

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of TEACH Back Training Intervention on Pulmonary Functions in COPD Patients

#### Protocol summary

##### Study aim

To determine significant effectiveness of teach back training intervention with breathing exercises including diaphragmatic breathing , pursed lip breathing and effective cough to improve the pulmonary functions in COPD patients.

##### Design

Randomized Control Trial with parallel groups , Single blinded with pre and post treatment readings

##### Settings and conduct

Fatima Memorial Hospital, Jinnah Hospital And Services Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age from 18 to 75 years old ,Male and Female, Diagnosed COPD with FEV1/FVC ratio <70% ,Lack of cognitive impairment ,Ability to attend training session, Clinical diagnosis of COPD confirmed by smoking history Exclusion Criteria: Long Term Bed Rest, Inability To Perform 6-minute Walk Test, Malignancy, Cardiovascular disease (Angina, MI),Stroke, Immunocompromised conditions, Cardiac and pulmonary surgical History

##### Intervention groups

Interventional Group(A):Teach Back training with breathing exercises along with Conventional treatment and educational session protocols among COPD patients. Control Group(B):Breathing Exercises with Conventional Training among COPD patients

##### Main outcome variables

Pulmonary Function Assessment using Digital Spirometry and Borg Dyspnea Scale

#### General information

##### Reason for update

##### Acronym

Randomized Control Trial

##### IRCT registration information

IRCT registration number: **IRCT20191117045462N25**

Registration date: **2025-04-23, 1404/02/03**

Registration timing: **retrospective**

Last update: **2025-04-23, 1404/02/03**

Update count: **0**

##### Registration date

2025-04-23, 1404/02/03

##### Registrant information

###### Name

Wajeeha Zia

###### Name of organization / entity

Riphah International University

###### Country

Pakistan

###### Phone

+92 42 35126110

###### Email address

wajeeha\_z@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-08, 1402/12/18

##### Expected recruitment end date

2024-07-10, 1403/04/20

##### Actual recruitment start date

2024-03-08, 1402/12/18

##### Actual recruitment end date

2024-07-10, 1403/04/20

##### Trial completion date

2024-07-10, 1403/04/20

##### Scientific title

Effects of TEACH Back Training Intervention on Pulmonary Functions in COPD Patients

##### Public title

Effects of TEACH Back Training Intervention on

Pulmonary Functions in COPD Patients

## **Purpose**

Education/Guidance

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Clinically diagnosed COPD patient with long chain smoking history Diagnosed COPD with FEV1/FVC ratio <70% Ability to attend training session Lack of cognitive impairment Both Male and female 18-75 years old Individuals

### **Exclusion criteria:**

Long Term Bed Rest Inability To Perform 6-minute Walk Test Cardiovascular Disease(Angina, Myocardial Infarction) Stroke Immunocompromised Conditions Cardiac, Pulmonary Surgery History

## **Age**

From **18 years** old to **75 years** old

## **Gender**

Both

## **Phase**

2

## **Groups that have been masked**

- Investigator

## **Sample size**

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **45**

English

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **40**

English

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patient will be recruited in the study through non-probability convenience sampling technique and then will be randomly assigned to each group through random sampling sealed opaque enveloped. Group 1 allocated as A and group 2 allocated as B. Half enveloped will be labeled with A and a half with labeled with B. If a patient gets the envelop with label 1 then will be in group A and if a patient gets the envelop with label 2 that will be treated as Group B

## **Blinding (investigator's opinion)**

Single blinded

## **Blinding description**

Investigator will be blinded .Assessment will be done by another therapist who will not be involved in treatment and data analysis

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Riphah College of Rehabilitation & Allied Health Sciences

##### **Street address**

25 Raza Saeed Road,Babra Block M Gulberg 3,Lahore,Punjab 25-Block Lahore

##### **City**

Lahore

##### **Postal code**

54000

#### **Approval date**

2023-11-20, 1402/08/29

#### **Ethics committee reference number**

RCR&AHS/REC/MS-CPPT

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Chronic Obstructive Pulmonary Condition

#### **ICD-10 code**

J44.9

#### **ICD-10 code description**

Chronic obstructive pulmonary disease, unspecified

## **Primary outcomes**

### 1

#### **Description**

Pulmonary Function Testing

#### **Timepoint**

Pre & Post Treatment

#### **Method of measurement**

Digital Spirometer

## **Secondary outcomes**

### 1

#### **Description**

Dyspnea

#### **Timepoint**

Pre-Post Treatment

#### **Method of measurement**

Borg Dyspnea Scale

## **Intervention groups**

### 1

#### **Description**

Intervention Group: Teach Back training with pursed lip and diaphragmatic breathing along with Conventional treatment and educational session protocols among

COPD patients.3 Times/week with 10 repetitions/3 set/session/day

**Category**

Rehabilitation

**2**

**Description**

Control group: Recieved Conventional Treatment along with breathing exercises(Pursed lip breathing & diaphragmatic breathing).

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Riphah College of Rehabilitation & Allied Health Sciences

**Full name of responsible person**

Hira Nadeem Bhatti

**Street address**

25 Raza Saeed Road,Bhabra Block M Gulberg 3,Lahore ,Punjab 25 -Block Lahore

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**Postal code**

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**Phone**

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**Email**

wajeeha\_z@yahoo.com

**Web page address**

<https://www.riphah.edu.pk>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Wajeeha

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**Grant name**

Educational

**Grant code / Reference number**

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

Yes

**Title of funding source**

Riphah International University

**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**

Riphah International University

**Full name of responsible person**

Wajeeha

**Position**

Senior Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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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 further Information

**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