Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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

Country
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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Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

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
MohammadSajjad Mousavi
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2

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3

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Sponsors / Funding sources

1

Sponsor
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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
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Full name of responsible person
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Position
Faculty instructor
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for updating data

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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