

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 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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Tabriz

**Postal code**

00

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00

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saghi.sima@gmail.com

**Web page address**

**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**

**Street address**

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mirg1385@yahoo.com

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<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*