

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of two educational methods- educational software and booklet- on knowledge, attitude and performance of adolescent girls regarding puberty hygiene: a randomized controlled trial.

Protocol summary

Summary

Objectives: This study aims to determine the effect of two educational methods- educational software and booklet- on knowledge, attitude and performance of adolescent girls regarding puberty hygiene. **Design:** Randomized Controlled Trial. **Setting and conduct:** This study will be conducted on 600 secondary schools students in Tabriz city. Multistage cluster sampling will be used for sampling. In first stage, 24 schools will be randomly selected from girls' state and non state secondary schools which have at least 100 students. Then, from each school, 25 students (from second and third grades) will be randomly selected. After acquiring informed consent from students and your parents, pre-test questionnaires will be completed by participants. Then, according to the similarity of the performance score of pre-test, 24 schools will be divided into 8 groups which contain 3 schools in each group. These 3 schools in each group will be randomly assigned to two intervention groups and one control group. The two intervention groups will receive educational software or booklet, respectively. The control group will receive no intervention. One month after education, post-test questionnaires will be completed by students. **Participants:** Adolescent girls between 11 to 13 years old who studying in Secondary Schools and experiencing menstruation. **Main outcome measures:** Knowledge, attitude and performance that will be measured before and one month after education by questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102010324N3**

Registration date: **2013-02-06, 1391/11/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-06, 1391/11/18

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2013-02-10, 1391/11/22

Expected recruitment end date

2013-05-10, 1392/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of two educational methods- educational software and booklet- on knowledge, attitude and performance of adolescent girls regarding puberty hygiene: a randomized controlled trial.

Public title

Effect of two educational methods- educational software and booklet- on knowledge, attitude and performance of adolescent girls regarding puberty hygiene.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Students studying in state and non state secondary schools except special schools; Students who have experienced menarche; Not participating in similar studies; Having access to a computer. Exclusion criteria: Dissatisfaction of students and their parents to participate in the research.

Age

From **11 years** old to **13 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **600**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences Ethical Committee

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, and East Azerbaijan

City

Tabriz

Postal code**Approval date**

2013-01-21, 1391/11/02

Ethics committee reference number

91195

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

Puberty hygiene

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Knowledge

Timepoint

Before and one month after education

Method of measurement

Knowledge questionnaire

2**Description**

Attitude

Timepoint

Before and one month after education

Method of measurement

Attitude questionnaire

3**Description**

Performance

Timepoint

Before and one month after education

Method of measurement

Performance questionnaire

Secondary outcomes**1****Description**

Not used

Timepoint

Not used

Method of measurement

Not used

Intervention groups

1

Description

First intervention group: Education through educational booklet which contains educational materials about physical health (skin and hair care, menstruation, physical activity and rest, nutrition), mental and social health in puberty.

Category

Other

2

Description

Second intervention group: Education through educational software which contains educational materials about physical health (skin and hair care, menstruation, physical activity and rest, nutrition), mental and social health in puberty.

Category

Other

3

Description

Control group will receive no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Girls' state and non state secondary schools in Tabriz

Full name of responsible person

Saghi Sima

Street address

South Artesh street, Education Office

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Shakouri Seyyed Kazem

Street address

Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences, Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Saghi Sima

Position

Master in midwifery

Other areas of specialty/work

Street address

School of Nursing and Midwifery, South Shariati Street

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Fax

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mirghafourvand Mojgan

Position

PhD in Reproductive Health

Other areas of specialty/work

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mirg1385@yahoo.com

Web page address

<http://nursing.tbzmed.ac.ir>

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty