

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of the educational program on quality of life in PCOS women in intervention and control groups

Protocol summary

Summary

Objective: This study assesses The effect of the educational program on quality of life in PCOS women
Design: randomized clinical trial will be conducted on 110 PCOS women in health centers in Hamadan city. They will be randomly assigned to intervention and control groups with regard to Allocation concealment (55 in intervention group and 55 in control group).
Setting and conduct: The eligible women who refer to health centers in 2016 will be enrolled. Inclusion criteria consisted of women: A confirmed case of PCOS was diagnosed based on the case definition of the Rotterdam diagnostic criteria; being 18-45 years of age; married; Sexual Dysfunction (having a score of 28 and less in the Female Sexual Function Index questionnaire; no sexual problem or disabling disease in the spouse; not being previously diagnosed with psychiatric disorders and not using psychiatric medications; do not suffer from other chronic diseases affecting the quality of life; being able to read and write. Exclusion criteria: unwillingness to continue cooperation; the emergence of any known physical or psychological illness that affects the quality of life; occurrence of pregnancy. intervention : The Sexual education program will be given once a week for 4 weeks and in control group the educational program not will be prescribed. Main outcome measures: the two groups will be compared in terms of the quality of life by Cronin or PCOSQ before the intervention, two weeks after the intervention and 3 months after the intervention.

General information

Acronym

PCOS: Polycystic Ovary Syndrome PCOSQ: Polycystic Ovary Syndrome Questionnaire

IRCT registration information

IRCT registration number: **IRCT201308289463N15**
Registration date: **2017-11-05, 1396/08/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Zahra Behboodi Moghadam

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

behboodi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-11-11, 1396/08/20

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the educational program on quality of life in PCOS women in intervention and control groups

Public title

The effect of the educational program on quality of life in PCOS women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A confirmed case of PCOS was diagnosed based on the case definition of the Rotterdam diagnostic criteria; being 18-45 years of age; married; Sexual Dysfunction (having a score of 28 and less in the Female Sexual Function Index questionnaire; no sexual problem or disabling disease in the spouse; not being previously diagnosed with psychiatric disorders and not using psychiatric medications; do not suffer from other chronic diseases affecting the quality of life; being able to read and write. Exclusion criteria: unwillingness to continue cooperation; the emergence of any known physical or psychological illness that affects the quality of life; occurrence of pregnancy.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Tehran University of Medical Sciences

Street address

Nosrat st. Tohid sq. Tehran I.IRAN 141973317

City

Tehran

Postal code

1419733171

Approval date

2016-10-15, 1395/07/24

Ethics committee reference number

IR.TUMS.FNM.REC.1395.781

Health conditions studied

1

Description of health condition studied

Quality of life in PCOS women

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Health related quality of life

Timepoint

before the intervention, two weeks after intervention, 3 months after the intervention

Method of measurement

PCOSQ or Cronin Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: In The sexual education program once a week for 4 weeks will be given. The quality of life will be measured by PCOSQ before the intervention, two weeks after the intervention and 3 months after the intervention.

Category

Other

2

Description

Control: In control group the education program not will be prescribed. The quality of life will be measured by PCOSQ before the study, two weeks after the study and 3 months after the study. In order to observe ethical issues, at the end of the study, the control group can use sexual counseling.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

Bitia Fereidooni

Street address

hamadan. pasdaran street

City

Hamadan

2

Recruitment center

Name of recruitment center

Atieh hospital

Full name of responsible person

zahra nazary

Street address

hamadan madan township

City

Hamadan

3

Recruitment center

Name of recruitment center

Private Pars Dermatology Clinic

Full name of responsible person

dr samadi

Street address

buali street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences

Street address

16 Azar Street, Keshavarz Blvd

City

Tehran

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, Tehran 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

Tehran University of Medical Science

Full name of responsible person

Bita Fereidooni

Position

Phd student of Reproductive health

Other areas of specialty/work

Street address

Hakim hamadan no 34

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

zahta behboodi moghadam

Position

PHD Reproductive health

Other areas of specialty/work

Street address

School of Nursing and Midwifery. Tehran University of Medical Sciences.

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Tehran

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran university of medical science

Full name of responsible person

Bita Fereidooni

Position

phd student in reproductive health

Other areas of specialty/work

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Hamadan hakim no 34

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Email

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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