Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Phone

+92 321 4883868

Email address

alwaheed28@gmail.com

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 patienťs 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
Street address
35-Km Ferozepur road Lahore
City
Lahore
Postal code
54600
Phone
+92 303 5879948
Email
drfareeha506@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rashid Latif Medical College
Full name of responsible person
Aleena Waheed
Street address
25-Km Ferozepur road Lahore
City
Lahore
Postal code
54600
Phone
+92 321 4883868
Email
alwaheed28@gmail.com
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
Other areas of specialty/work
Physiotherapy
Street address
35-Km Ferozepur Road Lahore
City
Lahore
Province
Punjab
Postal code
54900
Phone
+92 321 4883868
Email
drfareeha506@gmail.com

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
Street address
35-Km Ferozepur Road Lahore
City
Lahore
Province
Punjab
Postal code
54900
Phone
+92 321 4883868
Email
alwaheed28@gmail.com

Person responsible for updating data

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
Street address
35-Km Ferozepur road Lahore
City
Lahore
Province
Punjab
Postal code

54900

Phone

+92 321 4883868

Email

alwaheed28@gmail.com

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