

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,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8867 1613

Email

s-khanjari@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

seyed kazem malakouti

Street address

Iran university of medical sciences, Hemat Exp

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 1111

Email

kmalakouti@iums.ac.ir

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

Street address

School of nursing and midwifery, Rashid Yasemi St,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8867 1613

Email

s-khanjari@tums.ac.ir

Person responsible for scientific 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

Street address

School of nursing and midwifery, Rashid Yasemi St,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8867 1613

Email

s-khanjari@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Gharacheh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of nursing and midwifery, Rashid Yasemi St,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8867 1613

Email

gharacheh.m@iums.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

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