Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effect of the educational intervention based on positive psychology and exercise on depression anxiety and stress on students with premenstrual syndrome

Protocol summary

Study aim

A comparative study of the effect of the educational intervention based on positive psychology and exercise on depression anxiety and stress on students with premenstrual syndrome

Design

This study is a blinded clinical trial. The study population includes all students of girls' dormitories of Kermanshah University of medical sciences.120 eligible students will be selected conveniently and randomly will be assigned to four groups (three intervention groups, one control group).

Settings and conduct

This study, which will be conducted in girls' dormitories of Kermanshah University of Medical Sciences, is one blinded one that the statistical analyst is unaware of the allocation of study groups (experimental and control). The samples will be divided into four groups randomly

Participants/Inclusion and exclusion criteria

Inclusion criteria: Regular menstruation; The length of the menstrual cycle between 22-35 days; The number of menstrual bleeding days between 8-3 days; The grade higher than 18 on premenstrual symptoms questionnaire Exclusion criteria: A history of ovarian cysts or women's surgery; PMDD diagnosis

Intervention groups

The first intervention group will receive eight sessions of positive psychological intervention for 70 to 90 minutes per week. In the second intervention group, the regular exercise program will be performed three days a week, for 20-30 minutes and 8 weeks, including 5 minutes of warm-up body movements at the beginning of the program, 10-15 minutes soft running with rest intervals and at the end of the time, stretching and relaxing movements will be performed for 5 minutes to cool the body. The third intervention group will receive both interventions include sports activities and educational intervention based on positive psychology for eight weeks.The control group will not receive any intervention.

Main outcome variables

Anxiety, depression, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N97**
Registration date: **2018-08-11, 1397/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-11, 1397/05/20**
Update count: **0**

Registration date

2018-08-11, 1397/05/20

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of the educational intervention based on positive psychology and exercise on depression anxiety and stress on students with premenstrual syndrome

Public title

The effect of educational intervention based on positive psychology and exercise on depression anxiety and stress on students with premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regular menstruation The length of the menstrual cycle between 22-35 days The number of menstrual bleeding days between 8-3 days Grade higher than 18 on premenstrual symptoms questionnaire

Exclusion criteria:

A history of ovarian cysts or women's surgery History of taking or starting antidepressants, relaxing and hormonal medications The incidence of unfavorable events or the death of loved ones and divorce in the last three months Premenstrual dysfunction diagnosis

Age

From **20 years** old to **24 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Individually Randomization method by random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst is unaware of the allocation of study groups (experimental and control).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-06-12, 1397/03/22

Ethics committee reference number

ir.kums.rec.1397.136

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

Depression

Timepoint

The beginning of the study, the end of the study and two months after the end of the study

Method of measurement

Based on the Depression, Anxiety and Stress Scale

2

Description

Anxiety

Timepoint

The beginning of the study, the end of the study and two months after the end of the study

Method of measurement

Based on the Depression, Anxiety and Stress Scale

3

Description

Stress

Timepoint

The beginning of the study, the end of the study and two

months after the end of the study

Method of measurement

Based on the Depression, Anxiety and Stress Scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 8 training sessions per week for 70 to 90 minutes of positive psychology education.

Category

Behavior

2

Description

In the second intervention group, the regular exercise program will be performed three days a week, for 20-30 minutes and 8 weeks, including 5 minutes of warm-up body movements at the beginning of the program, 10-15 minutes soft running with rest intervals and at the end of the time, stretching and relaxing movements will be performed for 5 minutes to cool the body

Category

Behavior

3

Description

Third intervention group will receive both interventions include sports activities and educational intervention based on positive psychology for eight weeks.

Category

Behavior

4

Description

The control group will not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences student dormitories

Full name of responsible person

Farzaneh shahvisi

Street address

Shahid Beheshti Blvd., Taleghani Hospital

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shahvisif@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Farzaneh Shahvisi

Position

Masters student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Sosan Heydarpour
Position
Faculty Member of Faculty of Nursing and Midwifery
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Masters student in midwifery counseling
Latest degree
Bachelor
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
6 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 45-day period, the documents will be sent e-mail
Comments