Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Manual Diaphragm Manipulation and Diaphragm Release Technique in COPD

Protocol summary

Study aim

To compare the effects of Manual Diaphragm Manipulation and Diaphragm Release Technique on pulmonary functions, dyspnea, chest expansion and exercise capacity in COPD.

Design

60 participants will be recruited. Two parallel groups, double blinded, randomized clinical trial with pre and post assessment.

Settings and conduct

Pulmonology ward, Saleem Memorial Hospital Lahore

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with COPD according to the GOLD criteria, Age ranged from 45-65 years Moderate COPD (50% <Forced expiratory volume in first second "FEV1"<80%, Forced expiratory volume in first second per forced vital capacity FEV1/FVC <70% of predicted reversible airway obstruction) Person who is not involved in any rehabilitation program at least 4 months prior to the study No recent infectious exacerbations for the 2 months preceding the study Exclusion Criteria: History of gastroesophageal reflux of any degree Persistent hiccups within the previous three months History of serious injury to the spine or thorax, including costal or spinal fractures or history of diaphragm surgery Receiving long-term oxygen therapy Patients with unstable hemodynamic parameters (HR, BP, Cardiac output and Stroke volume) Patients who have undergone recent cardiothoracic or abdominal surgery Patients with a recent history of chest wall or abdominal trauma History of psychiatric illness

Intervention groups

Group A: It will be treated by Manual Diaphragm Manipulation Group B: It will be treated with Diaphragm Release Technique

Main outcome variables

Dyspnea measured using Modified Medical Research Council (MMRC) scale, Chest Expansion measured using Measuring tape, Pulmonary Function Tests using Diagnostic Spirometer and Exercise capacity with Six Minute Walk Test (6MWT)

General information

Reason for update

Acronym

Effects Of Manual Diaphragm Manipulation And Diaphragm Release In COPD

IRCT registration information

IRCT registration number: **IRCT20191117045462N20**
Registration date: **2024-07-27, 1403/05/06**
Registration timing: **retrospective**

Last update: **2024-07-27, 1403/05/06**
Update count: **0**

Registration date

2024-07-27, 1403/05/06

Registrant information

Name

Wajeeha Zia

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 42 35126110

Email address

wajeeha_z@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-16, 1403/04/26

Expected recruitment end date

2024-07-16, 1403/04/26

Actual recruitment start date
2024-07-16, 1403/04/26
Actual recruitment end date
2024-07-16, 1403/04/26
Trial completion date
2024-07-16, 1403/04/26

Scientific title
Effects of Manual Diaphragm Manipulation and Diaphragm Release Technique in COPD

Public title
Effects of Manual Diaphragm Manipulation and Diaphragm Release Technique in COPD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with COPD according to the GOLD criteria Age ranged from 45-65 years Moderate COPD (50% <Forced expiratory volume in first second "FEV1"<80%, Forced expiratory volume in first second per forced vital capacity FEV1/FVC <70% of predicted reversible airway obstruction) Person who is not involved in any rehabilitation program at least 4 months prior to the study No recent infectious exacerbations for the 2 months preceding the study
Exclusion criteria:
History of gastroesophageal reflux of any degree Persistent hiccups within the previous three months History of serious injury to the spine or thorax, including costal or spinal fractures or history of diaphragm surgery Receiving long-term oxygen therapy Patients with unstable hemodynamic parameters (HR, BP, Cardiac output and Stroke volume) Patients who have undergone recent cardiothoracic or abdominal surgery Patients with a recent history of chest wall or abdominal trauma History of psychiatric illness
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Taking into account the above mentioned inclusion and exclusion criteria, patients will be recruited into two groups labeled as 0 for group A and 1 for group B by simple random sampling through sealed opaque enveloped
Blinding (investigator's opinion)
Double blinded
Blinding description
The assessor physiotherapist and the patient both will be blinded. Although the consent form will be taken from the patient. But the patient will not be aware of the study. Accessor physiotherapist will be involved in the study. He or She must have 2 or 3 year experience in relevant domain. He will access the patient by defined outcome measure tools before the start of study at the end.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Riphah college of rehabilitation & Allied Health Sciences
Street address
25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore
City
Lahore
Postal code
54660
Approval date
2024-07-16, 1403/04/26
Ethics committee reference number
RCS&AHS/REC/MS-CPPT

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease
ICD-10 code
J44.8
ICD-10 code description
Chronic bronchitis

Primary outcomes

1

Description
Pulmonary function
Timepoint
Pre- Post Treatment
Method of measurement
Spirometer (Diagnostic)

2

Description
Dyspnea
Timepoint
Pre- Post Treatment
Method of measurement
Modified Medical Research Council Scale (MMRC)

3

Description
Chest expansion
Timepoint
Pre- Post Treatment
Method of measurement
Measuring Tape

4

Description
Exercise capacity
Timepoint
Pre- Post Treatment
Method of measurement
Six Minute Walk Test (6MWT)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Manual Diaphragm Manipulation: Manual Diaphragm Manipulation will be performed four days a week on a regular basis for four weeks. Each session will consist of three sets of four repetitions, with a two minute break in between each set. Patient will be in supine position Therapist positioned at the head side of the patient The therapist's forearms will aligned towards the patient shoulders. Therapist made manual contact with the hypothenar region and the last three fingers bilaterally on the underside of the seventh to tenth rib costal cartilages. During the inspiratory phase, the therapist gently pulled the points of contact with both hands in the direction of the head and slightly laterally, facilitating the elevation of the ribs. During exhalation, the therapist deepened the contact towards the inner costal margin, maintaining resistance. In the subsequent respiratory cycles, the therapist further deepened the contact inside the costal margin, adjusting it at specific points to ensure proper technique and effectiveness.
Category
Rehabilitation

2

Description
Intervention group B: Diaphragm Release Technique: Diaphragm release techniques focus on stretching and mobilizing the diaphragm muscle to enhance its flexibility and function. This can include stretching exercises such as Breath-hold Stretch، side stretch، seated diaphragmatic stretch، deep breathing and other therapeutic interventions aimed at improving diaphragmatic excursion and respiratory efficiency. The diaphragm release technique will be performed four days a week, with a rest period of two minutes in between each set of three sets of four repetitions. Every patient will be instructed to breathe as deeply and quietly as possible throughout the sessions, and they will all be attentively watched to look for any indicators that could compromise the study's ongoing continuity.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Saleem Memorial Hospital Lahore
Full name of responsible person
Rubab khalid
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Satluj Block Green Forts 2, Lahore, Punjab
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Riphah International University
Full name of responsible person
Wajeeha Zia
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25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore
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Grant name
Nill
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Riphah International University

Proportion provided by this source
15

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 International University

Full name of responsible person
Muhammad Umer Arshad

Position
Vice Principal-Allied Health Sciences-Diploma Courses, Avicenna Medical College and Hospital Lahore.

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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EXPERT CONSULTANT CLINIC 627, Khayaban e Jinnah, Iqbal Avenue Cooperative Housing Society - Phase 1, Airline Society, Lahore Punjab.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Wajeeha Zia

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
Student

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Master

Other areas of specialty/work
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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
There is no further information

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