Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Street address
khoramabad
City
khoramabad
Province
Lorestan
Postal code
6814967851
Phone
+98 66 3291 1047
Email
eli885falah@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Research Committee
Street address
khoramabad
City
khoramabad
Province
Lorestan
Postal code
6813833946
Phone
+98 66 3312 0192
Email
eli885falah@gmail.com
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
ElhamFallah
Position
nursing student
Latest degree
A Level or less
Other areas of specialty/work
Health Promotion
Street address
khoramabad, 30metri
City
khoramabad
Province
Lorestan
Postal code
6814967851
Phone
+98 66 3291 1047
Email
eli885falah@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
ElhamFallah
Position
nursing student
Latest degree
A Level or less
Other areas of specialty/work
Health Promotion
Street address
khoramabad, 30metri, no9
City
khoramabad
Province
Lorestan
Postal code
6814987821
Phone
+98 66 3291 1048
Email
eli885falah@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
elhamfallah

Position
nursingstudent

Latest degree
A Level or less

Other areas of specialty/work
Health Promotion

Street address
khorramabad, bakhshdehpir

City
khorramabad

Province
Lorestan

Postal code
6814967851

Phone
+98 66 3291 1047

Email
eli885falah@gmail.com

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