

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Pilates breathing versus Rhythmic Initiation Proprioceptive neuromuscular facilitation technique in Chronic Obstructive Pulmonary Disease (COPD) patients

#### Protocol summary

##### Study aim

To find the effects of Pilates breathing versus Rhythmic initiation Proprioceptive Neuromuscular Facilitation (PNF) on pulmonary function tests, dyspnea and chest expansion in Chronic Obstructive Pulmonary Disease (COPD) patients.

##### Design

Two parallel groups, double blinded randomized clinical trial with pre and post assessment

##### Settings and conduct

Pulmonology ward , Ittefaq hospital Lahore

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • Age group of 35-65years • Both male and females • COPD diagnosed according to the Global Initiative for Chronic Obstructive Lung Diseases (GOLD) guidelines at mild stage EXCLUSION CRITERIA • Patients with any recent surgery • Patients with other medical conditions that may interfere with exercise program • Patients doing yoga training • Diagnosis of other chronic lung disease such as (bronchiectasis, cystic fibrosis, asthma, interstitial lung disease, lung cancer etc. • Mental Illness

##### Intervention groups

Standardized pulmonary rehabilitation program along with Pilates breathing and Proprioceptive neuromuscular facilitation technique

##### Main outcome variables

Dyspnea measured using Modified Medical Research Council (MMRC) scale, Chest Expansion measured using Measuring tape, Pulmonary Function Tests using Portable Spirometer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191117045462N13**

Registration date: **2024-03-24, 1403/01/05**

Registration timing: **retrospective**

Last update: **2024-03-24, 1403/01/05**

Update count: **0**

##### Registration date

2024-03-24, 1403/01/05

##### 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

2023-11-30, 1402/09/09

##### Expected recruitment end date

2024-03-01, 1402/12/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Pilates breathing versus Rhythmic Initiation Proprioceptive neuromuscular facilitation technique in

Chronic Obstructive Pulmonary Disease (COPD) patients

### Public title

Effects of Pilates breathing versus Rhythmic Initiation Proprioceptive neuromuscular facilitation technique in Chronic Obstructive Pulmonary Disease (COPD) patients

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age group of 35-65years Both male and females Chronic Obstructive Pulmonary Disease (COPD) diagnosed according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines at mild stage.

#### Exclusion criteria:

Patients with any recent surgery Patients with other medical conditions that may interfere with exercise program Patients doing yoga training • Diagnosis of other chronic lung disease such as (bronchiectasis, cystic fibrosis, asthma ,interstitial lung disease, lung cancer) Mental Illness

### Age

From **35 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **52**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Convenient sampling technique will be used to recruit the COPD patients in the study and then they will be divided into two groups by simple random sampling through sealed opaque envelope system as mentioned below 1- Fifty- two sealed envelopes were randomly given to participating clinicians (in shuffled form) with half having treatment A and half having treatment B in them. 2- After taking consent from the patient, the clinician randomly picks up an envelope and allocates the patient to the treatment regimen mentioned in the envelope.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Both participants and outcome assessor will be blind. assessment will be done by second 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, Bhabra block M Gulberg 3, Lahore, Punjab 25-Block Lahore

##### City

Lahore

##### Postal code

54000

#### Approval date

2023-06-14, 1402/03/24

#### Ethics committee reference number

REC/RCR&AHS/23/0329

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Bronchitis

#### ICD-10 code

J41

#### ICD-10 code description

Simple and mucopurulent chronic bronchitis

### 2

#### Description of health condition studied

Emphysema

#### ICD-10 code

J43

#### ICD-10 code description

Emphysema

## Primary outcomes

### 1

#### Description

Dyspnea

#### Timepoint

Pre-post treatment

#### Method of measurement

Modified Medical Research Council scale (MMRC)

### 2

#### Description

Chest Expansion

#### Timepoint

Pre-post treatment

#### Method of measurement

Measuring Tape

### 3

#### **Description**

Pulmonary Function Tests

#### **Timepoint**

Pre-post treatment

#### **Method of measurement**

Portable Spirometer

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Conventional Pulmonary Rehabilitation with Pilates breathing. The Conventional treatment includes Pursed lip breathing, Diaphragmatic Breathing and Postural drainage.

#### **Category**

Rehabilitation

#### 2

#### **Description**

Intervention group: Conventional Pulmonary Treatment with Rhythmic Initiation PNF technique. The Conventional treatment includes Pursed lip breathing, Diaphragmatic Breathing and Postural drainage.

#### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Riphah college of Rehabilitation & Allied Health Sciences

##### **Full name of responsible person**

Riphah college of Rehabilitation & Allied Health Sciences

##### **Street address**

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

##### **City**

Lahore

##### **Postal code**

54000

##### **Phone**

+92 323 4500788

##### **Email**

wajeעה\_z@yahoo.com

##### **Web page address**

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

#### 2

#### **Recruitment center**

##### **Name of recruitment center**

Riphah college of Rehabilitation & Allied Health Sciences

##### **Full name of responsible person**

Mishal Fatim

##### **Street address**

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

##### **City**

Lahore

##### **Postal code**

54000

##### **Phone**

+92 307 4605469

##### **Email**

mishalfatim26@gmail.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**

Wajeעה

##### **Street address**

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

##### **City**

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##### **Postal code**

54000

##### **Phone**

+92 323 4500788

##### **Email**

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#### **Grant name**

educational

#### **Grant code / Reference number**

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

No

#### **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**

Mishal Fatim

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

wajeeha\_z@yahoo.com

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

Riphah International University

**Full name of responsible person**

Wajeeha

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Riphah International University

**Full name of responsible person**

Mishal Fatim

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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54000

**Phone**

+92 323 4500788

**Email**

mishalfatim26@gmail.com

**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