

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The comparison of the effectiveness of well-being therapy and acceptance and commitment therapy on pain coping strategies, psychological well-being, perception and pain self-efficacy among the patients with chronic neuropathic pain

Protocol summary

Study aim

The comparison of the effectiveness of well-being therapy and acceptance and commitment therapy on pain coping strategies, psychological well-being, perception and pain self-efficacy among the patients with chronic neuropathic pain

Design

Clinical trial, with control group, with parallel groups, without blinding, in which 45 patients with chronic neuropathic pain will be randomly assigned to three groups.

Settings and conduct

The study population will be patients aged 25 to 50 years with chronic neuropathic pain referred to the Babol Spiritual Medical Center. They will be assigned to three groups randomly (through lottery).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 25 to 50 years, not taking psychiatric medication during three last month, Diagnosis of chronic neuropathic pain by a neurologist, Minimum diploma education. Exclusion criteria: Cancer; multiple sclerosis; Alzheimer's disease; Having a mania or a psychiatric disorder

Intervention groups

Intervention group 1: They will receive group training on well-being therapy (well-being therapy) through 8 120-minute sessions. Intervention group 2: They will receive group training on acceptance and commitment therapy through 8 120-minute sessions. Control group: This group will not receive any therapeutic interventions. But after the follow-up period, treatment will also be considered for this group.

Main outcome variables

Pain coping strategies, Psychological well-being, Pain perception and Pain self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180607040001N2**

Registration date: **2022-02-27, 1400/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-27, 1400/12/08**

Update count: **0**

Registration date

2022-02-27, 1400/12/08

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

2022-02-20, 1400/12/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effectiveness of well-being therapy and acceptance and commitment therapy on pain coping strategies, psychological well-being, perception and pain self-efficacy among the patients with chronic neuropathic pain

Public title

The effectiveness of well-being and acceptance-based therapy on coping strategies with pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 25 to 50 years Not taking psychiatric medication during three last month Diagnosis of chronic neuropathic pain by a neurologist Minimum diploma education

Exclusion criteria:

Cancer Multiple sclerosis Alzheimer's disease Having a mania or a psychiatric disorder

Age

From **25 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)

Randomized

Randomization description

Patients will be assigned to 3 groups of 15 using simple randomization (by lottery method).

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 Islamic Azad University Sari Branch

Street address

Islamic Azad University Sari Branch, 7 km from Darya Road, Khazar Square, Sari

City

Sari

Province

Mazandaran

Postal code

4816119318

Approval date

2022-01-23, 1400/11/03

Ethics committee reference number

IR.IAU.SARI.REC.1400.114

Health conditions studied

1

Description of health condition studied

chronic neuropathic pain

ICD-10 code

G62.8

ICD-10 code description

Other specified polyneuropathies

Primary outcomes

1

Description

Pain coping strategies

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Coping Strategies Questionnaire (CSQ)

2

Description

Psychological well-being

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Psychological Well- Being Scale (PWB-18)

3

Description

Pain perception

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Pain Belief and Perception Inventory (PBPI)

4

Description

Pain self-efficacy

Timepoint

Before intervention, immediately after intervention, 2 months after intervention

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: They will receive group training on well-being therapy (well-being therapy) through 8 120-minute sessions.

Category

Behavior

2

Description

Intervention group 2: They will receive group training on acceptance and commitment therapy through 8 120-minute sessions.

Category

Behavior

3

Description

Control group: This group will not receive any therapeutic interventions. But after the follow-up period, treatment will also be considered for this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital of Babol

Full name of responsible person

Masoumeh Dehestani

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mohammad Farsi

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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

PhD Student in Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available