Effectiveness of feedback, by the use of telemonitoring, on daily activity patterns in patients with COPD

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The aim of this research is through feedback to increase physical activity of the patient and get a better distribution of activities over the day.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON34208

Source
ToetsingOnline

Brief title
COPD dot COM

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: ZON-MW

Intervention

Keyword: COPD, daily activity patters, Feedback, Telemonitoring

Outcome measures

Primary outcome

Following the main objective the following primary research question is:

Does activity increase in COPD patients, receiving feedback from the prototype COPD dot COM system, measured in number of steps per day, compared with a group of COPD patients without feedback?

Secondary outcome

Secondary questions are:

-Is the distribution of activities throughout the day more evenly distributed in patients using the COPD dot COM application with feedback compared with a group of patients who have received no feedback?

-What is the correlation between the two different measurements (pedometer and MTX-W motion sensor)?

Study description

Background summary

Feedback to the COPD patient about his condition and physical activity plays an important role in promoting self-management. Within the current care for patients with COPD, there is a lack of insight into daily activities and lack of understanding of the impact of physical training on the disease status. In addition, health care providers are still working with paper patient files with the disadvantage that they are not constantly updated and current information is missing. That's why the "COPD dot COM" study was launched with the objective to develop a prototype monitoring system for activity and symptoms in COPD patients. The system can be tailored to individual needs of patients. Issues within this study are the prevention of deterioration of disease status and

encouragement of an active lifestyle. The patient is supported and led by Information and Communication Technology (ICT) in achieving these goals. In addition, the system can give professionals involved timely insight so they can give advice and exchange information among themselves.

Study objective

The aim of this research is through feedback to increase physical activity of the patient and get a better distribution of activities over the day.

Study design

The COPD dot COM study is a proof of concept study which runs from October 2010 until January 2011. It is a randomized intervention study without invasive measurements. One group will get feedback based on motion sensors, the other group does not get feedback.

Intervention

Two groups of 16 patients will be formed. The control group wears a pedometer during four weeks, 4 days of the week (Yamax DigiWalker 200).
The intervention group uses the same pedometer as the control group with the COPD dot COM prototype system consisting of MTX-W motion sensor (Xsens) and Personal Digital Assistant ([PDA] (HTC P3600/P3700) and a touchscreen (or their own computer) linking to a Web portal.
The patients must wear both pedometer and MTX-W sensor and PDA around their waist, from when they wake up until at least eight PM. In the intervention group, the PDA provides feedback in the form of counseling. In addition, the intervention group completes a daily diary of their symptoms on the portal. Based on the subjective reports feedback about starting a course of prednisolone and / or antibiotics is given. Both groups have to write down per part of the day how many steps the pedometer measured.

Study burden and risks

The burden for patients is limited to wearing the pedometers and COPD dot COM application. Based on feedback, the patients in the intervention group are encouraged to change to a more even distribution of activities throughout the day. In addition, the patients keep a diary which can provide feedback with regard to taking a course of prednisolone and / or antibiotics in case of an impending exacerbation. The self-treatment of an exacerbation can be regarded as standard care, with minimal risk. The benefit to the patient is a better physical condition as the altered movement pattern will be sustained after this short proof of concept study.

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 stable COPD defined by GOLD criteria
-GOLD classification II-III
-Able to read, write and understand Dutch language
-Internet access at home

Exclusion criteria

-Exacerbation in four weeks prior to measurement
-Inability to control application
-Comorbidity which restricts movement activities
-Pathological changes which may affect activities of daily living (eg, stroke, osteoarthritis,

arthritis, rheumatoid arthritis)
-Asthma
-Other present and active lung disease
-Use of oxygen
-Less than six weeks ago started to workout with the physiotherapist.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2010
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	07-10-2010
Application type:	First submission
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	NL33403.044.10
Other	Volgt z.s.m.