Protocol Registration Receipt
06/22/2012

Muscle Training Effectiveness in the Degree of Dyspnea and Aerobic Capacity in COPD

This study is ongoing, but not recruiting participants.

Sponsor:	CES University
Collaborators:	La ceja Hospital
Information provided by (Responsible Party):	Nathalia Suarez, CES University
ClinicalTrials.gov Identifier:	NCT01452932

Purpose

Objective: To estimate the effectiveness of muscle training, the degree of dyspnea and aerobic capacity in patients over 50 with COPD, in a health care institution provider in Antioquia.

Question: What is the effectiveness of muscle training, in the degree of dyspnea and aerobic capacity in COPD patients over 50 years, in a health service institution provider in the department of Antioquia?

Hypothesis: Muscle training causes changes in the degree of dyspnea and aerobic capacity, other than the breathing exercises and relaxation

Design: Randomized clinical trial with allocation and blinding of the autcomes assesor.

Participants: COPD patients stage II and II, male and female, over 50 years old, who are attending to a community health service provider in the department of Antioquia.

Intervention: A physiotherapeutic intervention using PNF technique was applied to the experimental physiotherapy group versus Yoga sessions applied to the other group. Twelve weeks protocol performing three sessions per week.

Outcome measures: Dyspnea degree and aerobic capacity was measured using the MMRC scale and the six minute walking test respectively at the begining and the end of the study.

Condition	Intervention	Phase
Chronic Obstructive Pulmonary Disease Dyspnea	Physiotherapy Yoga	Phase 1/Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Single Blind (Outcomes Assessor), Randomized, Efficacy Study
Official Title: Muscle Training Effectiveness in the Degree of Dyspnea and Aerobic Capacity in COPD in an Institution Health Service Provider in the Department of Antioquia

Further study details as provided by Nathalia Suarez, CES University:

Primary Outcome Measure:

- Dyspnea degree [Time Frame: Up to 12 weeks] [Designated as safety issue: No]
  The degree of dyspnea is measured at baseline as one of the most important criteria for inclusion, after randomization of participants and past twelve weeks (duration of the intervention protocol) is measured this variable as a primary outcome.
- Aerobic capacity [Time Frame: Up to 12 weeks] [Designated as safety issue: No]
  Aerobic capacity is measured with the six minutes walking test (6MWT) at baseline as one of the most important criteria for inclusion, performed after randomization of participants and past twelve weeks (duration of the intervention protocol) is measured this variable as a secondary outcome.

Enrollment: 44
Study Start Date: June 2010
Estimated Study Completion Date: December 2012
Estimated Primary Completion Date: December 2012

Arms	Assigned Interventions
Experimental: Physiotherapy Group of participants who recive physiotherapy treatment using Kabat technique for the upper limbs resistance training during 12 weeks	Physiotherapy The physiotherapeutic intervention was based on the Kabat (PNF) technique. Thirty-three sessions were planed. Each session lasted between thirty and fifty minutes. The experimental group was guided by a physiotherapist or a physiotherapy student and each session took place in a hospital auditorium provided with oxygen cylinders, chairs and water. Each session consisted of a warm up and stretch period, a period of resistance training of the upper limbs with their rest periods in which diaphragmatic breathing exercises and finally a cooling period. The instructions and instruments given to each

Arms	Assigned Interventions
	participant such as weights and elastic bands were the same for all of them.
Yoga Group of participants who recive Yoga sessions during 12 weeks	Yoga The intervention for the other group was the Yoga technique. Thirty-six sessions were planed. Each session was based on breathing, relaxation, and stretching exercises. Each session lasted between thirthy and forty minutes. The group was led by a Yoga Instructor and each sessions took place in a hospital auditorium provided by oxygen cylinders, chairs and water. No instruments were needed for this intervention.

Chronic obstructive pulmonary disease (COPD) is defined by GOLD (The Global Initiative for Chronic Obstructive Lung Disease) as a disease process characterized by progressive airflow limitation associated with an abnormal inflammatory response of the lungs to particles or harmful gases and is not fully reversible. This restriction generates an expiratory flow of air entrapment resulting hyperinflation, coupled with the effects that systemic, structural changes occur in skeletal muscles which leads to greater fatigue causing dyspnea. Consequently, patients with COPD require participation of accessory muscles of respiration, which should have a dual function during activities involving the upper limbs, to supply the ventilatory requirements and movements of the shoulder girdle, which increases dyspnea carrying the patient to stop their activities, leading to physical deconditioning and progressively decreasing aerobic capacity. This demonstrates the need to improve the resistance of the upper limb muscles in these patients, thus contributing to a reduction in the degree of dyspnea and improved their aerobic capacity. The investigators propose a study aimed at determining the effectiveness of muscle training in the degree of dyspnea and aerobic capacity in COPD.

Eligibility

Ages Eligible for Study: 50 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Men and women over 50 years with a diagnosis of COPD stage II and III according to GOLD classification, performed spirometry
- Patients who manifest dyspnea on MRC
- Patients SGSS affiliates.
- COPD controlled, verified medical history
- Voluntary participation in informed consent

Exclusion Criteria:

- Higher mental functions altered
- Degenerative musculoskeletal diseases (acute state)
- Multisystem disease not controlled
- Perform a current fitness program

Contacts and Locations

Investigators

Principal Investigator:	Nathalia Suarez, Profesional	Professor CES University

More Information

Responsible Party:	Nathalia Suarez, Principal investigator, CES University
Study ID Numbers:	UCESCOPD
Health Authority:	Colombia: National Institutes of Health