

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the effectiveness of Metacognitive therapy (MCT), pharmacotherapy (SSRIs) and EEG biofeedback in Generalized Anxiety Disorders

Protocol summary

Summary

42 outpatient meeting DSM-IV criteria for GAD who had been referred to sohravardi clinical psychology and psychiatry center in Zanjan city were chosen on the basis of convenient sampling and were randomly assigned in to three treatment group : (MCT n=14), pharmacotherapy (n=14) and neurofeedback treatment (n=14). after signing the consent form of participating in research, All the patients in each groups were treated for 8 weeks. The General Anxiety Disorder Scale (GAD-7), were administered blindly in Pre-test and Post-test. Alpha brain waves in occipital area (O1 and O2) using neurofeedback (procomp-5) in Pretest and posttest were registered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061233946N4**

Registration date: **2017-08-27, 1396/06/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-27, 1396/06/05

Registrant information

Name

Mohsen Dadashi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3353 4500

Email address

mohsendadashi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Metacognitive therapy (MCT), pharmacotherapy (SSRIs) and EEG biofeedback in Generalized Anxiety Disorders

Public title

Comparing the effectiveness of Metacognitive therapy (MCT), pharmacotherapy (SSRIs) and EEG biofeedback in Generalized Anxiety Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : no medicine consumption 1 month before the intervention; age 18-50 years old; having a minimum grade education. Exclusion criteria: psychotic disorder; drug dependence.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Freeway, Tehran

City

Tehran

Postal code

Approval date

2014-09-20, 1393/06/29

Ethics committee reference number

93/105/2955

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Pretest, post test(8 months later)

Method of measurement

GAD-7 questionar

2

Description

Depression

Timepoint

Pretest, post test(8 months later)

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

Alpha Amplitude

Timepoint

Pretest, post test (8 months later)

Method of measurement

Baselin by Neurofeedback

Intervention groups

1

Description

10 session MCT based on MCT Manual

Category

Behavior

2

Description

50-100 mg sertraline 20-40 mg citalopram 8 week

Category

Treatment - Drugs

3

Description

EEG Biofeedback: 15 session, Increase Alpha in occipital 15 session, Increase theta in occipital

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sohravardi clinical psychology and psychiatry Center

Full name of responsible person

Mohsen Dadashi

Street address

Zanjan University of Medical Sciences

City

Ark Square, Beheshti Hospital, Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Mrs. Hahgshenas

Street address

Iran University of Medical Sciences, Hemmat High Way

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences and Health Services

Full name of responsible person

Mohsen Dadashi

Position

Assistant Professor, PhD in Clinical Psychology

Other areas of specialty/work**Street address**

Arq Square, Behshti Hospital, Zanjan

City

Zanjan

Postal code**Phone**

+98 24 3378 9469

Fax**Email**

psy.mohsen@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences and Health Services

Full name of responsible person

Mohsen Dadashi

Position

Assistant Professor, PhD in Clinical Psychology

Other areas of specialty/work**Street address**

Ark Square, Behshti Hospital, Zanjan

City

Zanjan

Postal code**Phone**

+98 24 3378 9469

Fax**Email**

psy.mohsen@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Zanjan University of Medical Sciences and Health Services

Full name of responsible person

Mohsen Dadashi

Position

Assistant Professor, PhD in Clinical Psychology

Other areas of specialty/work**Street address**

Ark Square, Beheshti Hospital, Zanjan

City

Zanjan

Postal code**Phone**

+98 24 3378 9469

Fax**Email**

psy.mohsen@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty