Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effects of the BETTER Model and Routine Care on Sexual Quality of Life and Sexual Satisfaction in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of BETTER model–based counseling compared with routine care on sexual quality of life and sexual satisfaction among women with polycystic ovary syndrome.

Design

A single-blind, parallel-group, randomized controlled trial with 70 participants, using block randomization; trial phase: Not Applicable.

Settings and conduct

This trial will be conducted at selected clinics affiliated with Isfahan University of Medical Sciences. Eligible participants will be enrolled after informed consent and baseline assessment and will be allocated to two groups using block randomization. The statistical analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

The inclusion criteria will include women aged 18–45 years with polycystic ovary syndrome diagnosed according to the Rotterdam criteria, who are married, able to read and write Persian, reporting reduced sexual quality of life or sexual dissatisfaction, and willing to provide written informed consent. The exclusion criteria will include pregnancy or postpartum period, menopause, severe psychiatric disorders, chronic medical conditions or medications affecting sexual function, and major stressful life events during the previous 3 months.

Intervention groups

Participants will be randomly allocated into two groups: the intervention group will receive BETTER model–based counseling plus routine care, while the control group will receive routine care only.

Main outcome variables

Sexual quality of life; Sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260723070319N1**
Registration date: **2026-07-27, 1405/05/05**
Registration timing: **prospective**

Last update: **2026-07-27, 1405/05/05**
Update count: **0**

Registration date

2026-07-27, 1405/05/05

Registrant information

Name

Negar Aliyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 930 269 1151

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effects of the BETTER Model and Routine Care on Sexual Quality of Life and Sexual Satisfaction in Women with Polycystic Ovary Syndrome: A Randomized Controlled Trial

Public title
Effect of the BETTER Model on Sexual Quality of Life and Sexual Satisfaction in Women with Polycystic Ovary Syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Women with a confirmed diagnosis of polycystic ovary syndrome (PCOS) based on the Rotterdam criteria, aged 18–45 years, married and living with their spouse, diagnosed with PCOS for at least 6 months, able to read and write Persian, reporting reduced sexual quality of life or sexual dissatisfaction at baseline assessment, with no participation in psychosexual counseling programs during the previous 6 months, willing to participate in the study, and providing written informed consent.

Exclusion criteria:
Pregnancy or postpartum period, menopause, severe psychiatric disorders or current psychiatric treatment, chronic medical conditions known to substantially affect sexual function (e.g., uncontrolled diabetes, cardiovascular disease, thyroid disorders, neurological diseases, or malignancy), current use of medications affecting sexual function, and major stressful life events during the previous 3 months.

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

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized using block randomization with variable block sizes of 4 and 6 and an allocation ratio of 1:1. The individual participant will be the unit of randomization. The random allocation sequence will be generated by an independent statistician using an online randomization program. After completion of baseline assessments, participants will be randomly assigned to either the intervention group or the control group according to the generated sequence. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) that will be prepared by a researcher who will not be involved in participant recruitment, intervention delivery, or outcome assessment. The envelopes will be opened sequentially only after participant enrollment and completion of baseline data collection. No stratified randomization will be used in this study.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the BETTER model–based counseling intervention, blinding of participants, the principal investigator delivering the intervention, and healthcare providers will not be feasible. In addition, the data collector will be aware of group allocation because of direct contact with the participants. However, the statistical analyst will remain blinded to group allocation, and the study data will be provided in a coded, anonymized format to ensure that the statistical analyses are performed without knowledge of treatment assignment. Therefore, this trial will be conducted as a single-blind study, with blinding limited to the statistical analyst.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University, Yazd Branch

Street address
Safaieh, Prof. Hesabi Square, Islamic Azad University, Yazd Branch, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
89168-71967

Approval date
2026-07-20, 1405/04/29

Ethics committee reference number
IR.IAU.YAZD.REC.1405.012

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 quality of life, assessed using the Sexual Quality of Life–Female (SQOL-F) questionnaire at baseline, immediately after the intervention, and 8 weeks after the intervention.
Timepoint
At baseline (before the intervention), immediately after completion of the intervention, and 8 weeks after completion of the intervention
Method of measurement
Sexual Quality of Life–Female Questionnaire

2

Description
Sexual satisfaction, assessed using the Larson Sexual Satisfaction Questionnaire (LSSQ) at baseline, immediately after the intervention, and 8 weeks after the intervention.
Timepoint
At baseline (before the intervention), immediately after completion of the intervention, and 8 weeks after completion of the intervention
Method of measurement
Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will receive four individual BETTER model–based educational counseling sessions, delivered once weekly, with each session lasting 60–90 minutes. The counseling will be provided according to the six components of the BETTER model, including Bring up, Explain, Tell, Timing, Educate, and Record, in addition to routine care.
Category
Lifestyle

2

Description
Control group: Participants will receive routine care provided at the clinic only and will not receive BETTER model–based counseling.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Teaching Hospitals Affiliated with Isfahan University of Medical Sciences, Isfahan, Iran
Full name of responsible person
Nilofar Ramineh
Street address
Astara Branch, Islamic Azad University, Astara, Gilan Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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City
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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University

Full name of responsible person
Niloufar Ramineh

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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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
Undecided - It is not yet known if there will be a plan to make this available