

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effect of educational methods of small groups and peers, with the participation of mothers on menstrual hygiene behaviors in school students

Protocol summary

Study aim

Comparison the effect of educational methods of small groups and peers, with the participation of mothers on menstrual hygiene behaviors in school students

Design

An interventional study of three randomized groups with at least 30 eligible individuals in each group. Of the high schools in Mashhad, three schools in one district are assigned to one of three groups by lottery.

Settings and conduct

Three high schools from one district are assigned to one of the three study groups (peers, small groups, control) by drawing. The menstrual health behaviors questionnaire is completed before and after the end of the first and second menstrual cycles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female student; single; age: 13 to 15 years old; having regular menstrual cycles; having physical health; not using medicines affecting the psyche; live with mother; the absence of an adverse or stressful incident in the last 6 months; lack of compliance with certain diets; interest in participating in a student study and her mother. Exclusion criteria: absence in more than one session; lack of access to the student; not having menstruation during the study; unwillingness to continue studying; participating in menstrual hygiene education classes during the study, absenteeism of any of the training sessions by mothers; filling the checklist by less than six days by mothers.

Intervention groups

In the peer group, a small selection of students are explained about menstruation hygiene, each one explained to the number of classmates. The members are divided into groups of 3 to 4, each session after the study and discussion, the results are presented to the entire group. For mothers in two intervention groups, two sessions of with the same content and for the control

group, routine training is done.

Main outcome variables

Menstrual hygiene behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180904040952N2**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Reihaneh Jarrahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3283 1661

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-15, 1397/08/24

Expected recruitment end date

2019-02-13, 1397/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of educational methods of small groups and peers, with the participation of mothers on menstrual hygiene behaviors in school students

Public title

Comparison of the effect of educational methods of small groups and peers, with the participation of mothers on menstrual hygiene behaviors in school students

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian and resident of Mashhad A female student is in the 7th or 8th grade The student and mother are interested in participating in the study and have written consent Be single Age of 15-13 years Have a history of at least one menstruation Regular menstrual cycles (within the range of 21 to 35 days) Live with her mother. The mother has literacy to read and write. Have a phone number

Exclusion criteria:

Use of medicines affecting the psyche (three-ring anti-depressant drugs, monoamine oxidase inhibitors and benzodiazepines) Over the past 6 months, she has experienced any disastrous or stressful incidents (deaths of first degree relatives, severe familial disorders, financial problems, major changes in living conditions, academic failure and probation, emotional problems) Follow certain diets such as diets of obesity, weight loss, vegetarianism, water therapy. Lack of physical health (a history of medical illness such as diabetes, thyroid disorders, Cushing's disease, pituitary tumors, genital diseases such as myoma, endometriosis, ovarian cysts, pelvic inflammatory disease). She has already participated in menstrual hygiene education classes.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the high schools in Mashhad, three schools are designated from one district, and each school is assigned to one of the three study groups through the lottery. In each school, two classes are selected at the age of 15-13, and all girls who meet the criteria for entering these classes are enrolled in the study. Then people in each group are randomly selected.

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**

The Ethics Committee of the Mashhad Medical Science University

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Mashhad, University Street, Quraishi Building

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Razavi Khorasan

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91735-951

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.024

Health conditions studied**1****Description of health condition studied**

Menstrual health

ICD-10 code

Z00.6

ICD-10 code description

Encounter for examination for normal comparison and control in clinical research program

Primary outcomes**1****Description**

Student's menstrual health behaviors

Timepoint

Before the onset of intervention, at the end of the first and second menstrual cycle

Method of measurement

Menstrual health behavior questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: In the peer group, a limited number of students are selected and they are explained in two 45-60 minutes sessions about menstrual hygiene (in the areas of personal hygiene, nutrition, physical activity, pain relief and psychological support), and each of them teach to a number of their classmates. For mothers, the training is done in two 2-hour sessions with the same educational content. The menstrual hygiene behaviors questionnaire is completed before the intervention and after the end of the first and second menstrual periods.

Category

Lifestyle

2

Description

Intervention group2: Training small groups, four sessions of 45 to 60 minutes a week about menstrual hygiene (in the areas of personal hygiene, nutrition, physical activity, pain relief and psychological support). The members are divided into groups of 3 to 4, In each session, individual, two to two study, a group discussion is done and eventually one will deliver the results of the discussion to the entire group. For mothers, the training is done in two 2-hour sessions with the same educational content. The menstrual hygiene behaviors questionnaire is completed before the intervention and after the end of the first and second menstrual periods.

Category

Lifestyle

3

Description

Control group: In the control group, routine school education is done on menstrual menstrual hygiene (in the areas of personal hygiene, nutrition, physical activity, pain relief and psychological support)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zaynab girl's high school

Full name of responsible person

Reihaneh Jarrahi

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Sarafrazan 7, Sarafrazan Ave, Mashhad

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Recruitment center

Name of recruitment center

Motahare girl's high school

Full name of responsible person

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Reihaneh Jarrahi

Position

Master of science student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Faculty of member

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available