

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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.<sup>7</sup> 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

#### 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

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#### 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

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#### City

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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University of Medicine and Pharmacy Victor Babes  
Timisoara

**Full name of responsible person**

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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