

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 questionnaire

## **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

**City**

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**Phone**

+98 21 4424 4916

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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

**Street address**

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Personal

**Full name of responsible person**

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**Position**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Personal  
**Full name of responsible person**  
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**Position**  
Phd student  
**Latest degree**  
Bachelor  
**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

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