

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of breathing exercises on pain, disability, range of motion and muscle endurance in patients with chronic low back pain: A randomized controlled trial

Protocol summary

Study aim

To compare mean pain, range of motion, disability and endurance in routine physical therapy with and without breathing exercises in patients with mechanical chronic low back pain.

Design

A concealed, randomized, triple blinded clinical trial with 132 patients followed by inclusion and exclusion criteria.

Settings and conduct

study will be conducted in Physical therapy department Gulab Devi Institute of Physiotherapy Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Patients with chronic low back pain (>12 weeks), on VAS >3. (30) • Main complaint of localized lumbar pain and decreased lumbar ROM from L1 to L5. Exclusion Criteria • Patients with spinal Tuberculosis • Patients with Spinal Muscular Atrophy

Intervention groups

Routine Physical Therapy + Breathing Exercises Total no of sessions will be 12, 3 sessions per week for 4 week Follow up will be done after 6 weeks

Main outcome variables

• Pain • Functional Disability • Range of Motion (ROM) • Muscle Endurance • Forced Expiratory Volume in one second (FEV1) • Oxygen saturation on pulse oximeter (SpO2)

General information

Reason for update

Acronym

breathing exercise

IRCT registration information

IRCT registration number: **IRCT20200901048579N1**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **prospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Muhammad Arif

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 35918040

Email address

drarifgdp@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-15, 1399/08/25

Expected recruitment end date

2022-05-16, 1401/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of breathing exercises on pain, disability, range of motion and muscle endurance in patients with chronic low back pain: A randomized controlled trial

Public title

Effects of breathing exercises on pain, disability, range of motion and muscle endurance in patients with chronic

low back pain.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-55 years. Patients of both Genders. Patients with chronic low back pain (>12 weeks), on VAS >3. Main complaint of localized lumbar pain and decreased lumbar ROM from L1 to L5.
Exclusion criteria:
Patients with spinal Tuberculosis Patients with Spinal Muscular Atrophy Patient with Mental disability. Patients with any Systemic Illness (e.g. Rheumatism) Patients with advanced lumbar spine degenerative changes. Patients with radiating pain. Patients with spinal injury. Patients with leg length discrepancies Patients having functional and structural disabilities Lactating and Pregnant females

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided in to two groups using random no table. i.e group A with group B Group-A: Routine Physical Therapy Group-B: Routine Physical Therapy + Breathing Exercises Assessor: Assessor will be expert physical therapist

Blinding (investigator's opinion)
Triple blinded

Blinding description
participant, Physiotherapist and investigator are blind. groups selection and tagging information will not open to the participant, therapist and assessor

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
university of lahore pakistan

Street address
1 km Defence road lahore

City
Lahore

Postal code
55150

Approval date
2019-07-25, 1398/05/03

Ethics committee reference number
BOS/UIPT/028-17

Health conditions studied

1

Description of health condition studied

Mechanical low back pain

ICD-10 code

M54

ICD-10 code description

Dorsalgia

Primary outcomes

1

Description

pain

Timepoint

breathing exercises and routine physiotherapy

Method of measurement

VAS

Secondary outcomes

1

Description

endurance, oxygen saturation

Timepoint

breathing exercises

Method of measurement

pulse oximeter, inclinometer

Intervention groups

1

Description

Intervention group: breathing exercises and routine physiotherapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy department Gulab Devi hospital lahore

Full name of responsible person

Prof. Dr. Majid Kaleem

Street address

Ferozepur road Lahore

City

Lahore

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54700

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Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

university of Lahore Pakistan

Full name of responsible person

Prof. Dr. Majid Kaleem

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1 Km defense road Lahore

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drarifgdpgmi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

university of Lahore Pakistan

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Riphah Institute of rehabilitation sciences

Full name of responsible person

Prof. Dr. Muhammad Salman Bashir

Position

Professor

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Riphah Institute of rehabilitation sciences

Full name of responsible person

Prof. Dr. Muhammad Salman Bashir

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Rehabilitation management

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

individual participant data must not be shared while results should shared

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Effect of breathing exercises on pain, disability, range of motion and muscle endurance in patient with chronic low back pain
When the data will become available and for how long
January 2022
To whom data/document is available
health care provider, PhD students, institutes
Under which criteria data/document could be used
for research purposes, evidence based practice
From where data/document is obtainable
drarifgdp@gmail.com
What processes are involved for a request to access data/document
through email
Comments