Telemonitoring in patients with chronic heart failure and COPD.

No registrations found.

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

Summary

ID

NL-OMON26920

Source
Nationaal Trial Register

Brief title
RPM-CHF/COPD

Health condition

COPD, chronic heart failure

Sponsors and support

Primary sponsor: Máxima Medical Centre, Eindhoven/Veldhoven, The Netherlands
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To investigate whether TM in patients with combined HF and COPD results in improved HRQoL (MLHFQ, SGRQ).

2. To investigate whether TM results in improved levels of self-management as compared to usual care (PAM13).

3. To investigate patient satisfaction with TM compared to usual care (CQi)

4. To investigate whether patients are compliant to the TM program.

5. To assess health-care costs of TM compared with usual care.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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 =/> 16 year.
4. Able to speak and read the Dutch language.
5. Life expectancy > 2.5 years.
6. Sufficient digital skills (or caregiver).

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2018
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-12-2017
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	NL6741
NTR-old	NTR6919
Other	METC Máxima Medisch Centrum // CCMO : W18.002 // NL64413.015.17

Study results