

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of puberty health education on the quality of life of girls aged 10 to 13 years

#### Protocol summary

##### Study aim

To determine the effect of puberty health education on the quality of life of girls aged 10 to 13 years

##### Design

This study is a randomized field trial with a control group.

##### Settings and conduct

This study will be conducted at the girl's public elementary schools in the west region of Tehran. The fifth- and sixth-grade students and their mothers meeting the inclusion criteria, will complete the Pediatric Quality of Life Inventory and KID Screen before the intervention. 45 days after the intervention and six months after the intervention, the questionnaires will again be completed by the participants.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: female students aged 10 to 13 years and their mothers; exclusion criteria: lack of parental permission for students' participation in the study, inability to use smart phone

##### Intervention groups

The intervention group will receive an educational application on puberty health. The program has been set based on five 90-minute sessions for the students and three 90-minute sessions for their mothers during 5 weeks. The control group will not receive any education.

##### Main outcome variables

Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180523039789N1**

Registration date: **2019-06-17, 1398/03/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-17, 1398/03/27**

Update count: **0**

##### Registration date

2019-06-17, 1398/03/27

##### Registrant information

###### Name

Maryam Gharacheh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8867 1613

###### Email address

gharacheh.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-07-21, 1398/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of puberty health education on the quality of life of girls aged 10 to 13 years

##### Public title

Effect of puberty health education on the girls' quality of life

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Girls aged 10 to 13 years and their mothers The absence

of underlying illnesses Having a smartphone or tablet under Android and IOS system  
**Exclusion criteria:**  
Lack of parental permission for students' participation in the study  
Inability to use smartphone

**Age**

From **10 years** old to **13 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, randomization will be conducted in two steps. In the first step, schools will be selected using the stratified random method and divided into several similar classes. From each class, one school will be allocated to the intervention group and another one to the control group, by ballot. Then, among each selected school, twenty students meeting the inclusion criteria, will equally be selected using the list of the fifth- and sixth-grade students through a random number table.

**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, Shahid Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-04-07, 1398/01/18

**Ethics committee reference number**

IR.IUMS.REC.1398.203

**Health conditions studied**

**1**

**Description of health condition studied**

Quality of life

**ICD-10 code**

Z71.9

**ICD-10 code description**

Counseling, unspecified

**Primary outcomes**

**1**

**Description**

Quality of life

**Timepoint**

Baseline, 45 days after the intervention and 6 months after the intervention

**Method of measurement**

Pediatric Quality of Life Inventory TM 4.0, KID Screen

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: The intervention includes a smartphone application on puberty health that will be available to eligible female students and their mothers. Its content includes physiology of puberty, changes during puberty, menstruation, premenstrual syndrome and nutrition during puberty. The mothers will receive an activation code after training. Then, with this code, the application will be activated for the student and they will be able to use it and receive the education. This program has been set based on five 90-minute sessions for students and three 90-minute sessions for their mothers during 5 weeks.

**Category**

Behavior

**2**

**Description**

Control group: will not receive any education.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

primary schools in Tehran

**Full name of responsible person**

Sedigheh Khanjari

**Street address**

School of nursing and midwifery, Rashid Yasemi St,  
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

seyed kazem malakouti

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Iran university of medical sciences, Hemat Exp

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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**

Sedigheh Khanjari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

Maryam Gharacheh

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable