Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of sensate focus technique and body image counseling on the sexual function of married women of reproductive age with polycystic ovarian syndrome: a Randomized Clinical Trial

Protocol summary

Study aim

Investigate the effect of sensate focus techniques and body image counseling on the sexual function of women with PCOS.

Design

60 married women with PCOS will be selected and randomly assigned to intervention and control groups using block randomization (in blocks of four).

Settings and conduct

Demographic questionnaires of fertility and concern about body image and sexual performance were completed by 60 eligible married women in obstetrics and gynecology offices in Yazd city. Then, people are randomly divided into intervention and control groups.The intervention group receives a face-to-face counseling session including sensory focus technique training and body image improvement. This two-hour workshop is held individually in a confidential room and the training booklet is also provided to the samples.The evaluation of the research units is done one and two months after the intervention by completing the questionnaires in person.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women aged 18-40؛ Having sex in the last 8 weeks؛ Having no known underlying disease except PCOS؛ Not having a mental illness؛ Literacy in reading and writing Persian language؛ Being Iranian؛ Exit criteria:Couples' addiction to drugs and alcohol; Stressful event in the past month; History of pelvic floor surgery; Use of medications affecting sexual function

Intervention groups

The intervention group will receive an in-person training session that includes sensory focus techniques and body image improvement along with slides and educational videos. This two-hour workshop will be conducted individually in a private room, and an educational handout will also be provided to the participants. The control group will not receive any intervention.

Main outcome variables

Sexual function, body image

General information

Reason for update

Acronym

Pcos

IRCT registration information

IRCT registration number: **IRCT20241121063792N1**
Registration date: **2025-03-18, 1403/12/28**
Registration timing: **prospective**

Last update: **2025-03-18, 1403/12/28**
Update count: **0**

Registration date

2025-03-18, 1403/12/28

Registrant information

Name

Mahla Payam askari

Name of organization / entity

Tarbiat modares University

Country

Iran (Islamic Republic of)

Phone

+98 35 3842 5778

Email address

mahla.payamaskari@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sensate focus technique and body image counseling on the sexual function of married women of reproductive age with polycystic ovarian syndrome: a Randomized Clinical Trial

Public title

Investigating the effect of sensate focus technique and body image counseling on the sexual function of married women of reproductive age with polycystic ovarian syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Married women aged 18-40 Having sex in the last 8 weeks Having no known underlying disease other than PCOS Not having a mental illness Being single and living with a spouse now and during the study Literacy in reading and writing Farsi language Being Iranian

Exclusion criteria:

Addiction of couples to drugs and alcoholic beverages Stressful incident in the past month History of pelvic floor surgery Use of medications that affect sexual performance

Age

From **18 years** old to **40 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

Randomization will be performed using a **block randomization** method to ensure balance between the intervention and control groups. In this study, blocks of four will be used, meaning that within each block, two participants will be assigned to the intervention group and two to the control group. All possible balanced sequences within a four-person block (IICC, ICIC, ICCI, CCII, CICI, CIIC) will be pre-generated. These sequences will then be randomly selected(Using a standard table of random numbers) and placed in sealed envelopes to maintain allocation concealment. Participants will sequentially select one of these envelopes, determining their group assignment, while group allocation will remain concealed from both researchers and participants until the end of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasser Bridge, Jalal Al Ahmad

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2025-01-25, 1403/11/06

Ethics committee reference number

IR.MODARES.REC.1403.149

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Sexual performance score

Timepoint

Before the intervention and one and two months after the intervention

Method of measurement

Sexual function index questionnaire

2

Description

Body image

Timepoint

Before the intervention and one and two months after the intervention

Method of measurement

Body image concern questionnare

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives a face-to-face counseling session including sensory focus technique training and body image improvement in the form of face-to-face counseling along with educational slides and videos, and exercises are performed for one and two months after the counseling.

Category

Treatment - Other

2

Description

Control group: will not receive an intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's office

Full name of responsible person

Mahla Payam Askari

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41 Kashani St., Hafez Alley, No. 10

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Dr. Mohammad Javan

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Jalal Al Ahmad, Paul Nasr, Tarbiat Modares University

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mahla Payamaskari

Position

Student

Latest degree

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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable