Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

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

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

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

Intervention groups
Group A: Diaphragm Training Group B: Myofascial Release technique

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220604055072N3**
Registration date: **2025-04-16, 1404/01/27**
Registration timing: **prospective**

Last update: **2025-04-16, 1404/01/27**
Update count: **0**

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

Registrant information
Name
Aleena Waheed
Name of organization / entity
Rashid Latif Medical College
Country
Pakistan
Phone
+92 321 4883868
Email address
alwaheed28@gmail.com

Recruitment status
Recruitment complete

Funding source

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

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

Public title
Comparative effect of diaphragmatic training and

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
City
Lahore
Postal code
54600
Phone
+92 305 4501212
Email
areejsaadia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rashid Latif Medical College
Full name of responsible person
Aleena Waheed
Street address
25-Km Ferozepur road Lahore
City
Lahore
Postal code
54900
Phone
+92 321 4883868
Email
alwaheed28@gmail.com

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

Street address
25-Km Ferozepur road Lahore

City
Lahore

Province
Punjab

Postal code
54600

Phone
+92 305 4501212

Email
areejsaadia@gmail.com

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
Physiotherapy

Street address
25-Km Ferozepur road Lahore

City
Lahore

Province
Punjab

Postal code
54900

Phone
+92 305 4501212

Email
areejsaadia@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rashid Latif Medical College

Full name of responsible person
Aleena Waheed

Position
Senior Lecturer

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
25-Km Ferozepur road Lahore

City
Lahore

Province
Punjab

Postal code
54900

Phone
+92 321 4883868

Email
alwaheed28@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