

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Efficacy of the Group Acceptance Based Behavior Therapy in Generalized Anxiety Disorder in Patient with Episodic Migraine

Protocol summary

Study aim

determining Effectiveness of the Group Acceptance Based Behavior Therapy in Generalized Anxiety Disorder in Patients with Episodic Migraine

Design

randomized control trial with control group, single blind
Sample size is calculated based on G-POWER (20 participant each group)

Settings and conduct

The intervention will be done in a neurologist private clinic and will be in 16 group sessions. Outcome assessment in groups is done by a third person and the researcher and statistical analyst will not know about it.

Participants/Inclusion and exclusion criteria

inclusion criteria: Have diagnostic criteria for episodic migraine based on Neurologist based on IHCD-II criteria; Having diagnostic criteria for generalized anxiety disorder according to SCID-5; Being at least 18 years old; Minimum diploma education. exclusion criteria: Symptoms of psychosis; Bipolar disorder; substance-related and addictive disorders based on SCID-5; Get other psychological treatments at the same time; Having the thoughts of suicide outright now; Having a debilitating physical condition or a serious medical condition; Have diagnostic criteria for; tension headache based on Neurologist based on IHCD-III criteria

Intervention groups

Group Acceptance Based Behavior Therapy Control group receiving only drug therapy It should be noted that in order to prevent drug interference, the current drug treatment of patients is kept constant and, if they take prophylactic medication, it is kept constant from 1 month before the intervention until the end of the follow-up period. But the use of painkillers as a variable will be examined in the study

Main outcome variables

severity of Generalized Anxiety Disorder; severity of headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190926044891N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Fateme Veisy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 5516 5560

Email address

veisy.f@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of the Group Acceptance Based Behavior Therapy in Generalized Anxiety Disorder in Patient with Episodic Migraine

Public title

Group Acceptance Based Behavior Therapy in Generalized Anxiety Disorder in Patient with Episodic Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Recurrent episodic migraine diagnoses based on IHCD-III criteria by neuroscientists Having a diagnosis of generalized anxiety disorder based on DSM-5 Minimum diploma education

Exclusion criteria:

Psychotic disorder based on DSM-5 Bipolar disorder based on DSM-5 Substance related and addictive disorder based on DSM-5 Get other psychological treatments at the same time Having suicidal thoughts now Having a debilitating physical condition or a serious medical condition

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For random assignment, randomization is blocked randomization with fixed block sizes. The size of the blocked is 4. Randomization was performed using <https://www.sealedenvelope.com/>.

Blinding (investigator's opinion)

Single blinded

Blinding description

Unawareness of the researcher and statistical analyst of the personal code in the intervention and treatment groups Performing assessments by another person

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of medical science ethics committee

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

۱۴۵۶۱۳۱۱۱

Approval date

2019-10-06, 1398/07/14

Ethics committee reference number

IR.IUMS.REC.1398.710

Health conditions studied

1

Description of health condition studied

Patients with Episodic Migraine comorbid with Generalized Anxiety Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of GAD

Timepoint

Before intervention, End of intervention and 3 months later for follow up

Method of measurement

Generalized Anxiety Disorder-7 questionnaire

Secondary outcomes

1

Description

headache severity

Timepoint

Before intervention, End of intervention and 3 months later for follow up

Method of measurement

Patients report their headaches every day from 0 to 10, and at the end, the average headache severity is reached

Intervention groups

1

Description

Intervention group: The ABBT, which offers 16 sessions of psychotherapy, is based on the ABBT protocol, which

details the structure of the meeting session by session. Duration of one to four sessions are 90 minutes, and session five to sixteen are 60 minutes. It should be noted that if consent is obtained for this study, drug treatment will be maintained for 1 month before the intervention until the end of the follow-up period. Patients will be excluded if the medication needs to be changed.

Category

Treatment - Other

2**Description**

Control group: if consent is obtained for this study, drug treatment will be maintained for 1 month before the intervention until the end of the follow-up period.

Patients will be excluded if the medication needs to be changed.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr Mansoure Togha clinic

Full name of responsible person

Dr Mansoure Togha

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NO 1, 24 street, Ghaem Magham Farahani Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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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

Iran University of Medical Sciences

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**

Iran University of Medical Sciences

Full name of responsible person

Fateme Veisy

Position

Ph.D candidate in clinical psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

data will be presented in the statistical analysis section
in the future article

When the data will become available and for how long

nearly 6 months to 1 year after the termination of the
projrct

To whom data/document is available

all people who will read the article

Under which criteria data/document could be used

researcher who aim to conduct any studies on the data

From where data/document is obtainable

corresponding author

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

sending email and explaining about the research aims an
the data

Comments