Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
drarifgdpgmi@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
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Postal code
54700
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+92 42 35918040
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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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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
Latest degree
Ph.D.
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)

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

drarifgdpgmi@gmail.com

What processes are involved for a request to access data/document

through email

Comments