Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Mindfulness-Based Cognitive Therapy Combined with Lifestyle Modification versus Lifestyle Modification Alone on Ovarian Sonographic Morphology in Reproductive-Age Women with Polycystic Ovary Syndrome: A 12-Week Randomized Clinical Trial

Protocol summary

Study aim

Does adding Mindfulness-Based Cognitive Therapy (MBCT) to a 12-week lifestyle modification program, compared with lifestyle modification alone, result in greater improvement in ovarian morphology (based on changes in follicle number, ovarian volume, and other structural characteristics) in reproductive-age women with Polycystic Ovary Syndrome (PCOS)?

Design

Participants are randomly assigned (using block randomization) to two groups. The study is single-blind. The sample size is 52 individuals per group.

Settings and conduct

The interventions will be delivered online through educational and counseling sessions. Participants will be recruited from Shahid Motahari Subspecialty Clinic in Shiraz, and ultrasound assessments will be performed at Tabesh Medical Imaging Center in Shiraz. The radiologist performing the ultrasound examinations, image analysts (manual and artificial intelligence-based), and statistical analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18–35 diagnosed with PCOS based on Rotterdam criteria. Exclusion criteria: Use of hormonal medications in the last three months, pregnancy or breastfeeding, and severe psychiatric disorders or other uncontrolled endocrine disorders.

Intervention groups

Lifestyle Modification Group: Involves nutrition education, physical activity, behavior change strategies, and regular participant follow-up, conducted over 12 weekly sessions. Counseling Group: In addition to receiving lifestyle modification training, participants receive 12 sessions of MBCT counseling.

Main outcome variables

Ovarian follicle number; ovarian volume; perceived stress; anxiety; quality of life related to Polycystic Ovary Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260809070585N1**
Registration date: **2026-09-25, 1405/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-25, 1405/07/03**
Update count: **0**

Registration date

2026-09-25, 1405/07/03

Registrant information

Name

Fahimeh Baghbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3720 1580

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s.baghbanif@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-21, 1405/06/30

Expected recruitment end date

2026-10-30, 1405/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Mindfulness-Based Cognitive Therapy Combined with Lifestyle Modification versus Lifestyle Modification Alone on Ovarian Sonographic Morphology in Reproductive-Age Women with Polycystic Ovary Syndrome: A 12-Week Randomized Clinical Trial

Public title

Effect of Mindfulness-Based Therapy Combined with Lifestyle Modification Compared with Lifestyle Modification Alone on Ovarian Appearance in Women with Polycystic Ovary Syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of polycystic ovarian syndrome (PCOs) based on the Rotterdam criteria Confirmation of polycystic ovarian morphology on baseline ultrasound No use of hormonal medications over the past three months. Written informed consent Women aged 18 to 35

Exclusion criteria:

Pregnancy or breastfeeding Severe psychiatric disorder Other uncontrolled endocrine disorders

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the two study groups using stratified block randomization with a 1:1 allocation ratio. The unit of randomization will be the individual participant. To ensure balance in participant allocation according to body mass index (BMI), randomization will be stratified into two BMI strata: BMI <30 and BMI ≥30. For each stratum, an independent random allocation sequence will be generated by an independent statistician using R statistical software and the blockrand package. Within each stratum, variable block sizes of 4 and 6 will be used, and block sizes will be randomly determined. Each block will contain an equal number of allocations to the two study groups, and the order of allocations within each block will be randomly determined by the software. After eligibility has been confirmed and the participant has formally entered the study, the participant will be assigned, according to the relevant BMI stratum, to the next available position in the allocation list for that stratum. Group assignment will then be determined according to the pre-generated random sequence. The random allocation sequence will be generated by an independent statistician, and the researcher responsible for participant recruitment will not have access to the allocation sequence during the baseline assessment. To ensure allocation concealment, the random allocation sequences for each BMI stratum will be placed in opaque, sealed, light-proof envelopes with sequential numbering. The envelopes will be prepared separately for each BMI stratum according to the allocation order. The envelope corresponding to each participant will be opened only after final confirmation of eligibility criteria, obtaining informed consent, and formal entry into the study. Therefore, group allocation cannot be predicted or altered before the participant formally enters the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistician, radiologist (ultrasound assessor), and imaging analyst performing the AI-based ultrasound image analysis will be blinded to participants' group allocation. Participants and the intervention provider will not be blinded due to the nature of the intervention. To maintain blinding: • DICOM files are coded and stored without reference to the intervention group prior to analysis. • The statistical dataset is analyzed using group codes (A/B) without disclosing the nature of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building, Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2026-07-21, 1405/04/30

Ethics committee reference number

IR.SUMS.REC.1405.315

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
Number of follicles in each ovary
Timepoint
Outcomes will be assessed at baseline, before the intervention (week 0), and immediately after completion of the 12-week intervention (week 12).
Method of measurement
Radiologists and Artificial Intelligence

Secondary outcomes

1

Description
Ovarian Volume
Timepoint
Outcomes will be assessed at baseline, before the intervention (week 0), and immediately after completion of the 12-week intervention (week 12).
Method of measurement
Radiologists and Artificial Intelligence

2

Description
Perceived stress
Timepoint
Outcomes will be assessed at baseline, before the intervention (week 0), and immediately after completion of the 12-week intervention (week 12).
Method of measurement
PSS questionarie

3

Description
Anxiety/Depression
Timepoint
Outcomes will be assessed at baseline, before the intervention (week 0), and immediately after completion of the 12-week intervention (week 12).
Method of measurement
GAD-7 and PHQ-9 questionarie

Intervention groups

1

Description
Intervention group: Lifestyle modification/Participants in this group will receive the lifestyle modification program for 12 weeks. The program will consist of 12 weekly online education and follow-up sessions. The content will include an introduction to Polycystic Ovary Syndrome (PCOS) and the principles of lifestyle modification; healthy nutrition and reducing dietary glycemic load; portion control and calorie management; meal planning and healthy snack selection; the importance and planning of physical activity; aerobic and resistance exercises; self-monitoring of diet and physical activity; prevention of relapse into unhealthy behaviors; and evaluation of goal achievement and development of a maintenance plan.
Category
Lifestyle

2

Description
Intervention group: Lifestyle modification and Cognitive therapy based on mindfulness/In addition to the 12-week lifestyle modification program, participants will receive Mindfulness-Based Cognitive Therapy (MBCT). The MBCT program will be based on a standard MBCT protocol and adapted for women with Polycystic Ovary Syndrome. It will consist of eight weekly 120-minute sessions, one booster session in week 10, and daily home practice. The sessions will cover an introduction to mindfulness and mindful eating and body scan exercises; awareness of thoughts and emotions and mindful breathing; sitting meditation; identification of automatic thoughts and negative thinking patterns; stress management and acceptance of difficult emotions; mindfulness in daily activities and interpersonal interactions; self-care and prevention of relapse into maladaptive patterns; and review and consolidation of mindfulness skills. The booster session will focus on addressing barriers to practice and strengthening adherence to mindfulness exercises. The sessions and educational exercises will be delivered online.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Clinic, Shiraz
Full name of responsible person
Fahimeh Baghbani
Street address
Shahid Motahari Clinic, Shiraz, Namazi Square, next to Namazi Hospital, Shiraz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Hossein Molavi Vardanjani
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Central Building, Shiraz University of Medical Sciences, Shiraz, Zand Street, opposite Palestine Street, Shiraz, Iran
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Shaghayegh Moradi Alamdarloo
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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shaghayeghmoradi84@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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