Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of Sexual Counseling on Sexual Dysfunction of Women with Polycystic Ovarian Syndrome

Protocol summary

Summary

This study is a randomized controlled trials without blinding. The aim of the study the effectiveness of sexual counseling on sexual dysfunction of women with polycystic ovarian syndrome. Inclusion criteria include married, having sexual activity during past six months, the definitive of diagnosis of the polycystic ovarian syndrome by a gynecologist and records in document with is based on the criteria of the Rotterdam, having sexual function score that is less than 28 before intervention, etc. If one of the exclusion criteria has happen, such as, missing one of the session, the patient cannot continue the study. The method of sampling is available sampling and then eighty women that are sexual scores less than 28, randomly, will be in working and control group by Balanced Block Randomization method. Intervention for working group include four individual counselling sessions for 60 minutes' consultation in accordance with PLISSIT model that will be carried out once a week. The first session is Permission, second session, Limited Information, third session, Specific Suggestion and the end session is Intensive Therapy. At the end of the intervention, training manual prepared and will be presented for control group. Female Sexual Function Index questionnaire for working group, prior, immediately and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512023034N16**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

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Name of organization / entity

Iran University Faculty of Nursing & Midwifery

Country

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Recruitment status

Recruitment complete

Funding source

Research Deputy School of Nursing and Midwifery , Iran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Sexual Counseling on Sexual Dysfunction of Women with Polycystic Ovarian Syndrome

Public title

Effectiveness of Counseling on Sexual Dysfunction of Women with Polycystic Ovarian Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Married; 18_45 years' old; Iranian; Having at least degree of knowledge; Having sexual activity during past six months; The definitive diagnosis of the polycystic ovarian syndrome by a gynecologist and records in document which is based on the criteria of Rotterdam; Having sexual function score that is less than 28 before intervention; Lack of pregnancy and lactation and unwillingness to be pregnant during intervention; Lack of other acute physical and mental disease and endocrine disorder like thyroid disorders, diabetes based on the patient's medical document; Lack of consumption alcohol and drugs by patients and her husband according to the patient's reports; Lack of consumption drugs that are effective on sexual activity like ant depression, antihypertensive drugs...; Lack of consumption of any drugs or hormonal intervention during the last 60 days before intervention; Lack of history of women surgery such as genital surgery and breast surgery; Lack of sexual dysfunction by patient's husband (according to patients reports); Lack of participation in training classes to counseling for sexual dysfunction; Lack of stressful events that are unrelated to pregnancy Exclusion criteria: Missing one of the session; Occurrences of stressful events that are unrelated to pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to the Milad Tower,Shahid Hemmat Highway, Tehran, Iran

City

Tehran

Postal code

19964

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

IR.IUMS.REC1395.9311373024

Health conditions studied

1

Description of health condition studied

Sexual Dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Satisfication

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

2

Description

Arousal

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

3

Description

Lubrication

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

4

Description

Orgasm

Timepoint

Prior, immediatly and eight weeks after last session of

counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

5

Description

Desire

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

6

Description

Sexual Dysfunction

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

7

Description

Pain

Timepoint

Prior, immediatly and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire

Method of measurement

Female Sexual Function Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First, the Female sexual Function Index questionnaire (FSFI) will be completed by 80 patients with inclusion criteria in the presence of researcher, individually . Then randomely , patients will be divided into two groups, intervention and control groups in the same time .Intervention for working group include four individual counseling sessions for 60 minutes' consultations in accordance with PLISSIT model that will be carried out once a week by researcher. The first meeting after introduction and description of the goal of study, the first step (Permission) runs. At this stage, the patient will be allowed to speak about her sexual problems. At this stage, counseling techniques such as listening skills and pay attention to non-verbal gestures will be used and understood false beliefs and knowledge of patients and by collecting history and completed Sexual Function Index questionnaire, their problems will be diagnosised. At second session (Limited Information) which consultant will talk about the anatomy and physiology of the reproductive system and sexual cycle. In addition, explain about the disease, its side effects and its effect on sexual function and for a better understanding, slides and images color will be used. Third session (Specific Suggestion) according to each patient by clients help, suggestions for remission of the disease will be done. For example,sensate focus technique,exersice, massage and etc, due to personal problem will be advised. Last session (Intensive Therapy) is the final step. Patients who pass previous three sessions of counseling are suspected to any mental disorder, a history of rape and etc., will be referred to health professionals. At the end of he each session, summery of that session, will be given to clients such as brochures and booklet. Female Sexual Function Index questionnaire for working group, prior, immediately and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire will be completed.

Category

Other

2

Description

At the end of intervention, training manual wich contains information about sexual responsive cycle, physiology and anatomy of the genital tract, polycystic ovarian syndrome and its side effects, etc, prepared and will be presented for the control group. Female Sexual Function Index questionnaire for working group, prior, immediately and eight weeks after last session of counseling in working group and for control group, eight weeks after filling out the initial questionnaire will be completed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar General Hospital

Full name of responsible person

Fahimeh Golbabaei, Master of Midwifery Student

Street address

Firoozgar General Hospital, Beh Afarin St. , Karimkhan St. , Valiasr Sq. , Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for Research, School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Dr Rafiei Frough, Dr Mousavi Alijavad

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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, School of Nursing and Midwifery, Iran 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

School Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

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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