

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the Efficacy of Respiratory Muscle Training on Balance and Gait Performance in Patients with severe COPD: A Randomized Controlled Trial

Protocol summary

Study aim

The aim of the study was to investigate the effects of respiratory muscle training on balance and gait in patients with moderate to severe COPD

Design

In this randomized interventional study, patients who met the inclusion criteria were randomly assigned to either the pulmonary rehabilitation protocol group (PR) or the pulmonary rehabilitation and inspiratory muscle training group (PR + IMT). Both groups underwent a comprehensive rehabilitation protocol twice a day for three weeks.

Settings and conduct

The study was performed at a single pulmonary rehabilitation center in Timisoara, Romania.

Participants/Inclusion and exclusion criteria

In this study, we enrolled individuals who were chronic COPD patients seeking treatment in our Pulmonary Rehabilitation Centre. The criteria for patient inclusion were: history of smoking of more than 20 packs per year, forced expiratory volume (FEV1) less than 80% of predicted, FEV1/forced vital capacity (FVC) ratio less than 0.7 predicted, and a physician diagnosis of COPD.7 The patients were excluded from the study if they had: severe comorbidities or acute conditions that could potentially interfere with their existing health status, medication that could potentially affect their exercise responses, as well as those diagnosed with postural orthostatic hypotension, neurological or musculoskeletal conditions that may contribute to falls and balance issues (such as Parkinson's disease, a history of cerebrovascular accident, acute or severe cardiovascular problems, transient ischemic attacks, or recent lower-extremity joint replacements), patients with exacerbations in the last 3 months or oxygen dependent, and individuals with impaired vision.

Intervention groups

Patients in the intervention group received pulmonary rehabilitation and additional inspiratory muscle training.

Main outcome variables

Balance and gait improved significantly in the study group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231115060065N1**

Registration date: **2023-11-23, 1402/09/02**

Registration timing: **retrospective**

Last update: **2023-11-23, 1402/09/02**

Update count: **0**

Registration date

2023-11-23, 1402/09/02

Registrant information

Name

Alexandru Florian Crişan

Name of organization / entity

University of Medicine and Pharmacy Victor Babes
Timisoara

Country

Romania

Phone

+40 765 525 688

Email address

crisan@umft.ro

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-08, 1402/02/18

Expected recruitment end date

2023-10-31, 1402/08/09

Actual recruitment start date

2023-05-08, 1402/02/18

Actual recruitment end date

2023-10-31, 1402/08/09

Trial completion date

2023-10-31, 1402/08/09

Scientific title

Investigating the Efficacy of Respiratory Muscle Training on Balance and Gait Performance in Patients with severe COPD: A Randomized Controlled Trial

Public title

Improving Extrapulmonary Symptoms in COPD: Respiratory Muscle Training and Its Impact on Balance and Gait

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of smoking of more than 20 packs per year
Forced expiratory volume (FEV1) less than 80% of predicted, FEV1/forced vital capacity (FVC) ratio less than 0.7
predicted Physician diagnosis of COPD
Age over 40 years

Exclusion criteria:

Severe comorbidities or acute conditions that could potentially interfere with their existing health status
Medication that could potentially affect their exercise responses
Diagnosis of postural orthostatic hypotension
Neurological or musculoskeletal conditions that may contribute to falls and balance issues
Patients with exacerbations in the last 3 months or oxygen-dependent
Individuals with impaired vision

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **65**

Actual sample size reached: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomized to either an interventional group or a control group according to their moment of admission. The patients who were admitted to the study at the same time were assigned to different treatment groups. This method of randomization was used to ensure that the patients in the two groups were similar in terms of their time of admission, which could affect the outcome of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Comisia de Etică a Spitalului de Boli Infecțioase și Pneumoftiziologie Victor Babes Timisoara

Street address

Gheorghe Adam

City

Timisoara

Postal code

300310

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

3815

Health conditions studied**1****Description of health condition studied**

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes**1****Description**

Significant improvements in all variables after rehabilitation compared to the pre-rehabilitation values.

Timepoint

At admission and at 3 weeks

Method of measurement

Lung volumes and respiratory muscle strength were measured with a spirometer. Balance assessment was made with: Berg Balance Scale, Timed Up and Go test, Single Leg Stance test, Activities-specific Balance Confidence scale questionnaire. Functional exercise level was evaluated with the Six minutes walking test.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Hospital of Infectious Diseases and Pulmonology, Victor Babes Timisoara, Romania

Full name of responsible person

Crisan Alexandru Florian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Medicine and Pharmacy Victor Babes Timisoara

Proportion provided by this source

100

Public or private sector

Public

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

University of Medicine and Pharmacy Victor Babes Timisoara

Full name of responsible person

Crisan Alexandru Florian

Position

Lecturer

Latest degree

Ph.D.

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable