

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Cognitive, emotional and neuropsychological indices of generalized anxiety disorder: effectiveness of unified transdiagnostic treatment with and without transcranial direct current stimulation

#### Protocol summary

##### Study aim

The aim of the current study is to compare unified protocol for transdiagnostic treatment of emotional disorders with and without tDCS in individuals suffering from generalized anxiety disorder (GAD) and comorbid depression.

##### Design

Participants with GAD and comorbid depression will assign to treatment groups and waitlist group on the basis of covariate adaptive randomization (minimization). The purpose of this method will control the gender variable.

##### Settings and conduct

Allocation of participants will administer by someone other than a therapist. For allocation of the participants, a roll of a die will use. Referrals for the treatment and wait-list groups will from the counseling center of the Ferdowsi University of Mashhad and mental health professionals.

##### Participants/Inclusion and exclusion criteria

The study population will include people with GAD and comorbid depression in Mashhad in 2018. The sample of research also will include a number of people with GAD with depression.

##### Intervention groups

The individuals suffering from GAD with comorbid depression will randomly assign in three groups including UP with tDCS, UP without tDCS and wait-list

##### Main outcome variables

Cognitive fusion; intolerance of uncertainty; cognitive avoidance; difficulties in emotion regulation; cognitive emotion regulation; anxiety sensitivity; cognitive flexibility; working memory; inhibition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140929019334N1**  
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

Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3522 3173

##### Email address

nasiri@stu.um.ac.ir

##### Recruitment status

Recruitment complete

##### Funding source

##### Expected recruitment start date

2017-12-09, 1396/09/18

##### Expected recruitment end date

2018-06-22, 1397/04/01

##### Actual recruitment start date

2017-11-22, 1396/09/01

##### Actual recruitment end date

2018-06-22, 1397/04/01

##### Trial completion date

2018-08-11, 1397/05/20

##### Scientific title

Cognitive, emotional and neuropsychological indices of generalized anxiety disorder: effectiveness of unified

transdiagnostic treatment with and without transcranial direct current stimulation

#### Public title

Effectiveness of unified transdiagnostic treatment with and without transcranial direct current stimulation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Diagnostic DSM-V criteria for GAD as the primary diagnosis and depression disorder as a comorbid disorder If the drug was taken, it was possible to maintain the type and amount of the drug during the study period Be a minimum 18 years and a maximum 40 years old Patient's consent to participate in research and to sign written consent Speak Persian fluently Ability to participate in all assessment and treatment sessions

##### Exclusion criteria:

Need for immediate medical treatment or the need for concurrent therapeutic interventions in such a way as to interfere with the treatment program Not having previous experience in at least eight sessions of treatment based on the cognitive-behavioural therapy in the last 5 years Having psychiatric disorders and substance abuse Current diagnosis of any mental disorder in the axes I and II, with the exception of GAD and depression Patient's opposition to collaboration at any time of research Having serious thoughts about Suicide History of experiencing other psychological treatments

#### Age

From **18 years** old to **40 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Data analyser

#### Sample size

Target sample size: **45**

Actual sample size reached: **43**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants with GAD and comorbid depression will assigne to treatment groups and wait- list group on the basis of covariate adaptive randomization (minimisation). The purpose of this method is to control gender variable. So if the first participant be female, she will assigne in group number one. When the second participant be a man, he will assigne in the first group. When the third participant be female, she will assigne to the second group. If the fourth participant be female, she will assigne to third group and then the rest of the participants will place in the groups by adjusting the gender variable.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Interviews will conduct by an expert clinical therapist to assess the inclusion and exclusion criteria. After that, individuals randomly will assign to treatment groups (UP group and UP-tDCS group) and wait- list group. Allocation of participants, will administer by someone other than therapist.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Bioresearch

##### Street address

Azadi Square., campus of Ferdowsi university of Mashhad., Central organization

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948974

#### Approval date

2018-12-26, 1397/10/05

#### Ethics committee reference number

IR MUM FUM REC .1397.047

## Health conditions studied

### 1

#### Description of health condition studied

Generalized anxiety disorder comorbid with depression

#### ICD-10 code

F41.1

#### ICD-10 code description

Generalized anxiety disorder

## Primary outcomes

### 1

#### Description

Score of generalized anxiety from GAD-Q-IV questionnaire

#### Timepoint

Pre-treatment; post-treatment; follow-up

#### Method of measurement

GAD-Q-IV questionnaire

## 2

### **Description**

Score of depression from Beck depression questionnaire

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

Beck depression questionnaire

## **Secondary outcomes**

## 1

### **Description**

Score of worry from PSWQ

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

PSWQ questionnaire

## 2

### **Description**

Score of intolerance of uncertainty from IUS

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

IUS questionnaire

## 3

### **Description**

Score of cognitive fusion from CFQ

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

CFQ questionnaire

## 4

### **Description**

Score of cognitive avoidance from CAQ

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

CAQ questionnaire

## 5

### **Description**

Score of difficulties in emotion regulation from DERS

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

DERS questionnaire

## 6

### **Description**

Score of cognitive emotion regulation from CERQ

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

CERQ questionnaire

## 7

### **Description**

Score of emotion regulation from ERQ

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

ERQ questionnaire

## 8

### **Description**

Score of anxiety sensitivity from ASI

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

ASI questionnaire

## 9

### **Description**

Score of cognitive flexibility from Wisconsin test

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

Wisconsin card sorting test

## 10

### **Description**

Score of inhibition from go/no go test

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

Go/no go software

## 11

### **Description**

Score of working memory from n-back test

### **Timepoint**

Pre-treatment; post-treatment; follow-up

### **Method of measurement**

N- back software

## **Intervention groups**

## 1

### **Description**

Intervention group: group 1: UP group. Unified protocol for transdiagnostic of emotional disorders consists of a maximum of 12, 60-minute individual treatment sessions. The UP targets and regulates emotional experiences by increasing emotion awareness and cognitive flexibility; identifying emotion-driven behaviors (EDBs) and replacing them with adaptive behaviors; identifying and preventing patterns of emotion avoidance; increasing awareness and confronting with physical sensations, and facing with emotions in situations. The treatment is preceded by enhancing

motivation and readiness of individuals for change and treatment engagement. Finally, the treatment ends by considering the progress of treatment and developing relapse prevention strategies.2:UP-tDCS. In the UP-tDCS group, for two weeks until the end of the UP sessions, the tDCS will perform. The treatment consists of 10 daily sessions (except for weekends) with a direct current of 2.0 mA for 30-minute stimulation session. The 25 cm<sup>2</sup> rubber electrodes will moistene with saline to reduce impedance. The cathode will place over the right dorsolateral prefrontal cortex (DLPFC).

#### Category

Treatment - Other

### 2

#### Description

Control group: wait-list group for Unified protocol.After completion of follow-up sessions of intervention groups, the UP treatment will be applied as intervention group 1.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Counselling center of Ferdowsi University of Mashhad

##### Full name of responsible person

Zahra Tabibi

##### Street address

Vakilabad Blvd; Ferdowsi University of Mashhad;  
Counselling center of University of Mashhad

##### City

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##### Province

Razavi Khorasan

##### Postal code

91177948974

##### Phone

+98 51 3880 6914

##### Email

tabibi@um.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ferdowsi University of Mashhad

##### Full name of responsible person

Ahmad Reza Bahrami

##### Street address

Vakilabad Blvd; Ferdowsi university of Mashhad

##### City

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##### Province

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##### Postal code

91177948974

##### Phone

+98 51 3880 2420

##### Email

pr@um.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ferdowsi University of Mashhad

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ferdowsi University of Mashhad

##### Full name of responsible person

Farzad Nasiri

##### Position

Ph.D. candidate

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

##### Street address

Vakilabad Blvd; Ferdowsi University of Mashhad

##### City

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##### Province

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##### Postal code

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##### Fax

##### Email

nasiri@mail.um.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ferdowsi University of Mashhad

##### Full name of responsible person

Farzad Nasiri

##### Position

Ph.D. candidate

##### Latest degree

Master  
**Other areas of specialty/work**  
Psychology  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Ferdowsi University of Mashhad  
**Full name of responsible person**  
Farzad Nasiri  
**Position**  
Ph.D. candidate  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
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nasiri@mail.um.ac.ir

## 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

Part of the data including information about the main consequence can be shared.

### When the data will become available and for how long

Start of accessibility will be one year after printing the results.

### To whom data/document is available

Data will only be available to researchers working in academic institutions.

### Under which criteria data/document could be used

Requests for data are only permitted for intercultural studies or the studies of meta-analysis.

### From where data/document is obtainable

Tel: 0098513-8805873, Fax: 0098-513-8783012  
Email: nasiri@mail.um.ac.ir

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

Data will be provided by email or post after evaluation of the request.

### Comments