Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Arooma Muzummil
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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 ≥ 80% predicted, GOLD 2: Moderate 50% FEV1 < 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 < 60mmHg for diastolic and mean arterial pressure (MAP)<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 their 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 symptom.
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
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Sponsors / Funding sources

1

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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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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