Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Diaphragm Release Technique and Breathing Exercises on Pain Intensity and Functional Disability in Patients with Chronic Non-Specific Low Back Pain

Protocol summary

Study aim

This study aims to compare the effects of the diaphragm release technique and breathing exercises on pain intensity and functional disability in patients with chronic non-specific low back pain.

Design

This study is a randomized, parallel-group, comparative clinical trial involving 66 female participants. Participants will be allocated using block randomization (block size: 4), with the randomization sequence generated through the Sealed Envelope web-based service to ensure allocation concealment.

Settings and conduct

Patients referred by a neurosurgeon to Omid Clinic will be screened for eligibility. Eligible participants who provide informed consent will be assessed, randomly allocated to the study groups, and receive 12 treatment sessions. Outcomes will be assessed after the 6th and 12th sessions.

Participants/Inclusion and exclusion criteria

Inclusion: Females aged 18–45 years with chronic non-specific low back pain for at least 3 months, moderate pain intensity (VAS 3–7), and no history of lumbar physiotherapy during the previous year; Exclusion: Radiculopathy or other structural spinal pathologies, spondylolisthesis, inflammatory spinal disorders, systemic infection, respiratory disorders, bowel or bladder dysfunction, pregnancy, use of psychotropic medications, alcohol consumption, or illicit drug use

Intervention groups

All participants will receive electrotherapy and lumbar stabilization exercises. In addition to standard care, Intervention Group 1 will receive the diaphragm release technique, and Intervention Group 2 will receive breathing exercises.

Main outcome variables

Primary outcomes: Pain intensity; functional disability

Secondary outcomes: Kinesio phobia; chest expansion; central sensitization

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20240613062111N2**
Registration date: **2026-07-12, 1405/04/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-12, 1405/04/21**
Update count: **0**

Registration date

2026-07-12, 1405/04/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2026-10-12, 1405/07/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Diaphragm Release Technique and Breathing Exercises on Pain Intensity and Functional Disability in Patients with Chronic Non-Specific Low Back Pain

Public title
The Effect of Breathing Exercises and Diaphragm Release in Patients with Chronic Low Back Pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with pain located between the costal margin and the gluteal fold Individuals aged between 18 and 45 years Female participants Individuals with low back pain, with or without leg pain, for at least 3 months Individuals who have not received physiotherapy for the lumbar region during the past year Individuals with moderate pain intensity (pain score between 3 and 7)
Exclusion criteria:
Individuals Exhibiting Signs of Spondylolisthesis Individuals with Systemic Infections Individuals with Respiratory Problems Individuals with Bowel and Bladder Issues Individuals who Are Pregnant Individuals Taking Psychotropic Medications Individuals Using Illicit Drugs Individuals with Alcohol Consumption Individuals with structural spinal pathologies, such as cauda equina syndrome
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size of this study is 66 participants, who will be randomly allocated to two groups of 33 participants each (intervention and control). Block randomization will be used for participant allocation. The randomization sequence was generated by a methodologist using the Sealed Envelope website. A block size of 4 will be used.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
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Babol University of Medical Sciences, Ganj Afrooz Ave.
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Postal code
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Approval date
2026-04-21, 1405/02/01
Ethics committee reference number
IR.MUBABOL.HRI.REC.1405.037

Health conditions studied

1

Description of health condition studied
Chronic Non_Specific Low Back Pain
ICD-10 code
M54.5
ICD-10 code description
Low Back Pain

Primary outcomes

1

Description
Pain Intensity
Timepoint
At baseline, at the end of week 2 (session 6), and at the end of week 4 (session 12).
Method of measurement
Visual Analogue Scale

2

Description
Functional Disability
Timepoint
At baseline, at the end of week 2 (session 6), and at the end of week 4 (session 12).
Method of measurement
Roland Morris Disability Questionnaire

Secondary outcomes

1

Description
Chest Expansion
Timepoint
At baseline, at the end of week 2 (session 6), and at the end of week 4 (session 12).
Method of measurement
Meter

2

Description
Fear-avoidance
Timepoint
At baseline, at the end of week 2 (session 6), and at the end of week 4 (session 12).
Method of measurement
Fear-avoidance Belief Questionnaire

3

Description
Central Sensitization
Timepoint
At baseline, at the end of week 2 (session 6), and at the end of week 4 (session 12).
Method of measurement
Central Sensitization Inventory Questionnaire

Intervention groups

1

Description
Intervention Group 1: All participants, irrespective of group allocation, will receive electrotherapy and lumbar stabilization exercises. For electrotherapy, participants will be positioned in side lying, and four electrodes will be placed bilaterally in a parallel arrangement over the lumbar paraspinal muscles. Acupuncture-like Transcutaneous Electrical Nerve Stimulation (AL-TENS) will be delivered at a frequency of 5 Hz to alleviate chronic low back pain. Electrotherapy will be administered for 20 minutes per treatment session. Lumbar stabilization exercise program: The program consists of exercises designed to retrain the activation and motor control of the deep trunk muscles and to improve coordination between the deep and superficial trunk muscles during static, dynamic, and functional activities. In addition to supervised sessions, participants will be instructed to perform the exercises at home twice daily. Each participant will receive an exercise logbook to record adherence to the home exercise program. Participants who fail to perform the exercises during two consecutive home sessions will be withdrawn from the study.Week 1: Activation of the Transversus Abdominis Muscle: Participants will be instructed to lie in the supine position with both knees flexed to 90°. To activate the transversus abdominis muscle, they will be asked to gently draw the lower abdominal wall (below the umbilicus) inward and upward without moving the rib cage, pelvis, or lumbar spine. The duration of the contraction will be gradually increased according to the participant's ability. Exercise progression will be permitted only when the participant is able to correctly activate the transversus abdominis muscle using a low-intensity contraction for 10 consecutive repetitions while maintaining proper technique. Week 2: Activation of the Multifidus Muscle: Participants will be instructed to sit upright on a chair. The therapist will palpate the lumbar paraspinal region and instruct the participant to simultaneously activate the transversus abdominis and multifidus muscles. Once appropriate muscle activation is confirmed by palpation, participants will be encouraged to palpate the same region themselves to enhance proprioceptive awareness. They will then be instructed to maintain the contraction for 10 seconds and perform 10 repetitions while breathing normally throughout the exercise. Week 3: Participants will be instructed to lie in the supine position with both knees flexed at 90°. While maintaining simultaneous activation of the transversus abdominis and multifidus muscles, they will be instructed to abduct one hip to approximately 45° and hold the position for 10 seconds. The exercise will be performed for 10 repetitions on each side while maintaining proper muscle activation throughout the movement.Week 4: Participants will remain in the same position as in Week 3 (supine with both knees flexed at 90°). While maintaining simultaneous activation of the transversus abdominis and multifidus muscles, they will be instructed to slowly slide one heel along the treatment table until the knee is fully extended. The contraction will be maintained for 10 seconds, after which the leg will be returned to the starting position. The exercise will be performed for 10 repetitions on each side while maintaining proper muscle activation throughout the movement. Specific Intervention for Group 1: Diaphragm Release Technique: The diaphragm release technique will be performed bilaterally at the costal, sternal, and lumbar attachments in two sets, each consisting of 10 deep breathing cycles (inspiration and expiration), with a 1-minute rest interval between sets. Participants will be positioned in the supine position while the therapist will place the hypothenar eminence and the last three fingers of both hands beneath the inferior costal margin. During inspiration, the therapist will gently follow the movement of the ribs in a superior and lateral direction. During expiration, contact will be maintained while the hands will be gradually directed toward the inner aspect of the costal margin to facilitate diaphragm release. The intervention will be administered three sessions per week for four weeks (12 sessions in total).
Category
Rehabilitation

2

Description
Intervention Group 2: All participants, irrespective of group allocation, will receive electrotherapy and lumbar stabilization exercises. For electrotherapy, participants will be positioned in side lying, and four electrodes will be placed bilaterally in a parallel arrangement over the lumbar paraspinal muscles. Acupuncture-like

Transcutaneous Electrical Nerve Stimulation (AL-TENS) will be delivered at a frequency of 5 Hz to alleviate chronic low back pain. Electrotherapy will be administered for 20 minutes per treatment session. Lumbar stabilization exercise program: The program consists of exercises designed to retrain the activation and motor control of the deep trunk muscles and to improve coordination between the deep and superficial trunk muscles during static, dynamic, and functional activities. In addition to supervised sessions, participants will be instructed to perform the exercises at home twice daily. Each participant will receive an exercise logbook to record adherence to the home exercise program. Participants who fail to perform the exercises during two consecutive home sessions will be withdrawn from the study.Week 1: Activation of the Transversus Abdominis Muscle: Participants will be instructed to lie in the supine position with both knees flexed to 90°. To activate the transversus abdominis muscle, they will be asked to gently draw the lower abdominal wall (below the umbilicus) inward and upward without moving the rib cage, pelvis, or lumbar spine. The duration of the contraction will be gradually increased according to the participant's ability. Exercise progression will be permitted only when the participant is able to correctly activate the transversus abdominis muscle using a low-intensity contraction for 10 consecutive repetitions while maintaining proper technique. Week 2: Activation of the Multifidus Muscle: Participants will be instructed to sit upright on a chair. The therapist will palpate the lumbar paraspinal region and instruct the participant to simultaneously activate the transversus abdominis and multifidus muscles. Once appropriate muscle activation is confirmed by palpation, participants will be encouraged to palpate the same region themselves to enhance proprioceptive awareness. They will then be instructed to maintain the contraction for 10 seconds and perform 10 repetitions while breathing normally throughout the exercise. Week 3: Participants will be instructed to lie in the supine position with both knees flexed at 90°. While maintaining simultaneous activation of the transversus abdominis and multifidus muscles, they will be instructed to abduct one hip to approximately 45° and hold the position for 10 seconds. The exercise will be performed for 10 repetitions on each side while maintaining proper muscle activation throughout the movement. Week 4: Participants will remain in the same position as in Week 3 (supine with both knees flexed at 90°). While maintaining simultaneous activation of the transversus abdominis and multifidus muscles, they will be instructed to slowly slide one heel along the treatment table until the knee is fully extended. The contraction will be maintained for 10 seconds, after which the leg will be returned to the starting position. The exercise will be performed for 10 repetitions on each side while maintaining proper muscle activation throughout the movement. Specific Intervention for Group 2: Breathing Exercises: Breathing exercises will be performed only during the treatment sessions under the supervision of a physiotherapist. The intervention will be administered three sessions per week for four weeks (12 sessions in total). Week 1: Participants will be instructed to lie in the supine position on a firm surface or treatment table with both knees flexed. One hand will be placed on the chest and the other on the abdomen, just below the costal margin. Participants will be instructed to inhale slowly through the nose, directing the air toward the lower abdomen. The hand placed on the chest will be kept as still as possible, while the neck and shoulder muscles will remain relaxed. Simultaneously, the hand placed on the abdomen will rise as the abdomen expands. Participants will then be instructed to gently contract the abdominal muscles and exhale through pursed lips. During exhalation, the hand on the abdomen will gradually return to its initial position. The exercise will be performed for 10 repetitions during each treatment session. Week 2: Participants will remain in the same position as in Week 1. An elastic resistance band will be applied around the thoracolumbar region to provide resistance during diaphragmatic breathing. Participants will then perform diaphragmatic breathing as described in Week 1 for 10 repetitions during each treatment session. Week 3: Participants will be instructed to sit upright on a chair with the hips, knees, and ankles maintained at 90° of flexion. They will be instructed to sit as tall as possible, as if "a string attached to the top of the head were gently pulling them upward," while performing diaphragmatic breathing in the same manner as described in Week 1. The exercise will be performed for 10 repetitions during each treatment session. Week 4: Participants will remain in the same sitting position as in Week 3. An elastic resistance band will be applied around the thoracolumbar region to provide resistance during diaphragmatic breathing. Participants will then perform diaphragmatic breathing as described in Week 3 for 10 repetitions during each treatment session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Clinic

Full name of responsible person

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Sponsors / Funding sources

1

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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
Babol 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data on primary outcomes, confounding variables, and demographic characteristics will be shared in a de-identified format to ensure participant anonymity.
When the data will become available and for how long
Access to the data will begin after the study results are published.
To whom data/document is available
Researchers working in the relevant field.
Under which criteria data/document could be used
Data from this study will be available for inclusion in systematic reviews.
From where data/document is obtainable
Requests for access to the data should be sent by email to the Principal Investigator, Dr. Maryam Abbaszadeh, at m.abbaszadeh@mubabol.ac.ir.
What processes are involved for a request to access data/document
Upon receipt of a data request, the Principal Investigator will review the request, and if the applicant is deemed eligible, the requested data will be shared with the applicant.
Comments