The value of ICT guided disease management combined with telemonitoring for heart failure patients.

No registrations found.

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

Summary

ID

NL-OMON20035

Source
NTR

Brief title
IN TOUCH

Health condition

Heart failure, disease management systems, ICT guided protocols, telemonitoring, telemedicine, telecare, cost effectiveness

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG), department of cardiology
Source(s) of monetary or material Support: Ministerie van Volksgezondheid, Welzijn en Sport. Directie Geneesmiddelen en medische technologie

Intervention

Outcome measures

Primary outcome

1. A composite end point for death;

2. Readmission for heartfailure;

3. Change in quality of life.

Secondary outcome

1. Death from any cause;

2. First readmission for heart failure;

3. Change in quality of life;

4. Treatment according to guidelines;

5. Optimal dosage of medication;

6. Number of visits to the heart failure clinic;

7. HF knowledge and self-care behaviour;

8. Cost-benefit ratio.

Study description

Background summary

Background:
Chronic heart failure is a rapidly increasing epidemic with high mortality and high morbidity, leading to increasing costs for the society. Although guidelines for the management of heart failure are clear, the quality of care for heart failure can still be improved. Disease management systems implemented in smart ICT solutions and telemedicine are expected to improve the quality of care and to reduce costs.

Aim:
To investigate the effect of ICT guided disease management (DM) and telemedicine (TM) on the quality and efficiency of care in patients with heart faillure after an hospitalisation.

Methods:
The study is devided in three arms; a control arm with care as usual

(CAU) in 10 hospitals and two randomized intervention arms (DM en DM+TM) in 10 other hospitals in the Netherlands. In total 450 patients will be included after an hospitalisation for heart failure (CAU: N=225, DM: N=75, DM+TM: N=150). Follow-up will be 9 months. Primary endpoint of the study is a composite score of: 1. death from any cause during the follow-up of the study, 2. first readmission for heart failure and 3. change in quality of life compared to baseline, assessed by the Minnesota Living with Heart failure Questionnaire

Results:The study will start in June 2009. Results are expected in 2012.

Conclusion:
The IN TOUCH study is the first to investigate the effect of an ICT guided disease management system in combination with telemedicine on the quality and efficiency of care in patients after an hospitalisation for heart faillure.

Study objective

ICT guided disease management combined with telemonitoring leads to a reduction of death and readmission for heart failure, and improves the quality of life.

Study design

1. Baseline (inclusion);

2. First control (14 day's after inclusion);

3. 9 month after inclusion (end of study).

Intervention

1. ICT guided disease management without telemedicine.
Patients will receive care with an ICT guided disease management system (CardioConsult). The patient will also recieve tailored information on life style changes, complying with the pharmacological and non pharmacological regimen, including symptom management;

2. ICT guided disease management with telemedicine.
The above described disease management system will function together with telemedicine devices (weightscale, ECG, healthmonitor and blood pressure meter). Collected data will be transferred automatically by the GPRS network in the disease management system CardioConsult. The system performs disease management in a fully automated manner using periodic interactive dialogs with the patients to obtain health state measurements from the patient to evaluate and assess the progress of the patients disease, to review and adjust therapy to optimal levels and to give the patient medical advice for administering treatment. The health proffesional will be informed automatically by mobile phone (SMS) or email when

the data of the measurements are out of range and indicate that medical care is necessary.

Contacts

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Eligibility criteria

Inclusion criteria

Patients are eligible when they are admitted to the IC/CCU or cardiology ward for heart failure, NYHA class III-IV, have evidence for structural underlying heart disease, are intravenously treated with diuretics during their hospitalisation, have a documented ejection fraction less or equal than 40% in the previous 3 months, are at least 18 years old, male or female and are able to understand content of and willing to provide informed consent.

Exclusion criteria

Patients will be excluded from the study when they have a history of myocardial infarction in the previous 1 month, have a life expectation less then 1 year, have a history of valve replacement or surgery within the previous 6 months, have undergone cardiac invasive intervention within the last 6 months or planned to have such a procedure in the following 3 months, are evaluated for heart transplantation prior or during the study, are inable to fill out

questionnaires, are inable to use telemedicine devices at home or participate at another clinical intervention trial.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	450
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-07-2009
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	NL1788
NTR-old	NTR1898
Other	METC UMC Groningen : METC 2008.350
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A