Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Azarbaijan Shahid 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
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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