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The eHealth Diary: digital pen telemonitoring of patients with advanced chronic obstructive pulmonary disease (COPD) and heart failure within specialised home care

Submission date
31/10/2013

Recruitment status
No longer recruiting

Registration date
12/11/2013

Overall study status
Completed

Last Edited
03/11/2017

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to investigate whether the use of digital pen technology for reporting of symptoms and measurement values from the home care patient to the professional care provider can improve the care of patients with severe chronic obstructive pulmonary disease (COPD) and/or heart failure (HF).

Who can participate?
Patients > 65 years admitted to hospital care at least two times during the last 12 months

What does the study involve?
All patients report daily on symptoms, measurements, and intake of medications using a digital pen and a Health Diary form. The patients also fill in questionnaires related to quality of life and the technology and method used.

What are the possible benefits and risks of participating?
Reporting on one's health condition each day will support the professional care providers to detect early signs of worsening of the health condition. Possible risks of being included in the study are that it can be tiresome to fill in the questionnaires.

Where is the study run from?
The study will be performed at the hospital-based home care clinic, Linköping University Hospital (Sweden).

When is the study starting and how long is it expected to run for?
November 2013 to December 2017

Who is funding the study?
The study is funded by the County Council of Östergötland, The European Regional Development Fund through the NovaMedTech venture and the Swedish ICT Research (Sweden).

Who is the main contact?
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Study website
https://www.sics.se/halsodagboken

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Telemonitoring of patients with advanced COPD and heart failure within specialised home care - based on digital pen technology and a Health Diary form

Acronym
The eHealth Diary

Study objectives

The hypothesis is that special home healthcare and use of the telehealth system will detect early signs of deterioration of heart failure and COPD and monitor drug intake, and thereby decrease acute hospital re-admissions and increase the patients quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Linköping, Sweden, 17/09/2013

Study design
Intervention non-randomized single-centre clinical study compared with expected outcomes

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet (available in Swedish)

Health condition(s) or problem(s) studied
COPD and/or heart failure

Interventions
This is a non-randomized single-centre study following an intervention group only. Expected outcomes will be calculated based on historical data from patients with the same characteristics out of data from our administrative register. The expected outcomes will be compared with the actual from our intervention group. This method is inspired from a discontinuity regression model, which is an alternative when randomisation is not feasible due to logistic and ethical reasons. Therefore this is an intervention clinical study compared with expected outcomes.

Study patients will report daily on various symptoms and measurement values (such as shortness of breath, cough, mucous, weight, blood pressure, pulse, oxygen saturation) and intake of p.r.n. medications, using a digital pen and a Health Diary form. The Health Diary form also allows free text messages from the patients.

Healthcare personnel will monitor the system and incoming patient reports on a daily basis. Alarms will be generated if a patient reports values outside of predetermined limits or if a patient fails to send in reports.

Patients will be asked to fill in the following questionnaires: (Swedish versions of) St George's Respiratory Questionnaire/Minnesota Living with heart failure questionnaire, the ED-5Q questionnaire and the SF-36 (at baseline, 1, 6 and 12 months), and eHealth Diary-related questionnaires (at 1, 6 and 12 months).

COPD patients will be asked to also fill in mMRC and COPD Assessment Test (CAT) at baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
All outcomes measured at 12 months using patient records/administrative registers:
1. Number of hospital admissions
2. Healthcare costs
3. Mortality

Secondary outcome measures
1. Health-related quality of life, measured using questionnaires at baseline, 1, 6 and 12 months
2. Patients ability to handle the technology and method, measured using questionnaires at 1, 6 and 12 months
3. Patients participation in their own care, measured using questionnaires at baseline, 1, 6 and 12 months
4. Patients knowledge of their illness, measured using questionnaires at baseline, 1, 6 and 12 months
5. Patients feeling of security, measured using questionnaires at baseline, 1, 6 and 12 months
6. Deterioration and exacerbations, measured using patient records at baseline, 1, 6 and 12 months

Overall study start date
11/11/2013

Completion date
02/12/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/05/2014:
1. Patients (men and women) > 65 years diagnosed with COPD and/or heart failure
2. With >= 2 hospital admissions during the last 12 months

Previous inclusion criteria:
1. Patients (men and women) > 65 years diagnosed with COPD and/or heart failure
2. With >= 3 hospital admissions due to COPD/heart failure during the last 12 months

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
130

Key exclusion criteria
1. Dementia/other cognitive impairment or psychotic illness
2. Lack of ability to understand Swedish
3. Severe hearing loss
4. Underwent surgery in the last 6 months or surgery planned in the next 6 months
5. Other life-threatening illness

Date of first enrolment
11/11/2013

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Linköping University
Linköping
Sweden
58185

Sponsor information

Organisation
Linköping University (Linköpings universitet) (Sweden)

Sponsor details
Department of Biomedical Engineering &
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Sponsor type
University/education

Website
http://www.imt.liu.se/

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type
Government

Funder Name
The County Council of Östergötland (Sweden)

Funder Name
The European Regional Development Fund through the NovaMedTech venture (Sweden)

Funder Name
Swedish ICT Research (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration