# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison the Effect of BETTER Sexual Counseling Model (in-person and online) on Sexual Self-Concept in Women with Polycystic Ovary Syndrome

## Protocol summary


**Study aim**
Determining and Comparing the Effect of the BETTER Sexual Counseling Model Delivered Face to Face and Remotely on the Sexual Self Concept of Women with Polycystic Ovary Syndrome Referred to Health and Medical Centers in Kerman in 1405

**Design**
A randomized controlled clinical trial with three parallel groups and a blinded data analyst, including 63 participants, using block randomization with blocks of nine. The randomization sequence will be generated using the online Sealed Envelope system.

**Settings and conduct**
This trial will be conducted in comprehensive health service centers and specialized women's and midwifery offices in Kerman. Eligible participants will be randomly assigned to three groups: face to face counseling, remote counseling, and control. The two intervention groups will receive four weekly counseling sessions based on the BETTER model, while the control group will receive usual care. The data analyst will be blinded to group allocation.

**Participants/Inclusion and exclusion criteria**
Married women aged 18 to 45 years with polycystic ovary syndrome diagnosed by at least two Rotterdam criteria, a stable marital relationship and active sexual life, who are literate, have smartphone and internet access, and provide written informed consent.Exclusion criteria: Active systemic or endocrine diseases other than polycystic ovary syndrome, psychiatric disorders, sexual dysfunction, use of medications affecting sexual function, concurrent sexual counseling or psychological or psychiatric interventions, pregnancy or breastfeeding, and alcohol or drug use.

**Intervention groups**
The face to face group will receive BETTER model based face to face counseling. The remote group will receive the same counseling online. The control group will receive usual care from health and medical centers and offices.

**Main outcome variables**
Sexual self concept


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20260602069613N1**
Registration date: **2026-09-10, 1405/06/19**
Registration timing: **prospective**

Last update: **2026-09-10, 1405/06/19**
Update count: **0**

**Registration date**
2026-09-10, 1405/06/19

**Registrant information**


**Name**
Narjes Salehi Derakhtanjani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-09-18, 1405/06/27

**Expected recruitment end date**
2027-02-14, 1405/11/25

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the Effect of BETTER Sexual Counseling Model (in-person and online) on Sexual Self-Concept in Women with Polycystic Ovary Syndrome

**Public title**

Comparison the Effect of BETTER Sexual Counseling Model (in-person and online) on Sexual Self-Concept in Women with Polycystic Ovary Syndrome

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of polycystic ovary syndrome based on the presence of at least two of the Rotterdam diagnostic criteria Married women Iranian nationality Aged 18–45 years Having a stable relationship for at least 6 months Being sexually active Having a monogamous spouse Ability to read and write Access to a smartphone and Internet Providing informed consent to participate in the study

**Exclusion criteria:**

Presence of active systemic medical disorders, including cardiovascular, renal, or hepatic diseases, and endocrine disorders other than polycystic ovary syndrome (PCOS) Presence of psychiatric disorders Presence of sexual dysfunction Use of medications that affect sexual function Participation in other psychological or psychiatric interventions, or receipt of sexual counseling within the past 6 months Substance abuse, including alcohol, narcotics, and psychoactive substances Pregnancy or breastfeeding Presence of an active divorce proceeding in judicial authorities Experience of major stressful life events during the past 6 months (e.g., accident, bereavement, or other significant stressors)

**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: **63**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will be randomly allocated to three groups (face-to-face, online, and control) using block randomization with a block size of nine. The random allocation sequence will be generated by an individual independent of the research team using the online randomization service available at https://www.sealedenvelope.com/simple-randomiser/v1/lists. To minimize selection bias, allocation concealment will be ensured through the use of sequentially numbered, opaque, sealed envelopes. These envelopes will be prepared and maintained by an individual independent of the research team and will contain the assigned group codes. The researcher will remain unaware of the participant's group assignment until the envelope is opened. Due to the nature of the intervention, blinding of participants and the researcher will not be feasible. However, to reduce measurement bias, the statistical data analyst will be blinded to group allocation throughout the analysis process.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Due to the nature of the intervention, blinding of participants and the researcher will not be feasible. However, to reduce measurement bias, the statistical data analyst will be blinded to group allocation throughout the analysis process.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

**Street address**

Kerman University of Medical Sciences Campus, Haft Bagh Alavi Highway, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7616910002

**Approval date**

2026-08-10, 1405/05/19

**Ethics committee reference number**

IR.KMU.REC.1405.288

## 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**
Total score on the Persian version of the 78-item Multidimensional Sexual Self-Concept Questionnaire
**Timepoint**
The Multidimensional Sexual Self-Concept Questionnaire will be completed at three time points: before the intervention, immediately after the intervention, and four weeks after the intervention.
**Method of measurement**
Persian version of the 78-item Multidimensional Sexual Self-Concept Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention Group 1 (Online Intervention Group): Participants in the online intervention group will receive BETTER model-based sexual counseling in four weekly individual sessions, each lasting 60–90 minutes. The content of the sessions will be developed according to the six stages of the BETTER model.In the online intervention group, participants will receive four weekly sexual counseling sessions through online chat via a private page on an accessible domestic or international messaging platform. Educational materials will be delivered in the form of audio files, video files, and written text, with the possibility of real-time voice communication with the researcher.A reminder text message will be sent one day before each session. Participants will be asked to be online at the scheduled time, ask their questions, and receive the required counseling from the researcher. To ensure adherence to the intervention and engagement with the educational content, participants will be asked questions about the topics covered in the previous session before the content of each new session is delivered, and these will be reviewed at the beginning of the session. Reminder messages regarding completion of assigned tasks will also be sent throughout the intervention period.The counseling sessions will be conducted by a trained MSc student in Midwifery Counseling under the supervision of a PhD in Reproductive Health. All sessions will be conducted with full respect for participant privacy and confidentiality. All participants will complete a demographic and obstetric characteristics questionnaire before the intervention. In addition, the Persian version of the 78-item Multidimensional Sexual Self-Concept Questionnaire (MSSCQ) will be completed before the intervention, immediately after the intervention, and four weeks after completion of the counseling sessions.
**Category**
Other

### 2

**Description**
Intervention Group 2 (Face-to-Face Intervention Group): Participants in the face-to-face intervention group will receive BETTER model-based sexual counseling in four weekly individual sessions, each lasting 60–90 minutes, delivered in person. The content of the sessions will be identical in both the face-to-face and online groups and will be designed based on the six stages of the BETTER model.A reminder text message will be sent one day before each session. Sessions will be conducted at the data collection site in a private room with appropriate lighting and temperature, ensuring full participant confidentiality.Throughout the intervention period, reminder messages regarding completion of assigned tasks will also be sent to all participants. The counseling sessions will be conducted by a trained MSc student in Midwifery Counseling under the supervision of a PhD in Reproductive Health. All participants will complete a demographic and obstetric characteristics questionnaire before the intervention. In addition, the Persian version of the 78-item Multidimensional Sexual Self-Concept Questionnaire (MSSCQ) will be completed before the intervention, immediately after the intervention, and four weeks after completion of the counseling sessions.
**Category**
Other

### 3

**Description**
Control Group: Participants in the control group will receive routine care as provided by health centers and outpatient clinics. Following completion of the study, the educational intervention materials will be offered to participants in the control group for ethical considerations.
**Category**
Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Comprehensive health service centers, women’s and midwifery offices and clinics in Kerman
**Full name of responsible person**
Narjes Salehi Derakhtanjani
**Street address**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Hamid Sharifi

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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**

Kerman University of Medical Sciences

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Narjes Salehi Derakhtanjani

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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Hadis Shahrahmani

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## Person responsible for updating data

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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