Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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.FHMPM.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
tw0 schools from the girls' secondary schools of the first period of Esfrayenn
Full name of responsible person
Melika Babaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
student
Latest degree
Bachelor
Other areas of specialty/work
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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
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