

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

**Investigating the effect of adding pain neuroscience education to stabilization exercises using a flexi-bar on pain, disability, abdominal and multifidus muscles geometry in patients with chronic non-specific low back pain.**

### Protocol summary

#### Study aim

Investigating the effect of adding pain neuroscience education to stabilization exercises using a flexi-bar on pain, disability, abdominal and multifidus muscle geometry in patients with chronic non-specific low back pain.

#### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, 26 patients in each group, randomization by permutation blocks.

#### Settings and conduct

Both groups of patients will receive their treatment at the Shiraz Rehabilitation Faculty clinic. In the control group, patients will be given stabilization exercises with flexi-bars, and In addition to this, PNE training will also be provided to the patients in the experimental group .Patients and co-evaluators will be blinded in the study.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group between 20 and 50 years of both sexes if more than 3 months have passed since the onset of symptoms, Average pain intensity between 3-7, minimum education level of diploma, Disability level greater than 8 . exclusion criteria: A history of malignancy in the area of the lumbar spine and its metastasis to any area, Systemic or local infections, History of inflammatory and systemic diseases, Presence of structural disorders of the spine, History of neurological diseases and brain damage, History of lower limb, abdominal and lumbar surgeries, Pregnancy, History of physiotherapy treatments and participation in regular sports exercises in the last three months, Musculoskeletal and orthopedic disorders of the limbs

#### Intervention groups

In the control group, patients will receive stabilization exercises with flexi bar, and in the experimental group, in addition to this, patients will also receive pain

neuroscience education training.

#### Main outcome variables

Pain, disability, geometry of abdominal muscles and multifidus muscle, fear of movement, fear-avoidance beliefs, pain catastrophizing

### General information

#### Reason for update

Considering that at the time of registration of the trial, we did not have an accurate prediction of the time of judging and acceptance of the trial, our expected time to start accepting patients was before the date of approval and registration of the code, therefore, we request to change the start time of accepting patients from 31 May 2023 to 17June 2023 we have Subsequently, the end time of sick leave will be changed to 17January 2024

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230505058095N1**  
Registration date: **2023-06-02, 1402/03/12**  
Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **1**

#### Registration date

2023-06-02, 1402/03/12

#### Registrant information

##### Name

Zahra Dehghani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 223 0842

##### Email address

**Recruitment status**

Recruitment complete

**Funding source****Expected recruitment start date**

2023-06-17, 1402/03/27

**Expected recruitment end date**

2024-01-17, 1402/10/27

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of adding pain neuroscience education to stabilization exercises using a flexi-bar on pain, disability, abdominal and multifidus muscles geometry in patients with chronic non-specific low back pain.

**Public title**

Investigating the effect of adding pain neuroscience education to stabilization exercises using a flexi-bar on pain, disability, abdominal and multifidus muscles geometry in patients with chronic non-specific low back pain.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age group between 20 and 50 years of both sexes if more than 3 months have passed since the onset of symptoms. Average pain intensity based on a visual analogue scale between 3-7 Having a minimum education level of a diploma If the functional disability level of the patients is more than 8 based on the Roland Morris Disability Questionnaire, they are included in the study.

**Exclusion criteria:**

A history of malignancy in the area of the lumbar spine and its metastasis to any area Systemic or local infections that cause acute and severe pain in the lower back History of inflammatory and systemic diseases such as diabetes and rheumatoid arthritis Presence of structural disorders of the spine History of neurological diseases and brain damage History of the lower limb, abdominal and lumbar surgeries Pregnancy History of physiotherapy treatments and participation in regular sports exercises in the last three months Musculoskeletal and orthopedic disorders of the upper and lower limbs

**Age**From **20 years** old to **50 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **52****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method used was permutation block method. (considering blocks of four with the number of 13 blocks)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A physiotherapist applies the interventions and another physiotherapist colleague, who is unaware of the patient grouping, performs the evaluations. Also, the participants of the two groups will be treated in a separate place where they will not have any contact with each other.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz Rehabilitation Faculty Ethics Committee

**Street address**

Faculty of Rehabilitation Sciences, 1 Abiverdi St., Chamran Blvd., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

71947-33669

**Approval date**

2023-05-03, 1402/02/13

**Ethics committee reference number**

IR.SUMS.REHAB.REC.1402.001

**Health conditions studied****1****Description of health condition studied**

Low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before, immediately and one month after the study

#### Method of measurement

Visual analogue scale

### 2

#### Description

Disability

#### Timepoint

Before, immediately and one month after the study

#### Method of measurement

Persian version of Roland Morris questionnaire

### 3

#### Description

Geometry of abdominal muscles and multifidus muscle

#### Timepoint

Before and immediately after the study

#### Method of measurement

Ultrasound device

## Secondary outcomes

### 1

#### Description

Fear of movement

#### Timepoint

Before, immediately and one month after the study

#### Method of measurement

Persian version of the Tampa questionnaire

### 2

#### Description

Pain catastrophizing

#### Timepoint

Before, immediately and one month after the study

#### Method of measurement

Persian version of pain catastrophizing questionnaire

### 3

#### Description

Fear-avoidance beliefs

#### Timepoint

Before, immediately and one month after the study

#### Method of measurement

Persian version of fear-avoidance beliefs questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Patients in the experimental group will perform stabilization exercises with flexi-bar in prone , standing, and quadruped positions simultaneously with the ADIM maneuver 3 times a week for 6 weeks. Also, once a week for six weeks, PNE training related to the physiology and neurophysiology of pain will be provided to the patients.

#### Category

Rehabilitation

### 2

#### Description

Control group: Patients in the control group will perform stabilization exercises with flexi-bar in prone , standing, and quadruped positions simultaneously with the ADIM maneuver 3 times a week for 6 weeks.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz Rehabilitation Faculty Specialized Clinic

##### Full name of responsible person

Sara Abolahari Shirazi

##### Street address

Faculty of Rehabilitation Sciences., 1 Abiverdi St.,  
Chamran Blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

71947-33669

##### Phone

+98 71 3626 5108

##### Email

SAhrari@Sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Hashem Hashempour

##### Street address

7th floor, central building of Shiraz University of  
Medical Sciences, next to Red Crescent., Zand St,  
Shiraz

##### City

Shiraz

##### Province

Fars

**Postal code**

71348-14336

**Phone**

+98 71 3235 7282

**Email**

hashempurm@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sara Abolahari Shirazi

**Position**

Assistant Professor of Shiraz University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Shiraz Faculty of Rehabilitation Sciences, 1 Abivardi St., Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

71947-33669

**Phone**

+98 71 3627 1551

**Email**

SAhrari@Sums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sara Abolahari Shirazi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Shiraz Faculty of Rehabilitation Sciences, 1 Abivardi St., Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۹۴۷-۳۳۶۶۹

**Phone**

+98 71 3627 1552

**Email**

SAhrari@Sums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zahra Dehghani

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Shiraz Faculty of Rehabilitation Sciences, 1 Abivardi St, Chamran Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۹۴۷-۳۳۶۶۹

**Phone**

+98 71 3627 1551

**Email**

zahradgh97@gmail.com

## Sharing plan

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

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

**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