Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Investigating the effect of implementation of Leventhal self-regulation model on menstrual distress among adolescent girls

Protocol summary

Study aim
Determining the Effect of Lovantal Self-Regulatory Model on Menstrual Distress in Young Adolescent Girls aged 14-19 in Qazvin in 1398

Design
Controlled clinical trial

Settings and conduct
From each section, a school attendee will be an intervention group and a control group school. An initial assessment of the severity of dysmenorrhea and menstrual pain in both groups will take place two months and then one month before the intervention. In the intervention group, based on The Leventhal model is based on the results of the sub-scales of the completed questionnaires by the girls, the educational content will be provided. The number of these sessions for the three sessions of the test group and the duration of each session is 60 Å 90 minutes and three consecutive weeks (in groups of 10 to 8), once a month after the completion of the sessions and once every three months by each The two groups will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: living in Qazvin, Age 14-19, high school student, Having regular menstruation, experiencing at least 2 years of menstruation, Menstrual pain 4 or more than 4 based on visual analouge scale Exclusion criteria: having secondary dysmenorrhea and its causes, history of known mental illnesses, Substance abuse history (self-declaration), Surgery related to gynecological problems, being married, No desire to participate in the study, Take special medication in the last 6 months, No attendance at all educational sessions .

Intervention groups
Teenage girls studying in high school

Main outcome variables
Menstrual distress

General information

Reason for update

Acronym
Leventhal model study

IRCT registration information
IRCT registration number: **IRCT20190625044002N1**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **prospective**

Last update: **2019-09-03, 1398/06/12**
Update count: **0**

Registration date
2019-09-03, 1398/06/12

Registrant information

Name
Somaye Asgari

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
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of implementation of Leventhal self-regulation model on menstrual distress among adolescent girls

Public title
Investigating the effect of implementation of Leventhal self-regulation model on menstrual distress

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The resident of Qazvin Have regular menstruation Experience at least 2 years of menstruation Severity of pain in menstruation 4 or more than 4 Enroll in high school Ages 14 to 19 years

Exclusion criteria:
The presence of secondary dysmenorrhoea and its underlying causes 2. History of known mental illnesses Substance abuse history (self-declaration) Surgical history of women Being Married Unwilling to participate in the study . Mandatory drug use in the last 6 months Not attending meetings (attendance at all meetings is obligatory)

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Because the presence of intervention and control group members in a school is likely to cause information leakage, random group assignment will be made. For this purpose, two schools will be randomly selected for intervention group and two schools will be randomly selected for control group.Random allocation will be done by simple random method using random number table.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Ghazvin, Shahid Bahonar Blvd. Ghazvin University of Medical Sciences

City
قزوین

Province
Qazvin

Postal code
3497135631

Approval date
2019-05-26, 1398/03/05

Ethics committee reference number
IR.QUMS.REC.1398.043

Health conditions studied

1

Description of health condition studied
Menstural distress

ICD-10 code
N94

ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
menstrual distress

Timepoint
Measurement of menstrual distress before intervention, one month and three months after intervention

Method of measurement
Moos menstrual distress questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Learning based on the Leventhal self-regulation model.Based on the Leventhal coordinate model and the results obtained from the subscales of the questionnaires completed by the girls, educational content will be provided. The number of sessions for the test group will be three sessions and the duration of each session is 60 to 90 minutes. In the first session, after initial communication with the patient, questions will be asked about their understanding and understanding of

the current disease and its consequences. The meeting is based on five dimensions of understanding the illness and the impact of understanding the disease on psychological outcomes. These dimensions will include the nature of the disease (symptoms related to illness such as fatigue, weakness), the cause of the disease, the duration or perception of the individual during the illness, the outcome and expected outcomes of the disease, the effectiveness of control, treatment and improvement of the disease. Interventions for understanding illness will include self-control techniques, verbal encouragement, goal-setting (eg, reducing stress with exercise), feedback, and evaluating behaviors, using successful people's experiences in the field. In the second session, after reviewing the patient's pre-session training, she will be asked to talk about her feelings and ambiguities. Training will be designed to change the negative and negative perceptions of the disease. Patients will be asked to ask the researcher if there is a question from the previous session. The final 30 minutes of stress and relaxation strategies will be taught for 30 minutes. Participants will be asked to practice these techniques. Third Session (Evaluation and Closure): The patient will be informed of the closure of the previous session. First, the training sessions are reviewed, and the patient will be asked about the impact of new training and experiences. Problems and obstacles for each patient will be reviewed, exercises for the previous session will be repeated, and participants' questions will be answered. At the end of the third session a booklet will be provided to the patient including issues such as disease identification and definition, personal hygiene, physical activity and exercise, a brief explanation of the misconceptions about menstruation developed by the researcher.

Category
Behavior

2

Description
Control group: No intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin city High schools

Full name of responsible person
Somaye Asgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Somaye Asgari

Position
Masters student

Latest degree
Master

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
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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Individual data will be published as an attachment in the article after being unidentifiable

When the data will become available and for how long
After completing the study and simultaneously publishing the results

To whom data/document is available
All researchers interested in the subject of research

Under which criteria data/document could be used
Written request for reasons requiring the use of data to be sent to the author

From where data/document is obtainable
Corresponding to the author

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

Comments