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

Department of Health Psychology ، Science and Research Branch, Islamic Azad University, Alborz

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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
Street address
Islamic Azad University of Alborz, Moazen Boulevared, 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-orientedexercises 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
Name of organization / entity
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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
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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, Rajaee 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