Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

disabbility 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.)
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target 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
Street address
ravand Ave, pezeshk Blvd
City
kashan
Province
Isfehan
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 generalizef 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: درمان حمایتی (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
Street address
Ravand Ave, Pezeshk Blvd
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Isfehan
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8715973446
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Email
mina_khalilisefat@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ravand Ave
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Postal code
81151-87159
Phone
+98 31 5554 0021
Email
Mina_khalilisefat@yahoo.com
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

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mina Khalilisafat

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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student

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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