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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26882

Bron
Nationaal Trial Register

Verkorte titel
PULMOFIT-MST

Aandoening

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.

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente Enschede
Overige ondersteuning: Astma Foundation (COPE II-studie)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2006
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	18-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1068
NTR-old	NTR1101
Ander register	METC : PO06-05
ISRCTN	ISRCTN99715969

Resultaten

Samenvatting resultaten
N/A