Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of metacognitive therapy based on mindfulness and transcranial direct current stimulation (tDCS) on experiential avoidance and cognitive emotional regulation and emotional processing on people with General Anxiety Disorder (GAD).

Protocol summary

Study aim
Comparison between two therapeutic methods metacognitive therapy based on mindfulness and Transcranial direct current stimulation (tDCS) on experiential avoidance and cognitive emotional regulation and emotional processing on people with General Anxiety Disorder (GAD).

Design
Randomized, Waiting-controlled group, Two experimental groups, Each group has 15 people

Settings and conduct
A study on people referring to a Nedaye Aramesh Ravan clinic in Tehran is done. Patients with generalized anxiety disorder are placed in two experimental and one control groups and treated

Participants/Inclusion and exclusion criteria
Not being under any psychotherapy over the past three months Lack of substance and drug abuse

Intervention groups
metacognitive therapy group, tdcs group, control group

Main outcome variables
experiential avoidance, cognitive emotional regulation, emotional processing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181008041271N1**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **retrospective**

Last update: **2019-01-08, 1397/10/18**
Update count: **0**

Registration date
2019-01-08, 1397/10/18

Registrant information
Name
nastaran mohajeri aval
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 45 3371 0333
Email address
nastaranmohajeri@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of metacognitive therapy based on mindfulness and transcranial direct current stimulation (tDCS) on experiential avoidance and cognitive emotional regulation and emotional processing on people with General Anxiety Disorder (GAD).

Public title
Comparison of the effectiveness of metacognitive therapy based on mindfulness and Transcranial direct

current stimulation (tDCS) on people with General Anxiety Disorder (GAD).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Catching general anxiety disorder according to DSM5 Not being under any psychotherapy over the past three months, Not having other psychiatric disorders Lack of substance and drug abuse

Exclusion criteria:

Having a history of epilepsy and mental retardation

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: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

individuals were randomly assigned to intervention and control groups. a random number table is used for this task

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's committee of Ardabil university of medical sciences

Street address

No 284, Rezvan 8 Ave, Rezvan Street

City

Ardabil

Province

Ardabil

Postal code

5615739556

Approval date

2018-10-07, 1397/07/15

Ethics committee reference number

ir.arums.rec.1397.093

Health conditions studied

1

Description of health condition studied

General anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Experiential avoidance

Timepoint

Before therapy and maximum one week after therapy

Method of measurement

Acceptance and Action Questionnaire

2

Description

Cognitive emotional regulation

Timepoint

Before therapy and maximum one week after therapy

Method of measurement

Cognitive emotional regulation scale

3

Description

Emotional processing

Timepoint

Before therapy and maximum one week after therapy

Method of measurement

Emotional processing questionaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group1", Fifteen sessions of tdcs treatment each session twenty minutes, It is a nerve therapy technique, Direct and weak electrical current flows into the cortical regions and facilitates or inhibits spontaneous neuronal activity.

Category

Treatment - Devices

2

Description

"Intervention group2": Eight sessions of metacognitive therapy based on mindfulness sessions per hour,

Metacognitive therapy deals with the control and interpretation of the thinking process, Treatment involves eliminating worries and disturbing thoughts without avoiding them

Category
Treatment - Other

3

Description
"Control group": Waiting for treatment

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nedaye Aramesh Ravan Clinic

Full name of responsible person
Nastaran Mohajeri Aval

Street address
No4, Shohadaye Sadeghiye Shomali Ave, Sattarkhan Street, Sadeghiye Blvd

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Tehran

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1484665865

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nastaranmohajeri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mohaghegh Ardabili University

Full name of responsible person
Nastaran Mohajeri Aval

Street address
Daneshgah Ave, Mohaghegh Ardabili University

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Grant name

Grant code / Reference number

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

Title of funding source
Mohaghegh Ardabili University

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
Mohaghegh Ardabili University

Full name of responsible person
Nastaran Mohajeri Aval

Position
Phd student

Latest degree
Master

Other areas of specialty/work
Psychology

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Other areas of specialty/work
Psychology

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Person responsible for updating data

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Full name of responsible person

Nastaran Mohajeri Aval

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Latest degree

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Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data is published without personal information of the participants

When the data will become available and for how long

One year after printing

To whom data/document is available

Researchers

Under which criteria data/document could be used

The use of information is possible only by mentioning the source

From where data/document is obtainable

The journals that are supposed to be published there

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

Download the article from the magazine

Comments

The results of this work are to be published as a paper