Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

Phone
+98 28 3349 0267

Email address
s.asgari71@gmail.com

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

Street address

Shahid Bahonar Blvd. Ghazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6003

Email

s.asgari71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Imam jomea

Street address

Ghazvin, Shahid Bahonar Blvd. Ghazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

1391134156

Phone

+98 28 3335 7039

Fax

Email

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

Street address

School of Nursing & Midwifery, Qazvin university of Medical Science, Bahonar blvd.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3333 6003

Email

s.asgari71@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Somaye Asgari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Province

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s.asgari71@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Somaye Asgari

Position

Masters student

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Province

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3419759811

Phone

+98 28 3333 6003

Email

s.asgari71@gmail.com

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