

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Investigating the Effect of Mental Health-Based Educational Intervention Compared to a Control Group on the Quality of Life of Secondary School Girls with Primary Dysmenorrhea

#### Protocol summary

##### Study aim

Determining the effect of educational intervention based on mental health on the quality of life of secondary school girls with primary dysmenorrhea

##### Design

The study will be a randomized, double-blind, parallel-group, controlled clinical trial. Different schools will be selected for the control and intervention groups, and students will be assigned to each group in blocks of two. The sample size will be 50 participants per group.

##### Settings and conduct

The study will be conducted among high school students in public schools in Rudbar County, Gilan Province, Iran. Using a stratified random sampling method, 100 students from multiple separate schools will be allocated to either the control or intervention group. The educational content of the intervention will be determined based on the most significant predictive factors identified during the descriptive phase of the study. Participants, outcome assessors, and data analysts will remain blinded to the group assignment (control or intervention).

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age group: 14 to 19 years old  
Enrolment in high school  
Informed and written consent to participate in the study  
Experience of any degree (mild, moderate, severe) of primary dysmenorrhea  
Experience of any degree of stress, anxiety, and depression  
Exclusion Criteria: Unwillingness of the student to participate in the study

##### Intervention groups

The intervention group will receive educational intervention on primary dysmenorrhea and preventive mental health behaviours. This program may include elements such as: Education on the causes and mechanisms of dysmenorrhea  
Relaxation techniques such as deep breathing stress management  
The control

group will not receive any intervention related to the research purpose.

##### Main outcome variables

Stress management; anxiety management; depression management; quality of life; menstrual pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240717062449N1**  
Registration date: **2024-07-25, 1403/05/04**  
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**

Update count: **0**

##### Registration date

2024-07-25, 1403/05/04

##### Registrant information

##### Name

Seyede Pegah Teimouri Sendesi

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3162 7072

##### Email address

pegah.teimouri@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-10-05, 1403/07/14

##### Expected recruitment end date

2024-11-04, 1403/08/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the Effect of Mental Health-Based Educational Intervention Compared to a Control Group on the Quality of Life of Secondary School Girls with Primary Dysmenorrhea

**Public title**

Investigating the Effect of a Mental Health-Based Educational Intervention on the Quality of Life of Girls with Primary Dysmenorrhea

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age group 14 to 19 years Registration in second secondary schools Informed and written consent of the student and one of their parents to participate in the study Experience any degree (mild, moderate, severe) of primary dysmenorrhea according to the questionnaire Having a regular menstrual cycle with intervals of 21 to 35 days and duration of 3 to 10 days for at least the last six months Experiencing at least 3 painful menstrual periods in the past 6 months Experience any degree of stress, anxiety and depression according to the questionnaire

**Exclusion criteria:**

Student unwillingness to participate in the study History of reproductive system diseases, surgeries and known chronic diseases Use of birth control pills in the last 6 months Suffering from hormonal disorders or irregular menstruation Having pelvic infections Burning, itching or abnormal vaginal discharge Participation in professional sports activities Complaints of any other pelvic pain as reported by the student History of using psychoactive drugs

**Age**

From **14 years** old to **19 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible students identified in the first phase of the study will be selected using multistage random sampling and according to the sample size, and will be divided into

intervention and control groups using block randomization. There will be 50 participants in each group, for a total of 100 participants. To avoid contamination between groups, the control and intervention groups will be selected from different schools.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, since the control and intervention groups are from separate schools, the students will not be aware of their allocation to either the control or intervention group. Additionally, as participants will be identified by code, the data analysts and outcome assessors will be blinded to the names of the participants and the control and intervention groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Prior to the intervention study, a descriptive-analytical study will be conducted to identify eligible participants. Similarly, in the intervention phase of the study, pre-test questionnaires will be administered to both the control and intervention groups simultaneously to ensure the equivalence of the two groups in terms of the relevant variables. Based on the results of the pre-test, the level of significance and impact of each mental health component (depression, anxiety, and stress) on the quality of life of girls with primary dysmenorrhea will be determined. After the completion of the educational intervention, following the recommendations of scientific sources, the follow-up and study questionnaires will be completed by the intervention and control groups in the first and third menstrual cycles after the last day of the intervention. Weekly follow-up sessions will be conducted with the intervention group to assess adherence to the program and answer questions.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tarbiat Modares University

**Street address**

Jalal Al Ahmad Highway, Nasr Bridge, Tarbiat Modares University

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Approval date**

2024-06-24, 1403/04/04

## Ethics committee reference number

IR.MODARES.REC.1403.042

## Health conditions studied

### 1

#### Description of health condition studied

Primary dysmenorrhea

#### ICD-10 code

N94.4

#### ICD-10 code description

Primary dysmenorrhea

## Primary outcomes

### 1

#### Description

Depression score in the 21-question depression, anxiety and stress questionnaire

#### Timepoint

Before the intervention, the first and third menstrual cycles after the educational intervention

#### Method of measurement

21-question depression, anxiety and stress questionnaire

### 2

#### Description

Anxiety score in the 21-question depression, anxiety and stress questionnaire

#### Timepoint

Before the intervention, the first and third menstrual cycles after the educational intervention

#### Method of measurement

21-question depression, anxiety and stress questionnaire

### 3

#### Description

Stress score in the 21-question depression, anxiety and stress questionnaire

#### Timepoint

Before the intervention, the first and third menstrual cycles after the educational intervention

#### Method of measurement

21-question depression, anxiety and stress questionnaire

## Secondary outcomes

### 1

#### Description

Menstrual pain score

#### Timepoint

Before the intervention, the first and third menstrual cycles after the educational intervention

#### Method of measurement

Visual analog scale

### 2

#### Description

Quality of life score

#### Timepoint

Before the intervention, the first and third menstrual cycles after the educational intervention

#### Method of measurement

12-question quality of life questionnaire

## Intervention groups

### 1

#### Description

Intervention group: The researcher will introduce themselves and the research goals to the students and provide the necessary explanations. It is important to note that the interests of the students, the analysis of preliminary data, the conditions of the school and the respected teachers, and the opinion of the research group will be considered in the design and implementation of the educational sessions. This will be decided during the course of the research. The intervention group will receive the necessary training on primary dysmenorrhea and preventive behaviours based on mental health. This program may include topics such as: education on the causes and mechanisms of dysmenorrhea, relaxation techniques such as deep breathing, and anxiety and stress management. Weekly follow-up sessions will be conducted with the intervention group to assess adherence to the program and answer questions.

#### Category

Prevention

### 2

#### Description

Control group: The control group will consist of 50 female high school students who will not receive any intervention during the study period. They will complete the research questionnaires before the intervention, during the first and third menstrual cycles after the intervention, and the results will be compared and statistically analyzed with the results of the intervention group.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Second secondary girls' schools in Rudbar city, Gilan

##### Full name of responsible person

Seyedeh Pegah Teimouri

##### Street address

Sadat Alley, Shahid Navid Khalili St., Tutkabon

##### City

Rudbar  
**Province**  
Guilan  
**Postal code**  
4465151814  
**Phone**  
+98 992 496 5214  
**Email**  
pegah.teimouri@madares.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tarbiat Modares University  
**Full name of responsible person**  
Sedigheh Sadat Tavafian  
**Street address**  
Jalal Al Ahmad Highway, Nasr Bridge, Tarbiat Modares University  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713116  
**Phone**  
+98 912 287 6439  
**Email**  
tavafian@modares.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tarbiat Modares University  
**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**  
Tarbiat Modares University  
**Full name of responsible person**  
Sedigheh Sadat Tavafian  
**Position**  
Professor  
**Latest degree**  
Ph.D.

#### Other areas of specialty/work

Health Promotion

#### Street address

Jalal Al Ahmad, Nasr Bridge, Tarbiat Modares University, Faculty of Medical Sciences, Department of Health Education

#### City

Tehran

#### Province

Tehran

#### Postal code

1411713116

#### Phone

+98 21 8288 4547

#### Email

tavafian@modares.ac.ir

#### Web page address

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tarbiat Modares University  
**Full name of responsible person**  
Sedigheh Sadat Tavafian  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
Jalal Al Ahmad Highway, Nasr Bridge, Faculty of Medical Sciences, Tarbiat Modares University, Department of Health Education  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1411713116  
**Phone**  
+98 21 8288 4547  
**Email**  
tavafian@modares.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tarbiat Modares University  
**Full name of responsible person**  
Seyedeh Pegah Teimouri Sendesi  
**Position**  
MSc student of health education and health promotion  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Public Health  
**Street address**

No. 16, Sadat alley, Shahid Navid Khalili street,  
Tutkabon city

**City**

Rudbar

**Province**

Guilan

**Postal code**

4465151814

**Phone**

+98 13 3162 7072

**Email**

pegah.teimouri@modares.ac.ir

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

Part of the data, such as information about the main outcome, can be shared.

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

The start of the access period will be 6 months after the publication of the results.

**To whom data/document is available**

The data will be available only to researchers working in academic and scientific institutions.

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

The data will be sent by official request through academic or organizational e-mail of researchers after confirming and identifying the identity of the sender.

**From where data/document is obtainable**

It can be reached through the researcher's email: pegah.teimouri@modares.ac.ir and also through the supervisor's email, Dr. Sedigheh Sadat Tavafian: tavafian@modares.ac.ir.

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

Applicants can apply to receive the results 6 months after the publication of the results by email, and a response will be given one week to ten days after sending the email.

**Comments**