Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of cognitive-behavioral consultation on the quality of life in women with polycystic ovary syndrome

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of cognitive-behavioral consultation on the quality of life in women with polycystic ovary syndrome. This is an one blinded clinical trial. The study population will be included women with polycystic ovary syndrome admitted to Akbarabadi educational hospital in Tehran. A total of 50 eligible patients will be selected and randomly will be assigned in two intervention and control groups. Beginning the study quality of life questionnaire for patients with polycystic ovary syndrome (PCOQ) will be provided to both groups. The intervention group will received individually 10 sessions of 30 to 45-minute cognitive-behavioral counseling with 7 days intervals. Participants in the control group will be given pamphlet that its content is simple and rational in the case of introduction of the disease. Before the first session and three weeks after the last session the quality of life of participants with the same scale will be measured and the two groups will be compared. Inclusion criteria: Lack of endocrine disease or any other chronic illness; Lack of mental illness; Lack of medicine use and psychotropic substances and narcotic drugs; Minimum age 15 and maximum age of 40 years; The ability to read and write or speak Persian; Residence in Tehran. Exclusion criteria: lack of participation in two or more sessions of counseling; unwillingness to participate in the continuation of the project.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021514333N69**
Registration date: **2017-03-04, 1395/12/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cognitive-behavioral consultation on the quality of life in women with polycystic ovary syndrome

Public title

Investigation of effectiveness of cognitive-behavioral consultation on the quality of life in women with polycystic ovary syndrome

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Lack of endocrine disease or any other chronic illness; Lack of mental illness; Lack of medicine use and psychotropic substances and narcotic drugs; Minimum age 15 and maximum age of 40 years; The ability to read and write or speak Persian; Residence in Tehran. Exclusion criteria: lack of participation in two or more sessions of counseling; unwillingness to participate in the continuation of the project.
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2017-02-04, 1395/11/16
Ethics committee reference number
kums.rec.1395.634

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Quality of Life
Timepoint
Baseline and 3 weeks after the end of the study
Method of measurement
Based on the quality of life questionnaire for patients with polycystic ovary syndrome (PCOQ)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will received individually 10 sessions of 30 to 45-minute cognitive-behavioral counseling with 7 days intervals
Category
Behavior

2

Description
Participants in the control group will be given pamphlet that its content is simple and rational in the case of introduction of the disease
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbari Hospital
Full name of responsible person
Farzaneh Jalilian
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person
Koroush Hamzehee

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Farzaneh Jalilian

Position
MA Student of consultation in midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty