

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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)

##### Phone

+98 31 3345 7837

##### 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

Khuzestan

##### 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

##### City

Abadan

##### Province

Khuzestan

##### Postal code

6316648371

##### Phone

+98 61 5332 3094

##### Email

zmonire74@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr. Mehdi Ahmadi Moghadam

##### Street address

Golestan Boulevard

##### City

Ahwaz

##### Province

Khuzestan

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6135539345

##### Phone

+98 61 3336 1968

##### Email

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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**

Bachelor

**Other areas of specialty/work**

Midwifery

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Kave

**City**

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**Province**

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## Person responsible for updating data

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Master student of midwifery Consulting

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**City**

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**Province**

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8138795846

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**Email**

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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