Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 illnessAddiction 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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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
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Person responsible for scientific inquiries

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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