

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

A Comparison of the effects of puberty health education for girls and mothers on girl students' self-esteem

Protocol summary

Study aim

The effect of puberty health education for Daughters and mothers on Daughters' self-esteem

Design

A blinded randomised controlled clinical trial with 3 groups include of 141 participants, that will be followed for one week and one month after education

Settings and conduct

the sampling method will be a multi-stage method. In the first step, 3 schools will be randomly selected from the first secondary school girls in the 4th district of Shiraz. Then, from selected schools, a class from each section is randomly selected as a cluster, and then individuals in each class will be selected by systematic randomization method. Selected individuals are randomly assigned to three groups of 47 participants by block randomization method.

Participants/Inclusion and exclusion criteria

Education of girls in secondary schools, Students and mothers willingness for participation in the study

Intervention groups

Intervention group 1: Puberty Health Education for girls
Intervention group 2: Puberty Health Education for mothers

Main outcome variables

Self esteem score from Cooper Smith questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037908N1**

Registration date: **2019-07-08, 1398/04/17**

Registration timing: **prospective**

Last update: **2019-07-08, 1398/04/17**

Update count: **0**

Registration date

2019-07-08, 1398/04/17

Registrant information

Name

Mitra Soltanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

soltanian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-25, 1398/07/03

Expected recruitment end date

2019-11-27, 1398/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the effects of puberty health education for girls and mothers on girl students' self-esteem

Public title

A Comparison of the effects of puberty health education for girls and mothers on girl students' self-esteem

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Education of girls in the first secondary schools Students and mothers willing to participate in the study

Exclusion criteria:
History of taking sedative medications Transfer to other school or city Having a chronic disorder Exposure to stressful incidents in the last three months

Age
From **13 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **141**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method will be a multi-stage method. In the first step, 3 schools will be randomly selected from the first secondary school girls in the 4th district of Shiraz. From selected schools, a class from each section is randomly selected as a simple cluster.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the training sessions will be conducted by the researcher, but the completion of the questionnaires will be done by the researcher-helper in three steps before the training, one week and one month after the training. In other words, the outcome assessor and data analyzer are unaware of how the groups are allocated.

Placebo
Not used

Assignment
Parallel

Other design features
Initially, for each of the three groups, demographic and Cooper Smith Self Esteem Questionnaires will be filled in. Then, Puberty health classes will be held in 5 sessions with slideshows, giving pamphlets and lectures for intervention group one and two. Control group will not receive any training. For each of the three groups, Cooper Smith Self Esteem Questionnaire will be filled one week and one month later.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science, Zand Street

City
Shiraz

Province
Fars

Postal code
7194818694

Approval date
2018-02-25, 1396/12/06

Ethics committee reference number
IR.SUMS.REC.1396.184

Health conditions studied

1

Description of health condition studied

Girls' self esteem

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-Esteem score from Cooper Smith Questionnaire

Timepoint

Before, one week and one month after education

Method of measurement

Cooper Smith self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

3 sessions on puberty health education in the form of lectures, slideshows and pamphlets, each session will be held during 45 minutes for the intervention group 1 (girl students) in their schools.

Category

Lifestyle

2

Description

3 sessions on puberty health education in the form of lectures, slideshows and pamphlets, each session will be held during 45 minutes for the intervention group 2 (Mothers of girl students) in their schools.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

First secondary girl's schools in the Fourth District of Shiraz

Full name of responsible person

Mr. Allah Yar Rezaei

Street address

Education Department of the Fourth District of Shiraz, Vali-e-Asr Square ,Shiraz

City

Shiraz

Province

Fars

Postal code

14894-71368

Phone

+98 71 3224 2315

Fax

+98 71 3222 6034

Email

nahieh4@farsedu.ir

Web page address

<http://shz4.farsedu.org/default.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice-Chancellor for Research & Technology - Seventh Floor - Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Web page address

<http://research.sums.ac.ir/fa>

Grant name

Research proposal budget

Grant code / Reference number

1396-01-08-15626

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mitra Soltanian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shiraz - Namazi Square - School of Nursing and Midwifery

City

Shiraz

Province

Fars

Postal code

13119-71936

Phone

+98 71 3647 4254

Fax

+98 71 3647 4252

Email

Soltanian@sums.ac.ir

Web page address

<http://nurs-midwif.sums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mitra Soltanian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Fatemeh college of Nursing and Midwifery, Namazee square, Shiraz, Iran

City

Shiraz

Province

Fars
Postal code
13119-71936
Phone
+98 71 3647 4254
Fax
+98 71 3647 4252
Email
Soltanian@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mitra Soltanian
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Nursery
Street address
Fatemeh college of Nursing and Midwifery, Namazi square, Shiraz
City
Shiraz
Province

Fars
Postal code
13119-71936
Phone
+98 71 3647 4254
Fax
+98 71 3647 4252
Email
Soltanian@sums.ac.ir

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

Not applicable

Informed Consent Form

No - There is not 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