

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effectiveness of home exercise with and without pain neuroscience training and breathing exercises on pain, disability and muscle function in people with chronic nonspecific back pain

Protocol summary

Study aim

The effect of a combination of pain neuroscience training and breathing exercises on pain, disability and muscle function in people with low back pain

Design

Clinical trial with control group, experimental, single blind, randomized on 40 patients. A sphere will be used for randomization

Settings and conduct

The study site is Faraz Clinic in Isfahan. This study is performed as a single blind in such a way that the subjects are not aware that they are in the control or experimental group and after taking out the number from the sphere receive their intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 60 years with normal body mass index; chronic low back pain (more than 3 months) and nonspecific (doctor's approval). Non-Inclusion criteria: spinal cord injury and diseases such as inflammatory tumor fracture, etc.; smoking

Intervention groups

The experimental group will perform breathing exercises (90/90 BRIDGE WITH BALL AND BALLOON) along with home exercises. The experimental group will participate in 3 sessions of pain neuroscience classes held by a therapist with knowledge in this field. Each session lasts between 30 and 60 minutes. The control group does only home exercises

Main outcome variables

Pain; Muscle function; Disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210618051611N1**

Registration date: **2021-08-11, 1400/05/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-11, 1400/05/20**

Update count: **0**

Registration date

2021-08-11, 1400/05/20

Registrant information

Name

Amir Mohamad Tarakameh Samani

Name of organization / entity

The university of kharazmi

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of home exercise with and without pain neuroscience training and breathing exercises on pain, disability and muscle function in

people with chronic nonspecific back pain

Public title

Effect of combination of pain neuroscience education and breathing exercise on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 60 years Normal body mass index Chronic back pain (more than 3 months) and nonspecific (doctor approved) Not using medication or other interventions during the research The person has the ability to perform rehabilitation steps without assistance and has obtained a score of at least 14 in the assessment of disability

Exclusion criteria:

Dissatisfaction to participate in research Having any lower limb injuries, fractures and visceral diseases Smoking Not having the minimum disability score Having spinal cord injuries and diseases such as (inflammatory fracture, etc.)

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly allocated into two groups of home exercises with and without pain neuroscience training and breathing exercises by taking out the number from a pre-designed ball. People who take the even number out of the sphere will be placed in the intervention group and people who take the odd number will be placed in the control group

Blinding (investigator's opinion)

Single blinded

Blinding description

An independent person who is not involved in any of the study processes will be responsible for how randomization is performed. Subjects are not aware of which training group they are allocated to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Physical Education Research Institute

Street address

building no 17; 21 Alley; Meraj Avenue

City

Esfahan

Province

Isfahan

Postal code

8199134569

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.SSRI.REC.1400.1052

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

The first day and 34 days after the interventions

Method of measurement

Pain questionnaire

2

Description

disability

Timepoint

The first day and 34 days after the interventions

Method of measurement

questionnaire

3

Description

Muscle function

Timepoint

The first day and 34 days after the interventions

Method of measurement

Testing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the experimental group, each person participates in 3 sessions of pain neuroscience training classes held by a knowledgeable therapist in this field, each session lasting between 30 to 60 minutes. The experimental group will also perform breathing exercises (90/90 BRIDGE WITH BALL AND BALLOON) along with home exercises

Category

Other

2

Description

Control group: The control group will do home exercises without receiving breathing exercises and pain neuroscience training.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Physiotherapy

Full name of responsible person

Amir Samani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Kharazmi

Full name of responsible person

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Grant name

Grant code / Reference number

1233

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Kharazmi

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

The University of Kharazmi

Full name of responsible person

Amir samani

Position

Consultant

Latest degree

Master

Other areas of specialty/work

sport injury

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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

After studying the data, such as age, sex, weight, pain, disability and muscle function will be shared anonymously

When the data will become available and for how long

The access period will start 6 months after the results are published

To whom data/document is available

Scholars and people who work the industry

Under which criteria data/document could be used

based on researchers agreement

From where data/document is obtainable

amirtarakameh@gmail.com

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

After sending the email and confirmation by the author, the file will be sent

Comments

I hope this research can help treat back pain