Self-Management And Telemedicine in patients with COPD and chronic Heart failure.

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During this pilot study, we intend to investigate the feasibility of a home-based patient-tailored telemedicine self-management intervention for patients with COPD and chronic heart failure over a 4-month period.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON46744

Source
ToetsingOnline

Brief title
MATCH study

Condition

- Heart failures
- Bronchial disorders (excl neoplasms)

Synonym
Chronic obstructive pulmonary disease (COPD); Chronic Obstructive Airway Disease/ chronic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Pioneers In Health Care Innovation Fund 2016

Intervention

Keyword: COPD, heart failure, self-management, telemedicine

Outcome measures

Primary outcome

Main study endpoints are the satisfaction of patients with and adherence to (the different components of) the telemedicine self-management interventions. Also, motivation of patients and health care providers to use the self-management platform is one of the main study endpoints. Semi-structured interviews with patients and case managers will be performed for a qualitative evaluation of these endpoints. Other assessments of satisfaction will be the Client Satisfaction Questionnaire and the rating of satisfaction by using a four-point scale. Adherence to the different components of the telemedicine self-management intervention will be assessed by the frequency and time that patients use the different modules of the platform, the number of diary completion and the frequency of acting according to action plans.

Secondary outcome

Secondary endpoints are: 1) the added value of the laboratory test NTproBNP to differentiate between dyspnoea caused by exacerbations of COPD or of heart failure during this self-management intervention (frequency of measuring NTproBNP and frequency of treatment change according the NTproBNP, 2) inhaler technique and patients* adherence to inhalation medication by using sensorised inhalers and 3) improvement of inhaler technique and adherence after feedback

(by measuring and comparing these variables at the first, sixth and last week

of the study). We will assess the effects of the intervention on quality of

life by using questionnaires.

Study description

Background summary

COPD is a very common progressive lung disease with distressing COPD exacerbations that accelerate the rate of lung function decline and thereby cause a decrease in health status, activity and quality of life. COPD self-management interventions are shown to have beneficial effects on health-related quality of life, reduction of respiratory-related hospitalisations and improvement of dyspnoea. Action plans for the self-treatment of COPD exacerbations are an intrinsic component of self-management programs. In the COPE-III study, a multi-centre randomized controlled trial, patient tailored action plans for the early self-treatment of deteriorating symptoms of COPD and comorbidities were developed. Positive effects on COPD exacerbation duration and respiratory-related hospitalisation rate were seen. Incorporating this self-management intervention in a home-based digital platform with an avatar for personalized feedback may improve the applicability of self-management interventions and could make it more patient-tailored. It may lead to earlier recognition of worsening of symptoms and quicker initiation of treatment because real time monitoring and prompt feedback is possible. Because of these factors, the use of telemedicine may improve the effectiveness of self-management interventions on health outcomes.

Study objective

During this pilot study, we intend to investigate the feasibility of a home-based patient-tailored telemedicine self-management intervention for patients with COPD and chronic heart failure over a 4-month period.

Study design

During this study, we will extend an existing COPD self-management telemedicine platform that will include an automated decision support system of action plans for exacerbations of COPD, heart failure and other comorbidities (ischemic heart disease, anxiety, depression, diabetes). These action plans were proven effective in the COPE-III study.

Intervention

First, patients will participate in three self-management courses. During the use of the telemedicine self-management intervention (follow-up), patients will complete their symptom diary every day. In case of symptom deterioration, the telemedicine platform will automatically launch the action plan that indicates what action should be taken (e.g., take prednisolone/antibiotics/furosemide). Furthermore, NTproBNP will be tested in case of doubts whether increased dyspnoea is caused by COPD or heart failure. Sensorised inhalers will be used to monitor patients* inhaler technique and adherence. An avatar will give personal feedback and reminders on patients* diary completion, action plan use and use/technique of inhalers and will motivate patients to use the different modules of the telemedicine platform.

Study burden and risks

The risk for adverse events due to participation in this study is negligible. Patients will receive their usual care (e.g., by visits to their pulmonologist and/or cardiologists) during the study. There is a chance that the patients who self-treat their symptoms will use more medication then necessary, however, in other studies on self-treatment of COPD patients (e.g COPE-III study), this was not an issue. The telemedicine self-management intervention will be used by health care providers with knowledge about and experience with COPD, heart failure, self-management and inhalers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- A clinical diagnosis of COPD according to the GOLD 2017 criteria (Forced Expiratory Volume in one second (FEV1) < 80% of the predicted value and FEV1/Vital Capacity (FVC) < 0.70
- Chronic Heart Failure (CHF) defined according to the current (2016) ESC guidelines
- * 2 COPD and/or CHF exacerbations* and/or *1 hospitalisation for COPD and/or CHF in the two years preceding study entry
- * 40 years of age
- At least 1 week after prednisolone/antibiotics/furosemide course. At least 1 week after hospitalisation. At least 4 weeks post-rehabilitation.
- Able to understand and read the Dutch language
- Able to use a tablet
- Written informed consent from the subject prior to participation.

Exclusion criteria

- Terminal cancer or the end stage of another serious disease;
- Other serious lung disease (e.g. 1-antitrypsin deficiency; interstitial lung diseases);
- Expected cardiovascular intervention within three months.
- Being currently enrolled in randomized controlled trials or trial with study medication
- Waiting for a heart or lung transplantation
- Receiving of renal dialysis
- Diabetes Mellitus type I
- HADS (Hospital Anxiety and Depression Scale)-score of * 11 for depression and/or anxiety

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	MATCH telemedicine self-management intervention
Registration:	No

Ethics review

Approved WMO Date:	18-10-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	03-11-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-07-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
CCMO	NL62299.044.17

Study results

Date completed:	08-05-2019
Actual enrolment:	12