E-health for optimization of the multidisciplinairy COPD care

Published: 22-03-2012
Last updated: 29-04-2024

Primary Objective: Can an e-Health application, based on objective measurements, maintain the daily physical activity of COPD patients after a period of rehabilitation?Secondary Objective(s): • Are COPD patients motivated to use the e-Health...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON39066

Source
ToetsingOnline

Brief title
E-health in COPD care

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Chronic Obstructive Pulmonary Disease (COPD), emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Innovatie Alliantie. Stichting ter bevordering van de kenniscirculatie tussen regionale partijen;in het bijzonder tussen kennisinstellingen als hogescholen;het mkb en publieke instellingen (www.innovatie-alliantie.nl). Projectnummer van de subsidie is: 2010-11-12B. De

coördinerend onderzoeker is in dienst bij de Hogeschool Utrecht en doet een promotie bij de Universiteit Utrecht. Zij heeft een 0-aanstelling bij het UMCU. Vanuit de Hogeschool Utrecht is er een promotievoucher beschikbaar gesteld voor de periode 1-1-2010 t/m 1-1-2014 (zie bijlage voor toekenningsbrief).

Intervention

Keyword: COPD, daily physical activity, feedback, monitoring

Outcome measures

Primary outcome

Performed daily physical activity measured with the multisensor armband

(SenseWear).

Main parameter: number of steps per day.

Secondary outcome

• Dyspnoe (measured with the CRQ-SAS)

• Longfunction (FEV1, FVC after bronchodilatation)

• Physical capacity (measured with the six minute walk test)

• Body mass index (length/weight^2)

• Medication usage (measured by usageoverview of pharmacist)

• Exacerbations (number during the study)

• Use of mobile phone application (days used/ total study days (6 mos),

measured by the website)

• Effective guidance by health care provider (number of messages sent by

patient and physiotherapist)

Study description

Background summary

Currently, 64 million people suffer from COPD (Chronic Obstructive Pulmonary Disease) and 3 million have died. The World Health Organizaion predicts that COPD will become the third leading cause of death worldwide by 2030. Total health care costs for the Netherlands in 200 are estimated at 280 million euro. Patients with COPD show a decreased daily physical activity (DPA) compared with healthy controls. Level of DPA is know to be related to hospital admittance and mortality.
After a period of rehabilitation, a patient recieves advice on how to maintain their DPA. Most of the COPD patients do not comply to this advice. This in turn results in a vicious cycle of inactivity, increasing of symptoms, such as dyspnoe, and deconditioning. It is important to find an intervention that will maintain DPA after rehabilitation and stop this vicous cycle of deconditioning.

Study objective

Primary Objective:
Can an e-Health application, based on objective measurements, maintain the daily physical activity of COPD patients after a period of rehabilitation?

Secondary Objective(s):
• Are COPD patients motivated to use the e-Health application for a long period of time?
• Is the e-Health application effective in monitoring COPD patients by health care providers?
• Does the e-health application have an effect on the daily physical activity, lungfunction, dyspnoe, BMI en medicationusage of COPD patients?

Study design

this is a singleblind controlled study

Intervention

The intervention comprises the monitoring of the daily physical activity by patients and their health care providers. The means are a mobile phone whith accelerometer (smartphone) and a website. Patients wear the phone in their pocket which measures their daily physical activity. They will use the phone as if it is their own. The display of the phone will give the patient information on their daily physical activitiy and tries to motivate/stimulate/compliment them is this regard.
The data of the mobile phone is sent to a secured website. There, the health care provider has an overview of the daily physical activity of all his patients. He can determine the amount of steps a patients should perform per day and the intensity. There is also the option of sending messages to the patient.

Study burden and risks

Risks:
- The six minute walk test can be tiresome and can cause shortness of breath
- The armband can be uncomfortable while wearing and it can cause irritation of the skin.

Burden:
4 hours for measurements and 28 days for measuring the daily physical activity with the multisensory armband (SenseWear), which is worn around the upper arm.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 40 years and over
- Suffering from COPD (GOLD stage 2 and 3), 30% <= FEV1 < 80%, FEV1/FVC < 70% after bronchodilation.
- Completed rehabilitation program with a duration of at least 3 months
- Living at home independently
- signed informed consent

Exclusion criteria

- suffering from a co-morbidity that influences daily physical activity
- use of aid for mobility
- Stopped temporarily with rehabilitation program
- experienced an exacerbation resulting in hospitalization in the last 6 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2012
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-08-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-06-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37206.041.11