

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

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Web page address

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2

Recruitment center

Name of recruitment center

Riphah college of Rehabilitation & Allied Health Sciences

Full name of responsible person

Mishal Fatim

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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?

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

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

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Wajeeha

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

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Position

Student

Latest degree

Master

Other areas of specialty/work

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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