

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effect of family centered and individual nutrition education on decrease bodily signs of premenstruation syndrom in daughters 14-18 years old

Protocol summary

Study aim

Comparison of effects of family centered and Individual nutrition education on bodily signs of premenstruation syndrom in daughters 14-18 years old.

Design

Randomised, clinical trial with one control and two intervention groups design of 342 samples.

Settings and conduct

The place of study is 5 high schools in Qazvin. At schools, with using premenstruation questionnaire, the students with premenstruation syndrom are recognized and based on inclusion and exclusion criteria 114 students are putting as intervention group and 114 students are putting as control group and 114 students are putting as parents group. After doing nutrition education intervention to students and parents, we spread questionnaire form after 1 month and evaluate the result of education in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have premenstruation syndrome, Have regular and natural menstruation, Not married, 14-18 years old, Live in Qazvin, Exclusion criteria: Supplements usage, Diseases, History of cancer in family, Have stress on three month ago,

Intervention groups

Intervention group 1: "students with premenstruation syndrom", convene 4 sessions education of self care of youth. Intervention group 2: "families of students with premenstruation syndrom". convene 4 sessions education of self care of youth. "Control group" students with premenstruation syndrom. There isn't any training.

Main outcome variables

Bodily signs of premenstruation syndrom, 24 hours nourishment recall.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180423039389N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Homa Javadiatabdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3368 5521

Email address

h.javadiatabdari@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2018-11-11, 1397/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of family centered and individual nutrition education on decrease bodily signs of premenstruation syndrom in daughters 14-18 years old

Public title

Effect of nutrition education on Premenstruation syndrom

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Have premenstruation syndrom, based on premenstruation questionnaire. Have regular and natural menstruation. Be single. Have 14-18 years old. Live in Qazvin. Be a student in one of schools in Qazvin.

Exclusion criteria:

Have diseases. Take Supplements. History of cancer in family Have stress on three month ago such as; death of relatives, marriage and operation.

Age

From **14 years** old to **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **342**

Randomization (investigator's opinion)

Randomized

Randomization description

Stage 1: At first, Qazvin is considered as 5 cluster. Then from each cluster, one high school is selected in simple random that in average 5 high schools are selected. Stage 2: The students who have moderate to severe premenstruation syndrom are detected based on premenstruation questionnaire and inclusion and exclusion criteria. Stage 3: Card shuffling with coloured cards is used for putting samples in three groups: "students", "families" and "control". For randomize allocation, we provide 342 coloured cards such as yellow, blue and green that are separated in 114 yellow cards, 114 green cards and 114 blue cards. Then after detecting students with premenstruation syndrom (moderate to severe) one coloured card is given to her. After ending of allocate, students with yellow cards are (intervention1), students with green cards are (intervention 2) and students with blue cards are Control group. At last, 114 persons with yellow cards are in intervention group 1, 114 persons with green cards are in intervention group 2 and 114 persons with blue cards are in control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

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

Qazvin university of medical sciences; Bahonar Blvd, Qazvin

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Qazvin

Province

Qazvin

Postal code

34199-15315

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.QUMS.REC.1397.045

Health conditions studied**1****Description of health condition studied**

Premenstruation Syndrom

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes**1****Description**

Bodily signs mark of premenstruation syndrom in premenstruation syndrom questionnaire.

Timepoint

Comparison of bodily signs of premenstruation syndrome before Intervention and 30 days after Intervention

Method of measurement

Premenstruation syndrom questionnaire.

2**Description**

Nurishment score based on recall nurishment questionnaire.

Timepoint

Comparison recall nurishment before Intervention and 30 days after Intervention

Method of measurement

Recall 24 hours questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 :The nutrition trainingto parents of students with premensturation syndrom. The nutrition training is based on hygiene ministry protocol at 4 weeks at 40 minutes.

Category

Prevention

2

Description

Intervention group 2 : The nutrition training to students with premensturation syndrom. The nutrition training is based on hygiene ministry protocol at 4 weeks at 40 minutes with pamphelets.

Category

Prevention

3

Description

Control group: The Students with Premenstruation Syndrom. This group wont have any Education.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat high school

Full name of responsible person

Fateme Shali

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No. 20, Aban Ave; Padegan Blvd.,

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2

Recruitment center

Name of recruitment center

Nastaran high school

Full name of responsible person

Elham Haidari

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3

Recruitment center

Name of recruitment center

Alzahra School Of Art

Full name of responsible person

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4

Recruitment center

Name of recruitment center

Narges

Full name of responsible person

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Name of recruitment center

Fatemiyeh

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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research.dpt@qums.ac.ir
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
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Midwife
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There isn't more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available