Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of pain neuroscience education with and without conventional physical therapy on psychosocial factors, function and pain in people with chronic neck pain - a clinical trial

Protocol summary

Study aim

The effect of pain neuroscience education on psychosocial factors, function and pain in people with chronic neck pain

Design

A clinical trial with a control group, with parallel groups, three-way blind, randomized, on 50 patients, Random Allocation computer software (version 1. 1 of Isfahan University of Medical Sciences, Iran) used for randomization.

Settings and conduct

The available population includes people with neck pain based on the diagnosis of specialists who will refer to physiotherapy clinics in Ahvaz, will be selected from the available population by simple non-probability sampling method and then randomly divided into two groups. And after obtaining informed consent, people enter the study. This is a three-way blind clinical trial in which patients are evaluated by another physiotherapist who is unaware of the group assignment, and patients and data analysts are unaware of the group assignment

Participants/Inclusion and exclusion criteria

Participants must be literate, have a central sensitization score above 40, a visual scale score above 30, with out cancer, fractures, metabolic diseases, rheumatism, cardiovascular disease, neurological and osteoporotic disorders, or psychiatric disorders.

Intervention groups

In this study, people will be received 12 sessions of treatment (4 weeks of treatment with frequency 3 times a week), in the first 4 sessions of treatment, group 2 (conventional physiotherapy treatment with pain neuroscience education) in addition to conventional physiotherapy treatment, will be received pain neuroscience education.

Main outcome variables

Primary outcome measures including pain, central sensitivity, function, concept of biological mechanism of pain, catastrophic pain, fear of movement, pain awareness and vigilance, and secondary outcome measures including, perception of pain, quality of life and general changes in this case study Was investigated.

General information

Reason for update

Acronym

PNE

IRCT registration information

IRCT registration number: **IRCT20210607051508N1**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Farzaneh Soleimani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3441 2754

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-19, 1400/03/29

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pain neuroscience education with and without conventional physical therapy on psychosocial factors, function and pain in people with chronic neck pain - a clinical trial

Public title

The effect of pain neuroscience education on the treatment of chronic neck pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 years Nonspecific neck pain with a history of at least 12 weeks (chronic) Ability to understanding, speaking and writing in Persian Has not used any other treatment 6 weeks before participating in this project and during it. (To get steady state) Minimum visual analog scale (VAS) 30 of100 mm Confirmation of central sensitization in people with CSI questionnaire (score above 40 CSI questionnaire is the reason for central sensitization)

Exclusion criteria:

Cancer, fracture, metabolic diseases, rheumatism, cardiovascular, neurological disorders and osteoporosis Neck radiculopathy, myelopathy and dizziness People with widespread pain disorders such as fibromyalgia syndrome or chronic fatigue syndrome Psychiatric disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by Random Allocation computer software (version 1.1 of Isfahan University of Medical Sciences, Iran) by a statistician Which has no role in the study in such a way that a random order of two letters A (intervention) and B (control) in blocks will be made with random numbers 4 and 6 (For example ABBA and ABABA). A research assistant then puts them in sealed envelopes. Before starting the intervention, one of the researchers opens one of the envelopes and thus the person will be placed in one of the two intervention groups (conventional physiotherapy with pain neuroscience education) or control (conventional physiotherapy).

Blinding (investigator's opinion)

Double blinded

Blinding description

A physiotherapist who has no information about patients' allocation and treatment will perform the assessments. The participants will receive information about their treatment program, but they will not be informed if they are in intervention or control group, and for this purpose we will make arrangements so that patients do not see each other. Patients in the intervention group receive treatment on even days and the control group receives treatment on odd days. A statistician who has no information about patients' allocation will perform the statistical analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

No.5, Yas Ave., Shahrak Aghajari Area., Ahvaz City

City

Ahvaz

Province

Khouzestan

Postal code

6166754871

Approval date

2021-05-16, 1400/02/26

Ethics committee reference number

IR.AJUMS.REC.1400.098

Health conditions studied

1

Description of health condition studied

Neck pain

ICD-10 code

M50.9

ICD-10 code description

Cervical disc disorder, unspecified

Primary outcomes

1

Description
Score of 100 mm visual analog scale to assess pain intensity
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Visual Analogue Scale

2

Description
Central Sensitization Inventory questionnaire to assess central sensitivity
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Central Sensitization Inventory questionnaire score

3

Description
Lutron Model 5020 Digital Tensile and pressure Algometer for Measuring Pressure Pain Threshold (PPT)
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Digital Tensile and pressure Algometer

4

Description
Score of Neurophysiology of Pain Questionnaire to evaluate the concept of biological mechanism of pain
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Neurophysiology of Pain Questionnaire

5

Description
Neck Disability Index questionnaire for disability evaluation
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Neck Disability Index questionnaire score

6

Description
Pain Catastrophizing Scale to assess pain catastrophizing
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Pain Catastrophizing Scale score

7

Description
Tampa Scale for Kinesiophobia Questionnaire to assess fear of movement
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Tampa Scale for Kinesiophobia Questionnaire score

8

Description
Pain Awareness and Vigilance questionnaire to assess pain awareness and alertness
Timepoint
Pre intervention, Post intervention, one month and 3 months after baseline
Method of measurement
Pain Awareness and Vigilance questionnaire score

Secondary outcomes

1

Description
Quality of life score
Timepoint
Pre Intervention, Post Intervention, one month and three months after baseline
Method of measurement
Score of SF3 6 questionnaires to assess the quality of life

2

Description
Score of a person's perception of their illness
Timepoint
Pre Intervention, Post Intervention, one month and three months after baseline
Method of measurement
Score of Brief illness perception questionnaire to assess a person's perception of their illness

3

Description
General measurement of the rate of change
Timepoint
Pre Intervention, Post Intervention, one month and three months after baseline
Method of measurement
General review of the amount of changes with the general form of the amount of changes

Intervention groups

1

Description
Control group: conventional physiotherapy treatment, Individuals 12 sessions of therapy (4 weeks of frequency

therapy 3 times a week) including 1-20 minutes of TENS and hot packs 2- Exercises to improve mobility (stretching exercises) 3- Exercises that aim to use deep muscles 4- Endurance exercises (Endurance) 5- They will receive strengthening exercises.

Category

Treatment - Other

2

Description

Intervention group: conventional physiotherapy treatment with pain neuroscience education. In this study, people will be received 12 sessions of treatment (4 weeks of treatment with frequency 3 times a week), in the first 4 sessions of treatment, conventional physiotherapy treatment with pain neuroscience education in addition to conventional physiotherapy treatment, will be received pain neuroscience education.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Hossein kouhzad Mohammadi

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No. 5, Yas Ave., Shahrak Aghajari, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadimoghaddam

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Ground floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science,Ahvaz,Iran

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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

Ahvaz University of Medical Sciences

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

Ahvaz University of Medical Sciences

Full name of responsible person

Hosein Kouhzad Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Physical therapy Department, Rehabilitation School, opposite the MRI Building, Jundishapour University of Medical Sciences, Ahvaz

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hosein Kouhzad Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Farzaneh Soleimani

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Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Physical therapy Department, Rehabilitation School, opposite the MRI Building, Jundishapour University of Medical Sciences, Ahvaz

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Province

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Phone

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be an research article and its protocol, results report and statistical analysis will be published to be used by therapists.

When the data will become available and for how long

If the journal has requested access to the data at any time, the data will be provided.

To whom data/document is available

Journal editors and Reviewers

Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

From where data/document is obtainable

Project manager

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

It should be send email to project manager and after reviewing the reason for requesting the data, they will be send

Comments