Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 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
City
Tabriz
Postal code
00
Phone
00
Fax
Email
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
Nursing & Midwifery Faculty, South Shariati Street
City
Tabriz
Postal code
347-51745
Phone
+98 41 1479 6770
Fax
+98 47 96969
Email
Mirghafourvandm@tbzmed.ac.ir;

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