Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Galance 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 Crișan

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 Infectioase si 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
Street address
Gheorghe Adam nr. 13
City
Timisoara
Postal code
300310
Phone
+40 765 525 688
Email
crisan@umft.ro

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Medicine and Pharmacy Victor Babes Timisoara
Full name of responsible person
Crisan Alexandru Florian
Street address
Eftimie Murgu
City
Timisoara
Postal code
300041
Phone
+40 765 525 688
Email
crisan@umft.ro
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
Physiotherapy
Street address
Eftimie Murgu
City
Timisoara
Province
Timis
Postal code
300041
Phone
+40 765 525 688
Email
crisan@umft.ro

Person responsible for scientific 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
Physiotherapy
Street address
Eftimie Murgu
City
Timisoara
Province
Timis
Postal code
300041
Phone
+40 765 525 688
Email
crisan@umft.ro

Person responsible for updating data

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
Physiotherapy

Street address
Eftimie Murgu

City
Timisoara

Province
Timis

Postal code
300041

Phone
+40 765 525 688

Email
crisan@umft.ro

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