

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Combined effect of Respiratory Muscle Stretching with Active cycle Breathing Technique on dyspnea related kinesiophobia among patients with chronic obstructive pulmonary disease (COPD)

Protocol summary

Study aim

This study aim to determine the combined effect of Active cycle Breathing Technique with Respiratory Muscle Stretching on dyspnea related kinesiophobia in patients with Chronic Obstructive Pulmonary Disease

Design

The design of this study is Randomized, parallel Clinical Trial. Randomization is done by lottery method. In this method, the researcher gives each participant of the trial a number. Researchers draw numbers from the box randomly to allocate participants in two groups

Settings and conduct

This study is conducted at Arif memorial teaching hospital and Gulab Devi Chest Hospital. In this trial participants are blinded through concealment to avoid biasness

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with moderate-to-severe COPD clinical stability (no changes in medication during the last month), no supplemental O2 dependence
Exclusion criteria: Presence of comorbidities affecting ambulation/activity (e.g., severe cardiac or neurological disorders, cancer, musculoskeletal problems) history of cognitive disorders

Intervention groups

Group A: Active Cycle Breathing Exercise Group B: Active Cycle Breathing Exercise + Respiratory Stretching Exercise (Pectoralis Major, Pectoralis Minor, Upper Trapezius, Scalene, Sternocleidomastoid, Intercostal and anterior serratus)

Main outcome variables

- Tampa Scale (Kinesiophobia) To evaluate kinesiophobia, the Tampa Scale (Kinesiophobia) is used, which consist of 17 items rated on a 4-point Likert scale: "strongly disagree (1 point)," "disagree (2 points)," "agree (3 points)," and "strongly agree (4 points)." For questions 4, 8, 12, and 16, the scores are reversed. Total

scores range from 17 to 68 points, with higher scores indicating a stronger degree of Kinesiophobia. TSK's internal consistency, retest reliability, and validity have already been confirmed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220604055072N1**

Registration date: **2022-11-25, 1401/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-25, 1401/09/04**

Update count: **0**

Registration date

2022-11-25, 1401/09/04

Registrant information

Name

Aleena Waheed

Name of organization / entity

Rashid Latif Medical College

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined effect of Respiratory Muscle Stretching with Active cycle Breathing Technique on dyspnea related kinesiophobia among patients with chronic obstructive pulmonary disease (COPD)

Public title

Combined effect of respiratory muscle stretching and active cycle breathing technique on dyspnea related kinesiophobia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with moderate-to-severe COPD
Clinical stability (no changes in medication during the last month), No supplemental O2 dependence

Exclusion criteria:

Presence of comorbidities affecting ambulation/activity (e.g., severe cardiac or neurological disorders, cancer, musculoskeletal problems) History of cognitive disorders

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were allocated into two groups i.e.; Group A and Group B, by lottery method. Lottery method is a type of simple random sampling. In this method, each participant of the trial is assigned a unique number. In the next step these numbers are written on separate cards which are physically similar in shape, size, color etc. 60 cards were used. Then they are placed in a basket and thoroughly mixed. In the last step the slips are taken out randomly without looking at them and are placed into two sets randomly. Total of 40 cards were taken out, 20 participants in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The blinding is achieved by concealment in which the treatment allocation for each patient is not revealed to the patient. This is done to avoid biasness.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board of Rashid Latif Medical College

Street address

35- km Ferozepur Road, Lahore

City

Lahore

Postal code

54000

Approval date

2022-10-05, 1401/07/13

Ethics committee reference number

IRB/2022/059

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

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

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

Kinesiophobia

Timepoint

Pre-intervention and 2 weeks Post-intervention

Method of measurement

Tampa Scale for Kinesiophobia

Secondary outcomes**1****Description**

Functional Capacity

Timepoint

Pre-intervention and 2 week Post-intervention

Method of measurement

6 Minute Walk Test

2

Description

Anxiety

Timepoint

Pre-intervention and 2 week Post-intervention

Method of measurement

Hospital Anxiety and Depression Scale

Intervention groups

1

Description

Intervention group 1: In which participants will be treated with Active Cycle Breathing Exercise (ACBT). This group will be the treated consisting of breathing control, thoracic expansion exercises, and the forced expiration technique in gravity assisted positions. In ACBT, breathing control are normal tidal volume breathing using the lower chest with relaxation of the upper chest and shoulders. Thoracic expansion exercises are deep-breathing exercises emphasizing inspiration. Inspiration is active and expiration is passive and relaxed. The cycle will be ended with the forced expiration technique consisting of huffs combined with breathing control. A huff to low lung volume will move the more peripherally situated secretions and a huff from a high lung volume will clear secretions that have reached the more proximal airways. The forced expiration technique can be explained using the concept of the equal pressure point, which is the point where the pressure within the airways is equal to the pleural pressure. Downstream of the equal pressure point, toward the mouth, the dynamic squeezing of airways allows secretions to be mobilized and cleared. As lung volume decreases equal pressure points move peripherally and a huff to low lung volume clears secretions from the peripheral airways. Secretions mobilized to the upper airways is cleared by a huff from high lung volume.

Category

Rehabilitation

2

Description

Intervention group 2: In which participants will be treated with Active Cycle Breathing Exercise and Respiratory Stretching Exercise (Pectoralis Major, Pectoralis Minor, Upper Trapezius, Scalene, Sternocleidomastoid, Intercostal and anterior serratus). Active Cycle Breathing Technique consist of breathing control, thoracic expansion exercises, and the forced expiration technique in gravity assisted positions. In ACBT, breathing control are normal tidal volume breathing using the lower chest with relaxation of the upper chest and shoulders. Thoracic expansion exercises are deep-breathing exercises emphasizing inspiration. Inspiration is active and expiration is passive and relaxed. The cycle will be ended with the forced expiration technique consisting of huffs combined with breathing control. A huff to low lung volume will move the more peripherally situated secretions and a huff from a high lung volume will clear

secretions that have reached the more proximal airways. The forced expiration technique can be explained using the concept of the equal pressure point, which is the point where the pressure within the airways is equal to the pleural pressure. Downstream of the equal pressure point, toward the mouth, the dynamic squeezing of airways allows secretions to be mobilized and cleared. As lung volume decreases equal pressure points move peripherally and a huff to low lung volume clears secretions from the peripheral airways. Secretions mobilized to the upper airways is cleared by a huff from high lung volume. Respiratory muscles stretching will be performed passively by a physical therapist. Subjects will be in the supine or lateral position, knees bent to correct the lumbar curve, with repositioning of the scapular waist as well as scapular and arm abduction in order to prevent postural compensations. Stretching will be performed bilaterally. For Upper trapezius stretching, patient will be in supine position with lateral flexion of the head to the opposite side of that stretched, the therapist supported the occipital region with one hand and the shoulder with the other hand, causing displacement of two support points in the craniocaudal direction. For Sternocleidomastoid stretching, patient will be in supine position with lateral flexion with rotation of the head to the opposite side of that stretched; the therapist placed one hand on the occipital region and the other on the sternal region, which was displaced in the cranial-caudal direction. For Scalene stretching, patient will be in supine position, with one hand on the occipital region and the other on the sternum region, the therapist promoted displacement of the two support points, in opposite directions. For Pectoralis major stretching, patient will be in supine position, on the side to be stretched, the patients arm was abducted, forearm flexed and hand resting on the occipital region. The displacement was performed with one of the therapist's hands on the upper third of the arm and the other on the lateral region of the upper chest, following the direction of muscle fibers. For intercostal and Serratus Anterior stretching patient will be in supine and lateral position on a half-moon-shaped foam roller in the infra-axillary region, forearms flexed and hands resting on the occipital region; the therapist used both palmar region hand's to mobilize the ribs in the craniocaudal direction. Stretching will be done during the expiratory phase, with two sets of ten consecutive incursions for each muscle and a one-minute interval between the series. For intercostal muscles stretching, a side stretch was performed in lateral decubitus at the moment of inspiration and the ribs were monitored during expiration.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Arif Memorial Teaching Hospital

Full name of responsible person

Fareeha Faisal

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rashid Latif Medical College

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?**

Yes

Title of funding source

Rashid Latif Medical College

Proportion provided by this source

100

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**

Rashid Latif Medical College

Full name of responsible person

Fareeha Faisal

Position

Physiotherapist

Latest degree

Bachelor

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rashid Latif Medical College

Full name of responsible person

Aleena Waheed

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

Rashid Latif Medical college

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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