Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of Mindfulness Based Stress Reduction(MBSR) through artificial intelligence on anxiety and pain caused by primary dysmenorrhea in the students of Medical Sciences

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based stress reduction counseling through artificial intelligence on anxiety and pain caused by primary dysmenorrhea

Design
The study includes an intervention group and a control group, which are determined through block randomization. The intervention group will undergo mindfulness-based stress reduction counseling through artificial intelligence. The sample size in this study is 66 people for each group.

Settings and conduct
The target population of this study is students of Kerman University of Medical Sciences living in the dormitory. In the intervention group, mindfulness counseling will be provided for 8 sessions in the form of photos, clips, and podcasts through artificial intelligence. In this study, an application will be designed that consists of two parts, the first part provides educational content and mindfulness counseling exercises, and the second part acts as a virtual coach through which the individual can ask their questions and get answers or receive guidance regarding the counseling program.

Participants/Inclusion and exclusion criteria
Students studying at Kerman University of Medical Sciences, aged 18-35 years, no known physical or mental illness or use of anti-stress, anxiety and depression medications (according to the participant's statement), no known chronic pelvic disease (according to the participant's statement), no surgery in the past 3 months, no use of birth control pills, painkillers and other herbal medicines, as well as relaxation or acupressure to relieve primary dysmenorrhea, onset of dysmenorrhea before the age of 20 and regular menstrual cycles with intervals of 21-35 days, mild to moderate pain intensity with a score of 4 to 8.

Intervention groups
Students studying at Kerman University of Medical Sciences, age 18-35 years

Main outcome variables
Anxiety reduction Pain reduction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250909067200N1**
Registration date: **2025-09-21, 1404/06/30**
Registration timing: **prospective**

Last update: **2025-09-21, 1404/06/30**
Update count: **0**

Registration date
2025-09-21, 1404/06/30

Registrant information

Name
fatemeh behnam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 935 926 6275

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-11, 1404/07/19

Expected recruitment end date
2025-10-21, 1404/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Mindfulness Based Stress Reduction(MBSR) through artificial intelligence on anxiety and pain caused by primary dysmenorrhea in the students of Medical Sciences

Public title

Investigating the effectiveness of Mindfulness Based Stress Reduction(MBSR) through artificial intelligence on anxiety and pain caused by primary dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Not having a known physical or mental illness or using anti-stress medications Absence of anxiety and depression No known chronic pelvic disease No surgery within the past three months Avoid using birth control pills, painkillers, and other herbal medicines, as well as relaxation or acupressure to relieve primary dysmenorrhea. Dysmenorrhea onset before age 20 and regular menstrual cycles with intervals of 21-35 days Mild to moderate pain intensity with a score of 4 to 8

Exclusion criteria:

Unwillingness to cooperate Having a known physical or mental illness or using anti-stress medications Having severe pain, scoring higher than 8 Dysmenorrhea starting after age 20 or having irregular menstrual cycles Using birth control pills, painkillers, and other herbal remedies, as well as relaxation techniques or acupressure to relieve primary dysmenorrhea History of surgery in the past three months Having a known chronic pelvic disease Suffering from anxiety and depression

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization

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 Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2025-09-05, 1404/06/14

Ethics committee reference number

IR.KMU..REC.1404.295

Health conditions studied

1

Description of health condition studied

Primary Dysmenorrhea

ICD-10 code

N94

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Anxiety

Timepoint

Before and two weeks after the start of the intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

2

Description

Pain

Timepoint

Before and two weeks after the start of the intervention

Method of measurement

Pain intensity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness-based stress reduction counseling through artificial intelligence
Category
Treatment - Other

2

Description
Control group: During the study, people in the control group do not undergo any intervention and can only use medication if they are unable to tolerate pain. If it is not possible to make adjustments between drug users in the control and intervention groups, those people will be removed from the study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Reyhaneh Dormitory, Kerman University of Medical Sciences
Full name of responsible person
Hossein Kalami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kerman 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
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable