

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

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

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Person responsible for scientific inquiries

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Web page address

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