Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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**
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

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Iran (Islamic Republic of)

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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

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
Neyshabour
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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
No special institution has been sponsored.
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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
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Full name of responsible person
Tahmine miri sargazi
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student
Latest degree
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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