A longitudinal prospective multicentre cohort study on the effect of Geriatric Rehabilitation in patients with severe COPD admitted to the hospital with an acute exacerbation

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Geriatric rehabilitation in patients with severe COPD, admitted to the hospital with an acute exacerbation, will improve health status and decrease the exacerbation frequency and hospital admissions in comparison to patients who do not receive this...

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

Samenvatting

ID

NL-OMON27813

Bron
Nationaal Trial Register

Verkorte titel
GR-COPD

Aandoening

Geriatric Rehabilitation, COPD, health status, post-acute pulmonary rehabilitation, functional status, cost-effectiveness

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: 1. Zorggroep Solis, Deventer, The Netherlands
2. Stichting Achmea Gezondheidszorg (SAG), projectcode Z614

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1.Health status as measured by the Clinical COPD Questionnaire (CCQ); delta-CCQ during follow-up , compared between GR-COPD intervention group and usual care.
2. Functional status as measured by the 6-minute walking test (6MWT); delta-6MWT during follow-up, compared between GR-COPD intervention group and usual care.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In view of the worldwide aging population, disease-specific geriatric rehabilitation (GR) programs are needed. One field in which development of disease-specific GR programs can be meaningful is progressive organ failure, such as chronic obstructive pulmonary disease (COPD). Prevalence of COPD is rising worldwide and disease severity is strongly related to age. Patients with advanced COPD suffer from a high symptom burden, deteriorating functional capacity and declining quality of life; moreover, their prognosis is poor, especially after hospital admission for an acute exacerbation. Therefore, we developed and implemented a post-acute GR program for patients with severe COPD, the GR-COPD program. We then conducted a pilot study to investigate the feasibility of the GR-COPD program and to present clinical data on patient characteristics and course of functional capacity and health status. Furthermore, we investigated the outcomes of the Clinical COPD Questionnaire (CCQ) and related (change in) health status to lung function, degree of dyspnea and (change in) functional capacity. We concluded that post-acute GR is feasible and likely to offer substantial improvements in health status and functional capacity and that health status measured by the CCQ is sensitive to change this specific group of patients.

Objective: To determine the (cost) effectiveness of the GR-COPD program in patients with severe COPD admitted to the hospital with an acute exacerbation.

Study design: A longitudinal prospective multicentre cohort study

Study population: Patients diagnosed with severe COPD and admitted to the hospital with an

acute exacerbation. Furthermore, patients need to have an indication for rehabilitation based on a set of standard major and minor criteria. Patient who suffer from conditions interfering with rehabilitation, such as: end-stage disease, a major psychiatric or cognitive disease or insufficient mastery of Dutch language, are excluded from participation.

Setting: This study is being conducted on the pulmonary department of two local hospitals in the Netherlands.

Intervention: The intervention group receives the GR-COPD program. The GR-COPD program consists of a multidisciplinary inpatient rehabilitation program and contains several modules concerning different aspects of rehabilitation: optimizing pulmonary medication use, compliance and inhalation techniques, physiotherapy (endurance, strength and inspiratory muscle training), occupational therapy, support of smoking cessation, nutritional analysis and advise, analysis of speech and breathing techniques, psychosocial intervention, education and peer support contact.

Main study parameters/endpoints:

Effect evaluation:

-Improvement in health and functional status as measured by the CCQ and the 6MWT.

-Reduction of the number of COPD exacerbations and number of hospital admissions and in-hospital-days as a result of COPD exacerbations.

Process evaluation: Within the framework of the process evaluation, fidelity; completeness; exposure; satisfaction; reach; recruitment and context will be evaluated by quantitative and qualitative analysis.

Economic evaluation: Cost analysis (from a healthcare perspective) and cost-utility analysis (comparing healthcare costs to Quality-Adjusted Life Years).

Statistical analysis

To balance potential confounders between patients in the intervention (GR-COPD) and the usual care group of this study, we will estimate the propensity score (PS). To estimate the PS we identified potential confounders based on subject matter knowledge and will include the following variables in the PS: age, sex, marital status, lung-function (FEV1%pred), short-term oxygen therapy (STOT), exacerbation-frequency (Ex-freq) in year before admission, co-morbidity (CCI-score), smoking status, functional status (BI), nutritional status (BMI, FFMi),

psychosocial functioning (HADS) and hospital location. All variables that are included in the PS are measured before treatment initiation (Indication-phase of the study). We then analysed distribution of all variables included in the PS within the dataset of the first 47 included patients. We will then estimate the PS (probability of receiving rehabilitation) for all individuals included in the dataset using a logistic model that includes 27 variables. Prior to data-analysis, continuous variables will be modelled in categorical variables when clinically relevant according to literature and when possible (not leading to instability), and when relation is not linear. We will consider the following clinically plausible interaction: sex vs marital status. In the third step the PS model will be evaluated using the standardized mean difference (SMD) to assess balance in potential confounders between the intervention and control groups with similar PS values. Distribution of the PS between treated and untreated groups will be examined by plotting histograms to assess extend of overlap. PS weighting technique will be used to estimate the treatment effect, as measured by the delta-CCQ. We will consider stratification methods as well. Primary analysis: intervention versus control group. Secondary analysis: Intervention versus several subgroups in control group; GR-general; Home-based-therapy; no therapy. Subgroup-analysis considering de two locations will not be performed because this was entered into the PS.

Doel van het onderzoek

Geriatric rehabilitation in patients with severe COPD, admitted to the hospital with an acute exacerbation, will improve health status and decrease the exacerbation frequency and hospital admissions in comparison to patients who do not receive this rehabilitation program.

Onderzoeksopzet

- Baseline measurements (T0): first week of admission to the hospital

- Follow up 1: 3 months after T0

- Follow up 2: 6 months after T0

- Follow up 3: 9 months after T0

- Follow up 4: 12 months after T0

Onderzoeksproduct en/of interventie

The control group receives care as usual. The intervention group receives the GR-COPD program. The GR-COPD intervention consists of a multidisciplinary inpatient rehabilitation program and contains several modules concerning different aspects of rehabilitation: optimizing pulmonary medication use, compliance and inhalation techniques, physiotherapy (endurance, strength and inspiratory muscle training), occupational therapy, support of smoking cessation, nutritional analysis and advise, analysis of speech and breathing techniques, psychosocial intervention, education and peer support contact.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Main inclusion criteria:

- Diagnosed with severe COPD

- Admitted to the hospital with an acute exacerbation

- Indication for rehabilitation: this is based on the presence of 2 major, or 1 major and 2 minor criteria.

Major criteria:

1. Decline of functional status (ADL, iADL)

2. Health status is severely impaired, as measured by the Clinical COPD Questionnaire (CCQ), score > 2,0

3. Frequent exacerbations; ¡Ý 2 in the last 6 months (excluding the present exacerbation)

Minor criteria:

1. Hypoxaemia (excluding pre-existent long-term oxygen treatment (LTOT))

2. Impaired nutritional status: body mass index (BMI)<21 kg/m2 and/or fat-free-mass- index (FFMi) depletion

3. Patients at risk for clinically relevant anxiety disorder or depression; hospital anxiety and depression score (HADS)>7 on either subscale

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

The patient has a condition interfering with rehabilitation, such as:

1. End-stage disease

2. A major psychiatric or cognitive disease

3. Insufficient mastery of Dutch language

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-01-2017
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	NL6122
NTR-old	NTR6261
Ander register	Commissie Medische Ethiek (CME) LUMC, Leiden : P14.248

Resultaten

Samenvatting resultaten

1. Dam van Isselt EF van, Groenewegen-Sipkema KH, Spruit-van Eijk M, Chavannes NH, Achterberg WP. Geriatric rehabilitation for patients with advanced COPD: programme characteristics and case studies. International journal of palliative nursing 2013;19(3):141-6.
2. Dam van Isselt EF van, Groenewegen-Sipkema KH, Spruit-van Eijk M, Chavannes NH, Achterberg WP. Geriatric rehabilitation for patients with advanced COPD; a naturalistic prospective cohort study on feasibility and course of health status. Chronic Respiratory Disease 2014 11: 111.
3. Dam van Isselt EF van, Groenewegen-Sipkema KH, Spruit-van Eijk M, Chavannes NH, Achterberg WP. Health status measured by the Clinical COPD Questionnaire (CCQ) improves following post-acute pulmonary rehabilitation in patients with advanced COPD. Prim Care Resp J. npj Primary Care Respiratory Medicine (2014) 24, Article number: 14007; doi:10.1038/npjpcrm.2014.7; published online 20 May 2014.
4. Dam van Isselt EF van, Groenewegen-Sipkema KH, Spruit-van Eijk M, Chavannes NH,

Janssen DJ, Achterberg WP. Pain in patients with COPD; a systematic review and meta-analysis. BMJ Open 2014;4:e005898.