

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effectiveness of gamification method for puberty health education in adolescent girls in Babol

#### Protocol summary

##### Study aim

Determining the effectiveness of the gamification method to teach pubertal health in adolescent girls of Babol city Determining the average score of pubertal health awareness and performance in adolescent girls of Babol city Comparison of the change in the average puberty health awareness score in two gamification and control groups, immediately and one month after the intervention in teenage girls of Babol city. Comparison of the change in the average puberty health performance score in two gamification and control groups immediately and one month after the intervention in adolescent girls of Babol city.

##### Design

Clinical trial with control group, with random selection, phase 3 on 90 students. A lottery will be used for randomization.

##### Settings and conduct

The location of the study is girls' schools in the city of Babol. An in-person meeting will be held to complete the questionnaire, and then the intervention will take place once a week for 4 weeks.

##### Participants/Inclusion and exclusion criteria

Students' willingness to participate in the study Parents' consent for their children's participation Acceptance of participation by the school female students aged 12-13 years 7th grade students Having at least three menstrual experiences The ability to work with mobile phones and laptops to implement gamification in the intervention group Obtaining an average and unfavorable score from the knowledge and performance questionnaire (scoring 32 to 85 points)

##### Intervention groups

Puberty health educational platform based on gamification components and according to the educational content of puberty health based on the educational package. These materials are presented to students once a week during four weeks. No intervention is performed in the control group.

##### Main outcome variables

The average score of adolescent girls' knowledge in the field of pubertal health

#### General information

##### Reason for update

Need more time for sampling

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180218038783N4**

Registration date: **2023-07-30, 1402/05/08**

Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**

Update count: **1**

##### Registration date

2023-07-30, 1402/05/08

##### Registrant information

##### Name

Fereshteh Behmanesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 0504

##### Email address

f.behmanesh@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-01, 1402/08/10

##### Expected recruitment end date

2025-01-09, 1403/10/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of gamification method for puberty health education in adolescent girls in Babol

**Public title**

The effectiveness of gamification method for puberty health education in adolescent girls

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Students' willingness to participate in the study  
Parents' consent for their children's participation  
Acceptance of participation by the school female students aged 12-13 years  
7th grade students  
The ability to work with mobile phones and laptops to implement gamification in the intervention group  
Obtaining an average and unfavorable score from the knowledge and performance questionnaire (scoring 32 to 85 points)  
Having at least three menstrual experiences

**Exclusion criteria:**

Parents' lack of consent for their children's participation  
Lack of access to mobile phones and laptops to implement gamification in the intervention group  
Obtaining a score less than 32 and more than 85 from the knowledge and performance questionnaire  
Absence of menstruation

**Age**

From **12 years** old to **13 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we need at least four schools, and an equal number of schools will be randomly assigned to the control and intervention groups using lottery.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this study, the design of an educational platform was used to implement gamification rules and teach puberty health to students.

**Secondary Ids**

empty

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

Ethics Committee of Babol University of Medical Sciences

**Street address**

Ganj Afrooz Street, University Square, Babol University of Medical Sciences

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Approval date**

2023-06-17, 1402/03/27

**Ethics committee reference number**

IR.MUBABOL.REC.1402.026

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

Awareness and performance in the field of puberty health

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

The average score of adolescent girls' knowledge in the field of pubertal health

**Timepoint**

before the start of the intervention, immediately and four weeks after the intervention in the intervention and control regimes

**Method of measurement**

Maturity Awareness and Knowledge Questionnaire

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

The average performance score of adolescent girls in the field of pubertal health

**Timepoint**

before, immediately and four weeks after the intervention in two intervention and control groups

**Method of measurement**

Maturity Awareness and Performance Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: receiving education related to puberty health using a platform designed by Danoosh Shira company, and its sessions and challenges are prepared by the researcher using gamification method, and students will complete it once a week for four weeks using laptops or mobile phones.

#### Category

Behavior

### 2

#### Description

Control group: There is no intervention. One hour of routine training is offered by midwives to both groups.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

First secondary schools of Babol city

##### Full name of responsible person

Dr. Fareshte Bahmanesh

##### Street address

Ganj Afrooz Street, University Square, Babol  
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##### Email

f.behmanesh@mubabol.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Mehdi Rajabnia

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##### Email

ramazan@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

##### Full name of responsible person

Fereshteh Behmanesh

##### Position

Assistant Professor of Babol University of Medical Sciences

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Reproductive Health

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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Assistant Professor of Babol University of Medical Sciences

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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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available