Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of Acceptance & Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache

Protocol summary

Summary

The purpose of this study was to investigate the effects of Acceptance and Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, headache disability and headache intensity among patients with chronic daily headache. The study is one-centered, non-blinded, and two-grouped. The population of this study is comprised of all adults with chronic daily headache, referring to the neurology clinic of the Shahid Beheshti Hospital of Kashan City, during 2016. A total of 40 patients selected as the study sample and assigned into intervention and control groups by block randomization method (20 participants in each group). Inclusion criteria include having chronic daily headache according to the International Classification of Headache Disorders, 3rd edition; informed consent to participate in the study and having old above 18. Major exclusion criteria include unwillingness to continue participation; having a medical diagnosis of organic brain disorder or psy-chotic disorder, having a history of psychological treatment during the preceding six months. The intervention group was trained for eight 90-min weekly group sessions. Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) have administered at pretreatment and post-treatment in both groups. By comparing the mean scores of the two groups, the effectiveness of Acceptance and Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, headache disability and headache intensity determines in patients with chronic daily headache.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091236145N1**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

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Name of organization / entity

Kashan university of medical science

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical science

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Acceptance & Commitment Therapy

on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache

Public title
The effectiveness of Acceptance & Commitment Therapy on cognitive emotion regulation strategies, Anxiety, Depression, Headache Disability and Headache intensity in patients with Chronic Daily Headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria included: having chronic daily headache according to the International Classification of Headache Disorders, 3rd edition (beta version), and tending to participate in the study exclusion criteria included: having a medical diagnosis of organic brain disorder or psychotic disorder and having a history of psychological treatments during the preceding six months.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Qotb-e Ravandi Blvd
City
Kashan
Postal code
Approval date
2017-10-17, 1396/07/25
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.53

Health conditions studied

1

Description of health condition studied
Chronic Daily Headache
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
cognitive emotion regulation strategies
Timepoint
pretreatment and posttreatment
Method of measurement
cognitive emotion regulation strategies (CERQ)

2

Description
depression and anxiety
Timepoint
pretreatment and posttreatment
Method of measurement
DASS-21 scale

3

Description
headache disability
Timepoint
pretreatment and 2 months after treatment
Method of measurement
headache disability inventory (HDI)

4

Description
headache intensity
Timepoint
pretreatment and 2 months after treatment
Method of measurement
diary scale of headache

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group (Acceptance and Commitment Therapy): Completion of Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) before intervention; going through 8 sessions of Acceptance and

Commitment Therapy training one session a week; completion of Questionnaires after intervention.

Category

Behavior

2

Description

Control Group (No intervention): Completion of Cognitive emotion regulation Questionnaire (CERQ), Depression anxiety stress scale (DASS-21), Diary scale for headache and Headache related disability inventory (HDI) before intervention; no intervention; completion of Questionnaires after intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

neurology clinic of Shahid Beheshti Hospital of Kashan City

Full name of responsible person

Dr Reza Daneshvar Kakhki (neurologist)

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

research committee

Street address

Qotb-e Ravandi Blvd

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan university of medical science

Full name of responsible person

Dr zanjani

Position

PHD/ science Committee of clinical psychology

Other areas of specialty/work

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Master degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty