Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

implement an interventional program for mental health in women with polycystic ovary syndrome

Protocol summary

Summary

Introduction: Polycystic ovary syndrome is the most common endocrine disorder in women of reproductive age. Promoting mental health of these women can improve the fertility and quality of life outcomes. Therefore, the purpose of this study was to implement an interventional program for mental health in women with PCOS. Materials and Methods: This is a clinical trial study. The researcher randomly assigned the research units into one of the two intervention or control groups and then designed the intervention on the intervention group and the results were collected by a 28-item general health questionnaire (GHQ-28) and compared to the control group. Discussion: It seems that the findings of this study are helpful in promoting the mental health of women with polycystic ovarian syndrome and improving the quality of life of these women in the community.

General information

Acronym

pcos

IRCT registration information

IRCT registration number: **IRCT2017092736445N1**
Registration date: **2017-10-03, 1396/07/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name

Fatemah Zaremobini

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 7500

Email address

m_kamravamanesh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study has been approved by the ethics committee affiliated with Isfahan University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

implement an interventional program for mental health in women with polycystic ovary syndrome

Public title

mental health for women with polycystic ovary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria Inclusion criteria are women aged between 15-49 years, Iranian nationality, consent to participate in the study, ability to understand questions or ability to read and write, not being in stressful situations such as immigration, death of loved ones and financial problems in the past 6 months, not participating in any other clinical trials at the same time, no severe mental disorders that requires to be under medical treatment or hospitalization. Exclusion criteria The

exclusion criterion is not completing the intervention for any reason such as severe life stress, the death of the spouse or immigration and so on.

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Random table number was done for randomization and day by day.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan-hezar jarib street-Isfahan University Of Medical Sciences

City

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2016-05-31, 1395/03/11

Ethics committee reference number

IR.MUI.REC. 1395.3.508

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

Mental health

Timepoint

before the intervention, 1 month after intervention, 3 month after intervention

Method of measurement

GHQ-28

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, an interventional program (education and supportive program) was performed for patients with polycystic ovary syndrome, and the usual care was taken for the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Mushtaq Infertility Center

Full name of responsible person

Fatemeh Zare Mobayeni, Ph.D. student of reproductive health

Street address

Esfahan, Bozorg Meher Square, Salman Fars Ave , Corner of Behesht Street, No. 23

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Ziba Farajzadegan

Street address

Isfahan- Hezar Jarib Ave.- Isfahan University of Medical Sciences- Faculty of Medicine- Social Medicine Center-2nd Floor- Dr. Ziba Farajzadegan

City

Isfahan

Grant name

IR.MUI.REC

Grant code / Reference number

1395.3.508

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

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Fatemeh Zare Mobini

Position

Student of Reproductive Health, Faculty of Nursing and Midwifery, Isfahan University of Medical Scie

Other areas of specialty/work

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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