

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### A Comparison between the Effects of School-based Education Programs provided by Peer Group versus Health Practitioners on Premenstrual Syndrome in Adolescents

#### Protocol summary

##### Study aim

compare the effectiveness of a school-based education by peer group vs health practitioner on PMS severity in adolescents

##### Design

a three-armed parallel-group non-randomized non-masked clinical trial with the comparison group of 90 participants

##### Settings and conduct

In all of the Participants, the starting checklist has been checked, and then qualified will complete Demographic, General Health, and Menstrual Disease Prevention Tools questionnaires. people with PMS, the DRSP will be given up to 2 consecutive periods. Among the Sufferers 10 peer educators will be selected, then 30 people will be randomly selected in each group. PMS and its management according to the protocol to peer educators (6 sessions) and then to intervention groups simultaneously by midwife counselor and peer educators six online sessions (60 min) in WhatsApp. After the intervention, the DRSP questionnaire will be completed in two consecutive periods by the students of the 3 groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : single; moderate to severe PMS according to the (PSST); regular menstrual periods (21 to 35 days); not a professional athlete , The satisfaction of students and their parents to attend the study, Regular menstruation for 21 to 35 days Exclusion criteria: use of therapies due to PMS; hormonal or psychiatric drug intake affecting PMS; diagnosis of a chronic disease; and occurrence of unfortunate/stressful events for adolescents or their family in the last six months and during the study.

##### Intervention groups

1-First Intervention Group (IG1) : peer-group education 2-Second Intervention Group (IG2) : health practitioner group education 3- Comparison Group (CG)

#### Main outcome variables

1- PMS severity: primary outcome; 2- PMDD frequency: secondary outcome; 3- General Health status: secondary outcome.

#### General information

##### Reason for update

(1) The research team decides to conduct the study with new approaches in clinical trial studies, so the initial version will be changed in some areas. (2) Due to the prevalence of coronary heart disease, school closures, and the impossibility of holding face-to-face sessions, the research team decided to hold distance learning sessions (online).

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150608022609N5**  
Registration date: **2019-08-04, 1398/05/13**  
Registration timing: **prospective**

Last update: **2020-09-16, 1399/06/26**

Update count: **2**

##### Registration date

2019-08-04, 1398/05/13

##### Registrant information

###### Name

Zohre Shahhosseini

###### Name of organization / entity

Mazandaran University of Medical Science, Nasibe  
School Of Nursing and Midwifery

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Iran (Islamic Republic of)

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**Recruitment status****Recruitment complete****Funding source**

Mazandaran University of Medical Sciences

**Expected recruitment start date**

2020-04-04, 1399/01/16

**Expected recruitment end date**

2020-08-31, 1399/06/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Comparison between the Effects of School-based Education Programs provided by Peer Group versus Health Practitioners on Premenstrual Syndrome in Adolescents

**Public title**

Effect of peer education on premenstrual syndrome

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

single satisfaction of students and their parents attending the study, , regular period of menstruation from 21 to 35 days moderate to severe PMS according to the Premenstrual Syndrome Screening Tool (PSST) not a professional athlete

**Exclusion criteria:**

use of therapies due to PMS, at baseline and during the study hormonal or psychiatric drug intake affecting PMS, at baseline and during the study diagnosis of a chronic disease occurrence of unfortunate/stressful events for adolescents or their family in the last six months and during the study

**Age**From **16 years** old to **18 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

1- from purposefully selected high schools in Iran's

educational system 2- Randomization at school level (using a random number table) and Allocated to peer-group education (IG1), health practitioner group education (IG2) and comparison group (CG). 3- Random selection of the eligible students in each group based on the required sample size, n=30, (using the built-in random number generator in Microsoft Excel)

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

**Street address**

Nasibeh School of Nursing and Midwifery, Vesal St., Amir Mazandarani Blvd., Sari, Mazandaran Province

**City**

Sari

**Province**

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**Postal code**

4816715793

**Approval date**

2017-07-23, 1396/05/01

**Ethics committee reference number**

Ir.mazums.REC.1396.9188

**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**

severity of premenstrual syndrome

**Timepoint**

Daily record of severity of premenstrual syndrome's problems within 2 consecutive months ( 2menstrual cycles)before intervention and within 2 consecutive months( 2menstrual cycles) after the end of the intervention.

**Method of measurement**

Premenstrual Symptoms Screening Tool (PSST) AND Daily Record of Severity of Problems Chart (DRSP)

## Secondary outcomes

### 1

#### Description

frequency of PMDD

#### Timepoint

At the baseline and after the intervention.

#### Method of measurement

PSST questionnaire

### 2

#### Description

General Health score

#### Timepoint

At the baseline and after the intervention.

#### Method of measurement

General Health Questionnaire- 28 Items (GHQ-28)

## Intervention groups

### 1

#### Description

Intervention group (1): Training of peer educators: At first, ten eligible volunteer students will be selected as potential peer educators to educate their peers. They will educate about life skills (include problem-solving, critical thinking, effective communication skills, decision-making, creative thinking, interpersonal relationship skills, self-awareness building skills, empathy, and coping with stress and emotions), puberty, menarche, physiology of menstruation, PMS, and its management (such as dietary changes and the use of aerobic exercise) by PI during six face-to-face 60-minutes sessions, in 3 weeks (twice a week). In the following, six of them who are qualified from school staff as well as PI's point of view will be select as peer educators to implement the intervention. The PI is a Master of Science degree student in midwifery and counseling. Peer group education: Participants in this group (IG1, n=30, three subgroups with ten members) educated by two peer educators in each subgroup in six-60-minutes sessions for 3 weeks (twice a week) which will be supervised by the PI. The sessions will be in form of online in WhatsApp application and include: voice records, audio PowerPoint, short video clips, educational pamphlets, and at the end of every session, sometime will be dedicated to question and answer. The content of sessions will include issues like puberty, menarche and menstrual cycles, PMS, and its management.

#### Category

Lifestyle

### 2

#### Description

Intervention Group (2): Health practitioner education: Simultaneously with the peer group education, participants in IG2 (n=30) will be educated by a health practitioner in six-60-minutes sessions for 3 weeks (twice

a week). The content and delivery route of each session will be similar in two intervention groups.

#### Category

Lifestyle

### 3

#### Description

Comparison group: The CG (n=30), as well as IGs, will receive school routine education provided by school counselors. In the Iranian educational system, in each school, a counselor position has been defined that she usually answers students' questions in many different areas as well as menstrual concerns.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sharif-Al-Olama high school

##### Full name of responsible person

Maryam Ghorbani

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Shahband Ave.

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### 2

#### Recruitment center

##### Name of recruitment center

Navabeliye high school

##### Full name of responsible person

Mitra Naseri

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### 3

#### Recruitment center

##### Name of recruitment center

Valiyeasr high school

**Full name of responsible person**

Zeynab Ghoreyshi

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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**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Farzaneh Babapour

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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Associate professor

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Ph.D.

**Other areas of specialty/work**

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**Position**

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**Other areas of specialty/work**

Midwifery

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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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data and effects are shared after being unidentifiable  
and ethical.

**When the data will become available and for how long**

Starting the access period from 2020

**To whom data/document is available**

Researchers working in academia and academia

**Under which criteria data/document could be used**

Analysis and modification of data and other  
documentation is not permitted

**From where data/document is obtainable**

Farzaneh Babapour f.bbp1991@gmail.com

**What processes are involved for a request to access data/document**

Send the email and complete introduction and request  
the requested file Adaptation to the terms of submission  
by the Dedicated Information Engine Posting if matching

**Comments**