The value of INnovative ICT guided Disease Management combined with Telemonitoring in OUt patient clinics for Chronic Heart failure patients

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The aim of this study is examine the effect on clinical endpoints (death, readmission for heart failure and quality of life) by comparing two intervention groups (Disease Management with or without Telemedicine) with the control group (care as usual...

Ethical review	-
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON33608

Source
ToetsingOnline

Brief title
IN TOUCH

Condition

- Heart failures

Synonym
Chronic Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: VWS; directie GMT; projectsubsidie

Intervention

Keyword: Chronic Heart Failure, Disease Management System, Telemedicine

Outcome measures

Primary outcome

Primary endpoint of the study is a composite score made up of weighted values for;

•Death from any cause;

•First readmission for heart failure, defined as an overnight stay in a hospital (with different dates for admission and discharge) for progression of heart failure or directly related to heart failure;

•Change in quality of life at end of study compared to baseline, assessed by the Minnesota Living with Heart Failure Questionnaire.

Secondary outcome

Secondary endpoints of the study are the separate components of the first primary endpoint;

•Death from any cause.

•First readmission for heart failure, defined as an overnight stay in a hospital (with different dates for admission and discharge) for progression of heart failure or directly related to heart failure.

•Change in Quality of life at end of study compared to baseline measured with the Minnesota Living with Heart Failure Questionnaire.

In addition, data will be collected on the following secondary endpoints:

•The number of days a patient was alive and out of the hospital after discharge.

•Total number and duration of hospital admissions related to heart failure.

•Total number and duration of all hospital admissions.

•Treatment according to guidelines using the criteria of the Guidelines Adherence Indicator-3 and 9 months after discharge. This instrument assesses 4 relevant groups of medication, dependent of New York Heart Association (NYHA) functional class; ACE-Inhibitors (ACE-I) or angiotensine receptor blockers (ARB), beta blockers (BB) and aldosteronantagonists (AA). Two aspects of Guideline Adherence will be evaluated;

- Is the patient on the type of medication described according to ESC guidelines

- Is the patient on optimal dose of medication according to ESC Guidelines. Actual daily doses for every medication from the drug classes ACE-I, ARB , BB and AA will be calculated in percent of daily target doses. Data will be adjusted for relative contraindications (COPD, bradycardia, symptomatic hypotension, renal dysfunction, hyperkalemia)

•The number of days necessary to establish optimal medication treatment, e.g. optimal dose of ACE-I or ARB, BB and AA, calculated from the day of discharge until the day a patient is on optimal medication. The maximum dose of medication which is tolerated by the patient.

•In both intervention groups, the moment optimal medication is reached will be assessed by ICT guided DMS. In the control hospitals, this moment will be assessed by the supervising cardiologist of the HF clinic.

•Number of days from discharge of the index hospitalisation until the moment

that a patient is on optimal heart failure medication (ACE-I, ARB, BB and AA).

The moment of optimal heart failure medication is defined as the moment that the patient endures the maximum dose of heart failure medication (ACE-I, ARB, BB and AA) which is prescribed according to latest ESC guidelines on acute and chronic heart failure.

•Number of visits to the outpatient HF clinic.

•Number of visits to the emergency department.

•Patient and carer satisfaction at end of study compared with baseline.

•HF knowledge and self-care behavioural end of study compared with baseline.

•Patients sense of control at end of study compared with baseline.

•Cost-benefit ratio

Study description

Background summary

The development of Disease Management Systems (DMS) in combination with the use of Telemedicine is expected to improve the quality of care, to reduce costs and to improve patient quality of life when compared to standard care in patients with heart failure (NYHA III-IV). The In TOUCH study is the first randomized study in the Netherlands to investigate the effect of the Disease Management System in combination with Telemedicine on the quality and efficiency of care in patients admitted to the IC/CCU or cardiology ward for heart failure (NYHA III-IV).

Study objective

The aim of this study is examine the effect on clinical endpoints (death, readmission for heart failure and quality of life) by comparing two intervention groups (Disease Management with or without Telemedicine) with the control group (care as usual).

Study design

A multicenter, three armstudy (one control arm and two randomised intervention arms) in which in total 450 heart failure patients (NYHA III-IV) will be included. Patients will be included in the control arm (n=225) or the two intervention arms (n=225). Patients in the control arm will receive care as usual whereas patients in the intervention arms will be randomised between a Disease Management System and Telemedicine (n=175) or Disease Management System alone (n=75) for a period of 9 months. Study duration has been defined as the time period between randomisation (during hospitalisation) and the end of study visit 9 months after discharge.

Intervention

Two types of interventions will be compared to a control group.
- Patients in the control group (n=225) will receive care as usual .
- Patients in intervention group 1 (n=150) will receive care driven by a Disease Management System and Telemedicine.
- Patient in intervention group 2 (n=75) will receive care driven by a Disease Management System without Telemedicine.

Study burden and risks

Patients in the control group and interventions groups will not have any risk or burden for participation in the study. Patients in the control group will receive care as usual and patients in the intervention groups will receive care with an ICT guided Disease Management System with or without Telemedicine. ICT guided Disease Management with Cardio Consult® has been used for several years in the Martini Hospital and some other hospitals. The study group is not aware of any potential risk or burden for the patient using this system. Unpublished data suggest that this system will improve patient treatment. The same expectations apply to the use of Telemedicine.

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

•Patients are diagnosed with systolic heart failure (NYHA III- IV)
•Evidence for structural underlying heart disease
•Patients are intravenously treated with diuretics during their hospitalisation
•Documented Ejection Fraction <= 40% in the previous 3 months
•Patients have to be older than >= 18 years
•Patients have to be able to understand content of and willing to provide informed consent

Exclusion criteria

•Patients <= 18 years
•History of myocardial infarction in previous 1 month
•Life expectation < 1 year
•History of valve replacement or surgery in the previous 6 months
•Have undergone cardiac invasive intervention the last 6 months (PTCA, CABG, HTX, valve replacement) or planned to have such a procedure in the following 3 months.
•Evaluation for heart transplantation prior or during the study
•The inability of patients to fill out questionnaires
•The inability of patients to use Telemedicine devices at home
•Participation at another clinical intervention trial

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-01-2010
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26271.042.08