Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of consultation based on mindfulness on health promoting behaviors of adolescents with premenstrual syndrome

Protocol summary

Study aim
Determining the effect of counseling with a mindfulness approach on health-promoting behaviors in adolescents with premenstrual syndrome

Design
By cluster sampling method, 4 schools randomly selected, 2 schools of control group and 2 schools of intervention group and among the students who had the criteria to enter the research, 46 people selected by random method.

Settings and conduct
Two control group schools and two intervention group schools and then eligible students are selected with informed consent

Participants/Inclusion and exclusion criteria
Criteria for entering the study: At least 1 year after the onset of the first menstrual period, regular periods with normal intervals in each period (21-35 days), high school girls aged 17-15 years, with moderate to severe premenstrual syndrome (Score 19 or more in the PSST questionnaire, consent to participate in the intervention, as well as criteria for withdrawal from this study. Irregular menstrual cycle, use of hormonal compounds, chronic mental and physical illness, any medication to relieve the symptoms of premenstrual syndrome, Being under any kind of stressful environmental and psychotherapeutic events and taking psychiatric medications and single parent families

Intervention groups
The sample size was 92 people (46 people in each group) who were randomly selected from the criteria criteria and the intervention group saw mindfulness exercises in 8 sessions and the control group did not see any training.

Main outcome variables
Health promotion; premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200308046720N1**
Registration date: **2020-06-08, 1399/03/19**
Registration timing: **retrospective**

Last update: **2020-06-08, 1399/03/19**
Update count: **0**

Registration date
2020-06-08, 1399/03/19

Registrant information

Name
Farahnaz Moradymahmodabade

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
2019-10-07, 1398/07/15

Actual recruitment end date
2019-11-06, 1398/08/15

Trial completion date
2020-01-20, 1398/10/30

Scientific title
The effectiveness of consultation based on mindfulness on health promoting behaviors of adolescents with premenstrual syndrome

Public title
The effectiveness of consultation based on mindfulness on health promoting behaviors of adolescents with premenstrual syndrome
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
At least 1 year has passed since the first menstruation Regular periods with normal intervals in each period (21-35 days) High school girls aged 17-15 Moderate to severe premenstrual syndrome (score 19 or higher in the PSST questionnaire) Satisfaction with participating in the intervention
Exclusion criteria:
Irregular menstruation Consumption of hormonal compounds Having a chronic mental and physical illness Medication to relieve the symptoms of premenstrual syndrome Being under any kind of environmental stressful event Psychotherapy and the use of psychiatric drugs Single parent families
Age
From **15 years** old to **17 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant

Sample size
Target sample size: **92**
Actual sample size reached: **92**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Random selection
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Yazd University of Medical Sciences
Street address
Saeedi Street
City
Meybod
Province
Yazd
Postal code
8961974360
Approval date
2020-02-20, 1398/12/01
Ethics committee reference number
IR.SSU.REC.1398.209

Health conditions studied

1

Description of health condition studied
Health promotion, premenstrual syndrome
ICD-10 code
N94.3
ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Behaviors promoting the health of adolescents with PMS
Timepoint
Intervention before, after and one month later
Method of measurement
Walker Health Promotion Lifestyle Questionnaire

2

Description
Behaviors promoting the health of adolescents with PMS
Timepoint
Intervention before, after and one month later
Method of measurement
Walker Health Promotion Lifestyle Questionnaire

Secondary outcomes

1

Description
Premenstrual Syndrome
Timepoint
Before, after and a month after the intervention
Method of measurement
PSST questionnaire

Intervention groups

1

Description
Intervention group:46 Meybod high school girls who meet the criteria for entering the study and their pms were confirmed and randomly selected by completing two consecutive courses of the psst questionnaire one week before menstruation. The present study is a quasi-

experimental study that will be conducted in parallel with the previous and subsequent methods.In this study, the intervention group received 8 counseling sessions with a mindfulness approach on a weekly basis for 5.1–2 hours and evaluated the health-promoting behaviors of the intervention group at the beginning of the study, the end of the eighth week, and the twelfth week.In addition to evaluating health-promoting behaviors, their premenstrual syndrome is assessed with a psst questionnaire.Counseling Content: Week 1: Automated Guidance, Week 2: Dealing with Obstacles and More Control Reaction to Daily Events, Week 3: Breathing with Mind Presence, Week 4: Present Present, Week 5: Acceptance and Permission, Week 6: Thoughts are not facts, Week 7: Self-care, Week 8: Using what you have learned

Category

Behavior

2

Description

Control group: Meybod's 46 high school girls met the criteria for entering the study, and their pms were confirmed and randomly selected by completing two consecutive courses of the psst questionnaire one week before menstruation.The present study is a quasi-experimental study that will be conducted in parallel with the previous and subsequent methods. In this research, the control group does not see any training and after the end of the research, they will receive all the training of the intervention group. Behavioral health promotion behaviors are assessed at the beginning of the study, at the end of the eighth week, and at the twelfth week.In addition to evaluating health-promoting behaviors, their premenstrual syndrome is assessed with a psst questionnaire.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Meybod High Schools

Full name of responsible person

Farahnaz Moradi

Street address

Saeedi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Massoud Mirzaei

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Commander Fallahi

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dvc.research@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Farahnaz Moradymahmodabade

Position

Midwif

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable