Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Effect of the educational intervention based on the health belief model on physical puberty health of girl students of 9th grade in public schools

Protocol summary

Study aim
Determine the Impact of educational intervention based on the health belief model on physical puberty health behavior of girl students of 9th grade in public schools in Rasht city, in 2018

Design
Randomized controlled trial, the intervention group (49) and control group (49), with parallel groups, not blind, random cluster.

Settings and conduct
Four schools are randomly selected from the list of schools in Rasht and randomly assigned to the control and test groups.To prevent the transmission of control and test information, the selected schools are randomly selected at a distance. From each school, a class is selected in the form of a draw. According to the research criteria, In total, 98 female students of the 9th grade will be included in the test and control groups.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: Employment at the ninth grade, having menarche experience (first menstruation). Exit criteria: physical and mental disability, not having satisfaction to participate in the study.

Intervention groups
Educational intervention program based on the health belief model will be carried out to improve the physical puberty health behavior of girl students. Before conducting the training classes, at first assessment will be based on the health belief model (pre-test) for the intervention and control group. Then, for intervention groups, 16 training sessions will be held between 45-60 minutes (for 4 subgroups of 12 people) and one month after the intervention, a reassessment based on the health belief model (post-test) will be performed for both intervention and control groups. In order to follow the ethical point of view, after the post-test, the training program for the control group is also conducted in two sessions.

Main outcome variables
Puberty health behavior

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181014041337N1**
Registration date: **2018-12-21, 1397/09/30**
Registration timing: **prospective**

Last update: **2018-12-21, 1397/09/30**
Update count: **0**

Registration date
2018-12-21, 1397/09/30

Registrant information

Name
Zahra Aghaee Kenari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-05, 1397/10/15

Expected recruitment end date
2019-01-20, 1397/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of the educational intervention based on the health belief model on physical puberty health of girl students of 9th grade in public schools

Public title
Study of The effect of educational intervention based on health belief model on health-puberty girls

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Employment at the ninth grade Having menarche experience (first menstruation)

Exclusion criteria:
Having physical and mental disabilities not having satisfaction to participate in the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is clustered. At first, each class is given from 1 to 4 numbers and using random numbers table, two of the 1-4 randomly selected and assigned to the intervention classes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Office center of Guilan University of Medical Sciences, Parastar Street, Rasht, IRAN

City
Rasht

Province
Guilan

Postal code
4157679466

Approval date
2018-09-22, 1397/06/31

Ethics committee reference number
IR.Gums.REC.1397.240

Health conditions studied

1

Description of health condition studied
Puberty health behavior in student girls

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Puberty health behavior

Timepoint
Before the intervention and one month after the intervention.

Method of measurement
Validated questionnaire of health belief model constructs.

Secondary outcomes

1

Description
knowledge

Timepoint
Before the intervention and one month after the intervention

Method of measurement
Validated questionnaire of health belief model constructs

Intervention groups

1

Description
Intervention group: educational intervention is organized in the form of holding educational classes based on the health belief model, in order to increase the awareness of puberty health behavior which includes 16 training sessions of 45-60 minutes for 4 subgroups of 12 people.Training is based on educational methods such as lectures, group discussions, role play, rewarding, and educational tools such as tracks, pamphlets, and powerpoint slides.Evaluation is based on the health belief model before the intervention and one month after the intervention.

Category
Behavior

2

Description
Control group: This group will not receive educational intervention and assessment will be done based on the health belief model in this group before and one month after the intervention. In order to follow the ethical point of view, after the post-test, the training program for the control group is also performed in two sessions.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Education of Guilan Province

Full name of responsible person
Dr. Nader Jahan Ara

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
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Street address
Opposite of 17 Shahrivar Hospital، Shahid Siadati Ave، Namjo Ave، Rasht

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Grant name

Grant code / Reference number

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

Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Zahra Aghaee Kenari

Position
MSc Student of Health Education and promotion

Latest degree
Bachelor

Other areas of specialty/work
Family Health

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Associate Professor of Health Education and promotion

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Person responsible for updating data

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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