COPD dot COM.

No registrations found.

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

Summary

ID

NL-OMON22011

Source
NTR

Health condition

Chronic Obstructive Pulmonary Disease (COPD)

Sponsors and support

Primary sponsor: Ziekenhuis Medisch Spectrum Twente
Haaksbergerstraat 55
7533 ER Enschede
Nederland
053-4872023
Fax 053-4872042
E-mail www.mst.nl
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

1. 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?

2. 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, still working with paper patient files with the disadvantage that they are not constantly updated and current information missing. That's why the 'COM dot COPD "study is designed to target a prototype system to develop and test, to manage symptoms in COPD patients where the system can be tailored to the individual needs of patients and so fits the current healthcare system that can be implemented in daily care. Considerations in this study with regard to preventing deterioration of disease status and encourage an active lifestyle. The patient is supported and led by Information and Communication Technology (ICT) in achieving its goals and self-management of complaints. In addition, the system can give insight professionals involved in the current disease status so they can give timely advice and mutual information exchange.

Study objective

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, still working with paper patient files with the disadvantage that they are not constantly updated and current information missing. This idea is the 'dot COM COPD "study designed to target a prototype system to develop and test, to manage symptoms in COPD patients where the system can be tailored to the individual needs of patients and so fits the current healthcare system that can be implemented in daily care. Considerations in this study with regard to preventing deterioration of disease status and encourage an active lifestyle. The patient is supported and led by Information and Communication Technology (ICT) in achieving its goals and self-management of complaints. In addition, the system can give insight professionals involved in the current disease status so they can give timely advice and mutual information exchange.

Study design

In the intervention group, the first five days the motion sensor detects movement activities measured without feedback. Based on this average measurement a reference line is calculated (by delta method).

The measurement takes over 4 weeks, 4 days a week.
In addition, both groups per half day (morning 8.00-13.00 hours 13.00-17.00 hours noon, evening 17.00-20.00 hours) record how many steps the pedo meter measured.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. A clinical diagnosis of stable COPD defined by GOLD criteria;

2. GOLD classification II-III;

3. Able to read, write and understand Dutch language;

4. Internet access at home.

Exclusion criteria

1. Exacerbation in four weeks prior to measurement;

2. Impaired hand function; inability to control application;

3. Comorbidity which restricts movement activities;

4. Pathological changes which may affect activities of daily living (eg, stroke, osteoarthritis, arthritis, rheumatoid arthritis);

5. Asthma;

6. Other present and active lung disease;

7. Use of oxygen;

8. 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)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-07-2010
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	NL2334
NTR-old	NTR2440
Other	ABR : 33403
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A