Telemonitoring in COPD patients

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21302

Bron
NTR

Verkorte titel
TBA

Aandoening

COPD

Ondersteuning

Primaire sponsor: Deventer Ziekenhuis
Overige ondersteuning: Deventer ZIekenhuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Deventer Ziekenhuis
Karin Groenewegen-Sipkema

0570-535100

Wetenschappelijk

Deventer Ziekenhuis
Karin Groenewegen-Sipkema

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

● 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2020
Aantal proefpersonen:	178
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8766
Ander register	METC Medical research ethics committee (MREC); in Dutch: medisch ethische commissie : ME 19-53

Resultaten

Samenvatting resultaten
NA