

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effects of Diaphragmatic Stretch technique and Manual Release Technique on Diaphragmatic Excursion and pulmonary function testing in COPD patients.

#### Protocol summary

##### Study aim

The Aim of this study is that these techniques will help to relax the resting state of the diaphragm among the COPD patients, enhancing its contraction and relaxation functions.

##### Design

randomized control trial study design, non blind trial, 2 Groups.

##### Settings and conduct

Jinnah Hospital Lahore, Pakistan.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: male and female(40-60 year), stable COPD, mild or moderate COPD on GOLD criteria.

Exclusion Criteria: acute exacerbation of COPD, unstable hemodynamic parameters, cardiothoracic or abdominal surgery, psychiatric illness.

##### Intervention groups

Patients randomly divided into two groups with 18 subjects in each group. Base line treatment will be started by diaphragmatic breathing technique, patient will perform 10 breaths for 5minutes. Group A will be treated with Manual Diaphragm Release Technique in which the participant was asked to lie supine with relaxed limbs, the therapist made manual contact. In the inspiratory phase, the therapist was gently pulling the points of contact with both hands in the direction of the head and slightly laterally, accompanied the elevation of the ribs. During exhalation, the therapist's contact was deepened towards the inner costal margin. Group B will be treated with Diaphragmatic Stretch Technique in which the subjects were asked to sit erect for the intervention. subject exhaled, the therapist easing their hands caudally grasped the lower ribs at the subcostal margin. This firm, but gentle, traction was maintained as the patient inhales. 3 sessions/week for an alternate days will be given for 6 weeks

##### Main outcome variables

Pulmonary function testing and Cirtometry

#### General information

##### Reason for update

##### Acronym

CEDSTMRTDEPFTCP

##### IRCT registration information

IRCT registration number: **IRCT20220405054419N1**

Registration date: **2022-04-27, 1401/02/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-27, 1401/02/07**

Update count: **0**

##### Registration date

2022-04-27, 1401/02/07

##### Registrant information

##### Name

Arooma Muzummil

##### Name of organization / entity

Riphah International University

##### Country

Pakistan

##### Phone

+92 333 1472522

##### Email address

arooma.bzu@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-11, 1400/08/20

##### 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**

Comparative effects of Diaphragmatic Stretch technique and Manual Release Technique on Diaphragmatic Excursion and pulmonary function testing in COPD patients.

**Public title**

Comparative effects of Diaphragmatic Stretch technique and Manual Release Technique on Diaphragmatic Excursion and pulmonary function testing in COPD patients.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with stable COPD of both genders who are referred for Physiotherapy by a pulmonologist/Physician in general Hospitals. Patients with mild or moderate COPD according to the GOLD criteria, 2016. GOLD 1: Mild FEV1  $\geq$  80% predicted, GOLD 2: Moderate 50% FEV1  $\geq$  80% Predicted. Age range 40-60 years old patients. gender both male and female.

**Exclusion criteria:**

Patients with acute exacerbation of COPD Patients with acute exacerbation of COPD systolic and  $\leq$  60mmHg for diastolic and mean arterial pressure (MAP) $\leq$ 80mmHg). Patients who have undergone recent cardiothoracic or abdominal surgery. Patients who have a recent history of chest wall or abdominal trauma; substantial chest wall deformity. History of psychiatric illness.

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **38**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Written informed consent will be taken. After enrollment into study, patient will be allocated either to group A or Group B by lottery method. No. of Chits will be equal to total sample size, odd Numbers will be allocated to Group A and even number will be allocated to Group B. Each patient will be requested to draw a chit from the box and after that patient will be recruited into either Group A or Group B.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Approval date**

empty

**Ethics committee reference number****2****Ethics committee****Name of ethics committee**

Riphah International University

**Street address**

28-M Quaid e Azam Industrial Estate Kot Lakhpat, Lahore

**City**

Lahore

**Postal code**

54000

**Approval date**

2021-11-24, 1400/09/03

**Ethics committee reference number**

REC/RCR & AHS/21/0125

**Health conditions studied****1****Description of health condition studied**

Chronic obstructive pulmonary disease is described as a condition in which there is a chronic inflammation of lungs that causes obstructed airflow from the lungs. It can cause many harmful symptoms such as breathing difficulty, cough, mucus (sputum) production and wheezing. Blueness of the lips or fingernail beds (cyanosis) is also one of the major symptoms.

**ICD-10 code**

J44.0

**ICD-10 code description**

Chronic obstructive pulmonary disease with acute lower respiratory infection

**Primary outcomes****1****Description**

Diaphragm Strength

**Timepoint**

Before Treatment & After treatment (6week)

**Method of measurement**

Cirtometry

## 2

### **Description**

PFTs

### **Timepoint**

Before and After treatment (6 week)

### **Method of measurement**

Spirometer

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: will be treated with Manual Diaphragm Release Technique in which the participant was asked to lie supine with relaxed limbs. Positioned at the head of the patient, the therapist made manual contact with the hypothenar region and last three fingers bilaterally to the underside of the seventh to tenth rib costal cartilages. The therapist's forearms were aligned towards the participant's shoulders. In the inspiratory phase, the therapist was gently pulling the points of contact with both hands in the direction of the head and slightly laterally, accompanied the elevation of the ribs. During exhalation, the therapist's contact was deepened towards the inner costal margin, maintaining resistance. In the subsequent respiratory cycles, the therapist deepened the Contact inside the costal margin.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: will be treated with Diaphragmatic Stretch Technique in which the subjects were asked to sit erect for the intervention. The therapist standing behind the subject pass their hands around the thoracic cage, introducing fingers in the subcostal margins. The subject's trunk was rounded slightly to relax the rectus abdominis. As the subject exhaled, the therapist easing their hands caudally grasped the lower ribs at the subcostal margin. This firm, but gentle, traction was maintained as the patient inhales.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Jinnah Hospital Lahore

##### **Full name of responsible person**

Arooma Muzummil

##### **Street address**

Usmania Road, Lahore

#### **City**

Lahore

#### **Postal code**

54000

#### **Phone**

+92 333 1472522

#### **Email**

arooma.bzu@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Riphah International University, Lahore

##### **Full name of responsible person**

Arooma Muzummil

##### **Street address**

House no 23, Street no 62 Sadi Road Islampura  
Lahore

##### **City**

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##### **Postal code**

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##### **Phone**

+92 333 1472522

##### **Email**

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#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Jinnah Hospital, Lahore

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **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**

Riphah International University, Lahore

##### **Full name of responsible person**

Arooma Muzummil

##### **Position**

Student

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

House no 23, Street no 62 Sadi Road Islampura  
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**City**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Riphah International University, Lahore.

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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 information decided yet.

**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