

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effectiveness two methods of lecture and group discussion on knowledge and performance of menstrual hygiene in high school girl students in Boroujerd city 2016-2017.

Protocol summary

Study aim

Determining the effect of two methods lecture and group discussion on knowledge and performance menstrual hygiene in high school girl students

Design

Clinical trial of two groups, with parallel groups, double blind, randomized

Settings and conduct

Schools in Boroujerd city, sampling method is multi-stage cluster so that the high school's girl's in Boroujerd are considered as clusters and then they are selected several schools randomly. Then, the students who have entry requirements to study the convenience selected and they by using random block method assigned to study groups. Analyzer: By coding questionnaires and counselor: No knowledge of codes

Participants/Inclusion and exclusion criteria

Inclusion criteria; Student girls have experienced at least 3 periods of a monthly menses, Students are aged 13-15years old, Students studying at the 7th and 8th grades of upper secondary education, Having no known disease affecting menarche such as diabetes and hormonal disorders, chemotherapy and radiotherapy, Resident in Boroujerd. Exclusion criteria; Students are absent for more than one training session, Due to changing the location of the high school, access to them is not possible, Unwillingness to continue the training program.

Intervention groups

Lecture and group discussion

Main outcome variables

Change knowledge level Change performance level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038210N1**

Registration date: **2018-06-11, 1397/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-11, 1397/03/21**

Update count: **0**

Registration date

2018-06-11, 1397/03/21

Registrant information

Name

Elham Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3291 1047

Email address

eli885falah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-27, 1396/09/06

Expected recruitment end date

2018-09-28, 1397/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness two methods of lecture and group discussion on knowledge and performance of

menstrual hygiene in high school girl students in Boroujerd city 2016-2017.

Public title

Effect two methods of lecture and group discussion on knowledge and performance of menstrual hygiene

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

- Student girls who have experienced at least 3 periods of a monthly menses Students are aged 13-15 years old Students studying at the 7th and 8th grades of secondary education Not having effect on menarche such as diabetes and hormonal disorders, chemotherapy and radiation therapy. Resident in Boroujerd

Exclusion criteria:

Students who are absent for more than one training session Access to them is not possible due to changing the location of the high school Unwillingness to continue the training program

Age

From **13 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Multi-stage cluster for selecting schools in different parts of the city, Quadruple random block in order to allocate balanced samples to the lecture group and group discussion

Blinding (investigator's opinion)

Double blinded

Blinding description

Data analyzer: Using questionnaire coding Psychologist: No knowledge of codes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

IRCT

Secondary trial Id

31673

Registration date

2018-06-03, 1397/03/13

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

khoramabad

City

khoramabad

Province

Lorestan

Postal code

6814967851

Approval date

2017-11-20, 1396/08/29

Ethics committee reference number

IR.LUMS.REC.1396349

Health conditions studied

1

Description of health condition studied

Menstrual hygiene

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

knowledge

Timepoint

Before, immediately after the intervention and one month after the intervention

Method of measurement

Researcher-made knowledge questionnaire

2

Description

performance

Timepoint

Before, immediately after the intervention and one month after the

Method of measurement

Researcher-made Function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lecture

Category

N/A

2**Description**

Intervention group: group discussion

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Secondary High School in Borujerd

Full name of responsible person

ElhamFalah

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Research Committee

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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

Khoram-Abad 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**

Khoram-Abad University of Medical Sciences

Full name of responsible person

ElhamFalah

Position

nursing student

Latest degree

A Level or less

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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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

Sample legal age

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the available information

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Blind data

From where data/document is obtainable

Author

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

email

Comments