Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mindfulness Exercises on Coronary Anxiety and Immune System on Clinical Psychology Students of Lahijan Islamic Azad University

Protocol summary

Study aim
The effect of mindfulness training on coronary anxiety and immune system on clinical psychology students of Lahijan Azad University

Design
The clinical trial has an intervention and control group. Statistical population of 160 people predicted on 30 students. Available and randomly (10 people in the experimental group, 10people in the control group). students complete the questionnaire and take the antibody test and only the test group is trained. Then post-test was taken from both groups.

Settings and conduct
Semi-experimental and pre-test-post-test research design with control group. The statistical population of this research will consist of master's degree students in clinical psychology of Lahijan Azad University in the academic year 1399-1400. Students complete the questionnaire and take the corona antibody test. Only the intervention group is taught. A mindfulness training package will be used for intervention.Its based on mindfulness-based cognitive therapy. Its provided in 8 sessions (90 minutes) in the university class.

Participants/Inclusion and exclusion criteria
Students of Clinical Psychology, Lahijan Azad University، Students who received the corona vaccine.

Intervention groups
Clinical psychology students undergoing mindfulness practice training. 10 people in the training group and 10 people in the control group. In connection with the therapeutic intervention, Beck Anxiety Questionnaire, Corona Antibody Test and Mindfulness Training Package will be used.students complete the questionnaire and perform antibody test. only the intervention group is trained in mindfulness. Its based on mindfulness-based cognitive therapy. Training is mindfulness with breathing, training to examine the body in detail, training to face dipole, familiarity with bodily senses, empathy and observation of thoughts without judgment.

Main outcome variables
Mindfulness، Corona Anxiety، Safety system

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210616051603N1**
Registration date: **2021-08-28, 1400/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-28, 1400/06/06**
Update count: **0**

Registration date
2021-08-28, 1400/06/06

Registrant information
Name
Mahmood Rezaee boosari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3381 3345
Email address
mahmoodrezaei776@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-26, 1400/06/04
Expected recruitment end date
2021-09-26, 1400/07/04
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Mindfulness Exercises on Coronary Anxiety and Immune System on Clinical Psychology Students of Lahijan Islamic Azad University

Public title
The effect of mindfulness on coronary anxiety and the immune system

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All clinical psychology students of Islamic Azad University, Lahijan Branch
Exclusion criteria:
Those who have received the Corona vaccine People with anxiety disorders

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, according to the inclusion criteria, patients are selected and then according to the random sequence obtained through random allocation software, patients will be randomly divided into experimental and control groups.

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 Lahijan Branch of Azad University
Street address
No 69, Villag Galeshkheil, Pirbazar
City
Rasht
Province
Guilan
Postal code
4165159577

Approval date
2021-06-24, 1400/04/03

Ethics committee reference number
IR.IAU.TMU.REC.1400.109

Health conditions studied

1

Description of health condition studied
Corona anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Anxiety score in Aliniya Anxiety Questionnaire

Timepoint
Measuring anxiety at the beginning of the study and eight sessions after the start of mindfulness training

Method of measurement
Aliniya Anxiety Questionnaire

2

Description
Corona antibody test response

Timepoint
Corona antibody test at the beginning of the study and eight sessions after the start of mindfulness training

Method of measurement
IGg, IGm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Students of clinical psychology are Lahijan Branch of Azad University. The statistical population of this study will consist of all master students of clinical psychology studying at the Islamic Azad University, Lahijan Branch in the academic year 1399-1400. According to available statistics, the number of these people is 160. 20 students will be selected at random and will be randomly assigned to two groups (10 in the experimental group and 10 in the control group). In relation to therapeutic intervention and data collection, the following protocols and tools will be used: - Mindfulness training package: In this research,

mindfulness training package will be used for intervention. This package is based on mindfulness-based cognitive therapy and was developed by Van Soon et al. (2011). The package is presented in 8 sessions (90 minutes) which includes mindfulness training with breathing, detailed body examination training, bipolar confrontation training, familiarity with bodily senses, empathy and observation of thoughts without judgment. . Mindfulness treatment program is performed for one month (4 weeks) twice a week for 90 minutes. Anxiety Scale: In this study, to measure the level of anxiety of the subjects, a scale made by Alipour et al. (1398) with 18 questions will be used. This questionnaire is scored in the 4-point Likert scale (never = 0, sometimes = 1, most times = 2 and always = 3). In total, the subjects' score varies between zero and 54. The high score in this questionnaire indicates a higher level of anxiety in individuals. Post-test sessions are also taken at the end.

Category

Prevention

2

Description

Control group: There are students of clinical psychology at Lahijan Azad University who do not receive mindfulness training. A total of 20 students were selected by random sampling into two groups (10 in the experimental group and 10 in the control group). Will be allocated. Anxiety Scale: In this study, to measure the level of anxiety of the subjects, a scale made by Alipour et al. (1398) with 18 questions will be used. This questionnaire is scored in the 4-point Likert scale (never = 0, sometimes = 1, most times = 2 and always = 3). In total, the subjects' score varies between zero and 54. The high score in this questionnaire indicates a higher level of anxiety in individuals.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Lahijan Branch of Azad University

Full name of responsible person
Mahmoud Rezaei Bousari

Street address
Lahijan Branch of Azad University complex, End of Shaghayegh street, Kashef sharghi Street

City
Lahijan

Province
Guilan

Postal code
4165159577

Phone
+98 13 3381 3345

Email
mahmoodrezaei776@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr.Gholamreza Vaghar Lahijani

Street address
No 69, Villag Galeshkheil, Pirbazar

City
Rasht

Province
Guilan

Postal code
4165159577

Phone
+98 13 3381 3345

Email
mahmoodrezaei776@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Lahijan Branch of Azad University

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
Islamic Azad University

Full name of responsible person
Mahmoud Rezaei Bousari

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

Street address
No 69, Villag Galeshkheil, Pirbazar

City
Rasht

Province
Guilan

Postal code
4165159577

Phone

+98 13 3381 3345

Email

mahmoodrezaei776@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahmoud Rezaei Bousari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No 69, Villag Galeshkheil, Pirbazar

City

Rasht

Province

Guilan

Postal code

4165159577

Phone

+98 13 3381 3345

Email

mahmoodrezaei776@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahmoud Rezaei Bousari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No 69, Villag Galeshkheil, Pirbazar

City

Rasht

Province

Guilan

Postal code

4165159577

Phone

0098133381334

Email

mahmoodrezaei776@gmail.com

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total results obtained from the results of the questionnaire and testing and performance improvement will be published

When the data will become available and for how long

Access period starts from September 1400

To whom data/document is available

Data and other documents are available to all researchers in the field of research

Under which criteria data/document could be used

If other people request data and documentation, send a message to my personal email.

From where data/document is obtainable

Applicants should refer to Lahijan, Kashif Sharghi St., at the end of Shaghayegh St., Lahijan Branch of Azad University, to receive the required documents or data. Mahmoud Rezaei Bosari by phone number 09377688854 and email mahmoodrezaei776@gmail.com Is responsive

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

Applicants should call 09377688854 or send an email to mahmoodrezaei776@gmail.com8 to receive the required documents or data. Documents will be provided to them within 72 hours to a week.

Comments