

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects Of Inspiratory Muscles Training On Dyspnea In Moderate Chronic obstructive pulmonary disease (COPD) Patients During Pulmonary Rehabilitation

Protocol summary

Study aim

To find out Effects of Inspiratory Muscles training in improving Dyspnea and quality of life in moderate COPD patients during Pulmonary Rehabilitation.

Design

Two parallel group , single blinded, randomized control trial with pre and post assessment

Settings and conduct

Pulmonology Ward/Intensive Care unit Nishtar Medical University and Hospital Multan

Participants/Inclusion and exclusion criteria

Inclusion criteria, •Moderate cases of COPD as per Gold Criteria •Moderate cases FEV1 =50-79 •Participants routinely visiting the OPD •Participants with significant history of smoking •Well controlled DM or HTN, if they have •Age 20 to 40 years. Exclusion criteria, •Pregnancy • History Of Recent Trauma/Fall Or Fracture •Red Flags Like: Fever, Night Sweats, Malaise Etc. • Patients Having History Of Pneumonectomy • Lobectomy In Previous 6 Months • Risk Of Pneumothorax/Presence Of Bulla • Rib Fracture • Acute Exacerbation Of COPD • Having History Of Drug Abuse • Unstable Cardiovascular Diseases • Unstable Orthopedic Problems

Intervention groups

Standardized pulmonary rehabilitation program along with Inspiratory muscle training

Main outcome variables

Multidimensional Dyspnoea Profile (MDP) •Assessment of quality of life using the SGRQ (Saint George Respiratory Questionnaire) • Pulmonary function changes by Inspiratory capacity at rest and inspiratory capacity at the end of the 6MWT using a portable spirometer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191117045462N2**

Registration date: **2021-04-19, 1400/01/30**

Registration timing: **prospective**

Last update: **2021-04-19, 1400/01/30**

Update count: **0**

Registration date

2021-04-19, 1400/01/30

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

2021-04-29, 1400/02/09

Expected recruitment end date

2021-06-30, 1400/04/09

Actual recruitment start date

2021-04-29, 1400/02/09

Actual recruitment end date

2021-06-30, 1400/04/09

Trial completion date

2021-07-10, 1400/04/19

Scientific title

Effects Of Inspiratory Muscles Training On Dyspnea In

Moderate Chronic obstructive pulmonary disease (COPD)
Patients During Pulmonary Rehabilitation

Public title

Effects Of Inspiratory Muscles Training On Dyspnea In
Moderate Chronic obstructive pulmonary disease (COPD)
Patients During Pulmonary Rehabilitation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate cases of Chronic obstructive pulmonary
disease (COPD) as per Gold Criteria Moderate cases
forced expiratory volume in 1 second (FEV1) =50-79
Participants routinely visiting the Hospital Participants
with significant history of smoking Well controlled
Diabetes or Blood Pressure if they have Age 20 to 40
years

Exclusion criteria:

Pregnancy History Of Recent Trauma/Fall Or Fracture
Red Flags Like: Fever, Night Sweats, Malaise etc. Patients
Having History Of Pneumonectomy Lobectomy In
Previous 6 Months Risk Of Pneumothorax/Presence Of
Bulla Rib Fracture acute Exacerbation Of COPD Having
History Of Drug Abuse Unstable Cardiovascular Diseases
Unstable Orthopedic Problems

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **58**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Taking into account the above mentioned inclusion and
exclusion criteria, patients will be recruited in the study
through convenient sampling technique and then will be
randomly assigned to each group through Random
Sampling sealed opaque enveloped. Labeled as 1 group
A and 2 for group b

Blinding (investigator's opinion)

Single blinded

Blinding description

Investigator will be blind. Assesmnt will be done by 2nd
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

13-14-C-civic center, township near Hamdard Chowk,
Lahore

City

Lahore

Postal code

54000

Approval date

2642-02-16, 2020/11/27

Ethics committee reference number

RCR&AHS/REC/MS-CPPT

Health conditions studied

1

Description of health condition studied

moderate COPD patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

5 Times Sit to Stand Test for dyspnea

Timepoint

Pre- Post treatment

Method of measurement

London Chest Activity of Daily Living scale for daily life

Secondary outcomes

1

Description

dyspnea

Timepoint

Pre-Post Treatment

Method of measurement

Multidimensional Dyspnoea Profile (MDP)

Intervention groups

1

Description

Intervention group: Standardized pulmonary
rehabilitation program along with Inspiratory muscle
training

Category

Rehabilitation

2

Description

Control group: Standardized pulmonary rehabilitation program

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

13-14-C-civic center, township near Hamdard Chowk, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 35126110

Email

mahnoorejaz76@gmail.com

Web page address

2

Recruitment center

Name of recruitment center

Riphah college of rehabilitation & Allied Health Sciences

Full name of responsible person

Mahnoor Ejaz

Street address

13-14-C-civic center, township near Hamdard Chowk, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 35126110

Email

mahnoorejaz76@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University

Full name of responsible person

Wajeeha

Street address

13-14-C-civic center, township near Hamdard Chowk, Lahore

City

Lahore

Postal code

54000

Phone

+92 42 35126110

Email

wajeeha_z@yahoo.com

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

Mahnoor Ejaz

Position

student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

13-14-C-civic center, township near Hamdard Chowk, Lahore

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 42 35126110

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
Senior Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
13-14-C-civic center, township near Hamdard Chowk,
Lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 35126110
Email
wajeeha_z@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Riphah International University
Full name of responsible person
Mahnoor Ejaz
Position
student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address

13-14-C-civic center, township near Hamdard Chowk,
Lahore
City
Lahore
Province
Punjab
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Phone
+92 42 35126110
Email
mahnoorejaz76@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