A novel monitoring system for continuous 24/7 monitoring of patients with COPD

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Present and evaluate a novel monitoring system for 24/7 continuously monitoring of COPD patients, using cHealth technologies.

Ethical review	Not approved
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON43106

Source
ToetsingOnline

Brief title
cHealth in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic obstructive pulmonary disease, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Ciro+ bv
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cHealth, COPD, monitoring

Outcome measures

Primary outcome

Evaluation of the opportunities of a novel monitoring system for continuously, 24/7 monitoring of COPD patients, using cHealth technologies. Evaluation will be based on the ability of the system to provide new insights into the management and treatment of COPD.

Secondary outcome

- Evaluation of data usability

- Examination of the accuracy of heart rate measurements from pulse oximetry

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is highly prevalent and is considered the fourth leading cause of death worldwide. Exacerbations are typical stressful events in the natural history of COPD. Exacerbations can lead to hospitalisations. Current treatment policy of COPD, including frequent hospitalisation, results in a high economic burden. Prediction of exacerbations could lead to prevention of hospitalisations, which would improve the quality of life of patients with COPD and reduce the economic burden of COPD. Studies using connected health (cHealth) solutions for exacerbation prediction are promising. Furthermore, cHealth solutions can be used to closely monitor COPD patients, making it possible to closely manage the treatment of the disease. In this study, a novel monitoring system for continuous, 24/7 monitoring of COPD patients using cHealth technologies will be presented and evaluated.

Study objective

Present and evaluate a novel monitoring system for 24/7 continuously monitoring

of COPD patients, using cHealth technologies.

Study design

Observational case-control study

Study burden and risks

The participants will have to wear a monitoring system for one week, 24 hours per day. The monitoring system consists of an armband measuring physical activity, a wrist-worn pulse oximeter with finger clip measuring heart rate and oxygen saturation, a black carbon aerosol monitor and a GPS travel recorder. The finger clip might hinder in some daily activities. The black carbon aerosol monitor and GPS travel recorder cannot be worn on-body and have to be carried along. Furthermore, one black carbon aerosol monitor will be placed in the home of the participants. Previous studies with these devices did not report any adverse effects.
Additionally, a chest strap measuring heart rate, physical activity and respiratory rate should be worn for 2 non-consecutive days during waking hours. The participant might experience some discomfort while wearing the chest strap. Previous studies with the device did not report any adverse effects.
At the end of the measuring week, a structured evaluation interview will be performed.

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

- COPD as a primary diagnosis, diagnosed by a chest physician
- Clinically stable
- Treated according to the current international guidelines
- Permission for voluntary participation

Exclusion criteria

- Lack of motivation for voluntary participation in this study
- Cognitive impairment (MMSE score < 24)
- Receiving oxygen therapy
- Making use of a rollator to assist walking
- Not having a partner
- Having a partner who:
° Is not willing to participate
° Is diagnosed of COPD
° Is not living on the same address
° Has cognitive impairment (MMSE score < 24)
° Has serious medical conditions that could prohibit mobility/physical activity (e.g. severe cardiovascular conditions, cancers, severe orthopedic problems)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved

Date:	21-04-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL57234.100.16