

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 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

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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

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Usmania Road, Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Person responsible for scientific inquiries

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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

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