

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of education based on the locus of control theory on the puberty health and fertility of the first-grade female high school students of Faruj in 96

Protocol summary

Study aim

Determine the effect of education based on the locus of control theory on the puberty health and fertility of the first-grade girl students of Faruj

Design

The study method is a clinical trial with control group. At first, high school girls of the first grade will be divided into two urban areas (three schools) and a rural one (with three schools). In the second stage, we assume each school as one cluster in each region. Then, Two clusters are randomly chosen from the clusters. In the next step, each class (7th, 8th, and 9th grade) of selected schools will be assumed as a cluster. Finally, the students will be selected randomly from each cluster based on the attendance list.

Settings and conduct

Two girls' high schools are randomly selected and 53 students from each high school will be entered into the study. At first, the test and control groups complete the puberty and locus of control questionnaires. Then, the test group is trained in 5 sessions of puberty health and the control group does not receive any training. The questionnaires are completed immediately after the training by both groups and followed up 3 months later.

Participants/Inclusion and exclusion criteria

Entrance criteria: The desire to participate in the study
Education at the 7th, 8th and 9th grade of the first grade high school ; Fluency in Farsi
Exclusion criteria: they are unable to answer questions For any reason;

Intervention groups

In this study, 7th, 8th and 9th grade girls are assigned to the test and control group. In the intervention group, the designed curriculum will consist of 5 sessions of theory training along with practical work and film screening on health of puberty and fertility. The control group does not receive any training.

Main outcome variables

Health of puberty and fertility

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N33**

Registration date: **2019-04-16, 1398/01/27**

Registration timing: **retrospective**

Last update: **2019-04-16, 1398/01/27**

Update count: **0**

Registration date

2019-04-16, 1398/01/27

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 502 6195

Email address

peymann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of education based on the locus of control theory on the puberty health and fertility of the first-grade female high school students of Faruj in 96

Public title
The effect of education based on the locus of control theory on the puberty health and fertility of the first-grade female high school students

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The desire to participate in the study Education at the 7th, 8th and 9th grade of the first grade high school
 Fluency in Farsi
Exclusion criteria:
 they are unable to answer questions For any reason

Age
From **12 years** old to **15 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, the first grade female high school will be divided into two urban areas (three schools) and a rural one (with three schools). In the second stage, each school will be assumed as one cluster and then be selected from the clusters by simple random sampling two clusters. In the next step, the selected schools will be assumed one class (7th, 8th & 9th grade) as a cluster and finally, the students are selected from each cluster based on the attendance list by simple random method.

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

Mashhad University of Medical Sciences School of Health

Street address

School of Health, Mashhad University of Medical Science, Mashhad, Iran

City

mashhad

Province

Razavi Khorasan

Postal code

9137673119

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.MUMS.REC.1397.201

Health conditions studied

1

Description of health condition studied

Puberty health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health of puberty and fertility

Timepoint

Before the intervention, immediately and 3 months after the intervention

Method of measurement

knowledge and performance of puberty questionnaire

2

Description

Health Locus of control score

Timepoint

Before the intervention, immediately and 3 months after the intervention

Method of measurement

Waltzton Health Locus of Control questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The curriculum included 5 sessions of 45-minute group instructional theoretical and practical training along with the presentation of films on puberty health and the locus of control. According to the locus of control theory, first was introduced by Rutter, people's

belief in their ability to control their outcomes is measured. The orientation of individuals' locus of control is defined as a attribution of success or failure to internal or external factors. Individuals with an internal control source believe that they have a serious control over their lives and behave based on it. But individuals with external orientation believe that their successes and failures are governed by external factors such as destiny, luck, powerful people and unpredictable environmental forces.

Category

Behavior

2

Description

"Control group": this group will not receive any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

First grade female High School in Farouj

Full name of responsible person

Dr Nooshin Peyman

Street address

Daneshgah18,Daneshgah street, The Faculty of Health

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3851 4548

Fax

+98 51 3852 2775

Email

Peymann@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

University Street, opposite University of Mashhad, 18Vice-Chancellor for Research ,Mashhad University of Medical Sciences,In front of Daneshgah18,Daneshgah Street,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3841 1538

Fax

+98 51 3843 0249

Email

Tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Nooshin Peyman

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Daneshgah18,Daneshgah Street,The faculty of Health,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3851 4548

Fax

+98 51 3852 2775

Email

Peymann@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Nooshin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Daneshgah18,Daneshgah street,The faculty of Health,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3851 4548

Fax

+98 51 3852 2775

Email

Peymann@mums.ac.ir

Mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3851 4548

Fax

+98 51 3852 2775

Email

Peymann@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Potential data is sharable after distinguishing people.

When the data will become available and for how long

Starting the access period one month after the publication of result

To whom data/document is available

Researchers who work at the university.

Under which criteria data/document could be used

The data is sent via an official request and by email.

From where data/document is obtainable

Dr Nooshin Peyman Peymann@mums.ac.ir

What processes are involved for a request to access data/document

The data is sent via an official request and by email.

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Nooshin Peyman

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Daneshgah18,Daneshgah Street,The faculty of Health,Mashhad

City