# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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

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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
**Street address**
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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wajeeha_z@yahoo.com
**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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## Person responsible for scientific inquiries

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**Position**
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Ph.D.

**Other areas of specialty/work**
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## Person responsible for updating data

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**Latest degree**
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**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