty/work
Midwifery
Street address
Bouali ave
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1754
Email
sh_mojahed@yahoo.com

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
Midwifery
Street address
Bouali ave
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1754
Email
sh_mojahed@yahoo.com

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