# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 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

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Iran (Islamic Republic of)

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**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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## 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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fnajafi@kums.ac.ir

**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

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**Position**
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## Person responsible for updating data

**Contact**
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**Latest degree**
Bachelor
**Other areas of specialty/work**
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**Province**
Kermanshah
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**Email**
shahvisif@yahoo.com

## 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**