

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, Nasibeh School Of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.shahhosseini@mazums.ac.ir

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

AgeFrom **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

Mazandaran

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

Street address

Shahband Ave.

City

Sari

Province

Mazandaran

Postal code

4811647366

Phone

+98 11 3332 2200

Email

Maryamghorbani@gmail.com

2

Recruitment center

Name of recruitment center

Navabeliye high school

Full name of responsible person

Mitra Naseri

Street address

Nader Ave, Jomhuri Ave.

City

Sari

Province

Mazandaran

Postal code

4849155356

Phone

+98 11 2227 3962

Email

Mitra-Naseri@yahoo.com

3

Recruitment center

Name of recruitment center

Valiyeasr high school

Full name of responsible person

Zeynab Ghoreyshi

Street address

Electric Power Alley, Imam Square

City

Sari

Province

Mazandaran

Postal code

4811836542

Phone

+98 11 3336 0440

Email

Zeynab060@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Research Administration of Mazandaran University of Medical Sciences., Moallem Square., Sari Town

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

Email

pajhooheshi@mazums.ac.ir

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

Street address

No. 61, Babapour Alley, Alinejad St., Asgari Mohammadian Boulevard, Railway Square

City

Sari

Province

Mazandaran

Postal code

4814785138

Phone

+98 11 3332 5205

Fax

Email

f.bbp1991@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Zohre Shahhosseini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

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

City

Sari

Province

Mazandaran

Postal code

3397148157

Phone

+98 11 3379 5555

Fax

Email

z.shahhosseini@yahoo.com

Web page address

Person responsible for updating data

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

Street address

No. 61, Babapour Alley, Alinejad St., Asgari
Mohammadian Boulevard, Railway Square

City

Sari

Province

Mazandaran

Postal code

4814785138

Phone

+98 11 3332 5205

Fax

Email

f.bbp1991@gmail.com

Web page address

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