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 questionnare

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 cm2 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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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

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Vakilabad Blvd; Ferdowsi university of Mashhad

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Ph.D. candidate

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Ferdowsi University of Mashhad

Full name of responsible person

Farzad Nasiri

Position

Ph.D. candidate

Latest degree

Master

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

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