# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Influence of the implementation of Leventhal self-regulation model on Illness perception and pain severity of primary dysmenorrhea

### Protocol summary

**Study aim**
To determine the effect of the Lundal self-regulation model on Illness perception and severity of primary dysmenorrhea in adolescent girls 14-14 years old in Qazvin in 2019

**Design**
The clinical trial with a control group, parallel, not blind, randomized

**Settings and conduct**
Our study population is adolescent girls. After enrolling in the study, two schools for intervention, two control schools will participate. Initial assessment of the severity of dysmenorrhea and menstrual distress will be done in both groups two months and then one month before the intervention. The intervention will consist of three sessions. The questionnaire will be completed by both groups once a month and two and three months later. There will also be a training session for the control group after the intervention.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: have regular menstruation; experience at least 2 years of menstruation; severity of pain in menstruation 4 or more than 4. Exclusion criteria: presence of secondary dysmenorrhea; history of known mental illnesses; substance abuse history; surgical history of women; being Married; unwilling to participate in the study; not attending meetings.

**Intervention groups**
The intervention group will receive three sessions and each session lasts 60 to 90 minutes and three consecutive weeks in the form of a psycho-educational intervention.The control group will receive a training class after the intervention.

**Main outcome variables**
Severity of primary dysmenorrhea; illness perception

### General information

**Reason for update**

**Acronym**
Leventhal model study

**IRCT registration information**
IRCT registration number: **IRCT20190625044002N2**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **prospective**

Last update: **2020-01-06, 1398/10/16**
Update count: **0**

**Registration date**
2020-01-06, 1398/10/16

**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**
2020-01-21, 1398/11/01

**Expected recruitment end date**
2020-06-21, 1399/04/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Influence of the implementation of Leventhal self-regulation model on Illness perception and pain severity

of primary dysmenorrhea

**Public title**
Influence of the implementation of Leventhal self-regulation model on Illness perception and pain severity of primary dysmenorrhea
**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 old
**Exclusion criteria:**
The presence of secondary dysmenorrhoea and its underlying causes History of known mental illnesses Substance abuse history (self-declaration) Surgical history of women Unwilling to participate in the study. Being Married 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**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **120**
**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**
Qazvin
**Province**
Qazvin
**Postal code**
3497135631
**Approval date**
2019-12-17, 1398/09/26
**Ethics committee reference number**
IR.QUMS.REC.1398.225

## 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**
Pain intensity of primary dysmenorrheal
**Timepoint**
Measurement of menstrual pain intensity one and two months before the intervention, one month and three months after the intervention
**Method of measurement**
Measurement of menstrual pain with visual analog scale for pain

## Secondary outcomes

**1**

**Description**
Illness Perception
**Timepoint**
Measurement of Illness Perception before the intervention, one month and three months after the intervention
**Method of measurement**
Illness Perception Questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Training based on Leventhal self-regulation model. Based on the Leventhal self-regulation

model and based on the results obtained from subscales of questionnaires completed by girls, educational content will be provided. The number of sessions for the test group will be set at three sessions and each session lasts 60 to 90 minutes and for three consecutive weeks (one session per week) in groups of 8-10. In total, 12 groups (6 test and 6 control groups) will be formed and 18 training sessions will be held within 2 months at the school. Individual counseling sessions related to dysmenorrhea and common personal problems will be conducted as far as the researcher can. The first session: Based on the 5 dimensions of understanding the disease will be designed. The therapist will first assess the adolescent's understanding of the nature of menstrual distress. The study includes psychological symptoms related to menstrual distress such as anxiety, depression, and physical disorders such as fatigue, pain and weakness. It also examines adolescents' beliefs and hearings about the prevalence of menstrual distress and its complications (beliefs related to the identity of the disease). The next step in adolescents' understanding of the cause of the disease and one's beliefs about menstrual distress is to eliminate false beliefs (beliefs related to the cause of the disease). Then the duration of the illness and the adolescent's understanding of the duration of the illness will be examined (timetable). The next step deals with the distressing effects of menstruation on adolescent life (Consequences). Finally, the researcher examines the adolescent's perception of the efficacy of existing treatments to control and improve the severity of menstrual pain and relieve menstrual distress symptoms (treatment and improvement ideas). This session will use techniques of self-control, verbal encouragement, exercise-related stress reduction, feedback, and behavior assessment, use of successful illness experiences, and adolescents will be asked to practice these techniques. Pre-adolescent session tutorials will be asked to talk about their feelings and ambiguities about menstrual distress and their beliefs and knowledge will be challenged by the therapist. The training will be to change the misperceptions and the negative about the disease. They 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 and teens will be asked to practice these techniques. Third Session (Evaluation and Closing): Teens from the previous session will be notified of this closing session. Pre-session tutorials will be reviewed first, and then teens will be asked about the impact of new training and experiences. Problems and obstacles for each teenager will be explored, rehearsals of the previous session will be repeated, and their questions answered. Different methods will be used to increase the effectiveness of the training program. To achieve the content needed by adolescents in cognitive and psychological dimensions, a booklet will be used in addition to individual and face-to-face education. The content of this booklet is easy to understand for all teens. It is an attempt to increase understanding of the disease by providing simple illustrations with textual explanations. The educational content of this leaflet includes the identification and definition of menstrual distress, a brief explanation of misconceptions about menstrual cycles and activities authorized and unauthorized during this period, personal hygiene, physical activity and exercise, nutrition and stress control techniques and relaxation. will be. The qualitative content of this booklet will be reviewed by ten faculty members. At the end of three sessions, this leaflet will be given to the intervention group. In addition, if you have any further questions about the study or illness, the teen will be contacted

**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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research.dpt@qums.ac.ir

**Web page address**

**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**

Somayeh Asgari

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**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**

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**

En 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**