Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effectiveness of Neurofeedback on psychological stress; salivary cortisol and α-amylase level in college students

Protocol summary

Study aim
The aim of this study was to evaluate the effectiveness of Neurofeedback on psychological stress and salivary cortisol and α-amylase level in students

Design
This study is a randomized, double -blind, with parallel groups clinical trial. Sixty students with Anxiety symptoms in two groups of 30 people in a trial are assigned randomly.

Settings and conduct
Location is Fetros Comprehensive Health Center. Sixty participants are selected. Thirty participants in control group and 30 participants in neurofeedback are assigned randomly. In this double-blind study, the psychiatrist and data analyser are kept blind to the treatment. Participants pick up envelopes inside the box randomly which are in an unspecified wrapper.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Achieving a score above 18 on the stress scale of the Stress, Anxiety and Depression Questionnaire (DASS-21), and age range between 18 to 25 years old, Exclusion criteria: Presence or history of severe psychiatric disorders (including periods of severe depression, anxiety disorders, substance use disorders), Smoking and psychedelic pills use, using psychiatric drugs, epilepsy, various cardiovascular and respiratory disorders and blood pressure

Intervention groups
The intervention group is the neurofeedback group and the control group is the non-experimental group. Participants in the intervention group receive 2 sessions of 30 minutes of neurofeedback training every week. The control group received no intervention.

Main outcome variables
Anxiety symptoms, stress, cortisol, α amylase

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190602043790N3**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **retrospective**

Last update: **2024-02-02, 1402/11/13**
Update count: **0**

Registration date
2024-02-02, 1402/11/13

Registrant information
Name
Saba Hasanvandi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-06, 1400/05/15

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
2021-08-06, 1400/05/15

Actual recruitment end date
2021-10-22, 1400/07/30

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Neurofeedback on psychological stress; salivary cortisol and α-amylase level in college students

Public title
Effectiveness of Neurofeedback on psychological stress
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Achieving a score above 18 on the stress scale of the Stress, Anxiety and Depression Questionnaire (DASS-21) Age range between 18 to 25 years old
Exclusion criteria:
Presence or history of severe psychiatric disorders (including periods of severe depression, anxiety disorders, substance use disorders) Smoking and psychedelic pills Using psychiatric drugs Epilepsy Various cardiovascular and respiratory disorders and blood pressure Aspirin use and acetaminophen over the past 48 hours history of cancer diabetes hypothyroidism or hyperthyroidism Addison disease Cushing's syndrome hypertension Use of corticosteroids and steroids
Age
From **18 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants are randomly allocated to the two groups by a table of random numbers. Each participant is given a number from 1 to n and using the table of random numbers, patients are randomly divided into two groups: control or Neurofeedback.
Blinding (investigator's opinion)
Double blinded
Blinding description
Psychiatrist and data analysts do not know how patients are assigned, but participants in the trial know which group they belong to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Science
Street address
Sheykhbahaie street, Molla Sadra street, Vanak square, Tehran
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2020-05-05, 1399/02/16
Ethics committee reference number
IR.BMSU.BAQ.REC.1399.003

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

2

Description of health condition studied
stress
ICD-10 code
F43.0
ICD-10 code description
Acute stress reaction

Primary outcomes

1

Description
Anxiety symptoms
Timepoint
At the beginning of the study (before the intervention), weeks 5 and 10 after the start of neurofeedback in intervention group
Method of measurement
Stress, anxiety and depression scales (DASS-21)

2

Description
stress
Timepoint
At the beginning of the study (before the intervention), weeks 5 and 10 after the start of neurofeedback in intervention group
Method of measurement
Stress, anxiety and depression scales (DASS-21)

3

Description
cortisol
Timepoint
At the beginning of the study (before the intervention), weeks 5 and 10 after the start of neurofeedback in intervention group
Method of measurement
Stress, anxiety and depression scales (DASS-21)

4

Description
α amylase
Timepoint
At the beginning of the study (before the intervention), weeks 5 and 10 after the start of neurofeedback in intervention group
Method of measurement
Stress, anxiety and depression scales (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants do not receive intervention during the 12 weeks
Category
Behavior

2

Description
Intervention group: Participants receive 2 30-minute neurofeedback training session (The EEG signals using the BioGraph Infinity EEG Suite SA7950 Software) undergoes a series of recording, processing, filtering, and representation procedures. This software amplifies the amplitude of the frequency bands, while the hardware Pro Comp 2 Infinity (Thought Technology Ltb; Montreal, Quebec) transmite the signal to the computer. The EEG serves both as a means of recording and as a source for feedback, with a sampling rate of 256 Hz samples/second, and the data was redirect to the computer via an A/D converter) every week for 10 weeks.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Fetros Urban Comprehensive Center
Full name of responsible person
Dr Gholam Hossein Alishiri
Street address
Delfani Street, Enghelab Street
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Saba Hasanvandi

Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for updating data

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data, such as information related to main outcome or like that , can be shared
When the data will become available and for how long
Start of access, 6 months after publishing the results
To whom data/document is available
Only people working in academic institutions could apply.
Under which criteria data/document could be used
People who intend to do clinical trials in this field can apply.
From where data/document is obtainable
By referring to the email address s.hasanvandi@alzahra.ac.ir
What processes are involved for a request to access data/document
The applicant can receive information by registering the exact personal details and sending it via email.
Comments