

# 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.

##### City

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

##### Street address

Tehran Ave.

##### City

Shahroud

##### Province

Semnan

##### Postal code

۳۶۱۴۷-۷۳۹۴۷

##### Phone

+98 23 3239 5054

**Email**

drbsalehin@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shahrbanoo Salehin

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PhD Student of Reproductive Health

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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shahrbanoo Salehin

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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