

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of group cognitive-behavioral therapy (CBT) on pain coping strategies, perception, intensity and pain self-efficacy in patients with chronic neuropathic pain

Protocol summary

Study aim

Determination the effectiveness of group cognitive-behavioral therapy on pain coping strategies, perception, intensity and pain self-efficacy in patients with chronic neuropathic pain.

Design

In this Randomized clinical trial, superiority, parallel group trial with blinded outcome assessment, initially, both groups (experimental and control) did, pain coping strategies, perception, intensity and pain self-efficacy questionnaires (pretest) then experimental group experienced 10 sessions of 120 minutes of cognitive behavioral group therapy and control group didn't have any therapy except medicine therapy. Finally, both groups (experimental and control) did pain coping strategies, perception, intensity and pain self-efficacy questionnaires (post-test). After follow up of 45 days, both groups did pain coping strategies, perception, intensity and pain self-efficacy questionnaires (follow up).

Settings and conduct

The female patients with chronic neuropathic pain who referred to Ayatollah Rouhani Hospital in Babol from January 2017 to April 2017 participants were purposeful (non-randomly) selected and randomly assigned in two equal experimental and control groups.

Participants/Inclusion and exclusion criteria

All participants 20 to 60 years old female living in Babol city (North of Iran) who received a diagnosis of chronic neuropathic pain by a neurologist and were not physical and mental disease, significantly and participants who have had more than two absentee sessions or they did not want to continue to participate in the research were excluded.

Intervention groups

Experimental group experienced cognitive behavioral group therapy (CBT) while control group didn't have any

therapy except medicine therapy. Experimental and control group did pretest, post-test and follow up.

Main outcome variables

Pain coping strategies; Pain perception; Pain intensity; Pain self-efficacy;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180607040001N1**

Registration date: **2018-10-21, 1397/07/29**

Registration timing: **retrospective**

Last update: **2018-10-21, 1397/07/29**

Update count: **0**

Registration date

2018-10-21, 1397/07/29

Registrant information

Name

Masoumeh Dehestani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-22, 1395/11/03

Expected recruitment end date

2017-04-23, 1396/02/03

Actual recruitment start date

2017-01-22, 1395/11/03

Actual recruitment end date

2017-04-23, 1396/02/03

Trial completion date

2017-04-23, 1396/02/03

Scientific title

The effectiveness of group cognitive-behavioral therapy (CBT) on pain coping strategies, perception, intensity and pain self-efficacy in patients with chronic neuropathic pain

Public title

Effect of cognitive behavioral group therapy in patients with chronic neuropathic pain

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants who recognized chronic neuropathic pain by neurologist and don't have significant physical sickness. Whole participants are female. Age range of 20 to 60 years old. Inhabitant of Babol (from Babol). They haven't mental disorders. They have conscious satisfaction. They have education of high School and higher. They haven't participation in another instructional and therapeutic classes, simultaneously.

Exclusion criteria:

The participants who are absent for over two sessions. The participants who are unwilling to participate in this study. The participants who suffer from mental disorders. The participants who are physically illness.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, a simple randomization was performed using a random numbers table, and the direction of reading numbers was assigned from right to left in the current study. The randomization unit was individual. In the second stage, the random allocation concealment was done using the sequentially numbered, opaque, sealed envelopes (SNOSE) method. In the third stage, the random allocation process was implemented as well as to avoid the bias, it was necessary to choose a person other than the researchers who were involved in creating a randomized program in order.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current study, the analyst and participants were not aware of any type of intervention in each group and it was a double-blind study. The participants were blind to their allocation, meaning that they were unaware of being in experimental and control groups until after the completion of the study. In addition, the outcome evaluator did not know the group of each patient or participant.

Placebo

Not used

Assignment

Parallel

Other design features

Pain coping strategies were measured by pain coping strategies questionnaire (CSQ) (Rosenstiel and keefe, 1983) , pain perception was measured by pain beliefs and perception inventory (PBPI) (Williams and Thorn, 1989) , pain intensity was measured by west Haven-Yale multidimensional pain inventory (Kerns et all, 1985) and pain self- efficacy was measured by pain self- efficacy questionnaire (Nicholas, 1989)

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University Sari Branch

Street address

Assistance of Medical, Islamic Azad University Sari Branch

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Mazandaran

Postal code

4816119318

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.IAU.SARI.REC.1396.73

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

chronic neuropathic pain

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

1

Description

Pain coping strategies, pain perception, pain intensity, pain self-efficacy

Timepoint

Two weeks before intervention

Method of measurement

Pain coping strategies were measured by pain coping strategies questionnaire (CSQ) (Rosenstiel and keefe, 1983) , pain perception was measured by pain beliefs and perception inventory (PBPI) (Williams and Thorn, 1989) , pain intensity was measured by west Haven-Yale multidimensional pain inventory (Kerns et al, 1985) and pain self- efficacy was measured by pain self- efficacy questionnaire (Nicholas, 1989)

Secondary outcomes

1

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Intervention groups

1

Description

Intervention group: Intervention group experienced cognitive behavioural group therapy (CBGT) and did pretest, posttest and follow up.

Category

Behavior

2

Description

Control group: control group didn't have any therapy except medicine therapy. Control group did pretest, post-test and follow up.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital of Babol

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

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

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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

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

-

When the data will become available and for how long

-

To whom data/document is available

Public

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

-