ISRCTN14648515 https://doi.org/10.1186/ISRCTN14648515

Effectiveness of pulmonary rehabilitation: The role of interval and continuous endurance exercise training, lower and upper extremity strengthening and other intervention modalities

Submission date
30/01/2018

Recruitment status
No longer recruiting

Registration date
15/02/2018

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a group of common lung conditions that cause breathing difficulties. It often has multiple diseases or disorders that occur alongside it, called comorbidities. Specialised exercise and education programmes (pulmonary rehabilitation) are an intervention that is used for COPD patients who still have symptoms, despite pharmaceutical treatment. This study aims to examine the effect of a pulmonary rehabilitation program on comorbidities in COPD patients.

Who can participate?
Adults aged 49-76 years with stable chronic obstructive pulmonary disease (COPD)

What does the study involve?
Participants undergo clinical examination, blood gas analysis and lung function tests. Shortness of breath and breathing difficulty (dyspnea) and quality of life are measured. Two exercise tests (the six minute walking test and incremental cardiopulmonary exercise test) are carried out to measure work rate, airflow, heart rate and the amount of oxygen in the blood and expired air. After the initial assessment, participants start an individualized rehabilitation program, at the Pulmonary Rehabilitation Department of Sotiria Hospital, twice a week, for a period of 13 weeks. The program includes interval, endurance exercise training using exercise bikes, continuous endurance exercise training using treadmill, and lower and upper extremity strengthening exercise training-conditioning using mainly weight lifting, breathing retraining, respiratory muscle training, education, diet and psychological support. Other important interventions that are stressed during the program include smoking cessation, oxygen therapy, and use of bronchodilators, antibiotics and nutritional support. At the end of the 13 week period of training, participants are reassessed using the same testing protocol.

What are the possible benefits and risks of participating?
Benefits include potential improvement to the participant’s health. The only risks are common

risks associated with exercise, however these are minimized as the study takes place in a hospital.

Where is the study run from?
National and Kapodistrian University of Athens School of Medicine (Greece)

When is the study starting and how long is it expected to run for?
November 2012 to December 2014

Who is funding the study?
Exercise Physiology Laboratory (Greece)

Who is the main contact?
Dr Pantelis Nikolaidis
pademil@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Pantelis Nikolaidis

ORCID ID
http://orcid.org/0000-0001-8030-7122

Contact details
Exercise Physiology Laboratory
Thermopylon 7
Nikaia
Greece
18450

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Subjective and objective outcomes in patients with COPD after pulmonary rehabilitation - The impact of comorbidities

Study objectives
The aim of the present study was to further evaluate pulmonary rehabilitation outcomes focusing on QOL, dyspnea and aerobic capacity (expressed by both 6MWT and VO2peak) in stable COPD patients with comorbidities, in terms of specific conditions and total number.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of National and Kapodistrian University of Athens School of Medicine Alexandra Hospital of Athens, 01/09/2012, ref: EPL/9/12

Study design
Interventional non-randomised two arm study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Comorbidities in chronic obstructive pulmonary disease.

Interventions
Participants are allocated to one of two groups, according to the presence or the absence of comorbidities. Patients with none or only one comorbidity (n=11, Group 1) are compared to those who have two or more comorbidities (n=21, Group 2), in terms of dyspnea, quality of life (QOL) and exercise capacity, before and after a pulmonary rehabilitation program, twice a week, for 13 weeks.
At baseline, each participant undergoes clinical examination, arterial blood gases analysis and Pulmonary Function Tests (PFTs): spirometry (pre/post bronchodilation), diffusing capacity and static lung volumes. Dyspnea and QOL are assessed. Six minutes walking test (6MWT) and standard cardiopulmonary exercise test are also carried out, while breathing room air. Expiratory oxygen and carbon dioxide fractions, work rate, airflow, cardiac frequency and oxygen saturation are continuously recorded.
The results are obtained
1. At rest
2. After 1 min of unloaded exercise
3. During incremental exercise

The incremental rate is 25 Watts per minute and the pedaling frequency is constant at 60 revolutions per minute. Each participant exercises against progressive workloads up to symptom-limited, maximum exercise capacity.

After the initial assessment, each participant starts an individualized rehabilitation program, at the Pulmonary Rehabilitation Department of Sotiria Hospital, twice a week, for a period of 13 weeks. The program includes interval, endurance exercise training using cycloergometers, continuous endurance exercise training using treadmill, and lower and upper extremity strengthening exercise training-conditioning using mainly weight lifting, breathing retraining, respiratory muscle training, education, diet and psychological support. Other important therapeutic modalities that are stressed during the program include smoking cessation, oxygen therapy, and use of bronchodilators, antibiotics and nutritional support. At the end of the 13 week period of training, the participants are reassessed using the same testing protocol.

Intervention Type
Behavioural

Primary outcome measure
1. Arterial blood gases are measured and analysed using the GEM premier 3500 blood gas analyser at baseline and after 13 weeks
2. Pulmonary function is measured using Pulmonary Function Tests (spirometry, diffusing capacity and static lung volume) at baseline and after 13 weeks
3. Dyspnea is assessed using the modified Medical research Council (MRC) scale and the COPD Assessment Test at baseline and after 13 weeks
4. Quality of Life is assessed by the St George Respiratory Questionnaire (SGRQ) at baseline and after 13 weeks

Secondary outcome measures
1. Expiratory oxygen and carbon dioxide fractions are measured using the six minute walking test (6MWT) and standard cardiopulmonary exercise test at baseline and after 13 weeks
2. Work rate is measured using the six minute walking test (6MWT) and standard cardiopulmonary exercise test at baseline and after 13 weeks
4. Airflow is measured using the six minute walking test (6MWT) and standard cardiopulmonary exercise test at baseline and after 13 weeks
5. Cardiac frequency is measured using the six minute walking test (6MWT) and standard cardiopulmonary exercise test at baseline and after 13 weeks
6. Oxygen saturation is measured using the six minute walking test (6MWT) and standard cardiopulmonary exercise test at baseline and after 13 weeks

Overall study start date
01/11/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. COPD diagnosis of any stage (A, B, C, D)
2. Aged 49-76 years
3. Stable condition

4. Optimal bronchodilation therapy
5. Optimal therapy of comorbidities
6. Reduced exercise capacity
7. Full compliance to the rehabilition program and recommendations

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Total final enrolment
32

Key exclusion criteria
1. Active or unstable cardiovascular disease (within three months: myocardial infarction, severe uncontrolled arrhythmia, symptomatic or unstable cardiovascular disease, severe heart valve disease or severe heart failure)
2. Pulmonary embolism in the last three months
3. Ischemic cardiovascular stroke or hemorrhagic stroke in the last three months
4. Non-controlled arterial hypertension
5. Large abdominal aortic aneurysm
6. Severe orthopaedic disorders
7. Severe osteoporosis
8. Any condition that does not allow the performance of aerobic exercise
9. Severe dementia
10. Severe untreated psychiatric conditions
11. Unwilling, undisciplined patient who does not comply with medical recommendations

Date of first enrolment
01/03/2013

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Greece

Study participating centre
National and Kapodistrian University of Athens School of Medicine
Alexandra Hospital of Athens

Athens
Greece
18450

Sponsor information

Organisation
Exercise Physiology Laboratory

Sponsor details
Thermopylon 7
Nikaia
Greece
18450

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Exercise Physiology Laboratory

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/04/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Pantelis Nikolaidis at pademil@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/03/2019	23/11/2020	Yes	No