

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of education based on self-regulation education on reducing the anxiety of second-year high school students

Protocol summary

Study aim

Effect of Education Based on Self-Regulatory Theory on Reducing Anxiety in Secondary School Students in Mashhad, 1396

Design

This is a semi-experimental study. The statistical population of this study is female secondary school students. Sample size was calculated using the mean and standard deviation of the self-regulating variable (according to the formula) of 57 individuals in each group, with a probability estimated of 60 people, which included 120 people. The sampling method was done in a cluster fashion. , So that from 7 education districts of Mashhad a randomly selected area is selected and from high school schools covered by the above two state schools are selected and samples are collected

Settings and conduct

This intervention was conducted in Mashhad

Participants/Inclusion and exclusion criteria

The criteria for entering this study include the desire to participate in the study, high school students, female gender, lack of records of mental illnesses and residents of Mashhad. Exit criteria include, reluctance to continue cooperation, absence of maximum two educational sessions, non-compliance Accountability is more than 10% to questionnaire questions

Intervention groups

The control group does not receive any educational intervention, but in the experimental group, educational intervention based on self-regulation theory aims to improve mental health and reduce anxiety in secondary school students. Mean scores of mental health, anxiety and self-regulation learning strategies before, immediately and three months after intervention were measured and compared by a questionnaire in two groups of test and control

Main outcome variables

Measurement of the scores of mental health questionnaire, anxiety and self-regulation learning

strategies before, immediately and three months after the intervention in the target group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N31**

Registration date: **2018-07-30, 1397/05/08**

Registration timing: **retrospective**

Last update: **2018-07-30, 1397/05/08**

Update count: **0**

Registration date

2018-07-30, 1397/05/08

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

2017-10-09, 1396/07/17

Expected recruitment end date

2017-10-12, 1396/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of education based on self-regulation education on reducing the anxiety of second-year high school students

Public title
Effect of education based on self-regulation education on reducing the anxiety of second-year high school students

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Desire to participate in the study, high school students, female gender, lack of records of mental illnesses and residents of Mashhad
Exclusion criteria:
Exclusion criteria: unwillingness to continue cooperation, absence of maximum two training sessions, failure to answer more than 10% of questions to the questionnaire

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The cluster sampling method is used to select a randomly selected area from the 7 educational districts of Mashhad and select two state schools from the high school schools covered by the district and collect the samples

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
دانشگاه علوم پزشکی مشهد
Street address
خیابان دانشگاه - دانشگاه 18

City
مشهد
Province
Razavi Khorasan
Postal code
254649896456
Approval date
2018-07-08, 1397/04/17
Ethics committee reference number
IR.MUMS.REC.1397.089

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
Beck Anxiety Inventory Score
Timepoint
Before, immediately and 3 months after the intervention
Method of measurement
Beck Anxiety Inventory

2

Description
Mental Health Score
Timepoint
Before, immediately and 3 months after the intervention
Method of measurement
Mental Health Questionnaire

3

Description
Self-regulation score
Timepoint
Before, immediately and 3 months after the intervention
Method of measurement
Self-regulation questionnaire

Secondary outcomes

1

Description
Timepoint
Method of measurement

2

Description

Timepoint
Method of measurement

Intervention groups

1

Description

The intervention group received 4 sessions of 40 minutes to improve mental health and reduce anxiety.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Secondary High School Girls in Mashhad

Full name of responsible person

Dr. Noushin Peyman

Street address

University Street between 16-18

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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

Dr. Noushin Peyman

Position

Associate Professor of Health Education and Promotion of Health

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

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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 can be interchangeable after the
differentiation of individuals

When the data will become available and for how long

Researchers who work at the University Researchers who
work at the University

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. Noushin Peyman

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

The data is sent via an official request and by email

Comments