Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of teaching of coping skills and acupressure on premenstrual syndrome in undergraduate students of Sanandaj Azad University، 2023

Protocol summary

Study aim
Comparison of the average premenstrual stress score among the study groups by controlling the effect of the baseline score

Design
A semi-experimental study with a control group with parallel, randomized groups, which will be used for randomization using the random block method.

Settings and conduct
Students in the coping skills training group are trained in coping skills for 5 weeks and every week for 60 minutes, before and at the end of 3 months, students complete the stress and coping skills questionnaire again. For the acupressure group for 3 months and 2 times a day, morning and evening, each time for 60 seconds, in a sitting position, with pressure at the sp6 point, depending on the duration of PMS, at home or in the dormitory. It is done and on the last day of the menstrual cycle, the students complete the stress questionnaire again.

Participants/Inclusion and exclusion criteria
The inclusion criteria : 1- Female students who want to participate in the study 2. Suffering from premenstrual syndrome with moderate to severe severity (0-3) based on the PSST questionnaire. 2. Undergraduate student of Sanandaj Azad University School of Medicine who are studying in 1401. 3. Having regular menstruation with intervals of 28-35 days with a duration of 3-5 days 4. Being single Exclusion criteria: 1. Suffering from physical and mental diseases with the approval of a doctor 2. Use of other medicinal methods and complementary treatment 3. Female students who have severe mental crises or physical disabilities.

Intervention groups
The coping skills training group is treated for 5 weeks and the acupressure group for 3 months with pressure on sp6 point. The control group does not receive any training

Main outcome variables
premenstrual tension

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230618058517N1**
Registration date: **2023-06-26, 1402/04/05**
Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**
Update count: **0**

Registration date
2023-06-26, 1402/04/05

Registrant information

Name
Behnaz Manochehri

Name of organization / entity
Islamic Azad University Sanandaj Branch

Country
Iran (Islamic Republic of)

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+98 87 3318 4715

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of teaching of coping skills and acupressure on premenstrual syndrome in undergraduate students of Sanandaj Azad University، 2023

Public title

Comparison of the effect of teaching of coping skills and acupressure on premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female students who want to participate in the study Premenstrual syndrome with moderate to severe severity (0-3) based on the PSST questionnaire Undergraduate student of Sanandaj Azad University School of Medicine who are studying in 1402 Having regular menstruation with intervals of 28-35 days with a duration of 3-5 days being single

Exclusion criteria:

Suffering from physical and mental diseases with the approval of a doctor Use of other medicinal methods and complementary treatment Female students who have severe mental crises or physical disabilities.

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomly divided into three groups (two test groups and one control group) using the random block method.

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 Islamic Azad University Sanandaj Branch

Street address

Kurdistan Province, Sanandaj, Janbazan Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.IAU.SDJ.REC.1401.100

Health conditions studied

1

Description of health condition studied

premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

Physical symptoms of premenstrual syndrome

Timepoint

Before and three months after the intervention

Method of measurement

questionnaire

2

Description

Mood symptoms of premenstrual syndrome

Timepoint

Before and three months after the intervention

Method of measurement

questionnaire

3

Description

Behavioral symptoms of premenstrual syndrome

Timepoint

Before and three months after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the coping skills training group, they are trained for 5 weeks and every week for 60 minutes
Category
Other

2

Description
Intervention group: acupressure for 3 months, twice a day, in the morning and evening, for 60 seconds each time, in a sitting position, with pressure At point sp6, depending on the duration of pms, the person himself is done at home or in the dormitory.
Category
Other

3

Description
Control group: There was no intervention in the control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sanandaj Azad University
Full name of responsible person
Behnaz manouchehri
Street address
At the end of Palestine street, Bostan alley, first floor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University Sanandaj Branch
Full name of responsible person
Ali Agha Mohammadi
Street address
Kurdistan Province, Sanandaj, Janbazan Blvd ,Research Vice-Chancellor-Sanandaj
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ucms@iausdj.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University Sanandaj Branch
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
Islamic Azad University Sanandaj Branch
Full name of responsible person
Behnaz Manouchehri
Position
faculty of Medical Sciences, Sanandaj Branch
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Faculty of Islamic Azad University, Sanandaj branch

Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information about the main outcome is provided to individuals in the form of a printed article.

When the data will become available and for how long
After printing the results in the form of an article

To whom data/document is available
The data can be used for all people with premenstrual syndrome.

Under which criteria data/document could be used
The data will be made available to researchers

From where data/document is obtainable
Required information through the postal address b.manouchehri@iausdj.ac.irIt will be available to researchers.

What processes are involved for a request to access data/document
Information will be sent to researchers upon request.

Comments