Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
- Outcome assessor

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
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Faculty of Rehabilitation Sciences., 1 Abiverdi St., Chamran Blvd
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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
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Shiraz
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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
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
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Other areas of specialty/work
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Person responsible for updating data

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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