

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of puberty health education on mothers and girls on general self-efficacy of Ghaemshahr public school girls in 2018

Protocol summary

Study aim

Determining the effect of puberty health education on mothers and girls on general self-efficacy of Ghaemshahr female public school students

Design

The clinical trial has a control group and two interventional groups, community based and pragmatic, with parallel and randomized groups in the classification method.

Settings and conduct

The intervention was conducted on 150 female students aged 13 and 14 years old, one year old from their menstruation, and 7th and 8th grade students in Ghaemshahr high school girls, and 50 of their mothers. A randomized sampling will be classified. In the first step, three schools will be selected from the education system and from each selected school, 10 students from the seventh and eighth grades will be randomly selected and, if the student is satisfied, And his or her parents to participate in the research, pre-test questionnaires will be completed by them. Then, based on the homogeneity of the mean score of the pre-test performance, each school will be randomly assigned to intervention and control groups. The education of puberty health will include lectures and presentations to intervention teams.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having the age of 13 - 14 years 2. Having real mothers 3- Passing at least one year from the menstrual period as they say 4- Education in Ghaemshahr State Schools Exclusion criteria : 1- Study in non-governmental schools of Qaemshahr 2. Education other than the seventh and eighth

Intervention groups

Group 1: Community Health Nurse Group: 4 lecture sessions and using educational aids Group 2: Mothers-trained group: Mothers' training (previously seen in community education nurses at two 90-minute sessions) is given to their daughters at home. Control group: Without intervention, at the end of the study, receive

educational pamphlets.

Main outcome variables

Public self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040461N1**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

Simin Khatirpasha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1000

Email address

khatirpasha.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-01, 1397/08/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

2018-11-06, 1397/08/15

Actual recruitment end date

2019-02-04, 1397/11/15

Trial completion date
2019-02-04, 1397/11/15

Scientific title
The effect of puberty health education on mothers and girls on general self-efficacy of Ghaemshahr public school girls in 2018

Public title
Evaluation of puberty health education on girl's self-efficacy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
1. Having an age of 14-13 years 2. Pass at least one year from the time period, according to your statement 3. Not having chronic physical or mental illness 4. Students at Ghaemshahr girls' high school 5. Girls who live with their true mothers.
Exclusion criteria:
Absence of a student at the seventh and eighth grade

Age
From **13 years** old to **14 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**
Actual sample size reached: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
By random sampling with a draw from the list of government schools in Ghaemshahr, three schools will be randomly selected (two schools for intervention groups 1 and 2 and one for the control group). From Schools Intervention and control groups are selected individually and randomly from the list of students of each base in each school by drawing lots to the required number and completing 50 individuals in each intervention group to conduct a sample 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 Iran University of Medical Sciences
Street address
, Iran University of Medical Sciences, next to Milad Tower, Hemat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-08-26, 1397/06/04
Ethics committee reference number
IR.IUMS.REC.1397.342

Health conditions studied

1

Description of health condition studied
Puberty health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
General Self-Efficacy
Timepoint
Before training and 12 weeks after puberty health education
Method of measurement
Sherer General Self-efficacy Inventory

Secondary outcomes
empty

Intervention groups

1

Description
intervention group 1: training in the form of 4 half-hour training sessions, question and answer lecture, and the use of teaching aids (slideshows for educational materials in the field of physical health (skin and hair, menstruation, physical activity, and rest and nutrition) , psychological and social maturity.
Category
N/A

2

Description

The intervention group 2: The mothers' training group, where the mothers are previously trained in two 90-minute training sessions by the health nurse, and they train their daughters at home.

Category

N/A

3

Description

Control group: There is no special intervention; at the end of the intervention, educational pamphlets receive the same as the other two groups.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaemshahr State Schools

Full name of responsible person

simin khatirpasha

Street address

Education Department, Danesh Street

City

Qaemshahr

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Mazandaran

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Email

robatkarim@iums.ac.ir

Web page address

<http://qaemshahr.mazand.medu.ir/fa/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malekoti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Marhamat Farahaninia

Position

Master of nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as the original outcome information

When the data will become available and for how long

Start the access period 1 year after the print results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

If they are similar in the type of statistical methods or statistical community.

From where data/document is obtainable

Using the email address author
skhatirpasha@yahoo.com Library of the Faculty of
Nursing and Midwifery, Iran University of Medical
Sciences

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

First, the request email is sent to the author and the author will send the confirmation email to the requestor after confirmation and acceptance.

Comments