

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of education based on self-regulation theory on risk-taking in female students in Eesfarayen city

Protocol summary

Study aim

Determining the effect of educational intervention based on self-regulation theory on the risk-taking of female students of the first secondary school in Esfarayen

Design

A semi-experimental study with two experimental and control groups, on 90 first-year secondary school girls

Settings and conduct

This study is aimed at the effect of education based on self-regulation theory on the risk-taking of female students Esfarayen city. In this study, students are selected and entered into the study using a multi-stage random sampling method. In this way, girls' secondary schools of the first period were first selected, then two schools were randomly selected by lottery and given the social and economic similarity in an area with an acceptable geographical distance from each other and were assigned to the test group and the control group. is assigned. Then, qualified female students are selected from each school and entered into the study.

Participants/Inclusion and exclusion criteria

First high school girl students
Consent to participate in the study
Having a normal mental state

Intervention groups

In this study, in order to determine the effect of education based on self-regulation theory on the risk-taking of female high school students of the first year of Esfarayen, educational sessions are conducted on 45 students in the test group, and the control group does not receive any educational intervention.

Main outcome variables

Risk-taking, self-regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231125060167N1**

Registration date: **2023-11-27, 1402/09/06**

Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**

Update count: **1**

Registration date

2023-11-27, 1402/09/06

Registrant information

Name

Melika Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 936 063 6925

Email address

melikaababaei1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-17, 1402/09/26

Expected recruitment end date

2024-03-16, 1402/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on self-regulation theory on risk-taking in female students in Eesfarayen city

Public title

The effect of education based on self-regulation theory on risk-taking in female students in Eesfarayen city

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

First high school girl students Consent to participate in the study Having a normal mental state

Exclusion criteria:

Unwillingness to continue cooperation in the study Students who change schools for any reason during their studies Students who drop out during their studies The occurrence of unfortunate events during the study for the target group (death of students)

Age

From **13 years** old to **15 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Students are selected and entered into the study using a multi-stage random sampling method. In this way, first the secondary girls' schools of the first period of selection, then two schools, taking into account the social and economic similarity in an area with an acceptable geographical distance from each other, were randomly selected by lottery and assigned to the test group and the control group. It will be given.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

12, Modares Blvd

City

Esfarayen

Province

North Khorasan

Postal code

9661715793

Approval date

2023-04-29, 1402/02/09

Ethics committee reference number

IR.MUMS.FHMPPM.REC.1402.025

Health conditions studied

1

Description of health condition studied

Risk taking (risky behaviors)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-regulation, risk-taking

Timepoint

In this study, the measurement is done in three stages, before the intervention, compared to before the intervention, three months after the intervention

Method of measurement

In this study, a questionnaire is used to measure the variable

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

two schools from the girls' secondary schools of the first period of Esfarayen

Full name of responsible person

Melika Babaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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

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
Melika Babaei

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
Health Promotion

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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

Not applicable

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