CoCo in COPD treatment: Evaluation of use, satisfaction and clinical effects.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21635

Source
Nationaal Trial Register

Brief title
CoCo COPD

Health condition

COPD
Telemedicine
Self-management
Physical Activity

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: Zorginnovatieplatform

Intervention

Outcome measures

Primary outcome

The CoCo application will be evaluated among patients in terms of use of the application (registered by system), satisfaction with the application, satisfaction with received care, and

quality of care.

Secondary outcome

Outcome measures to evaluate the clinical effects are: Exacerbations (number, duration), amount of activity, exercise tolerance, fatigue, health status and symptoms, and quality of life.

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a chronic, progressive lung disease. The prevalence and associated costs of COPD are projected to increase the upcoming decades. The treatment of COPD aims to reduce risk factors, prevent disease progression and manage exacerbations. Physiotherapy, increasing physical participation in daily activities, and early detection and treatment of exacerbations are important elements of COPD treatment to achieve these goals, besides medication and smoking cessation. For optimization of COPD treatment, the treatment programme should be individually based, and is therefore time- and labour intensive for the patient and the professional.

Home-training programs and self-management of exacerbations have proven to be effective new treatment methods. If these programmes are offered as a telemedicine application, they could contribute to a reduction in labour and costs.
Therefore, the telemedicine application CoCo (ConditionCoach) will be used in the COPD treatment after summer. CoCo supports the treatment of COPD patients through active self-management and promotion of an active lifestyle. The healthcare professional can supervise from a distance. To justify the implementation of the CoCo application in the regular treatment program (on the long term) and to allow further scaling, evaluation of the deployment of the CoCo application is important. the primary objective of this study is to evaluate the CoCo application in the regular treatment of the MST and associated physiotherapy practices. We will investigate the use of the application, the application satisfaction, satisfaction of care and quality of care. The secondary aim of this study is to explore the clinical changes of the CoCo application in the regular treatment on the health status of the patient. It is expected that the deployment of the application will have at least similar effects on the patient¡¯s health (compared to the regular treatment program without using CoCo). In a randomised study, the deployment of the CoCo application will be evaluated. In addition, the effects of the use of CoCo on the health status will be investigated. The following conditions will be compared: 1) regular treatment program, 2) treatment program with the CoCo application. Study participants are people with COPD who are under treatment of the lung physician, with a history of >=3 exacerbations or one hospitalisation for COPD in the two years preceding study entry, and without an exacerbation in the month prior to enrolment.The CoCo application is a technology-supported care service for self-management of COPD exacerbations and for promotion of an active lifestyle.

Study objective

Chronic Obstructive Pulmonary Disease (COPD) is a chronic, progressive lung disease. The prevalence and associated costs of COPD are projected to increase the upcoming decades. The treatment of COPD aims to reduce risk factors, prevent disease progression and manage exacerbations. Physiotherapy, increasing physical participation in daily activities, and early detection and treatment of exacerbations are important elements of COPD treatment to achieve these goals, besides medication and smoking cessation. For optimization of COPD treatment, the treatment programme should be individually based, and is therefore time- and labour intensive for the patient and the professional.

Home-training programs and self-management of exacerbations have proven to be effective new treatment methods. If these programmes are offered as a telemedicine application, they could contribute to a reduction in labour and costs.
Therefore, the telemedicine application CoCo (ConditionCoach) will be used in the COPD treatment. CoCo supports the treatment of COPD patients through active self-management and promotion of an active lifestyle. The healthcare professional can supervise from a distance. To justify the implementation of the CoCo application in the regular treatment program (on the long term) and to allow further scaling, evaluation of the deployment of the CoCo application is important.

Study design

T0 (inclusion), T1 (1 month), T2 (3 months), T3 (6 months) and T4 (9 months).

Use of the application is registered by the system. Satisfaction with the application is measured by a questionnaire based on the Unified Theory of Acceptance and Use of Technology (UTAUT). Satisfaction with received care is measured by the Client Satisfaction Questionnaire (CSQ). Quality of care is measured by a questionnaire based on the RATER model (Reliability, Assurance, Tangibles, Empathy, Responsiveness). The UTAUT and RATER questionnaires are assessed before use of CoCo “expectations” and during use of CoCo “experiences”. Outcome measures to evaluate the clinical effects are: Exacerbations (number, duration), amount of activity (accelerometer), exercise tolerance, fatigue, health status and symptoms , and quality of life.

Intervention

The primary objective of this study is to evaluate the CoCo application in the regular treatment of the MST and associated physiotherapy practices. We will investigate the use of the application, the application satisfaction, satisfaction of care and quality of care. The secondary aim of this study is to explore the clinical changes on the health status of the patient by the CoCo application in the regular treatment. It is expected that the deployment of the application will have at least similar effects on the patient’s health (compared to the regular treatment program without using CoCo).

The CoCo application is a technology-supported care service for self-management of COPD exacerbations and for promotion of an active lifestyle. The application consists of three modules:

1. Activity registration and feedback;

2. Online webportal with online training program;

3. Self-management of exacerbations by a triage diary on a smartphone.

In addition, CoCo has a telemonitoring module for the patient and the professional, for monitoring the progress of the patient, and where the physiotherapist can adjust the training program.

Total duration of the intervention is 9 months. The participants will participate in the self-management program of exacerbations, and in addition their physiotherapists decides how and when they use the activity registration module. The physiotherapist also selects the exercises per patient for the online training program and adapts this training program following the progress of the patient. The control group receives usual care. Patients are randomized in either the control or intervention group.

Contacts

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Eligibility criteria

Inclusion criteria

1. A clinical diagnosis of COPD according to the GOLD criteria;

2. No exacerbation in the month prior to enrolment;

3. > or = 3 exacerbations or one hospitalization for respiratory problmens in the two years preceeding study entry;

4. (Ex)smoker;

5. Age > 40 years;

6. Post-bronchodilator FEV1 25-80% of predicted;

7. Able to understand and read Dutch;

8. Internet access at home.

Exclusion criteria

1. Serious other disease with a low survival rate;

2. Other diseases influencing bronchial symptoms and/or lung function (e.g. cardiac insuficiency, sarcoidosis);

3. Severe psychiatric illness;

4. Uncontrolled diabetes mellitus during a COPD exacerbation in the past or a hospitalization for diabetes mellitus in the two year preceding the study;

5. Need for regular oxygen therapy (>16 h per day or pO2<7.2 kPa);

6. Maintenance therapy with antibiotics;

7. Known alpha1-antitrypsine deficiency;

8. Disorders or progressive disease seriously influencing daily activities (e.g. amputation, paralysis, progressive muscle disease);

9. Impaired hand function causing inability to use application.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2011
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	NL2925
NTR-old	NTR3072
Other	ABR : 38014
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A