# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 66 3324 2643

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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
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## Sponsors / Funding sources

**1**

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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**
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**Full name of responsible person**
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**Position**
Assistant professor
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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**