

Telemonitoring in patients with chronic heart failure and COPD.

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Telemonitoring in patients with chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD) might result in improvement of quality of life as compared to usual care.

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

Samenvatting

ID

NL-OMON26920

Bron

Nationaal Trial Register

Verkorte titel

RPM-CHF/COPD

Aandoening

COPD, chronic heart failure

Ondersteuning

Primaire sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is to investigate whether TM in patients with combined HF and COPD results in improved quality of life (EQ-5D), as compared to usual care.

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD) often co-exist and are associated with high morbidity and mortality. Telemonitoring (TM) can improve early detection of deterioration and prevent re-admissions. Although telemonitoring is already implemented in several Dutch hospitals for CHF or COPD, care pathways for these conditions are usually separated. Because there is a call for a more holistic approach, we propose a combined TM approach for both diseases in an integrated care pathway.

Doel van het onderzoek

Telemonitoring in patients with chronic heart failure (CHD) and chronic obstructive pulmonary disease (COPD) might result in improvement of quality of life as compared to usual care.

Onderzoeksopzet

We conduct a quasi-experimental time-series study in which the main endpoint is assessed every month between during 2.5 years.

Onderzoeksproduct en/of interventie

During a period of 2 years patients receive a personalized set of sensors for monitoring relevant vital signs (e.g. blood pressure, weight, oxygen saturation, energy expenditure and/or temperature). Sensor data in combination with short questionnaires on clinical status will be uploaded on a digital platform on a regular basis. Data are reviewed in the hospital by a specialized nurse who serves as the patients' case manager. If measurements exceed predefined limits, the cardiologist and pulmonologist are consulted in a multidisciplinary setting on the same day to determine the treatment strategy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients diagnosed with both CHF (HFrEF, HFpEF or HFmrEF) and COPD regardless of aetiology.
2. At least one hospital admission during the last year (due to CHF/COPD).
3. Age $\geq$ 16 year.
4. Able to speak and read the Dutch language.
5. Life expectancy > 2.5 years.
6. Sufficient digital skills (or caregiver).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients that do not have an internet connection.
2. Patients with psychological disorders preventing participation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	11-12-2017
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	NL6741
NTR-old	NTR6919

Ander register METC Máxima Medisch Centrum // CCMO : W18.002 // NL64413.015.17

Resultaten