# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## A Comparative Study of the Impact of Progressive Muscle Relaxation and Mindfulness Artificial Intelligence-Based on Fatigue Levels and Pain Intensity in Women Suffering from Polycystic Ovary Syndrome: A randomized controlled trial

## Protocol summary

**Study aim**
Comparative Evaluation of the Effects of AI-Based Progressive Muscle Relaxation and Mindfulness on Fatigue Levels and Pain Intensity in Women with Polycystic Ovary Syndrome

**Design**
Clinical trial with control group, with parallel, randomized groups, 72 children

**Settings and conduct**
After obtaining ethics approval, participants will complete demographic info, a fatigue questionnaire, and a visual analog scale at the study start. The intervention groups (progressive muscle relaxation and mindfulness) will be trained by the researcher using ChatGPT and perform the exercises individually at home for 8 weeks. The control group will receive no training. After the intervention, fatigue and visual analog scales will be completed again. Sampling will occur at hospitals affiliated with Yasuj University of Medical Sciences, and interventions will be done in a private room at the women's clinic.

**Participants/Inclusion and exclusion criteria**
Admission requirements: Age between 18 and 40 years. Conditions of non-entry: Presence of severe psychiatric disorders (such as severe depression or severe anxiety) requiring specialized treatment.

**Intervention groups**
Intervention Group 1: Progressive Muscle Relaxation: In this group, after training with ChatGPT by the researcher, interventions will be performed individually by the patients at home. The intervention will last for a total of 8 weeks. Intervention Group 2: Mindfulness: In this group, after training with ChatGPT by the researcher, interventions will be carried out individually by the patients at home. The intervention will last for a total of 8 weeks. Control group: non-intervention: this training group will not be given.

**Main outcome variables**
Multidimensional Fatigue Inventory and Visual Analogue Scale

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200107046044N5**
Registration date: **2025-06-09, 1404/03/19**
Registration timing: **prospective**

Last update: **2025-06-09, 1404/03/19**
Update count: **0**

**Registration date**
2025-06-09, 1404/03/19

**Registrant information**

**Name**
Mohammadsajjad Mousavi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-07-23, 1404/05/01

**Expected recruitment end date**

2025-11-01, 1404/08/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Comparative Study of the Impact of Progressive Muscle Relaxation and Mindfulness Artificial Intelligence-Based on Fatigue Levels and Pain Intensity in Women Suffering from Polycystic Ovary Syndrome: A randomized controlled trial

**Public title**

A Comparative Study of the Impact of Progressive Muscle Relaxation and Mindfulness Artificial Intelligence-Based on Fatigue Levels and Pain Intensity

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Ability to communicate and respond to the Multidimensional Fatigue Inventory and Visual Analogue Scale Age between 18 and 40 years Willingness to participate in the study and signing the informed consent form Definitive diagnosis of polycystic ovary syndrome by the relevant specialist physician Scoring 60 or above on the Multidimensional Fatigue Inventory Having chronic pain or similar symptoms such as lower abdominal pain or pain caused by ovarian issues No prior training or participation in studies similar to the current research within the past 6 months

**Exclusion criteria:**

Not meeting the inclusion criteria Presence of severe psychological disorders (such as major depression or severe anxiety) requiring specialized treatment Physical or mental disabilities—individuals who, due to their condition, are unable to perform relaxation or mindfulness exercises Use of sleeping pills, anti-anxiety, or antidepressant medications prior to the intervention Worsening of symptoms and the need for immediate medical treatment

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block random assignment will be done in such a way that according to the number of study groups (three groups) consisting of intervention 1 (Progressive Muscle Relaxation), intervention 2 (Mindfulness) and control and calculated based on the factorial law, i.e. 3!= 3×2×1= 6, all the possible arrangement modes of people will be compiled based on the table below, considering A for intervention group 1 (Progressive Muscle Relaxation), B for intervention group 2 (Mindfulness) and C for control group: 1 2 3 4 5 6 ABC ACB BAC BCA CAB CBA Then, since the estimated sample size was 99 people, in each block, three samples, each representative of a study group and their arrangement order was also different, from these blocks, placement sampling will be done. After the study objectives are fully explained, eligible research samples will be selected and, based on the time priority of referral, each of them will be assigned a code. By matching that number with the block random allocation list, the patients participating in the study will be assigned to one of the intervention 1 (Progressive Muscle Relaxation), intervention 2 (Mindfulness), and control groups. This process will continue until the estimated sample size is completed.

**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 Yasuj University of Medical Sciences

**Street address**

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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7591741417

**Approval date**

2025-06-03, 1404/03/13

**Ethics committee reference number**

IR.YUMS.REC.1404.045

## Health conditions studied

### 1

**Description of health condition studied**

Polycystic Ovary Syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**
Polycystic ovarian syndrome

## Primary outcomes

### 1

**Description**
The fatigue score is derived from the Multidimensional Fatigue Inventory
**Timepoint**
Before and after the interventions
**Method of measurement**
Multidimensional Fatigue Inventory

### 2

**Description**
Pain score based on Visual Analogue Scale
**Timepoint**
Severity of pain before, during and after the intervention
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention Group 1: Progressive Muscle Relaxation (PMR): In this group, the patient is placed in a lying down and comfortable position. On the first day, the relaxation training includes the following steps: identifying the target muscles, demonstrating and explaining the relaxation technique by the researcher, and practicing the technique under the researcher's supervision according to the protocol. Once patients are fully capable of performing the technique, they will repeat it every night at home before sleep. The researcher will follow up on their adherence at home. After the initial training by the researcher, the interventions will be carried out individually by the patients at home. The intervention consists of 8 sessions, each lasting 1 hour, held once a week over a period of 8 weeks. Prior to the start of the interventions, the artificial intelligence program, including ChatGPT, will be introduced to the participants by the researcher. The researcher will fully explain how to use these tools, including initial training, guidance, and troubleshooting any technical issues. As such, in the event of any questions, participants will refer only to these smart tools to find their answers. The intervention protocol will also be selected and implemented using the mentioned AI tools.
**Category**
Lifestyle

### 2

**Description**
Intervention Group 2: MindfulnessThis group will undergo an 8-session mindfulness protocol as outlined below: Session 1: Introduction of participants and a brief overview of the 8 sessions. Raisin-eating exercise, followed by a 30-minute body scan meditation and discussion about the feelings experienced during the practice. Session 2: Body scan meditation and discussion of the experience. Seated meditation practice. Session 3: Practicing awareness and focus on emotions. Paying attention to the present moment, breathing, and body sensations. Three-minute breathing space exercise. Session 4: Breathing-focused meditation. Practicing the expression and listening of one’s own emotions. Session 5: Meditation practice. Practicing self-acceptance and acceptance of one’s emotions. Session 6: Breathing space practice. Practicing non-judgmental awareness of emotions and events. Session 7: Meditation focused on awareness of anything that enters consciousness in the present moment. Session 8: Review of experiences and implementation of the post-test.A follow-up phone call will be made to monitor the continuation of home practice. After the initial training by the researcher, the interventions will be carried out individually by the patients at home.The intervention includes 8 sessions, each lasting 1 hour, conducted once a week over a period of 8 weeks, in accordance with similar studies.Before the start of the intervention, artificial intelligence tools, including ChatGPT, will be introduced to the participants by the researcher. The researcher will provide full instructions on how to use these tools, including initial training, guidance, and troubleshooting of any technical issues. Consequently, if any questions arise, participants will only refer to these smart tools to find their answers. The intervention protocol will also be selected and implemented using the aforementioned AI tools.
**Category**
Lifestyle

### 3

**Description**
Control group: non-intervention: There will be no intervention in this group.
**Category**
Lifestyle

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Sajjad Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

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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**
Yasouj 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
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**Position**
Faculty instructor
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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