

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

An Empirical Examination of the Mindfulness-Based Cognitive Therapy on cognitive adjustment and management of chronic pain in the patient with primary Headache Pain

Protocol summary

Study aim

Aim 1: To examine pain management, data will be collected regarding participant flow across each stage of the study design. Includes pain interference, mindfulness, pain intensity, cognitive process pain related. Furthermore, pre-treatment cognitive flexibility will be assessed. Aim 2: As a Secondary estimate of the efficacy of MBCT for improvement of the Pain-Related cognitive process, the investigators will compare cognitive flexibility moderation role in probable outcomes, in pre- and post-intervention measures. Time constraints of the current project will necessitate follow-up assessment to be part of future proposals.

Design

Two arms parallel group randomized trial with the control group.

Settings and conduct

Eligible and interested participants after completing consent forms and baseline questionnaires (T1) will be screened randomly assigned via a web-based random number sequencer (<http://www.randomizer.org>) to intervention and control group. Additional questionnaires will be mailed out immediately after (T2), after the 8-week intervention (T3), and 3 months after (T4).

Participants/Inclusion and exclusion criteria

Aged 18 to 65 years old; Having the primary headache.
Exclusion criteria: Having the significant Cognitive impairment

Intervention groups

Intervention group: MBCT through 8 two hour psychological sessions incorporates specific components of mindfulness and cognitive behavioral therapy to form a comprehensive treatment approach. Control group: The APC condition involved eight 45-minute sessions the promising discussion group without active guidance for reducing pain and with its social support and attention aspects.

Main outcome variables

primary outcome variables: Pain interference; Pain Intensity; Mindfulness; Pain-Related Cognitive Processes, Pain-Related Cognitive content and secondary outcome variable: Depression and Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141012019511N4**
Registration date: **2018-07-12, 1397/04/21**
Registration timing: **retrospective**

Last update: **2018-07-12, 1397/04/21**

Update count: **0**

Registration date

2018-07-12, 1397/04/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Empirical Examination of the Mindfulness-Based Cognitive Therapy on cognitive adjustment and management of chronic pain in the patient with primary Headache Pain

Public title

Mindfulness-Based Cognitive Therapy for the Treatment of primary Chronic Headache Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 19 years of age At least 3 pain days per month (for the past 3 month) due to a primary headache pain type headache pain was the primary source of pain if currently using psychotropic or headache medications, use of these medications must have begun at least 4 weeks before baseline assessment reading ability was sufficient to comprehend self-monitoring forms

Exclusion criteria:

human immunodeficiency virus-related pain and cancer pain because these are associated with malignant disease history of seizure or facial neuralgia, as these conditions might preclude the accurate diagnosis of headache significant cognitive impairment

Age

From **19 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization was the Simple randomization assignment. The Unit of randomization was individual. Random sequence was created via a web-based random number sequencer (<http://www.randomizer.org>). in order to Hide the random allocation, the individual involved in the implementation of the randomization process was separated from other researchers in order to reduce the probable bias.

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**

Ethics committee of Alborz Islamic Azad University of Medical Sciences

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Islamic Azad University of Alborz, Moazen Boulevarad, Rajai Street, Karaj, Alborz

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Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.IAU.K.REC.1397.26

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

Primary Headache Pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain interference

Timepoint

From baseline until 6 months

Method of measurement

The Brief Pain Inventory (BPI)

2**Description**

Pain-Related Cognitive Processes

Timepoint

From baseline until 6 months

Method of measurement

Pain-Related Cognitive Processes Questionnaire

3**Description**

Pain intensity

Timepoint

From baseline until 6 months

Method of measurement

Numerical Rating Scale (NRS)

4

Description

Pain intensity

Timepoint

From baseline until 6 months

Method of measurement

The Brief Pain Inventory (BPI)

Secondary outcomes

1

Description

Mindfulness

Timepoint

From baseline until 6 months

Method of measurement

Mindful Attention Awareness Scale (MAAS)

2

Description

Negative Emotions and Affects

Timepoint

From baseline until 6 months

Method of measurement

Depression Anxiety and Stress Scales (DASS-21)

3

Description

Cognitive flexibility

Timepoint

Before the intervention

Method of measurement

Cognitive Flexibility Inventory (CFI)

4

Description

Alexithymia

Timepoint

Before the intervention

Method of measurement

Toronto Alexithymia Scale

5

Description

Pain Self Efficacy

Timepoint

From baseline until 6 months

Method of measurement

Pain Self Efficacy Questionnaire (PSEQ)

6

Description

Pain Acceptance

Timepoint

From baseline until 6 months

Method of measurement

Chronic Pain Acceptance Questionnaire (CPAQ)

7

Description

Pain Catastrophizing

Timepoint

From baseline until 6 months

Method of measurement

Pain Catastrophizing Scale (PCS)

Intervention groups

1

Description

Intervention group: The MBCT for pain approach incorporates one of the strengths of CBT protocols in that cognitive exercises are included that train the mind to be more aware, more often, of cognitions, emotions, behaviors, and pain, and the links between them. Unlike in CBT however, the CBT-oriented exercises in the MBCT protocol are not aimed toward changing any of these aspects of the moment-to-moment experience. Rather they are geared toward simply heightening awareness, thereby providing an entry point to stepping out of automatic pilot and doing mode, and into being mode. In The MBCT protocol, the first half of treatment is focused on enhancing awareness of our habitual patterns, and this awareness is built upon in the second half of treatment to enhance skillful, wise responding (i.e., choosing to intentionally respond rather than react—this is what is meant by “skillful” here). The main modules of MBCT for chronic pain include session 1; Stepping Out of Automatic Pain Habits, session 2; Facing the Challenge. session 3; The Breath as an Anchor, session 4; Learning to Stay Present, session 5; Active Acceptance, session 6; Seeing Thoughts as Just Thoughts, session 7; Taking Care of Myself, session 8; Harnessing the Power of the Mind for Chronic Pain Management.

Category

Behavior

2

Description

Control group: Attention Placebo Control group (APC): Control group that serves as a baseline for comparison for assessment of the effects of the particular intervention. While persons in the treatment group receive the experimental treatment being studied, the attention placebo control group receives a treatment that mimics the amount of time and attention received by the treatment group but is thought not to have a specific effect upon the subjects.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Farhad Assarehzadegan

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Sponsors / Funding sources

1

Sponsor

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farhad Assarehzadegan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The only part of the data, such as information on the main outcome, that in the present study, is the severity of pain and Some of the secondary outcomes (Depression) variable will be shared.

When the data will become available and for how long

Starting the access period from 1399

To whom data/document is available

Data will only be available to researchers in academia and universities.

Under which criteria data/document could be used

The application of the present study documents is permitted in the development of clinical research and referral in the compilations.

From where data/document is obtainable

Dr Sarah Namjoo, No 12, Moazzen Blvd, Rajae Shahr, Karaj, Alborz. Postal code: namjoopsy@gmail.com

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

The applicant for research information can receive a documentation of study at the end of 2018-2019 by email to Dr. Sarah Namjoo.

Comments