

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effect of diaphragmatic training and myofascial release on patients with chronic non-specific low back pain

Protocol summary

Registration timing: **prospective**

Study aim

To compare the effect of Diaphragm training and myofascial release back pain patients with non-specific chronic low back pain.

Last update: **2025-04-16, 1404/01/27**

Update count: **0**

Registration date

2025-04-16, 1404/01/27

Design

A concealed, randomized, blinded, clinical trial with a parallel group design of 44 patients, enrolled between April 2025 and June 2025

Registrant information

Name

Aleena Waheed

Name of organization / entity

Rashid Latif Medical College

Country

Pakistan

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Settings and conduct

The study was held at Arif Memorial Teaching hospital and Hameed Latif Hospital Lahore. The blinding is achieved by concealment in which the treatment allocation for each patient. This is done to avoid biasness

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Participants were included if they had intermittent nonspecific CLBP for ≥ 12 weeks, with VAS between 3 to 7. All participants were active at a recreational level, for 2-4 times per week, since at least 3 years. Patients with low back pain without radiculopathy. Individual willing to participate in study
Exclusion Criteria: Upper abdominal surgery, lumbar surgery experience, inflammatory spinal disease, spinal deformities, neurologic radiating pain

Expected recruitment start date

2025-04-20, 1404/01/31

Expected recruitment end date

2025-07-20, 1404/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Group A: Diaphragm Training Group B: Myofascial Release technique

Scientific title

Comparative effect of diaphragmatic training and myofascial release on patients with chronic non-specific low back pain

Main outcome variables

Numeric pain rating scale was used to measure the intensity of pain, Oswestry Disability Index for the measurement of disability and Schober's test for lumbar flexibility

Public title

Comparative effect of diaphragmatic training and

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220604055072N3**

Registration date: **2025-04-16, 1404/01/27**

myofascial release on pain, flexibility and disability in patients with chronic non-specific low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants were included if they had intermittent nonspecific CLBP for ≥ 12 weeks, with VAS between 3 to 7. All participants were active at a recreational level, for 2-4 times per week, since at least 3 years. Patients with low back pain without radiculopathy Individual willing to participate in study

Exclusion criteria:

Upper abdominal surgery Lumbar surgery experience
Inflammatory spinal disease Spinal deformities
Neurologic radiating pain

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated randomly to study groups using the lottery method. Each patient was asked to draw a closed slip marked with number 1 or 2 from a box. Group A include participants in box number one, while group B include participants of box number two. 48 patients were allocated based on randomization in two groups equally, i.e., 24 in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The interventions were based on outpatient rehabilitation program in both groups. The study participants were blind about groups a treatment protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institutional Review Board of Rashid Latif Medical College

Street address

25-Km Ferozepur road Lahore

City

Lahore

Postal code

54600

Approval date

2024-12-12, 1403/09/22

Ethics committee reference number

IRB/2024/213

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

Timepoint

Pre-intervention and Post-4 week intervention

Method of measurement

Pain level was assessed by the Numerical Rating Scale (NRS). The participants rated their pain on a defined 0-10 scale, where 0 is no pain, and 10 is the worst pain imaginable.

2

Description

Disability

Timepoint

Pre-intervention and Post-4 week intervention

Method of measurement

The ODI is one of the most common scoring systems used for patients with LBP. The total score ranges from 0 to 100, where a higher score indicates a higher level of disability.

3

Description

Flexibility

Timepoint

Pre-intervention and Post-4 week intervention

Method of measurement

The examiner puts his thumbs on the inferior margin of the subject's PSIS. An ink mark is drawn along the midline of the lumbar spine horizontal to the PSIS (lower landmark). While the examiner holds the tape firmly against the subject's skin, he marks a second line 15 cm above the original one (higher landmark). Then the subject is asked to do an active anterior flexion of the

trunk without increasing the pain. The new distance between the lower and higher landmarks is then measured. The subject returns to the neutral position. The difference in the initial distance between the skin markings in the neutral position and the new measurements made in the flexion position is used to indicate the amount of lumbar flexion.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diaphragm Training. The diaphragm has a dual role of respiration and postural control. However, the role of the diaphragm is often overlooked in core stability exercise regime low back pain rehabilitation. Abdominal hollowing exercise, also known as the 'tummy tuck' exercise focusing on TrA and lumbar multifidus. Diaphragmatic breathing on activation of trunk muscles of patients with low back pain. Diaphragmatic breathing may affect activation of trunk muscles. Diaphragmatic breathing increases intra-abdominal pressure, and the increased intra-abdominal pressure may contribute to the lumbar stability. Experimental group performed diaphragmatic breathing exercise with six breathing positions. First week: Supine breathing + Crocodile breathing. Second week: Supine breathing with TheraBand + Crocodile breathing with TheraBand. Third week: Seated breathing + 90/90/90 breathing Fourth week: Seated breathing with TheraBand + TheraBand.

Category

Treatment - Other

2

Description

Comparative Intervention group: Myofascial Release technique. Myofascial release technique diaphragm performed as follow: The participant lay supine with relaxed limbs. Positioned at the head of the participant, the therapist made manual contact with the pisiform, hypothenar region and the last three fingers bilaterally to the underside of the seventh to tenth rib costal cartilages, with the therapist's forearms aligned toward the participant's shoulders. In the inspiratory phase, the therapist gently pulled the points of contact with both hands in the direction of the head and slightly laterally, accompanying the elevation of the ribs. During exhalation, the therapist deepened contact toward the inner costal margin, maintaining resistance. The manoeuvre was performed in two sets of 10 deep breaths, with a 1-minute interval between them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arif Memorial Teaching Hospital

Full name of responsible person

Sadia

Street address

25-Km Ferozepur road Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rashid Latif Medical College

Full name of responsible person

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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

Rashid Latif Medical College

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Rashid Latif Medical College

Full name of responsible person

Sadia Ahmed

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rashid Latif Medical College

Full name of responsible person

Sadia Ahmed

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Aleena Waheed

Position

Senior Lecturer

Latest degree

Master

Other areas of specialty/work

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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