Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Combined effects of inspiratory and expiratory muscle training on pulmonary function and disease severity in patients with pneumonia

Protocol summary

Study aim
The aim of this study is to check the combined effects of inspiratory muscle training and expiratory muscle training through the breather device vs diaphragmatic breathing on the pulmonary function and severity of the disease in patients with pneumonia

Design
parallel group, randomized clinical trial

Settings and conduct
research will be conducted in Gulab Devi Chest Hospital Lahore in which subjects will be randomly allocated to both group through lottery method

Participants/Inclusion and exclusion criteria
Inclusion Criteria • Adults aged 35-55 years • Both gender male and female • Patients having stage 2 to 4 according to pneumonia severity index • Participants willing to be the part of the research Exclusion Criteria • Participant with acute heart disease (Heart Failure) and acute coronary artery disease • Participants with other respiratory condition (Asthma, COPD) • Participants with the diseases leading to the impairment of respiratory muscle (Mysthenia Gravis)

Intervention groups
Intervention Group (IMT and EMT combined through the breather device) 3d/week for upto 3 weeks through the breather device by starting with 15% maximum inspiratory and expiratory resistance. At the starting of intervention Pt will perform 5-6 diaphragmatic breathing in upright position. The patient will be asked to inhale deeply and then hold for 2-3 second and breathe out through the device with the 3 sets with each set including 8 repetitions of IMT and 8 repetitions of EMT in same cycle with diaphragmatic breathing between each set. Control group (Diaphragmatic breathing) The group B will be the control group that will receive baseline treatment of diaphragmatic breathing alone.

Main outcome variables
Pulmonary function and severity of Pneumonia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230622058556N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

Registration date
2023-07-24, 1402/05/02

Registrant information

Name
Tehreem Khawar

Name of organization / entity
Riphah college of rehabilitation and allied health sciences

Country
Pakistan

Phone
+92 331 4833135

Email address
tehreemkhawar98@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-28, 1402/05/06

Expected recruitment end date
2023-08-20, 1402/05/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Combined effects of inspiratory and expiratory muscle training on pulmonary function and disease severity in patients with pneumonia

Public title
Combined effects of inspiratory and expiratory muscle training on pulmonary function and disease severity in patients with pneumonia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
• Adults aged 35-55 years • Patients having stage 2 to 4 according to pneumonia severity index • Participants willing to be the part of the research • Both gender male and female

Exclusion criteria:
• Participant with acute heart disease (Heart Failure) and acute coronary artery disease • Participants with other respiratory condition • Participants with the diseases leading to the impairment of respiratory muscle (Mysthenia Gravis)

Age
From **35 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
total 50 patients are randomly allocated to Group A (n=25) and Group B (n=25) through individual simple randomization method of concealed lottery technique.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research & Ethics Committee Riphah College of Rehabilitation and Allied Health Sciences

Street address
26 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab

City
Lahore

Postal code
54660

Approval date
2023-03-01, 1401/12/10

Ethics committee reference number
REC/RCR&AHS/23/0325

Health conditions studied

1

Description of health condition studied
Pneumonia

ICD-10 code
J18

ICD-10 code description
Pneumonia, Inspiratory muscle training, Expiratory muscle training, Pulmonary function, The Breather, Diaphragmatic Breathing

Primary outcomes

1

Description
pulmonary function

Timepoint
The Primary outcomes will be measured at two points before starting the treatment and after the treatment ends.

Method of measurement
Pulmonary function will be assessed through digital spirometer (FEV1, FVC, FEV1/FVC)

2

Description
Disease Severity

Timepoint
The Primary outcomes will be measured at two points before starting the treatment and after the treatment ends.

Method of measurement
disease severity through Pneumonia Severity index, and Modified Borg scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention was given 3 days per week for upto 3 weeks starting with 15% of maximum inspiratory load and maximum expiratory load then was incrementally increased 5-10% per weeks to

reach 60% at the end of the training. The Patient at first were asked to do 5-6 diaphragmatic breathing in upright position and then asked to breathe with the breather device at 15% of MIR by adjusting the dial. The patient were asked to inhale for 2-3 and then hold for 2-3 second and breathe out through the device with the 3 sets with each set including 8 repetitions of inspiratory muscle training and 8 repetitions of expiratory muscle training in same cycle with relaxed diaphragmatic breathing between each set.

Category

Treatment - Devices

2

Description

Control group: will receive baseline treatment of diaphragmatic breathing alone. The Patient will be asked to do 5-6 diaphragmatic breathing in upright position.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gulab Devi Chest Hospital Lahore

Full name of responsible person

Dr. Muhammad Arif PT Consultant CardioPulmonary Physical Therapist

Street address

F8MV+5HW, Ferozepur Rd, Nishtar Town, Lahore, Punjab 54000

City

Lahore

Postal code

05307

Phone

+92 333 8523002

Email

muhammad.arif@gdec.edu.pk

Sponsors / Funding sources

1

Sponsor

Grant name

Grant code / Reference number

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

No

Title of funding source

Riphah College of Rehabilitation and Allied Health Sciences

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 College of Rehabilitation and Allied Health Sciences Lahore

Full name of responsible person

Tehreem Khawar

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore

City

Lahore

Province

Punjab

Postal code

54660

Phone

+92 309 6543405

Email

tehreemkhawar98@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah college of rehabilitation and allied health sciences

Full name of responsible person

Qurat-ul-Ain

Position

senior Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Riphah international university ferozepur road Gulberg 3 Lahore

City

Lahore

Province

Punjab

Postal code

54660

Phone

+92 312 1707719

Fax

Email
qurat.ain@riphah.edu.pk

Person responsible for updating data

Contact

Name of organization / entity
Riphah College of Rehabilitation and Allied Health Sciences

Full name of responsible person
Wajeeha Zia

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
25 Raza Saeed Rd, Bhabra Block M Gulberg III, Lahore, Punjab 25-M Block, Lahore

City
Lahore

Province
Punjab

Postal code
54660

Phone
+92 323 4500788

Email
wajeeha.zia@riphah.edu.pk

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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