

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Improving menstrual hygiene in girls aged 12 to 16 years through the training of health educators

Protocol summary

Study aim

Improving menstrual hygiene in girls aged 12 to 16 years through the training of school teachers

Design

The study group: female students, ages 14 to 16 years old, in the second level of high school in Islamshahr. Sample size: 100 students randomly from 37 Islamic schools in the city, a total of 3,700 people who will enter the study then 740 of them receive training in the initial survey, and evaluated after the exam. Trial phase: not applicant Not blinded According to the statistics and methodology expert, only up to 15% absenteeism and non-response and defects in the questionnaire are not a problem. If it is more than that, the alternative sample will be selected.

Settings and conduct

Place: IslamShahr The current research is a semi-experimental interventional study. Before-after evaluation, single group, the research units two months after completing the training; They are randomly tested based on the questionnaire prepared and the level of awareness of menstrual hygiene is checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having perfect health, having the experience of starting menstruation, and willingness to participate in research Exclusion criteria: presence of any special problems and diseases, unwillingness

Intervention groups

Girls in the age group of 12 to 16 years old in Islamshahr schools In this intervention, after the initial evaluations, menstrual health training is given to the trainers and they give it to the students, and the level of the girls is evaluated and compared with the original sample.

Main outcome variables

Awareness of menstrual hygiene, menstrual hygiene behaviors, symptoms and examination of PMS, PCOS symptoms, presence of endometriosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231023059817N2**

Registration date: **2023-12-29, 1402/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-29, 1402/10/08**

Update count: **0**

Registration date

2023-12-29, 1402/10/08

Registrant information

Name

Mohammad Haddadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2253 9892

Email address

mohammadhaddadi1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improving menstrual hygiene in girls aged 12 to 16 years through the training of health educators

Public title
Improving menstrual hygiene in girls aged 12 to 16 years through the training of health educators

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
having perfect health (no history or known disease)
Having the experience of starting menstruation (at least two cycles have passed since the start of menstruation)
Willingness to participate in the research (through the informed consent of the parents to participate in the research, every parent who is satisfied registers their consent in the school office for their child to participate in the study)
Exclusion criteria:
The existence of any special problem and disease
Reluctance to participate in classes

Age
From **12 years** old to **16 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **740**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Imam Khomeini Hospital Complex

Street address

Imam khomeni hospital complex, Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-10-10, 1402/07/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.274

Health conditions studied

1

Description of health condition studied

Menstrual hygiene in girls

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Menstrual health behaviors

Timepoint

Before and after training

Method of measurement

questionnaire

2

Description

Awareness of menstrual hygiene

Timepoint

Before and after training

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Menstrual hygiene (bathing during menstruation; the role of washing in causing uterine infection; the normality of pain under the heart in the first days of menstruation; the correct action in case of no menstruation and physical changes during menstruation; mental and mood changes during menstruation; how Nutrition during menstruation) - Training on premenstrual syndrome and its symptoms - Training on symptoms of endometriosis - Training on symptoms of polycystic ovary syndrome

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

High schools for girls in Islam Shahr

Full name of responsible person

Sedigheh Hantoushzadeh

Street address

Vali-E-Asr Reproductive Health Research Center,
Family Health Research Institute, Tehran University of
Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 912 127 1209

Email

Hantoushzadeh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ZARRIN ROYA

Full name of responsible person

Kamyar Tabarokpour

Street address

No. 30, Seventh Avenue, Khaled Islambuli St.
(Vozara), Argentina Square

City

Tehran

Province

Tehran

Postal code

15113714511

Phone

+98 21 8810 7040

Email

kamyar.tabarokpour@zarrinc.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

ZARRIN ROYA

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sedigheh Hantoushzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vali-e-Asr Reproductive Health Research Center,
Imam Hospital Complex, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1616

Email

hantoushzadeh@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sedigheh Hantoushzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Vali-e-Asr Reproductive Health Research Center,
Imam Hospital Complex, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1616

Email

hantoushzadeh@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Haddadi

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Vali-e-Asr Reproductive Health Research Center,
Imam Hospital Complex, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6693 9320

Email

mohammadhaddadi1997@gmail.com

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file will not be publicly available in any way, but only its report will be published in the form of an article.

The data will be made available separately to the Ministry of Health and Medicine on their request, or to the researchers if it is known which data will be used in which case. The informed consent form will also be provided during the publication of the article upon the request of the editor of the journal, and the methods of statistical analysis will be partially represented in the article, and the rest of the information will be available to the researchers upon request.

When the data will become available and for how long

Start of access based on the protocol up to one year after publishing the results

To whom data/document is available

Ministry of Health The researchers behind the plan The editor of the magazine to be published Researchers based on the protocol Responsible sponsor of the plan

Under which criteria data/document could be used

In the case of health planning by the Ministry of Health and in case of use in other approved research projects

From where data/document is obtainable

An official email should be sent to the main person responsible for the project

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

First, the request in the official form and letterhead is sent to the project manager. This request will be reviewed at the M. Red Nahar Research Center and the requested data will be provided after being blinded and anonymized if approved.

Comments