Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 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
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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
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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
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Jalal Al Ahmad, Nasr Bridge, Tarbiat Modares University, Faculty of Medical Sciences, Department of Health Education
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
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Other areas of specialty/work
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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