

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The efficacy of cognitive behavior therapy on declining severity of pain and psychological distress among women with chronic back pain

Protocol summary

Summary

Objective: This study has been conducted to investigate the effectiveness of cognitive behavior therapy on severity of pain and psychological distress among women with chronic back pain. Method: This research was conducted by using semi- experimental study with pretest-posttest design, using control group. So, from females with chronic back pain who appointed in Emam Khomeini hospital and a private clinic in Tehran in 2010, 30 participants were selected and randomly assigned in two equal experimental and control groups. Experimental group experienced 12 weeks over 90 minutes of Turk and Free cognitive behavior therapy, while control group were just followed. All of the participants completed the items of DASS, and pain scales prior to and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110143457N4**

Registration date: **2012-04-16, 1391/01/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

Name

Masoud Janbozorgi

Name of organization / entity

Behavioral Science Research Center, Shahid Beheshti
Medical University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Pyame Noor University

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2010-05-07, 1389/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of cognitive behavior therapy on declining severity of pain and psychological distress among women with chronic back pain

Public title

The efficacy of cognitive behavior therapy on declining severity of pain and psychological distress among women with chronic back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Included criteria: being female, having chronic back pain, higher pain score of pain scale , non of surgery background, completing consent paper Excluded criteria having personality disorder, any psychological disorder, any medical problems, taking any analgesics

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

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**

Payame Noor University

Street address

Nejatollahi st.

City

Tehran

Postal code**Approval date**

2009-02-18, 1387/11/30

Ethics committee reference number

130-0089۲

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

Chronic back pain

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

Declining pain

Timepoint

Prior to and after intervention

Method of measurement

Quebec Back Pain Disability Scale

Secondary outcomes**1****Description**

Psychological Distress

Timepoint

Prior to and after intervention

Method of measurement

Depression, Anxiety, Stress Scale(DASS)

Intervention groups**1****Description**

Intervention plan is based on Turk(2004) and Free (2007) cognitive- behavior and it is for the control of chronic pains and included 12 sessions over 90 minutes

Category

Treatment - Other

2**Description**

They had no treatment and were in waiting list

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini hospital

Full name of responsible person

Dr. Yousefi

Street address

Keshavarz Boulvar. Emam Khomeini Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hooze and University

Full name of responsible person

Gharavi

Street address

Qum-

City

Qum

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hooze and University

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

Hoze and Daneshgah

Full name of responsible person

Masoud Janbozorgi

Position

MSc, in psychology

Other areas of specialty/work

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Person responsible for scientific inquiries

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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