

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

۴۵۱۵۴

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

Street address

Eastern Side of Shahid Beheshti Hospital-Ork Gate

City

zanjan

Province

Zanjan

Postal code

56184- 45139

Phone

+98 24 3354 2401

Email

h.abdiyan25@yahoo.com

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

Other areas of specialty/work

Psychology

Street address

Eastern Side of Shahid Beheshti Hospital-Ork Gate

City

zanjan

Province

Zanjan

Postal code

56184- 45139

Phone

+98 24 3354 2401

Email

h.abdiyan25@yahoo.com

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

Other areas of specialty/work

Psychology

Street address

Eastern Side of Shahid Beheshti Hospital-Ork Gate

City

Zanjan

Province

Zanjan

Postal code

56184- 45139

Phone

+98 24 3354 2401

Email

h.abdiyan25@yahoo.com

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