Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of a two-week lecture-based versus problem-based learning on menstrual hygiene behaviors and food habits of adolescent girls: A community-based three-arm study

Protocol summary

Study aim

Determine and compare the effect of Lecture-Based Learning and Problem-Based Learning on menstrual hygiene behaviors and food habits in adolescent girls

Design

This randomized controlled trial was conducted on 85 high-school female students (30 in control group, 27 in lecture-based learning group and 28 in problem-based learning group) who were selected by a multi-stage cluster sampling method.

Settings and conduct

This study was conducted in government girls' high-schools located in the seven education district of Tehran. Educational program related to menstrual hygiene behaviors and healthy diet was implemented in four 60-minute training sessions in the LBL group by lecture method and in the PBL group by problem-based method held by the first researcher. The educational content included these items: the definition of healthy diet, macronutrients needs during adolescence, introducing of healthy snacks, disadvantages of fast foods and the risks of obesity in adolescence, as well as the definition of menstruation and premenstrual syndrome, menstrual pain management, the principles of personal hygiene during menstruation, consisting of cleanliness and bath methods, underwear hygiene and vaginal hygiene.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- An age range of 14-15 years 2- Students' verbal assent 3- A written informed consent from the students' parents Exclusion criteria: 1- Missed more than one learning session 2- Filling out the questionnaires incompletely 3- No history of menstruation 4- Had not passed at least one year since her menarche

Intervention groups

This study includes three intervention groups: problem-based learning, lecture-based learning and control group which investigates the effect of LBL and PBL on menstrual hygiene behaviors and food habits of adolescent girls.

Main outcome variables

Menstrual Hygiene Behaviors and Food Habits

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049514N1**
Registration date: **2020-12-30, 1399/10/10**
Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**
Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Seyedeh Atefeh Koohpayeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 5643

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skoohpayeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date
2020-01-21, 1398/11/01
Actual recruitment end date
2020-02-19, 1398/11/30
Trial completion date
2020-02-19, 1398/11/30

Scientific title
Effects of a two-week lecture-based versus problem-based learning on menstrual hygiene behaviors and food habits of adolescent girls: A community-based three-arm study

Public title
A comparative study of the effect of lecture-based learning and problem-based learning on menstrual hygiene behaviors and food habits in adolescent girls
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
An age range of 14-15 years Students' verbal assent A written informed consent from the students' parents
Exclusion criteria:
Missed more than one learning session Filling out the questionnaires incompletely No history of menstruation Had not passed at least one year since her menarche
Age
From **14 years** old to **15 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Actual sample size reached: **85**
Randomization (investigator's opinion)
Randomized
Randomization description
Multi-stage cluster sampling method by a random number table. First, District 7 was selected from five education districts located in the central areas of Tehran using a random number table. Then, from 13 government girls' high-schools in this district, three were randomly selected by a random number table. Each of the selected school was considered as each study's arm. For this purpose, we allocated first, second, and third selected school to three groups of PBL, LBL and control by lottery method. The ninth-grade classes in each school were serially numbered and one class was randomly selected using a table of random numbers; then, all students of the selected class were invited to participate in the study.
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 Shahid Beheshti University of Medical Sciences
Street address
ValiAsr Street
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-07-15, 1398/04/24
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.129

Health conditions studied

1

Description of health condition studied
Menstrual Hygiene Behaviors
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Food Habits
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Menstrual Hygiene Behaviors - Food Habits
Timepoint
Before, immediately and three months after the last learning session by lecture-based and problem-based methods.
Method of measurement
Information about menstrual hygiene behaviors (MHBs) was collected by the 16-item researcher-made questionnaire (MHBsQ) and information about food habits (FHs) was collected by presenting the Persian version of Adolescent Food Habits Checklist (AFHC) with 23 items.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group (LBL group): ninth grade female students in one of the three selected government girls' high-schools located in the seven education district of Tehran. The educational program in LBL group was performed in four 60-minute training sessions by lecture and the question-and-answer methods using teaching media (i.e., whiteboard, pictures). The educational contents for LBL and PBL groups were similar and were adapted from valid books and articles and it was validated by a gynecologist and two nursing and nutrition faculty members of SBMU. The educational content included these items: the definition of healthy diet, macronutrients needs during adolescence, introducing of healthy snacks, disadvantages of fast foods and the risks of obesity in adolescence, as well as the definition of menstruation and premenstrual syndrome, menstrual pain management, the principles of personal hygiene during menstruation, consisting of cleanliness and bath methods, underwear hygiene and vaginal hygiene.

Category

Behavior

2

Description

Second intervention group (PBL group): ninth grade female students in one of the three selected government girls' high-schools located in the seven education district of Tehran. The educational program in PBL group was performed in four 60-minute training sessions using teaching media (i.e., whiteboard, pictures). In the PBL group, five small groups were established, and then four scenarios were presented (two for menstrual hygiene and two for a healthy diet). The PBL steps were as follow: 1) presenting situation and scenario and clarifying the concepts, 2) defining the problem and reviewing scenario, 3) discussing and analyzing the problem with brain storming technique, 4) finding the possible solutions, 5) identifying learning needs, 6) seeking information, and 7) reporting, assessing, and using of new information. The educational contents for LBL and PBL groups were similar and were adapted from valid books and articles and it was validated by a gynecologist and two nursing and nutrition faculty members of SBMU. The educational content included these items: the definition of healthy diet, macronutrients needs during adolescence, introducing of healthy snacks, disadvantages of fast foods and the risks of obesity in adolescence, as well as the definition of menstruation and premenstrual syndrome, menstrual pain management, the principles of personal hygiene during menstruation, consisting of cleanliness and bath methods, underwear hygiene and vaginal hygiene.

Category

Behavior

3

Description

Control group: ninth grade female students in one of the three selected government girls' high-schools located in the seven education district of Tehran. At the end of study, students of control group received a 1-hour education session by a designed booklet about menstrual hygiene and a healthy diet in order to observe the ethical issues of the research.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Selected schools located in the 7 District of Tehran

Full name of responsible person
Parvaneh Vasli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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Web page address

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Grant name

Thesis grant

Grant code / Reference number

-

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvaneh Vasli

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments
-