Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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
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
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Sarafrazan 7, Sarafrazan Ave, Mashhad
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2

Recruitment center
Name of recruitment center
Motahare girl's high school
Full name of responsible person
Reihaneh Jarrahi
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Ab o Bargh St, 8th Shahrivar Blvd, Mashhad
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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
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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 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