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Study of the effects of self-treatment and an exercise program within a self-management program in outpatients with chronic obstructive pulmonary disease (COPD): the COPE II-study

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
21/07/2015

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR325; Astma Fonds: 3.4.02.12; MEC:P04-13

Study information

Scientific Title
Study of the effects of self-treatment and an exercise program within a self-management program in outpatients with chronic obstructive pulmonary disease (COPD): the COPE II-study

Acronym
COPE II

Study objectives
A self-management program including self-treatment of exacerbations, leads to a reduction in the severity and duration of exacerbation compared to a similar self-management program without these self-treatment guidelines in hospital out-patients with chronic obstructive pulmonary disease (COPD) after one year and after two years. A self-management program including a COPE-active program, has an additional effect on functional exercise performance compared to a similar program without this COPE-active program in hospital out-patients with COPD after one year and after to years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised active-controlled factorial trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
The study will be divided into two periods. During the first three-month period, smokers motivated to quit are offered an intensive smoking cessation program. In the second phase, all patients will be ordered over four groups: A1, A2, B1 and B2, according to a two by two factorial design. The division of 200 patients over the four study groups will be done with the help of a balancing program. Potential confounders such as smoking status, gender, lung function,

participation in physiotherapy programs and the use of inhaled corticosteroids will be balanced over the four groups. After division, all patients will receive a self-management program (four group sessions of two hours and several phone calls made by a respiratory nurse). During the self-management program, only the patients in the groups A1 and B1 will learn to treat themselves in case of an exacerbation. This will be done with help of individual guidelines for self-treatment of exacerbations (action plans). After the last group session of the self-management program, patients in the groups A1 and B1 will be obliged to participate in an intensive physical exercise program (COPE-active) program for six months, which can be continued until a maximum of eleven months.

Intervention Type
Behavioural

Primary outcome measure
1. Effect of self-treatment within a self-management program: duration and severity of the exacerbations. Measured by daily diaries which are filled out by all the patients during the total length of the study.
2. Effect of an exercise program within a self-management program: Functional exercise capacity: Shuttle Walk Test

Secondary outcome measures
1. Quality of life: Chronic Respiratory Questionnaire (CRQ) (Self-Administered Standarised version)
2. Health Status: Clinical COPD Questionnaire (CCQ)
3. Social Support: Social Support List (SSL-12)
4. Anxiety and depression: Hospital Anxiety and Depression Scale (HADS)
5. Self-Efficacy: Self-Efficacy list
6. Dypnoe Medical Research Council Scale
7. Lung function: FEV1, FEV1/inspired vital capacity (IVC), FEV1/forced vital capacity (FVC)
8. Percentage of Fat Free Mass: Bioelectrical Impedance Measurements
9. Utilities: Euroqol 5D + Visual Analogue Scale (VAS)
10. Activity at home: Pedometers
11. Costs: Program costs, Direct medical costs (e.g the number of hospitalisations, emergency room visits, doctor consultations, and the medication used for COPD), direct non-medical costs (e.g. travel costs), indirect costs (e.g. lost productivity including usual daily activities and time costs borne by the individual)
12. Number of patients who quitted the COPE-active program: during the first 6 months, after the 6th month
13 Adverse events: co-morbidity, social events, etc.

Overall study start date
01/11/2004

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Forced expiratory volume in one second (FEV1) between 25% and 80% of the predicted value
2. Three or more exacerbations or one hospitalisation in the two years preceding study entry

3. A signed and dated written informed consent from the subject prior to study participation
4. Patients of the outpatient clinic of the Medisch Spectrum Twente
5. Aged between 40 and 75 years
6. A clinical diagnosis of COPD as defined by the GOLD-criteria
7. Stable and well controlled COPD, at least one month before inclusion
8. Current smoker or ex-smoker
9. Able to understand, read and write Dutch

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Serious other disease with a low survival rate
2. Other disease which influences bronchial symptoms and/or lung function (e.g. cardiac insufficiency, sarcoïdosis)
3. Severe psychiatric illness
4. A disregulation of diabetes mellitus during an exacerbation in the past or a hospitalisation for diabetes mellitus in the two years preceding the study
5. Need for regular oxygen therapy
6. Maintenance therapy with antibiotics
7. Known alpha1 antitrypsine deficiency
8. Disorders or progressive diseases, which influence seriously the ability to walk (e.g. amputation, paralysis, progressive muscle diseases)

Date of first enrolment
01/11/2004

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Medisch Spectrum Twente
Enschede
Netherlands
7500 KA

Sponsor information

Organisation
Medisch Spectrum Twente (Netherlands)

Sponsor details
P.O. Box 50000
Enschede
Netherlands
7500 KA

Sponsor type
Hospital/treatment centre

Website
http://www.ziekenhuis-mst.nl/

ROR
https://ror.org/033xvax87

Funder(s)

Funder type
Charity

Funder Name
Astmafonds (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2011		Yes	No
Results article	results	01/10/2014		Yes	No