Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 cute 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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Riphah International University
Full name of responsible person
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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
Mahnoor Ejaz
Position
student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

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Wajeeha

Position
Senior Lecturer

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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