Immediate in hospital reactivation of patients with an exacerbation of COPD: Pulmofit-MST

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26882

Source
Nationaal Trial Register

Brief title
PULMOFIT-MST

Health condition

1. COPD;

2. exacerbation;

3. reactivation;

4. physiotherapy;

5. hospitalisation;

6. exercise;

7. length of hospital stay;

8. walking distance;

9. activities of daily living;

10. health status.

COPD, exacerbatie, reactivatie, fysiotherapie, ziekenhuisopname, beweging, opnameduur, loopafstand, ADL-activiteiten, kwaliteit van leven.

Sponsors and support

Primary sponsor: Medisch Spectrum Twente Enschede
Source(s) of monetary or material Support: Astma Foundation (COPE II-studie)

Intervention

Outcome measures

Primary outcome

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

Walking distance (3 minutes walking test), dyspnoea (BORG-scale), health status (Clinical COPD Questionnaire), activities of daily living (Barthel Index), and readmissions due to a COPD-exacerbation (<28 days).

Study description

Background summary

Little is known about effects of immediate reactivation in COPD-patients hospitalized for an acute exacerbation. In a semi-randomised trial, the effects of an immediate reactivation programme (PULMOFIT-MST) on length of stay in the hospital will be evaluated.

Directly after admission patients are allocated to an intervention (n=40) or control ward (n=40). All patients receive usual care. In addition, intervention patients receive PULMOFIT-MST. The protocol of the programme aims at an active role of COPD-patients during their stay in the hospital. Patients are asked to perform three daily training sessions of 15 minutes each. One daily session is assisted by a physiotherapist, while the other two have to be

performed by the patients themselves.

We developed an immediate reactivation programme, entitled PULMOFIT-MST, which can hypothetically 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. We will evaluate the effect of the programme on length of hospital stay. Secondary outcome measures are: changes in walking distance, activities of daily living, dyspnoea, quality of life, and number of readmissions within 28 days.

Study objective

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.

Study design

All patients had to undergo measurements on day 0, day 4 and day of medical discharge.

Intervention

The protocol of the programme aimed at an active role of COPD-patients during their stay in the hospital. Patients 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 conrol group received usual care, meaning treatment the patients would have received prior to this study.

Contacts

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Eligibility criteria

Inclusion criteria

1. a clinical diagnosis of COPD according to the 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.

Exclusion criteria

1. pneumonia;

2. fever (>38.5 C°);

3. severe confusion;

4. severe heart failure; NHYA class III or IV;

5. relevant co-morbidity seriously influencing mobility.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2006
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	18-10-2007
Application type:	First submission

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
NTR-new	NL1068
NTR-old	NTR1101
Other	METC : PO06-05
ISRCTN	ISRCTN99715969

Study results

Summary results
N/A