

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effectiveness of Acceptance and Commitment Therapy (ACT) compared with Cognitive Behavior Therapy (CBT) on quality of life in patients with chronic low back pain

Protocol summary

Summary

The purpose of this study is to evaluate the impact of Acceptance and Commitment Therapy (ACT) compared with Cognitive Behavior Therapy (CBT) on quality of life in patients with chronic low back pain. For this purpose, according to chronic pain criteria and other inclusion criteria, such as having 18 to 50 years, do not using any treatment (other than medication) during the intervention period and willingness to participate in the study and finally, after diagnosis by pain specialist, 45 patients with chronic low back pain select by purposive sampling from patients referred to a pain clinic in Akhtar Hospital. Then, they are randomly (using lottery) assigned to the ACT (15 patients), CBT (15 patients) and control (15 patients) group. In acceptance and commitment therapy, in order to enhance quality of life in patient, focus on their psychological flexibility and commitment to the implementation of the value of their lives. The cognitive and behavioral therapy, in order to enhance the quality of life in patients, focus on the challenge with thoughts and exposure and in control group do not implement any intervention. Quality of Life Questionnaire conduct in the three groups at pretest and posttest, and finally, after the interventions, results of the groups compare with together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092615577N2**

Registration date: **2014-12-25, 1393/10/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-25, 1393/10/04

Registrant information

Name

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Name of organization / entity

Shahed University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mental Health Research Center, Tehran Institute of Psychiatry

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Acceptance and Commitment Therapy (ACT) compared with Cognitive Behavior Therapy (CBT) on quality of life in patients with chronic low back pain

Public title

The comparison of ACT and CBT effectiveness on chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having criteria for chronic low back pain according to pain specialist diagnosis; having 18 to 50 years; do not using any treatment (other than medication) during the intervention period; willingness to participate in the study. Exclusion criteria: Not meet the listed conditions and comorbidity with mental disorders using the MCMI-III questionnaire.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single 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 Iran University of Medical Sciences

Street address

Tehran Institute of Psychiatry, Iran University of Medical Sciences, No. 1, Mansouri martyr Street, Worship Street, Sattarkhan Street, Tehran, Iran.

City

Tehran

Postal code

Approval date

2014-09-22, 1393/06/31

Ethics committee reference number

24859

Health conditions studied

1

Description of health condition studied

Chronic back pain

ICD-10 code

M54.5

ICD-10 code description

Loin pain, Low back strain, Lumbago NOS

Primary outcomes

1

Description

Quality of life

Timepoint

Before the intervention, after the intervention

Method of measurement

Quality of life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cognitive behavior therapy (CBT) for chronic pain is a 11 sessions (11 weeks) group therapy program. The sessions include: Session 1: Learning about chronic pain; Session 2: Theories of pain and abdominal breathing; Session 3: Progressive muscle relaxation and visual imagery; Session 4: Automatic thoughts and pain; Session 5: Cognitive restructuring; Session 6: Stress managing; Session 7: Scheduler activity; Session 8: Planning a pleasant activity; Session 9: Anger management; Session 10: Sleep Health; Session 11: The prevention of relapse and recurrence of pain

Category

Behavior

2

Description

Intervention group: ACT is a 8 week group therapy program, with sessions of 2 hours per week. Treatment sessions is based on ACT protocol for chronic pain. In general, the content of the sessions is as follows: Session 1: Meeting members with together and introducing treatment sessions; Session 2: Evaluating of potential values of clients, introducing the model of behavior and concept of behavior change and practice of mindfulness; Session 3: Clarificating of the concept of acceptance, determining the values and practice of mindfulness; Session 4: Clarificating the values and necessary goals to achieve them, clarificating the barriers to access them, introducing the committed behavior and practice of mindfulness; Session 5: Practicing the defusioin (detachment from painful thoughts and feelings) and practice of mindfulness; Session 6: Clarificating the committed behavior and practice of mindfulness; Session 7: Evaluating primary and secondary suffering, commitment and barriers to achieve the acceptance and

practice of mindfulness; Session 8: Review the values, checking recurrence and goodbye.

Category

Behavior

3

Description

Control group: The control group receive routine medical treatment in hospital.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital Pain Clinic

Full name of responsible person

Dr. Masud Hashemi

Street address

Akhtar Hospital Pain Clinic, Sharifi Manesh Street, Rumi Poul, Shariati Street, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mental Health Research Center, Iran University of Medical Sciences

Full name of responsible person

Dr.Vahid Shariat

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Tehran Institute of Psychiatry, Iran University of Medical Sciences, No. 1, Mansouri martyr Street, Worship Street, Sattarkhan Street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Mental Health Research Center, Iran 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

Tehran Institute of Psychiatry

Full name of responsible person

Dr. Ali Asghar Asghar nejad

Position

PhD in Clinical Psychology/ Assistant Professor

Other areas of specialty/work

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Web page address**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