Cost effectiveness analysis " Telemonitoring in Heart Failure"

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON30939

Source
ToetsingOnline

Brief title
TEHAF 2

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
heart failure - heart decompensation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Provincie Limburg: subsidie projectbeleid "optimale zorg voor oudere mensen met een handicap".

Intervention

Keyword: Case management, Cost effectiveness, Heart failure, Telemonitoring

Outcome measures

Primary outcome

Hospital admissions.

Health care related costs

Secondary outcome

Related at outcome:

· amount of planned and unplanned contacts with cardiologist, heart failure

nurse, cardiac emergency and general practitioner;

. amount of hospital admissions (related and not related to heart failure)

· mortality (cardiac reason or not)

· costs related to hospital admissions and contacts with caregivers

Related at intervention:

· Compliance for drugs and non-medical regimen;

. State of health in terms of complaints (tiredness and dyspnoea), risk

factors (smoking, obesity, drink), instability, mobility, depression, self

efficacy and quality of live

Study description

Background summary

The application of E-Health creates several opportunities to improve the quality of care in regard to the case management of patients with heart failure

in the Netherlands. In the United States this way of e-monitoring was already tested on safety and feasibility, and currently positive results were also shown in the Dutch setting. Based on the feasibility study the content of the Health Buddy is adjusted recording to the recommendations of patients and caregivers. In the current study the hypothesis is that telemonitoring results in a decrease of hospital admissions, with equal quality of care defined as mortality, quality of live and unplanned visits with caregivers. By this telemonitoring is expected to be more cost effective than usual care in patients with heart failure.

Study objective

The aim of the study is to investigate to what extent telemonitoring is justifiable for patients with heart failure, with the focus on tailored care and substitution of care. The study will be carried out on three different institutions in the region South-Limburg. The following questions will be answered:
Primary
1. To what extent does the use of the Health Buddy result in a decrease of hospital admissions? 2. To what extent is the Health Buddy® more cost effective than usual care? 3. To what extent will the amount of planned contacts decrease without an increase of unplanned contacts? 4. Does the use of the Health Buddy result in equal mortality rates compared with the control group?
Secundary
5. What is the effect of the Health Buddy® in patients with heart failure in regard to drugs consumption and therapy compliance and level of knowledge, and quality of live ? 6. To what extent is it possible to identify - based on patientcharacteristics -a category patients showing divergent effects with regard to care consumption, level of knowledge and compliance ? 7. To what extent is there a relationship between symptoms, knowledge and behaviour?

Study design

The design of the study consists of a randomised - per hospital stratified-controlled trial. Respondents will be recruited during 8 months at three locations, i.e. the academic hospital Maastricht, Orbis Medical and Care concern (Maaslandziekenhuis) and the Atrium Medical Centre.
390 respondents will be recruited. The follow up period is 12 months.

Intervention

Patients from the intervention group receive treatment and guidance based on information acquired via the Health Buddy. That information will be obtained by daily offered dialogues. These will take five minutes per day. On yearly basis two contacts will be planned, respectively with the cardiologist and the heart failure nurse.

Patients of the control group will receive care as usual in the participating centres, according to the guidelines.
Newly diagnosed patients in the intervention and control group will receive oral and written information as usual .

Study burden and risks

Completion of the dialogues takes five minutes daily. Quarterly patients receive a questionnaire witch takes on average 40 minutes to complete. The patients of the intervention group will have less face to face contacts with the cardiologist and the heart failure nurse. This could result in a - by specialists - undiagnosed worsening of heart failure.
Participation in this study is justified because patients will be asked daily about their complaints and symptoms, allowing earlier adjustment of therapy and prevent hospital admission.
Quarterly patients receive a questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient > 18 years;
Patients with heart failure NYHA classification II-III-IV;
patient experienced a period of fluid retention;
Patient is treated by a cardiologist;
Patient is followed-up by a heart failure nurse;
Adequate level of the Dutch language;
Patient has an active telephone connection, preferably analogue ;
Patient is mental competent;
Patient has the disposal of a balance.

Exclusion criteria

Patients suffers from COPD, Gold classification 3 or 4
patient is a dialysis patient;
Patient has a visual restriction to read the dialogues on the Health Buddy;
Patient is hard of hearing or deaf;
Patient suffers from a lethal sickness with a prognosis < 1 year;
Patient participates in another trial;
Patient needs a hospital admission on short time, i.e. < 3 months;
Patient used the Health Buddy in an earlier stage;
Patient is an illiterate person.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	390
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	10-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL17061.068.07