

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

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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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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

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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