

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of cognitive-behavioral therapy and dialectical behavior therapy on emotional dimensions, quality of life, migraine-induced disability, severity of headache and severity of anxiety symptoms in migraine patients with generalized anxiety symptoms

Protocol summary

Study aim

Comparison of the effectiveness of cognitive-behavioral therapy and dialectical behavior therapy on emotional dimensions, quality of life, migraine-induced disability, severity of headache and severity of anxiety symptoms in migraine patients with generalized anxiety symptoms

Design

The present study is an experimental pretest-posttest with a control group that has a follow-up period. First, the researcher will refer to the neurological clinics by diagnosing the doctor and referring to the patient records and conducting a clinical interview with those who are eligible for inclusion criteria, and then the participants will be equally matched based on their age, gender, employment status And marital status will be divided into three groups (two treatment groups and one control group).

Settings and conduct

Interventions will be held at the psychological clinic of Kargarnejad Hospital in kashan city. The DBT group will receive 16 treatment sessions. The CBT group will receive 16 sessions of treatment. And the control group will receive a supportive treatment group and do not receive any psychological treatment in order to control the common factors.

Participants/Inclusion and exclusion criteria

Inclusion criteria for satisfying patients Reasons for detecting migraine disorder aged 40-18 No history of drug abuse No history of psychotic disorders . Non-compliance criteria any psychotherapy simultaneously Two or more absences during psychiatric sessions Severe psychiatric disorders (psychotic, suicidal thoughts, etc.) in the participants

Intervention groups

This study has two intervention groups (a special treatment intervention group (DBT) and a common

intervention group (CBT). Intervention 1: 16 sessions of 2 hours of admission and admission therapy. Intervention 2: 16 sessions of 2 hours of cognitive-behavioral therapy

Main outcome variables

disability by headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180815040797N1**

Registration date: **2019-09-08, 1398/06/17**

Registration timing: **prospective**

Last update: **2019-09-08, 1398/06/17**

Update count: **0**

Registration date

2019-09-08, 1398/06/17

Registrant information

Name

Mina Khaliliseafat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

khalilisefat-m@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of cognitive-behavioral therapy and dialectical behavior therapy on emotional dimensions, quality of life, migraine-induced disability, severity of headache and severity of anxiety symptoms in migraine patients with generalized anxiety symptoms

Public title

Comparison of the effectiveness of cognitive-behavioral therapy and dialectical behavior therapy on emotional dimensions, quality of life, migraine-induced disability, severity of headache and severity of anxiety symptoms in migraine patients with generalized anxiety symptoms

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction of references There is a diagnosis of migraine disorder A score of over 10 in terms of incidence of generalized anxiety disorder Age 40-18 No history of drug use No history of psychotic disorders

Exclusion criteria:

Getting Simultaneous Psychotherapy 2 or more absences during psychotherapy sessions Participant's willingness to exit the study Participants with severe psychiatric disorders (psychotic, suicidal ideation, etc.)

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Among all patients referring to neurosurgical clinics in Kashan, 100 individuals who were diagnosed by a specialist in migraine diagnoses and who had an anxiety score above 10 according to the clinical psychologist's diagnosis. Then, using the random number table, sixty of these individuals are selected and then divided into three groups of twenty.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each person's information is entered into the software

code and the groups are entered as encoded, and this information is confidential to the researcher.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

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ravand Ave, pezeshk Blvd

City

kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2018-01-29, 1396/11/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.007

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

2**Description of health condition studied**

Generalized Anxiety Disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

disability by headache

Timepoint

Before and after the intervention

Method of measurement

Migraine Disability Scale

2

Description

Headache severity

Timepoint

Before and after the intervention

Method of measurement

Migraine Disability Scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before and after the intervention

Method of measurement

Migraine quality of life questionnaire

2

Description

Distress Tolerance

Timepoint

Before and after the intervention

Method of measurement

Before and after the intervention

3

Description

Emotion regulation

Timepoint

Before and after the intervention

Method of measurement

Difficulty scale in emotional regulation

4

Description

Severity of anxiety symptoms

Timepoint

Before and after the intervention

Method of measurement

The scale of generalized anxiety disorder 7 questions

Intervention groups

1

Description

Intervention group: 16 sessions of 2 hours of dialectical behavioral therapy

Category

Behavior

2

Description

Intervention group: 13 sessions of 2 hours of cognitive-

behavioral therapy

Category

Behavior

3

Description

Control group: (بدون دریافت تکنیک درمانی)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Beheshti Hospital in Kashan

Full name of responsible person

Mina Khalilisefat

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Ravand Ave, Pezeshk Blvd

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8715973446

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kashan 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

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Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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