

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

Emotion Regulation, quality of life

#### 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](http://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

### 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 specialized 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](http://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**

Isfahan

**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

##### **City**

Kashan

##### **Province**

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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  
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Pezeshk Blvd; Qutb Ravandi Blvd - Kashan  
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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

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**  
Psychology  
**Street address**  
Doctor's Blvd - Qutb Ravandi Blvd - Kashan  
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## Person responsible for scientific 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**  
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Psychology  
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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  
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Bachelor  
**Other areas of specialty/work**  
Psychology  
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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**