

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### **Efficacy of QEEG Guided Neurofeedback treatment on decreasing symptoms and signs of Generalized Anxiety Disorder and emotion regulation strategies.**

#### **Protocol summary**

##### **Study aim**

Determining the effect of QEEG-based neurofeedback therapy on reducing symptoms and symptoms of people with generalized anxiety disorder and improving the emotional regulation strategies

##### **Design**

In this study, 30 patients with generalized anxiety disorder who were admitted to treatment were selected from student population of Zanjan city and divided into intervention and control groups.

##### **Settings and conduct**

After clinical interview (SCID-I) and confirmation of the criteria for entry and exit of patients, all of the subjects used a questionnaire for general anxiety disorder, an emotional regulation strategy questionnaire, a depression questionnaire, and anxiety and stress by a researcher at the educational center - Shahid Beheshti treatment will be implemented. Treatment protocols will be written and implemented in the QEEG based neurofeedback therapy group using data from brain wave patterns

##### **Participants/Inclusion and exclusion criteria**

Having DSM-5 diagnostic criteria for generalized anxiety disorder diagnosed by a psychiatrist based on diagnostic interview and clinical psychologist. Psychotic Disorder and Substance Abuse Based on Diagnostic Interview

##### **Intervention groups**

15 subjects will be treated on the basis of QEEG-based neurofeedback training, and 15 subjects will not receive any intervention in the control group, and individual treatment will be followed for subjects in the QEEG-based neurofeedback treatment group.

##### **Main outcome variables**

Decrease Signs and symptoms of people with generalized anxiety disorder!Improves the emotional regulation of people with generalized anxiety disorder

#### **General information**

##### **Reason for update**

##### **Acronym**

NT

##### **IRCT registration information**

IRCT registration number: **IRCT20171102037181N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **prospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

##### **Registration date**

2018-01-21, 1396/11/01

##### **Registrant information**

##### **Name**

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3286 7507

##### **Email address**

hassan.abdiyan89@zums.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2018-01-31, 1396/11/11

##### **Expected recruitment end date**

2018-06-21, 1397/03/31

##### **Actual recruitment start date**

2018-01-31, 1396/11/11

##### **Actual recruitment end date**

2018-06-21, 1397/03/31

##### **Trial completion date**

empty

## Scientific title

Efficacy of QEEG Guided Neurofeedback treatment on decreasing symptoms and signs of Generalized Anxiety Disorder and emotion regulation strategies.

## Public title

Efficacy of Neurofeedback treatment on Anxiety

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having DSM-5 diagnostic criteria for generalized anxiety disorder diagnosed by a psychiatrist based on diagnostic interview and clinical psychologist; as well as on the basis of the 7-item GAD-7 questionnaire and DSM-5 Clinical Interview for generalized Anxiety Disorder At least 18 years and maximum 50 years Study at one of the academic levels Patient agrees to participate in research and sign a written consent

### Exclusion criteria:

Suffering Psychotic disorder And Substance Abuse Based on Diagnostic Interview. Not receiving psychological treatment at least 6 months before entering the research. No drug use at least one month before entering the research. Having complete criteria for personality disorder in axis II based on diagnostic interview. The apparent risk of suicide is now. Having more than two absentee sessions.

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

Actual sample size reached: **30**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Zanjan University of Medical Sciences Ethics

Committee.

## Street address

Central Station of Zanjan University of Medical Sciences-Beginning of the Islamic Republic Boulevard-Azadi Square.

## City

zanjan

## Province

Zanjan

## Postal code

45154

## Approval date

2017-09-11, 1396/06/20

## Ethics committee reference number

ZUMS.REC.1396.138

## Health conditions studied

### 1

#### Description of health condition studied

Generalized Anxiety Disorder

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

The severity of the signs and symptoms of generalized anxiety disorder

#### Timepoint

The effect of neurofeedback treatment in patients with generalized anxiety disorder before, after and three months after treatment.

#### Method of measurement

The score that the subject gained from the GAD-7 questionnaire is the GAD-7. This scale has been developed to diagnose anxiety disorder and to measure the severity of clinical symptoms.

## Secondary outcomes

### 1

#### Description

Emotional regulation.

#### Timepoint

Evaluating the improvement of emotional regulation strategies before, after and three month following the treatment of neurofeedback.

#### Method of measurement

The score for the subject of the Emotional Regulation Strategies Questionnaire (ERQ; Grass & John, 2003) was designed to evaluate two emotion regulation strategies, including suppression and re-evaluation. This questionnaire has 10 sentences.

## 2

### **Description**

Anxiety

### **Timepoint**

Evaluation before, after, and in the following three months.

### **Method of measurement**

The score that the subject obtained from the Depression, Anxiety and Stress Questionnaire (DASS).

## 3

### **Description**

Depending on the DSM-5 criteria, depression involves a number of disorders that all agree on three types of symptoms: mood symptoms that include: feeling sad, empty, worrying and irritable. Vegetative symptoms that include fatigue, social deprivation and diabetes.

Disturbances in appetite (depression or increased sleep) are also common. The cognitive symptoms of these disorders include centralized problems, difficulty in resolving, low self confidence, negative thoughts about oneself, the world, and others, and guilty and suicidal ideation.

### **Timepoint**

Evaluation before, after, and in the following three months.

### **Method of measurement**

The score that the subject obtained from the Depression, Anxiety and Stress Questionnaire (DASS).

## **Intervention groups**

### 1

#### **Description**

Intervention group: 15 subjects will be treated on the basis of QEEG-based neurofeedback training, and 15 subjects will not receive any intervention in the control group, and individual treatment will be followed for subjects in the QEEG-based neurofeedback treatment group.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Specialized and specialized specialty clinic of Suhrawardi.

##### **Full name of responsible person**

Hasan Abdiyan Kalibar

##### **Street address**

Eastern Side of Shahid Beheshti Hospital.Ork Gate

##### **City**

Zanjan

##### **Province**

Zanjan

##### **Postal code**

56184- 45139

##### **Phone**

+98 24 3354 2401

##### **Fax**

+98 24 3354 2401

##### **Email**

h.abdiyan25@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Zanjan University of Medical Sciences

##### **Full name of responsible person**

Dr. Alireza Shaghli

##### **Street address**

Central Station of Zanjan University of Medical Sciences-Beginning of the Islamic Republic Boulevard-Azadi Square.

##### **City**

zanjan

##### **Province**

Zanjan

##### **Postal code**

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##### **Phone**

##### **Email**

h.abdiyan25@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

##### **Full name of responsible person**

Hasan Abdiyan Kalibar

##### **Position**

Student

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hasan Abdiyan Kalibar

**Position**

Student

**Latest degree**

Bachelor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Hasan Abdiyan Kalibar

**Position**

Student

**Latest degree**

Bachelor

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

In the consent form, personal information will be confidential and the data will be published by the general and a group of members.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable