Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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), pharmachotherapy (n=14) and neurofeedback treatment (n=14). after signing the consent form of participating in research, All the patients in each groups were treated for8 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
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Iran (Islamic Republic of)
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+98 24 3353 4500
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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 Univercity 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 Neuroffedback

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 Univercity of Medical Sciences
City
Ark Square, Beheshti Hospital, Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran Univercity of Medical Sciences

Full name of responsible person

Mrs. Hahgshenas

Street address

Iran Univercity 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 Univercity 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

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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