Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of group therapy based on acceptance and commitment compared to critical thinking skills on improving pain self-efficacy, psychological distress, difficulty in regulating excitement and quality of life of people with chronic musculoskeletal pain.

Protocol summary

Study aim

Determining the effectiveness of acceptance and commitment group therapy on pain intensity, psychological distress, difficulty in regulating emotions, and quality of life in people with chronic musculoskeletal pain.

Design

A clinical trial with an intervention group based on acceptance and commitment and control of critical thinking skills training, with parallel groups, single blind, phase 3 and online randomization through www.randomization.com and on 44 patients

Settings and conduct

The place of intervention: Faculty of Medical Sciences; The studied population: people with chronic musculoskeletal pain referred to Shahid Beheshti Hospital in Kashan; Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people with chronic musculoskeletal pain; having a diagnosis of chronic pain; age range of 35 to 65 years; minimum literacy level; absence of mental disorders; no psychological interventions during the last year. Exclusion criteria: lack of motivation and satisfaction to participate in the research; suffering from infectious diseases such as Malt fever; Having a mental disorder requiring treatment; intense thoughts about harming yourself or killing yourself; simultaneous participation in another treatment program; receiving drug treatment related to the disorder

Intervention groups

The intervention group will receive treatment based on acceptance and commitment, and the control group will receive critical thinking skill training.

Main outcome variables

Pain self-efficacy, Psychological Distress, Difficulties in Emotion Regulation, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230806059054N1**
Registration date: **2024-02-12, 1402/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-12, 1402/11/23**
Update count: **0**

Registration date

2024-02-12, 1402/11/23

Registrant information

Name

zahra ajdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5557 0930

Email address

ajdani-z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of group therapy based on acceptance and commitment compared to critical thinking skills on improving pain self-efficacy, psychological distress, difficulty in regulating excitement and quality of life of people with chronic musculoskeletal pain.

Public title
The effect of acceptance and commitment group therapy on chronic musculoskeletal pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of chronic pain by a specialzed doctor in physical medicine and rehabilitation Age range from 35 to 65 years Having a minimum level of literacy
Exclusion criteria:
Lack of motivation and satisfaction to participate in the research Infectious diseases such as Malt fever Having a mental disorder that requires immediate treatment, such as drug and alcohol use disorder and psychotic disorders Intense thoughts about self-harm or suicide Concurrently participating in another treatment program receiving drug treatment related to the disorder, at least one month before the pre-test phase until the end of the follow-up phase Receiving psychological interventions during the last year
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
The people who meet the entry criteria are randomly assigned and using the randomization internet site in psychological experiments, medical trials and field studies at www.randomization.com , online in two treatment groups based on Acceptance and commitment (ACT) and control group are included.
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 Kashan University of Medical Sciences
Street address
Kashan - Qutb Ravandi Boulevard - Doctor's Boulevard
City
kashan
Province
Isfehan
Postal code
8715973474
Approval date
2023-08-08, 1402/05/17
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.105

Health conditions studied

1

Description of health condition studied
Chronic Musculoskeletal Pain
ICD-10 code
G89.29
ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
Pain self-efficacy score
Timepoint
Before the intervention, after the intervention, in the follow-up phase
Method of measurement
PSEQ

2

Description
DASS-21 questionnaire score
Timepoint
Before the intervention, after the intervention, in the follow-up phase
Method of measurement
DASS-21 questionnaire

3

Description

DERS score

Timepoint

Before the intervention, after the intervention, in the follow-up phase

Method of measurement

DERS questionnaire

4

Description

WHOQOL-BREF score

Timepoint

Before the intervention, after the intervention, in the follow-up phase

Method of measurement

WHOQOL-BREF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment based on acceptance and commitment is one of the third wave psychological approaches that seeks comprehensive awareness and education to patients in the field of controlling the controllable aspects, acceptance and openness to the uncontrollable aspects of the disease, that is, the person without trying to controlling the thoughts related to the disease allows them to be present in the mind. It has six central processes, which are acceptance, disfusion, self as background, present time, values and committed action, the goal of which is psychological flexibility. The participants based on Hayes and Strosahl's acceptance and commitment group treatment protocol in 8 sessions. They will participate in 1.5 hour group therapy weekly. Content of the sessions: First session: presenting the basic concepts of treatment; Familiarizing people with the subject of research; Examining chronic pain in each member of the group and the measures taken; discussion about experiential avoidance and the creation of creative helplessness; Explaining the importance of homework. The second session: regaining the relationship with values (what values are important to them), examining the actions they want to take in the rest of their lives to discover values; How well controlling pain is consistent with their values; Are there other options for living with pain and discomfort? Initial practice of mindfulness (eating raisins) and presenting homework (eating food consciously even in pain). The third session: - Assignment review; awareness of inner experiences; A thought about the door is just a thought; having a thought against the contents of a thought; distancing from self-conceptualized harm; living with chronic pain and discomfort; Practicing body inspection and offering meditation at home (paying attention to the body parts while sleeping, even in the presence of pain). Fourth session: - Review homework at home, mindfulness and conscious breathing practice; Being in the present moment and exercises; Non-judgment of thoughts and feelings about chronic pain and only observing them; Examining the existing obstacles on the way of values; Providing homework at home (paying attention to breathing while sleeping). The fifth session: - review of the previous session, homework and expressing the experiences of the homework about conscious breathing; What goals in your life are in line with the values that chronic pain does not allow you to move towards? moving step by step towards the goal; practicing mindfulness of conscious movement; Providing homework at home (consciously lying down and paying attention to the rise and fall of the abdomen during sleep). The sixth session: - Reviewing homework at home; What measures have you taken to achieve your values and goals? planning to achieve the goal with committed action; Providing homework at home. Seventh session: Having awareness in life and daily activities (informal exercises); Having a beginner's mind and familiarity with language barriers and the metaphor of the lion, giving homework at home. Eighth session: review of past sessions, the importance of consistency in doing exercises; The importance of just observing thoughts; The importance of having commitment in achieving values even in spite of pain and life goals.

Category

Treatment - Other

2

Description

Control group: Critical thinking skill training is conducted based on the Hyper protocol in six sessions: First session: Analysis of topics and experiences. The second session: the concept of interpretation, interpretation of experiences and renewal of views. The third session: The role of evaluation in the development of thinking. The fourth session: exchange of code signs to speech signs. The fifth session: Drawing the concept in the form of a whole, explaining the appropriate introduction of the skill of explanation for the material, speaking and its principles. The sixth session: Understanding and recognizing one's own mental abilities, the role of self-management skill attitude in self-confidence.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Dr. Elaheh Mianesaz

Street address

Pezeshk Blvd; Qutb Ravandi Blvd - Kashan

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Kashan

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Pezeshk Blvd; Qutb Ravandi Blvd - Kashan
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+98 31 5510 9999
Fax
+98 31 5558 9444
Email
info@kaums.ac.ir
Web page address
https://kaums.ac.ir/
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
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
Dr.Hamid Amiri
Position
Faculty member of clinical psychology department
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Kashan University of Medical Sciences
Full name of responsible person
Dr.Hamid Amiri
Position
Faculty member of clinical psychology department
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Pezeshk Blvd; Qutb Ravandi Blvd - Kashan
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Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zahra Ajdani
Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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No 57; Yas Alley; Motahari Blvd

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8714917763

Phone

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Fax

Email

ajdani-z@kaums.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data related to participants can be shared after being anonymized.

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

By sending your request, the researcher's email will be allowed to be used

From where data/document is obtainable

Send an email to researcher Zahra Ajdani to the address: Ajdani-z@Kaums.ac.ir Call the researcher's mobile number: 09039274424 Visit in person to Kashan University of Medical Sciences - Doctor Blvd - Qutb Ravandi Blvd - Kashan

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

2 working days after sending an email or contacting the researcher or visiting in person, the data file will be provided to the applicant

Comments