Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Phone
+98 51 3189 2110
Email
peymann@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Noushin Peyman
Street address
University College-University18- Faculty of Health
City
Mashhad
Province
Razavi Khorasan
Postal code
36468547
Phone
+98 51 3854 1514
Email
peymann@mumus.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. Noushin Peyman
Position
Associate Professor of Health Education and Promotion of Health
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Health Research Center of Health Faculty, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
365463
Phone
+98 31892110
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. Noushin Peyman
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Social Health Effects Research Center, School of Public Health
City
Mashhad
Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

Email

peymann@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Noushin Peyman

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education and Health Promotion, University Street, between University Street 16-18

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3854 1514

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 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