

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Mindfulness-Based Stress Reduction on Mental Health, Salivary Cortisol and α -amylase level in students

Protocol summary

Study aim

The present study was conducted with the aim of determining the effectiveness of mindfulness-based stress reduction training on the level of mental health and salivary cortisol and α -amylase levels of students.

Design

Semi-experimental studies with pre-test-post-test-follow-up design and control group, one-sided blind, randomized, performed on 15 subjects.

Settings and conduct

After obtaining the necessary permission from Baqiyatullah University of Medical Sciences (AS), the relevant universities in the target community were referred and according to the entry criteria, 30 people were selected. In order to carry out the research, in the pre-test phase, first a saliva sample was taken to determine the concentration of cortisol and the amount of salivary α -amylase in resting conditions (8-9 am before breakfast) and then the stress, anxiety and depression scale (DASS-21) and The General Health Questionnaire (GHQ-28) is completed on the same day.

Participants/Inclusion and exclusion criteria

entry: obtaining a score higher than 14 in the depression and anxiety subscales and higher than 18 in the stress subscale of the Stress, Anxiety and Depression Questionnaire (DASS-21); age range 18 to 25; Exclusion: presence or history of severe psychiatric disorder; smoking and psychoactive pills; taking psychiatric drugs; epilepsy; diabetes; hypothyroidism or hyperthyroidism; Edison; Cushing syndrome; High blood pressure; Taking corticosteroids and steroids.

Intervention groups

The subjects of the experimental group will be trained in mindfulness-based stress reduction intervention by the researcher during 8 sessions of 90 minutes per week, and the control group will be informed that they are on the waiting list and after the end of the intervention of the first group, the intervention in The second group is also done

Main outcome variables

Mental health; Cortisol levels; Salivary α -amylase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190927044898N1**

Registration date: **2023-06-28, 1402/04/07**

Registration timing: **retrospective**

Last update: **2023-06-28, 1402/04/07**

Update count: **0**

Registration date

2023-06-28, 1402/04/07

Registrant information

Name

reza mohammadzadeghan

Name of organization / entity

Azərbaycan Şahid Madani University

Country

Iran (Islamic Republic of)

Phone

+98 44 3633 8394

Email address

reza.moh1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

2021-08-01, 1400/05/10

Actual recruitment end date

2021-09-22, 1400/06/31

Trial completion date
2021-09-22, 1400/06/31

Scientific title
Effectiveness of Mindfulness-Based Stress Reduction on Mental Health, Salivary Cortisol and α -amylase level in students

Public title
The Effectiveness of Mindfulness-Based Stress Reduction on Mental Health and Salivary cortisol and α -amylase

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Score above 14 on the Depression and Anxiety subscales and above 18 on the Stress subscale of the Stress of DASS-21 The age range of 18 to 25 Sign the ethical consent Minimum education of reading and writing
Exclusion criteria:
Existence or history of severe psychiatric disorder Smoking and psychotropic pills Use of psychiatric drugs Epilepsy Various cardiovascular and respiratory and blood pressure disorders Aspirin use a acetaminophen over the past 48 hours A history of cancer Diabetes Hypothyroidism or hyperthyroidism Addison, cushing's and cushing's syndrome, hypertension, corticosteroid and steroid medications.

Age
From **18 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The study will be one-way blinded, the participants of two groups will be blinded to receive the intervention

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatullah Hospital
Street address
South Sheikh Bahai Street, Molla Sadra Street, Vanak Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2020-05-05, 1399/02/16
Ethics committee reference number
IR.BMSU.BAQ.REC.1399.004

Health conditions studied

1

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

2

Description of health condition studied
Depression
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Improve mental health
Timepoint
The subjects of the two groups will complete the DASS-21 and GHQ-28 questionnaires in the pre-test and post-test phases.
Method of measurement
Stress, Anxiety and Depression Scale (DASS-21) and General Health Questionnaire (GHQ-28)

2

Description
Decreased levels of cortisol and alpha-amylase
Timepoint
Saliva collection in this study was done in two stages: pre-test (before the intervention and during rest) and post-test (after the intervention).
Method of measurement
To collect saliva samples, the participants are asked to

passively collect their secreted saliva for 5 minutes in designated tubes.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group - the recipient of mindfulness intervention

Category

Treatment - Other

2

Description

Control group: They did not receive any special intervention and were on the waiting list

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah University of Medical Sciences

Full name of responsible person

shima shahyad

Street address

Neuroscience Research Center, South Sheikh Bahai Street, Mollasadra St., Vanak Square, Tehran

City

Teran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 4148

Email

research.bmsu@gmail.com

Web page address

<https://www.bmsu.ac.ir/portal/home/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Hassan Abul Qasimi

Street address

South Sheikh Bahai Street, Molla Sadra Street, Vanak Square, Tehran, Ir

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 4574

Email

R.bmsu@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Reza Mohammadzadeghan

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Zeynali 2 Alley, Neighborhood of No. 94 Dastgah, Shams Tabrizi Boulevard, Khoy, Iran

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58718744747

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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

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

Data file and collected samples and executed
questionnaires and protocol

When the data will become available and for how long

Whenever needed

To whom data/document is available

For all but no participant identification information

Under which criteria data/document could be used

Any type of analysis is allowed

From where data/document is obtainable

reza mohammadzadeghan

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

After email within 1 working week

Comments