

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of mothers' educational intervention on reproductive health of adolescent girls

Protocol summary

Study aim

The effect of mothers' educational intervention on reproductive health of adolescent girls

Design

Randomized Controlled Trial, with case and control groups, Sample size 100 (50 samples per group)

Settings and conduct

Sampling is done randomly, First, all elementary and secondary schools in Shahroud are listed and one school is randomly selected, then the number of school students is listed and 50 mothers are randomly selected for each group. After coordination with the mothers, the research instrument is completed by the intervention and control groups. After 6 weeks of training for the intervention group, the research instrument is completed by both groups and then 3 months later.

Participants/Inclusion and exclusion criteria

Mothers residing in Shahrood; Mothers have at least one daughter; ages 11-19 years old; The girl is studying in one of the schools; Satisfaction to participate in the survey.

Intervention groups

Mothers who are in the intervention group, using the educational package based on the results of qualitative study and literature review and is based on the educational needs of mothers regarding the reproductive health of adolescent girls (based on evidence), receive 6 90-minute training sessions per week. The booklet that has been prepared in this regard is also available to mothers. No action is taken for the control group. Only after the study, for ethical considerations, adolescent reproductive health education booklet given to the control group.

Main outcome variables

1. Understanding the Necessity of Adolescent Girls' Reproductive Health Education to Mothers
2. Educational content
3. Empowering Mothers in Promoting Adolescent Girls' Reproductive Health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191229045929N1**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **retrospective**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Shahrbanoo Salehin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

drbsalehin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-03-05, 1398/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mothers' educational intervention on reproductive health of adolescent girls

Public title

The effect of mothers' educational intervention on reproductive health of adolescent girls

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers residing in Shahrood Mothers have at least one daughter, ages 11-19 years old. The girl is studying in one of the schools Satisfied to participate in the survey

Exclusion criteria:

Unwillingness to participate in the study

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method is using a quadruple block. According to the blocks, there are six states under ABBA 6-, 5- ABAB, 4- BAAB, BABA 3-, BBAA 2-, 1- AABB. Using random numbers table, obtained numbers are used for orders of blocks. Then 100 envelopes are prepared and numbered from 1 to 100 in the above order and the letters inside them are written. The word A or B is placed inside the envelopes. Individuals receive one of these envelopes according to arrange entrance to study and determine which group they belong to.

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 Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Scienc

Street address

School of Nursing and Midwifery, opposite Shahid Rajaei Heart Hospital, Naiayesh intersection, Valiasr

Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-01-19, 1394/10/29

Ethics committee reference number

IR.SBMU.PHNM.1394.283

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

Maternal educational needs about reproductive health of adolescent girls

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Understanding the Necessity of Adolescent Girls' Reproductive Health Education to Mothers

Timepoint

Before, immediately after and 3 months after intervention

Method of measurement

Questionnaire "Understanding the Necessity of Reproductive Health Education for Mothers"

2**Description**

Educational content

Timepoint

Before, immediately after and 3 months after intervention

Method of measurement

Questionnaire "Educational characteristics of reproductive health"

3**Description**

Empowering Mothers in Promoting Adolescent Girls' Reproductive Health

Timepoint

Before, immediately after and 3 months after intervention

Method of measurement

Questionnaire "Empowering Mothers in Promoting Adolescent Girls' Reproductive Health"

Secondary outcomes

1

Description

Mothers' knowledge of reproductive health of adolescent girls

Timepoint

Before, immediately after and 3 months after intervention

Method of measurement

questionnaire"Mothers' knowledge of reproductive health of adolescent girls"

Intervention groups

1

Description

Intervention group: using the educational package based on the results of qualitative study and literature review and educational needs of mothers regarding the reproductive health of adolescent girls (based on evidence), 6 training sessions (90-minute per week). The booklet that has been prepared in this regard is also available to mothers.

Category

Other

2

Description

Control group: Based on the quadruple blocking of mothers who are in the Control group, no action is taken for this group. Only after the study, for ethical considerations, adolescent reproductive health education booklet given to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Education of Shahroud

Full name of responsible person

Shahrbanoo Salehin

Street address

Azadi Ave.

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Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Phone

+98 23 3222 7052

Email

drbsalehin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masumeh Simbar

Street address

Vali Asr Ave.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

msimbar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

30

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahrbanoo Salehin

Position

PhD Student of Reproductive Health

Latest degree

Master

Other areas of specialty/work

Midwifery

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Tehran Ave.

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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