Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of metacognitive sterategies training on the health anxiety and mental health of students.

Protocol summary

Study aim
The effect of teaching metacognitive strategies on health anxiety and psychiatric students of Mashhad University of Medical Sciences

Design
A randomized controlled clinical trial on 56 students used a random number table.

Settings and conduct
The statistical population is all students of Mashhad University of Medical Sciences. After the project is registered in the University Ethics Committee and the Clinical Trial Center, students will be invited to participate in the project in cyberspace and students interested in research will register. If they meet the inclusion criteria, they will enter the study. Individuals are randomly divided into two groups of intervention and control (based on the method of random permutation blocking). For the intervention group, 8 sessions of metacognitive strategies training Minutes of online meetings will be held on Skype.

Participants/Inclusion and exclusion criteria
Participants of students of Mashhad University of Medical Sciences, Admission requirements: Student of Mashhad University of Medical Sciences Absence of psychiatric disorder (short interview with each person to ensure that there is no psychiatric disorder) Having conscious satisfaction from participating in research Age range 18 to 30 years Conditions for non-entry: Participation in similar training programs in the last 6 months Having a mental disorder (psychotic disorder, bipolar disorder, major depression, suicide attempt ...)

Intervention groups
The intervention group receives 8 sessions of metacognitive strategies training, The control group does not receive any intervention.

Main outcome variables
Health anxiety; mental health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210424051070N1**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date
2021-08-06, 1400/05/15

Registrant information

Name
Nafise Nouri Siahdasht

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3646 0106

Email address
nourisn981@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-01, 1400/05/10

Expected recruitment end date
2021-08-11, 1400/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of metacognitive sterategies training on the health anxiety and mental health of students.

Public title
"The effect of metacognitive sterategies training on the health anxiety and mental health of students"
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Student of Mashhad university of medical science Absence of psychiatric disorder(A short interview is conduct edwith each person to ensure that there is no disorder) Absence of effective physical disorder Having conscious satisfaction from participating in research Age range 18-30 year
Exclusion criteria:
acute psychiatric disorder that makes it difficult to participate in treatment (such as bipolar disorder, major depression, psychotic disorders, suicide attempt). Participate in similar training programs in the last 6 months
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, the permutation random blocking method is used. In this method, 14 blocks of 4 from a combination of letters A and B will be randomly selected. These blocks are AABB, ABBA, BBAA, BAAB, ABAB, BABA. The blocks are selected in such a way that the following numbers are assigned to the blocks: 1:AABB 2:ABBA 3:BBAA 4:BAAB 5:ABAB 6:BABA Then 14 one-digit random numbers are selected from the table of random numbers. If the number 7 8 9 is among these digits, they will be deleted. In this way, 14 blocks are selected. Assigning the letters A and B to the intervention and control groups will be done randomly before randomization and the data analyst will be unaware of the intervention and control groups. Having a list of people (a list of 56 people who are going to participate in the project), the researcher assigns a numeric code to each person. It then provides the anonymous list of members (containing only the numeric code) to the sample assignor to the groups. The sample assignee to the groups first prepares the selected blocks as described, writes them on separate sheets of paper (14 separate sheets), and places them in sealed envelopes. It then randomly selects the envelopes and, based on the previously selected codes A and B, determines the numerical code number of the individuals assigned to intervention A and B and provides it to the researcher. For example, if the BABA block is selected first, the first person on the list will be assigned to group B, the second person to group A, the third person to group B, and the fourth person to group A. Similarly, person 5 to 56 will be assigned to groups A and B.
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
Ethics Committee of Mashhad University of Medical Sciences
Street address
University Street, next to Hoveyzeh Cinema, Ghorashi Building, Deputy of Research and Technology
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2021-03-13, 1399/12/23
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.826

Health conditions studied

1

Description of health condition studied
Anxiety and mental health of students
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Health anxiety
Timepoint
Beginning and end of the intervention
Method of measurement
Salkovskis and Warwick Health Anxiety Questionnaire

2

Description

Mental health

Timepoint

Beginning and end of the intervention

Method of measurement

GHQ-28 General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Teaching metacognitive strategies in 8 sessions for one hour twice a week.The content of the meetings is as follows:Session 1: Welcoming and getting to know the members, introducing the members to each other, getting to know the rules of the group and the training course, explaining the goals, introducing metacognitive intervention Session 2: Familiarity with the metacognitive model of beliefs related to uncontrollable anxiety,Homework: Paying attention to dissociative awareness and postponing worry Session 3: Uncontrollable verbal and behavioral re-documentation,Homework: Continue to postpone the concern and introduce the loss control test and introduce the loss test Session 4: Identify and stop mismatch control avoidance behaviors,Homework: Continue to procrastinate and try to lose control Session 5: Challenging Beliefs Related to Uncontrollable Anxiety - Challenging Negative Beliefs Related to the Danger of Worry,Homework: A test of intentional anxiety to assess whether anxiety is dangerous Session 6: Challenging Negative Beliefs Related to the Danger of Concern_Experimenting,Homework: Behavioral tests to challenge beliefs related to the dangers of worry Session 7: Challenging with positive metacognitive beliefs,Homework: An inconsistent strategy or other experiment to challenge positive metacognitive beliefs Session 8: Summary of treatment and completion of treatment planHomework: Specify the continuity of use .

Category

N/A

2

Description

Control group: The control group does not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences, medical school

Full name of responsible person

Nafise nouri Siahdasht

Street address

Khaghani19, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9194966973

Phone

+98 51 3800 2000

Email

MDS.Dean@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

فرهاد فعال

Street address

Shahid Fakoori Boulevard, between Shahid Javan and Al-Shahidi Squares, Danesh va Salamat Town, second floor

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3879 5031

Email

vcr.pr@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

Nafise nouri Siahdasht

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Khaghani19, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9194966973

Phone

+98 58 3646 0106

Email

nourisn981@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nafise nouri Siahdasht

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Khaghani19, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9194966973

Phone

+98 58 3646 0106

Email

nourisn981@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nafise nouri Siahdasht

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

Khaghani19, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9194966973

Phone

+98 58 3646 0106

Email

nourisn981@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the dissatisfaction of the research participants with the publication of the results, the results will not be published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available