A study evaluating the effects of a structured lifestyle intervention on daily physical activity level of COPD patients in the first, second and third echelon.

Published: 14-08-2006
Last updated: 20-05-2024

The aim of the study is to investigate the effects of a structured lifestyle program (in the first, second and third echelon) on the physical activity level of COPD patients

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON30446

Source
ToetsingOnline

Brief title
COACH in COPD patients

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Lifestyle, Pedometer

Outcome measures

Primary outcome

Daily physical activity (steps/ day)

Secondary outcome

Personal characteristics, Body Mass Index, Fat Free Mass, lung function (FEV1), physical fitness (arm strength, leg strength, respiratory muscle strength, 6MWT), COPD related costs, ADL activities, type of activity, attitude towards physical activity, health status, physical fitness, psychological factors (self-efficacy, depression), quality of life, fatigue.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is increasing in the Netherlands. The incidence of COPD is about 2-3 per 1000 and the prevalence of 12-19 per 1000 patients in the Dutch primary health care. The World Health Organization (WHO) states that its prevalence in 2020 will be on the fourth rank of death and the fifth rank of causes of disability-adjusted life years lost worldwide. COPD is characterized by a deterioration of lung function, a lowering physical activity level and a low state of quality of life.

Study objective

The aim of the study is to investigate the effects of a structured lifestyle program (in the first, second and third echelon) on the physical activity level of COPD patients

Study design

It concerns a randomized controlled study. In this study a structured lifestyle program will be compared with usual care in the first, second and third echelon

of the health care.

Intervention

A structured lifestyle program, based on the COACH method, will be used. This method was developed by the Institute of Human Movement Sciences of the University of Groningen (RUG). Using COACH, patients will be stimulated individually to enhance a physically active lifestyle.

Study burden and risks

According to the study protocol patients in the experimental group and the control group participate in five measurement sessions. In each assessment a physical fitness test, lung function, questionnaires is taken. Total duration of the assessments is about 7 hours and 45 minutes. Al participants use a pedometer. Patients of the experimental group participate in three individual counseling sessions (total duration 90 minutes) and one telephonic counseling (15 minutes) as well. As a result of the type of assessments used, the study has a very low risk profile.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 40-80 years,
COPD GOLD stage I-IV,
written informed consent.

Exclusion criteria

Comorbidity, like cardiovasculair problems, serious limitations in neuromuscular performance and exacerbations in the previous two months, which can effect the outcome of the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	14-08-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-03-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12651.042.06