Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The impact of guided imagery-based counseling on the quality of life of women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of the study is to determine the effectiveness of guided imagery on hirsutism, weight, anxiety, and stress related to infertility, menstrual disorders, emotional issues, and quality of life in women with polycystic ovary syndrome.

Design
A clinical trial with a control group, parallel groups, double-blind, randomized, conducted on 66 patients.

Settings and conduct
In healthcare centers, both public and private, in Ramhormoz County, including the Women's Clinic of Mother Hospital and private offices of midwives and gynecologists, consultations will be held. Counseling sessions will be conducted in the researcher's private office.

Participants/Inclusion and exclusion criteria
Inclusion Criteria for the Study: 1. Age between 18 and 35 years 2. Diagnosed cases of Polycystic Ovary Syndrome (PCOS) based on Rotterdam criteria 3. At least two years after menarche 4. A score higher than 26 on the Polycystic Ovary Syndrome Quality of Life Questionnaire (PCOSQ) 5. Ability to participate in 8 educational classes 6. Literacy in reading and writing 7. Proficiency in Persian.

Intervention groups
The intervention group will receive guided imagery education to examine its effect on the quality of life of women with polycystic ovary syndrome (PCOS).

Main outcome variables
"Consultation based on guided visualization, quality of life, age, education, marital status, employment and economic status, infertility, number of children."

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241026063502N1**
Registration date: **2025-02-14, 1403/11/26**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-14, 1403/11/26**
Update count: **0**

Registration date
2025-02-14, 1403/11/26

Registrant information

Name
maria Ahmadirad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-11, 1403/10/22

Expected recruitment end date
2025-03-12, 1403/12/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The impact of guided imagery-based counseling on the quality of life of women with polycystic ovary syndrome

Public title
the effect of guided imagery on the quality of life of

women with polycystic ovary syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 35 years Known cases of polycystic ovary syndrome based on Rotterdam criteria At least two years since menarche A score of more than 26 on the quality of life questionnaire for women with polycystic ovary syndrome(PCOSQ) The ability to attend 8 training sessions Having literacy skills (reading and writing) Proficiency in the Persian language

Exclusion criteria:

Diagnosed physical health problems and diseases Use of psychiatric medications addiction to drugs and alcohol Simultaneous use of other relaxation methods Pregnancy and breastfeeding The occurrence of stress-related events in the past three months (Death of a relative, divorce...)

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals in the research community who meet the inclusion criteria and do not meet the exclusion criteria will be randomly assigned to two groups: intervention (33 individuals) and control (33 individuals) using a random number table. The allocation of intervention to individuals will be done randomly using a randomized block design with block sizes of 4, 6, and 8 (utilizing a table of random permutations). The randomization list will be prepared by a statistician. The intervention used in this study will be allocated according to the randomized list by an individual outside the study, who is unaware of the research goals, based on the corresponding codes in sealed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapur University of Medical Sciences, Ahvaz

Street address

Golestan highway-Jandishapur University of Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2024-12-21, 1403/10/01

Ethics committee reference number

IR.AJUMS.REC.1403.509

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

quality of life

Timepoint

"Before starting the study, immediately after, and two weeks after the end of the counseling sessions."

Method of measurement

:Data collection tools include: A: Demographic information questionnaire, which includes personal, medical, and obstetric information such as age, marital status, body mass index, education level of the individual and spouse, employment status of the individual and spouse, number of children, and history of infertility of the individual. B: Quality of life questionnaire for women with polycystic ovary syndrome (PCOSQ).

Secondary outcomes

empty

Intervention groups

1

Description

The test group will undergo eight sessions of group counseling based on guided visualization, led by a researcher who has previously completed a guided visualization counseling course under the supervision of a thesis advisor. After the sessions, they will be provided with a checklist to record the date and time of their exercises daily, marking their progress in the

corresponding table. This table will be reviewed weekly by the researcher. The counseling sessions will be held in person for 45 minutes in groups of 5 to 6 participants. The content of the counseling sessions will be derived from relevant sources, supported by research, and developed in consultation with a psychology advisor. The most common duration for psychological interventions is 20 minutes, and the guided visualization sessions will consist of two main parts: 1) relaxation and 2) receiving guided visualization. Initially, relaxation will take place for 10 minutes, followed by the exercise for 20 minutes. After this, participants will share their experiences with their peers for 10 minutes, followed by a 5-minute Q&A session. Participants are asked to practice the techniques presented in each session for 20 minutes a day, six days a week.

Category

Treatment - Other

2

Description

Control group: During the research period, no intervention will be done for the control group and they will continue with their daily activities, and in order to appreciate them and in terms of observing the ethical principles, at the end of the research, we will provide them with guided visualization educational pamphlets and a two-hour counseling session based on guided visualization for free.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother hospital

Full name of responsible person

Ismail Jamshid Nejad

Street address

Moalem boulevard

City

Ramhormoz

Province

Khouzestan

Postal code

6381651154

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+98 61 4352 2130

Email

name@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnosh Zaker Kish

Street address

Jundi Shapur University، Golestan Boulevard، Ahvaz

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Maria Ahmadirad

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

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Position
student

Latest degree
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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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data includes information about the main outcome of the sharing.

When the data will become available and for how long
Access starts 6 months after results are published

To whom data/document is available
Researchers working in the university institute

Under which criteria data/document could be used
via email

From where data/document is obtainable
Email address: maria.ahmadirad123@gmail.com

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

Comments