

# 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)

###### Phone

+98 31 3580 6106

###### Email address

amirtarakameh@gmail.com

##### 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

##### Street address

No. 7; West Arghavan Ave; Farahzadi Blvd; Qods

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##### Phone

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##### Web page address

http://dr-golshani.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

The University of Kharazmi

##### Full name of responsible person

Amir letafatkar

##### Street address

No. 7; West Arghavan Ave; Farahzadi Blvd; Qods  
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#### Web page address

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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

Consultan

##### Latest degree

Master

##### Other areas of specialty/work

sport injury

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## Person responsible for scientific

## **inquiries**

### **Contact**

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The University of Kharazmi

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**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

The University of Kharazmi

**Full name of responsible person**

Morteza Samani

**Position**

Consultant

**Latest degree**

Bachelor

**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