ISRCTN99715969 https://doi.org/10.1186/ISRCTN99715969

Immediate in-hospital reactivation of patients with an exacerbation of Chronic Obstructive Pulmonary Disease (COPD): Pulmofit-MST

Submission date 13/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/01/2008	**Overall study status** Completed	
Last Edited 07/01/2008	**Condition category** Respiratory	

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
NT1101

Study information

Scientific Title

Acronym
PULMOFIT-MST

Study objectives
Chronic Obstructive Pulmonary Disease (COPD) is a major cause of disability and mortality worldwide. Morbidity and mortality among COPD-patients are strongly related to acute exacerbations of COPD, which can be defined as sustained worsening of the patients condition, from stable state and beyond normal day-to-day variations, that is acute in onset and may warrant additional treatment in a patient with underlying COPD. Severe exacerbations may lead to hospital admissions and have a major impact on disease evolution and costs.

Pulmofit-MST, an immediate reactivation programme, will induce a reduction of the length of stay in the hospital, by preventing loss of peripheral muscle force and exercise capacity and thereby initiating a faster recovery of activities of daily living.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee (Medisch Etische Toetsingscommissie Medisch Spectrum Twente) on the 16th January 2006 (ref: P06-05).

Study design
Randomised, active controlled, parallel group, two armed 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 protocol of the programme aimed at an active role of COPD-patients during their stay in the hospital. Patients in the intervention group were asked to perform three daily training sessions

of 15 minutes each. One daily session was assisted by a physiotherapist, while the other two had to be performed by the patients themselves.

PULMOFIT-MST consists of four levels of increasing difficulty. Within four hours after admission, level I was started by the nurse who distributed the workbook with the description of all exercises and who instructed the first exercises to the patient. Within 24 hours after admission, the physiotherapist visited the patient and continued the programme by choosing the appropriate follow-up level and determining the intensity of the exercises. Every day the physiotherapist evaluated the exercises and the appropriateness of the training level and training intensity. A workbook functioned as a daily diary in which the intensities of training exercises were noted by the physiotherapist and daily experiences and improvements by the patient. All disciplines (chest physicians, nurses, and physiotherapists) stimulated patients to perform all three daily PULMOFIT-MST sessions.

Patients in the control group received usual care, meaning treatment the patients would have received prior to this study.

The duration of the treatment depends on the length of the hospitalisation. Patients of the intervention group are treated according to the PULMOFIT-MST protocol during the whole hospitalisation period.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Length of hospital stay, defined as number of days between day of admission and day of medical discharge. Day of medical discharge was distinguished from the actual day of discharge because some patients remain in hospital longer than medically necessary (e.g. patients could not yet be referred to a nursing home).

Secondary outcome measures
1. Walking distance (3 minutes walking test)
2. Dyspnoea (Borg scale)
3. Health status (Clinical COPD Questionnaire)
4. Activities of daily living (Barthel Index)
5. Readmissions due to a COPD-exacerbation (less than 28 days), measured at 28 days

Measurements take place at the day of admission, day 4 and the day of medical discharge.

Overall study start date
01/02/2006

Completion date
01/02/2007

Eligibility

Key inclusion criteria

1. A clinical diagnosis of COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria
2. A clinical diagnosis of an exacerbation of COPD for which hospitalisation was required
3. (Ex-) smoker
4. Age above 40 years
5. A life expectancy of at least 3 months
6. Able to understand and read Dutch
7. An informed consent from the subject prior to participation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Pneumonia
2. Fever (greater than 38.5°C)
3. Severe confusion
4. Severe heart failure, New York Heart Association (NHYA) class III or IV
5. Relevant co-morbidity seriously influencing mobility

Date of first enrolment
01/02/2006

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Haaksbergerstraat 55
Enschede
Netherlands
7513 ER

Sponsor information

Organisation
Dutch Asthma Foundation (The Netherlands)

Sponsor details
Postbus 5
Leusden
Netherlands
3830 AA

Sponsor type
Charity

ROR
https://ror.org/00ddgbf74

Funder(s)

Funder type
Charity

Funder Name
Dutch Asthma Foundation (The 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