

# 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

##### Email address

jarrahir951@mums.ac.ir

##### 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

**Street address**

Mashhad, University Street, Quraishi Building

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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

##### Street address

Sarafrazan 7, Sarafrazan Ave, Mashhad

##### City

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##### Province

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##### Postal code

9137913199

##### Phone

+98 51 3882 8717

##### Email

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### 2

#### Recruitment center

##### Name of recruitment center

Motahare girl's high school

##### Full name of responsible person

Reihaneh Jarrahi

##### Street address

Ab o Bargh St, 8th Shahrivar Blvd, Mashhad

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### 3

#### Recruitment center

##### Name of recruitment center

Shahid Hamami girl's high school

##### Full name of responsible person

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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

##### Street address

Qureishi building, Daneshgah Ave, Mashhad

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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

**Contact**

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Faculty of member

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## Person responsible for updating data

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**Other areas of specialty/work**

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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