

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of mindfulness based on stress reduction therapy and neurofeedback training on the clinical symptoms of individual with generalized anxiety disorder

Protocol summary

Study aim

The aim of this study is compare effectiveness of mindfulness based on stress reduction therapy and neurofeedback training on the clinical symptoms of individual with generalized anxiety disorder.

Design

In a quasi-experimental study, 30 individual with generalized anxiety disorder who referring to counseling centers of Neyshabur will select by available sampling method and will divide to mindfulness based on stress reduction therapy and neurofeedback training. The first group will participate in 8 sessions of mindfulness based on stress reduction, while second group will participate in sessions of neurofeedback training.

Settings and conduct

Counseling center of the university of Neyshabur. We have two groups: mindfulness based on stress reduction and neurofeedback training, which is treated with mindfulness treatment in eight sessions and neurofeedback training in 15 sessions.

Participants/Inclusion and exclusion criteria

persons with generalized anxiety disorders

Intervention groups

mindfulness based on stress reduction therapy and neurofeedback training

Main outcome variables

Generalized anxiety disorder

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Tahmine Mirisargazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3355 1149

Email address

tahmine.miri@chmail.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-29, 1397/05/07

Expected recruitment end date

2018-09-29, 1397/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mindfulness based on stress reduction therapy and neurofeedback training on the clinical symptoms of individual with generalized anxiety disorder

Public title

Comparison of the effectiveness of mindfulness based on stress reduction therapy and neurofeedback training

General information

Reason for update

Acronym

MBSR & NT

IRCT registration information

IRCT registration number: **IRCT20180523039809N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **registered_while_recruiting**

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inflammation to generalized anxiety disorder
Lack of synchronization in other treatment programs
Informed consent
Participation to pharmaceutical and non-pharmaceutical treatment programs during this project

Exclusion criteria:

Use of psychiatric drugs

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Flip the coin
One of the groups was considered the lion and the second group was considered the line and we threw the coin according to the size of the sample group.

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 Islamic Azad University,
Neishabour Branch

Street address

Research Blvd, Neishabour Azad University, Office
Building

City

Neishabour

Province

Razavi Khorasan

Postal code

4979155581

Approval date

2017-08-16, 1396/05/25

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1396.4

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

Generalized anxiety disorder

Timepoint

3 Month

Method of measurement

generalized anxiety disorder 7-item scale (2006), Penn state worry questionnaire (1990), intolerance of uncertainty scale (1994), metacognition questionnaire (2004) & EEG Neurofeedback Tool & Protocol of mindfulness based on stress reduction therapy.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mindfulness based on stress reduction therapy, Treatment protocol: mindfulness based on stress reduction, number of treatment sessions: 8 sessions, 150 min, once a week, treatment is done in group,

Category

Treatment - Other

2

Description

Intervention group: neurofeedback training, Training is conducted in 15 sessions and three times a week for 45 minutes. Training is done with the ProComp2 device.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Advice and Psychology Services of Azad University, Neishabour

Full name of responsible person

MR Mahroghi

Street address

Noishabour Blvd Research Center, Neishabour Azad University, Faculty of Humanities, Psychological Consulting and Services

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Full name of responsible person

Tahmine miri sargazi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

No special institution has been sponsored.

Full name of responsible person

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Grant name

0

Grant code / Reference number

0

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

Yes

Title of funding source

No special institution has been sponsored.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Ahmad Mansuri

Position

Profossor

Latest degree

Ph.D.

Other areas of specialty/work

Professor

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Person responsible for updating data**Contact****Name of organization / entity**

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Tahmine miri sargazi

Position

Psychologist

Latest degree

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Other areas of specialty/work

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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

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

Data Dictionary

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

Title and more details about the data/document

The total potential data can be shared after unidentifiable persons.

When the data will become available and for how long

Upon completion of research and becoming an article, Six months after printing results

To whom data/document is available

All Scholars & researchers

Under which criteria data/document could be used

Participants' information content is not distributed due to privacy issues, please do not request.

From where data/document is obtainable

tahmine.miri@chmail.ir

What processes are involved for a request to access data/document

Approximately two weeks after request

Comments