

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Mindfulness counseling on sexual satisfaction and function in women with polycystic ovary syndrome

Protocol summary

Study aim

Evaluation of the effectiveness of mindfulness-based counseling on sexual satisfaction and performance in women with polycystic ovary syndrome(PCO)

Design

The method of random block allocation is divided into two groups of intervention and control (4 blocks). The sample size of people in group therapy with mindfulness approach should not exceed 14 people, because the effectiveness of psychotherapy decreases with increasing sample size, so the intervention group was divided into three groups of 9 patients and control group of 27 people.

Settings and conduct

.Altered performance and sexual satisfaction in people with PCO

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 55 years Married BMI less than 30 Diagnosis of polycystic ovary syndrome based on Rotterdam criteria Score less than 26.5 from the Sexual Function Questionnaire Score less than 75 on the Sexual Satisfaction Questionnaire 6 months have passed since the start of treatment. Do not be treated with infertility drugs No entry conditions: Having a specific physical and mental illness Addiction to alcohol, drugs and other psychotropic drugs Having sexual dysfunction in yourself and your spouse Pregnancy and lactation

Intervention groups

The sample size of people in group therapy with mindfulness approach should not exceed 14 people, because the effectiveness of psychotherapy decreases with increasing sample size. Therefore, the intervention group was divided into three treatment groups of 9 people and the control group of 27 people. Then the intervention is performed as a pre-test, post-test so that all women in the three groups at the beginning of the study, week 8 and week 12 after the intervention questionnaire They complement Larson sex and sexual function in the form of self-report.

Main outcome variables

Altered performance and sexual satisfaction in people with pco

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049216N1**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**

Update count: **0**

Registration date

2021-02-08, 1399/11/20

Registrant information

Name

Monire Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

zmonire74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-12, 1399/11/24

Expected recruitment end date

2021-09-11, 1400/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Mindfulness counseling on sexual satisfaction and function in women with polycystic ovary syndrome

Public title
The effect of Mindfulness counseling on sexual satisfaction and function in women with polycystic ovary syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18 to 55 years Married Have a minimum literacy rate BMI less than 30 Diagnosis of polycystic ovary syndrome based on Rotterdam criteria (oligomenorrhea / amenorrhea, ultrasound evidence, clinical signs such as acne, hirsutism, and laboratory signs of hyperandrogenism (also recorded and diagnosed by a gynecologist) Score less than 26.5 from the Sexual Function Questionnaire(FSFI) Score less than 75 on the Sexual Satisfaction Questionnaire(ISS) 6 months have passed since the start of treatment Do not be treated with infertility drugs
Exclusion criteria:
 Having a specific physical and mental illness Addiction to alcohol, drugs and other psychotropic drugs Having sexual dysfunction in yourself and your spouse Pregnancy and lactation

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Structuring is performed by structural block method to create a balance in the number of samples specified to each of the study groups. In this method, the measurement of blocks can be fixed or variable. In this study, we use blocks with an equal number of 4 safe. For the specific feature using the blocking method and individual characteristics into 2 intervention groups (A) and intervention group (B), there are six modes for blocks, including: AABB, ABAB, ABBA, BBAA, BABA and BAAB using The computer generates random numbers. For number 1 of combination 1 (BAAB), for number 2 of combination 2 (BBAA), for number 3 of combination 3 (ABBA), for number 4 of combination 4 (ABAB), for number 5 of combination 5 (BAAB) and For number 6, use combination 6 (AABB).

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan Boulevard

City

Ahwaz

Province

Khouzestan

Postal code

6135539345

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.AJUMS.REC.1399.623

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Sexual function

Timepoint

Evaluation of sexual function and satisfaction before the intervention and in week 8 and week 12 after the intervention

Method of measurement

FSFI Sexual Function Questionnaire(FSFI)

2

Description

Sexual Satisfaction Questionnaire

Timepoint

Evaluation of sexual function and satisfaction before the intervention and in week 8 and week 12 after the intervention

Method of measurement

Larson Sexual Satisfaction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will receive 8 sessions of cognitive counseling based on group mindfulness for 120 minutes once a week on a specific day. The sessions will be held by a researcher who has received the necessary training and certification in mindfulness-based cognitive counseling, and the counselor will attend some sessions to ensure the correctness of the intervention, and finally take a post-test after the sessions. will be.

Category

Treatment - Other

2

Description

Control group: Due to the fact that the control group did not receive any intervention despite sexual and marital dissatisfaction. In order to make the research ethical, after completing the study, an educational booklet and a summary of the contents of the sessions are given to them.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Abadan Shahid Beheshti Hospital Clinic

Full name of responsible person

Monire zarei

Street address

Ahmadabad Street

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6316648371

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Ahmadi Moghadam

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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

Mitra Tadayon

Position

Faculty of Ahvaz University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Monire Zarei

Position

Master student of Dermatology Consulting

Latest degree

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Person responsible for updating data

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Latest degree

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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