

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Study the effectiveness and non-effectiveness of group discussion on menarche anxiety in girls primary school students

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of group discussion on menarche anxiety in girls primary school students. This is not blinded clinical trial. The study population will be included all eligible students of Gilangharb city that a total of 60 of them will be selected by cluster sampling and randomly will be assigned in to two experimental and control groups. At baseline Spielberger questionnaire will be provided for both groups. Intervention group to create knowledge and increasing awareness will receive 6 sessions of group discussion in the field of genital tract activity and Menstrual cycle and the changes associated with puberty once a week and the control group will not receive any training. 4 weeks after the last group discussion the questionnaire will be completed by both control and intervention groups and both groups will be compared in terms of level of anxiety. Inclusion criteria: Age between 10 and 12 years; Have not experienced first menses; Having secondary sexual characteristics; No special physical and psychiatric disease Exclusion criteria: The occurrence of menarche in girls before the completion of group discussion; No participate in two or more sessions of group discussion

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050114333N74**

Registration date: **2017-07-04, 1396/04/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-04, 1396/04/13

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effectiveness and non-effectiveness of group discussion on menarche anxiety in girls primary school students

Public title

The effect of group discussion on the menarche's anxiety among girls elementary students

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 10 and 12 years; Have not experienced first menses; Having secondary sexual

characteristics; No special physical and psychiatric disease Exclusion criteria: The occurrence of menarche in girls before the completion of group discussion; No participate in two or more sessions of group discussion

Age

From **10 years** old to **12 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

kums.rec.1396.79

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhoea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhoea

Primary outcomes

1

Description

Menarche anxiety

Timepoint

Baseline, four weeks after the end of the study

Method of measurement

Using the Spielberger questionnaire (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

The control group will not receive any training

Category

Other

2

Description

Intervention group to create knowledge and increasing awareness will receive 6 sessions of group discussion in the field of genital tract activity and Menstrual cycle and the changes associated with puberty once a week

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Gilan Gharb city schools

Full name of responsible person

Zhra Pourfarjam

Street address

Gilan Gharb

City

Gilan Gharb

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Zahra Pourfarjam

Position
MA Student of consultation in midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty