Telemonitoring in COPD patients

No registrations found.

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

Summary

ID

NL-OMON21302

Source
NTR

Brief title
TBA

Health condition

COPD

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Deventer ZIekenhuis

Intervention

Outcome measures

Primary outcome

Level of self-management as measured with the Patient Activation Measure (PAM-13) at baseline, 3, 6 and 12 months

Secondary outcome

- Quality of Life (measured with EQ-5D-5L at baseline, 3, 6 and 12 months)
- Patient satisfaction (measured with CSQ-8 at baseline, 3, 6 and 12

months)
● Physical activity (number of steps each day during one week at baseline, 3, 6 and 12 months)
● Number of exacerbations (mild and severe)
● Number of hospital admissions
● Number of ED visits
● Length of hospital stay
● Health status (CCQ)
● Prescription rate of systematic corticosteroids and/or antibiotics
● Mortality during follow-up
● Loss to follow-up

Parameters evaluated in intervention group only
● Patient adherence to telemonitoring
● Number of video consultations

Study description

Background summary

Rationale:
The number of patients with Chronic Obstructive Pulmonary Disease (COPD) is growing rapidly. COPD is associated with high mortality rates, high use of healthcare resources and lower quality of life. The increasing prevalence of COPD and accompanying increased workload leads to a substantial impact on the healthcare society worldwide. Therefore, structural changes in the organization of healthcare are needed to accommodate this patient population, with an important role for improving selfmanagement for COPD patients using telemonitoring interventions. Telemonitoring may support activation for self-management while enabling quicker treatment in the early phase of patient deterioration. In addition, it is expected to reduce exacerbation frequency, number of hospital readmissions and costs.
The aim of this study is therefore to test the hypothesis that telemonitoring with telecare in COPD-patients will improve self-management. In addition, it is hypothesized that telemonitoring with telecare will reduce disease burden and healthcare resource usage.
Objective: The primary aim of this study is to test the hypothesis that telemonitoring with telecare in COPD-patients will improve self-management, as measured with the 13-item Patient Activation Measure (PAM-13). Furthermore, we hypothesize that telemonitoring with telecare will reduce disease burden and healthcare resource usage.
Study design: A pragmatic unblinded randomized controlled trial with 12-months follow up. The control group receives care as usual. The intervention group receives usual care in addition to the telemonitoring intervention.
Study population: 178 adult patients with COPD GOLD stage B and D will be randomly assigned to the intervention or control group at the Deventer Hospital
Intervention ((if applicable): an integrated home telemonitoring solution that consists of

at home measurements of the clinical COPD questionnaire (CCQ), saturation, pulse rate and weight via a specially designed telemonitoring application on a patient's phone or tablet. Video consultations by nursing staff are initiated if patient specific alerts are generated.
Main study parameters/endpoints: The primary endpoint is self-management as measured with the Patient Activation Measure (PAM-13) at baseline, 3, 6 and 12 months. Secondary outcomes are quality of life (EQ-5D-5L), number of exacerbations, number of hospital admissions, number of ED visits and patient satisfaction.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All patients, regardless of randomization will receive standard of care for COPD management. In addition, patients in both the intervention and control group will fill in questionnaires on patient-self management (PAM-13) and quality of life (EQ-5D-5L) at baseline, 3, 6 and 12 months. It is expected that the burden to fill in both these questionnaires is extremely low, since short questionnaires are selected. Telemonitoring of COPD patients in the intervention group could be perceived as an additional patient safety net since patients in the intervention group receive telemonitoring care in addition to usual care. Therefore, there are no conceivable risks to taking part in this study.

Study objective

We hypothesize that telemonitoring with telecare in COPD-patients will improve selfmanagement.
In addition, it is hypothesized that telemonitoring with telecare will reduce disease burden and healthcare resource usage.

Study design

The main study parameter is self-management as measured with the Patient Activation Measure (PAM-13) at baseline, 3, 6 and 12 months.

Intervention

This present study is an unblinded prospective randomized controlled trial with 12-months follow up in a Teaching Hospital (Deventer Ziekenhuis). The control group receives care as usual. The intervention group receives the telemonitoring intervention in addition to usual care. Since telemonitoring is not part of the current care pathway, we choose to provide usual care to the intervention group as well.

Contacts

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Eligibility criteria

Inclusion criteria

● COPD GOLD grade B or D
● Having access to and being able to use a mobile phone (Android/Iphone) or Tablet/iPad
● Native language: Dutch

Exclusion criteria

● Hospitalized patients
● Inability to give written informed consent
● The patient does not have WiFi at home

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2020

Enrollment:	178
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	08-07-2020
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	NL8766
Other	METC Medical research ethics committee (MREC); in Dutch: medisch ethische commissie : ME 19-53

Study results

Summary results
NA