

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 17 June 2023. Subsequently, the end time of sick leave will be changed to 17 January 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

AgeFrom **20 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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
 71947-33669
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
 71947-33669
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