Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of mindfulness-based sexual counseling, virtual reality, and cognitive-behavioral therapy on sexual function, quality of sexual life, and sexual health literacy of infertile women with polycystic ovary syndrome

Protocol summary

Study aim
Evaluate the effects of mindfulness-based sexual counseling, virtual reality (VR), and cognitive-behavioral therapy (CBT) on sexual function, quality of life, and sexual health literacy in infertile women with polycystic ovary syndrome (PCOS). Compare sexual function between intervention and control groups, assess differences in sexual quality of life at various time points, evaluate sexual health literacy in both groups, and determine the relative effectiveness of these methods.

Design
Randomized, parallel-group clinical trial conducted in Kashan health centers to assess the effects of mindfulness-based sexual counseling, VR, and CBT on sexual function, quality of life, and literacy in PCOS women. Participants are convenience-sampled and randomly allocated using block randomization. Blinding participants is not feasible.

Settings and conduct
Parallel randomized trial in Kashan health centers. Participants are convenience-sampled and assigned using block randomization to intervention (8 combined in-person/online sessions) and control groups. Assessments with FSFI, SQOL-F, and SHELA questionnaires occur at baseline and one month post-intervention. Control group receives no intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women aged 18-45 with infertility and PCOS, no psychiatric disorders, no medications affecting sexual function, minimum one year of infertility, sexual activity, and not pregnant or undergoing infertility treatment. Exclusion criteria: Unwillingness to continue, pregnancy during the study, or non-compliance with intervention.

Intervention groups
Receiving mindfulness-based sexual counseling, virtual reality interventions, and CBT.

Main outcome variables
Sexual function (measured by FSFI), sexual quality of life (assessed by SQOL-F), and sexual health literacy (evaluated by SHELA).

General information

Reason for update
Change in sample size

Acronym
MVR-CBT-INFERTILITY

IRCT registration information
IRCT registration number: **IRCT20250711066445N1**
Registration date: **2025-07-20, 1404/04/29**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **1**

Registration date
2025-07-20, 1404/04/29

Registrant information

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fatemeh hadian
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Tarbiat modares university
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15
Expected recruitment end date
2026-03-06, 1404/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of mindfulness-based sexual counseling, virtual reality, and cognitive-behavioral therapy on sexual function, quality of sexual life, and sexual health literacy of infertile women with polycystic ovary syndrome

Public title
Evaluating the effects of new counselling methods on sexual health and quality of life in infertile women with polycystic ovary syndrome
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Married women aged 18-45 years Not having any underlying disease except infertility and polycystic ovary syndrome Not taking medications that affect sexual function Not being addicted to alcohol or tobacco by the couple Not having any mental illnesses Being single and living with a spouse currently and during the study Being Iranian At least one year of unsuccessful attempts to conceive and not being pregnant No stressful event during the past month Literate in reading and writing Persian Not having uterine and pelvic problems and male-related infertility Having had sexual intercourse in the last 8 weeks Not undergoing infertility treatment.
Exclusion criteria:
Becoming pregnant during the study Failure to perform the intervention regularly and correctly
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: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In the first phase (screening), participants will be selected non-randomly using a convenience sampling method based on the study's inclusion and exclusion criteria. After initial screening and data collection, eligible participants will be randomly assigned to intervention and control groups using block randomization (blocks of four) based on a predetermined allocation list. In the block randomization process, all eligible participants are grouped into blocks of four, and for each block, one of the six possible allocation sequences (e.g., AABB, ABAB, BBAA, etc.) is randomly selected using a random number table or computer software. Participants are then assigned to either the intervention (A) or control (B) group according to the selected sequence. Allocation concealment will be ensured using sealed, opaque envelopes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This is a two-arm, parallel, randomized, open-label clinical trial evaluating psychological interventions (mindfulness-based counseling, virtual reality, and cognitive behavioral therapy) on sexual function and quality of life in infertile women with polycystic ovary syndrome.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares University
Street address
Jalal Al-Ahmad Highway/Tarbiat Modares University, Tehran
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TEHRAN
Province
Tehran
Postal code
1411713116
Approval date
2025-07-09, 1404/04/18
Ethics committee reference number
IR.MODARES.REC.1404.055

Health conditions studied

1

Description of health condition studied
Polycystic Ovary Syndrome (PCOS) in infertile women
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Sexual function
Timepoint
Baseline, 1 month post-intervention, and 2 months post-intervention
Method of measurement
Sexual function will be measured using the Female Sexual Function Index (FSFI).

2

Description
Sexual quality of life
Timepoint
Baseline, 1 month post-intervention, and 2 months post-intervention
Method of measurement
Sexual quality of life will be measured using the Sexual Quality of Life Questionnaire for Women (SQOL-F).

3

Description
Sexual health literacy
Timepoint
Baseline, 1 month post-intervention, and 2 months post-intervention
Method of measurement
Sexual health literacy will be measured using the Sexual Health Literacy for Adults (SHELA) assessment tool.

Secondary outcomes

1

Description
No secondary outcome variables identified; the study focuses solely on primary outcomes
Timepoint
Not applicable
Method of measurement
Not applicable

Intervention groups

1

Description
The intervention consists of a structured 8-session sexual counseling program (each session lasting 90 minutes, held once a week) designed for infertile women with polycystic ovary syndrome (PCOS). This group-based intervention (6 to 8 participants per group) incorporates mindfulness techniques (such as guided meditation and conscious breathing to reduce sexual anxiety), virtual reality (simulated scenarios to improve body image and reduce sexual anxiety), and cognitive-behavioral therapy (cognitive restructuring and behavioral exercises to modify negative beliefs and enhance marital communication). Each session includes individual assessments, interactive exercises, and homework assignments to reinforce the therapeutic process.
Category
Behavior

2

Description
Control group: The control group will not receive any intervention except routine treatment during the study. After the research period concludes, free sexual health promotion counseling sessions will be provided to them if they wish.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers in Kashan
Full name of responsible person
DR Shadab Shahali
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Sponsors / Funding sources

1

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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
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Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol and findings will be provided to the applicant upon a written request to the corresponding author and approval by the Research Council of Tarbiat Modares University.
When the data will become available and for how long
The course access begins 12 months after the publication of results.
To whom data/document is available

Researchers employed at academic and scientific institutions

Under which criteria data/document could be used

Use in review studies

From where data/document is obtainable

After submitting a written request by the corresponding author (Shadab Shahali via email: shadab.shahali@modares.ac.ir) and obtaining approval from the Research Council of Tarbiat Modares University, the data will be provided to the applicant.

What processes are involved for a request to access data/document

After submitting a written request by the corresponding author (Shadab Shahali via email: shadab.shahali@modares.ac.ir) and obtaining approval from the Research Council of Tarbiat Modares University, the data will be provided to the applicant.

Comments