Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 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 copying 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3222 9146

Email address

stu.dehestani@iausari.ac.ir

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
City
Sari
Province
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 auestionnaire (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 outcomes

1

Description
Pain coping strategies, pain perception, pain intensity, pain self-efficacy
Timepoint
Two weeks after intervention
Method of measurement
En Pain coping strategies were measured by pain coping strategies auestionnaire (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)

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: cortrol 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
Masoumeh Dehestani
Street address
Ganjafrooz Ave.
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3223 8301
Email
info@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Mohammad Farsi
Street address
Assistance of Medical, Islamic Azad University Sari Branch
City
Sari
Province
Mazandaran
Postal code
4816119318
Phone
+98 11 3344 4512
Fax
+98 11 3344 4512
Email
mfarsi2008@gmail.com
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

Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoumeh Dehestani
Position
Clinical Masters
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No 96 , Edalat 2 alley , Baghban mahale st. , Modaress St. , Babol , Mazandaran
City
Babol
Province
Mazandaran
Postal code
0000000000
Phone
+98 11 3222 9146
Fax
Email
ddehestanim@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Bahram Mirzaian
Position
Psychology (Ph.D)
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Psychotherapy and consultation center of Bamdad, peyvandi street
City
Sari
Province
Mazandaran
Postal code
0000000000
Phone
+98 11 3325 9528
Email
bahrammirzaian@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Masoumeh Dehestani
Position
Clinical Masters
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
No 96 , Edalat 2 alley , Baghban mahale st. , Modaress St. , Babol , Mazandaran
City
Babol
Province
Mazandaran
Postal code
0000000000
Phone
+98 11 3222 9146
Fax
Email
ddehestanim@gmail.com

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
-