Netherlands Heart Foundation Coordinating study evaluating Outcomes of Advising and Counselling in Heart Failure.

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1. To determine the effectiveness of 2 interventions (basic support (A&Cb) vs intensive support (A&Ci) compared to care as usual in CHF patients on time to first major event (HF hospitalisations and death), quality of life and costs; 2. To…

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

Samenvatting

ID

NL-OMON22884

Bron
NTR

Verkorte titel
NHS-COACH

Aandoening

Patients from the control group will receive usual treatment and care. After hospital discharge patients assigned to the control care continue to receive routine management by the cardiologist, and, subsequently, their general practitioner. No extra follow-up by a HF nurse or a multidisciplinary team is provided.
Patients in the intervention group 1 (A&Cb) will receive extra visits to outpatient clinic where they will visit the HF nurse. Education according to guidelines starts during hospital phase. Behavioural strategies will be used to improve compliance. In addition, patients are instructed to contact the HF nurse if there is a change in the patients condition or if there are any problems related to HF needing assistance of a health care provider.
Patients in intervention group 2, (A&Ci) are provided with more intensive advising and counselling. Patients in this group will receive support similar to this in intervention group 1, to which further support is added: patients in this group will be seen each month during the course of the study by the HF nurse. The first month telephone calls are made weekly and at

least one home visit is made within 10 days. The nurse consults a multidisciplinary team at least once to optimise her advice for each patient. This team will consist of a physiotherapist, dietician and social worker.

Ondersteuning

Overige ondersteuning: Netherlands Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to first event (HF readmission and death).

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

While there are data to support the use of comprehensive non-pharmacological intervention programs in patients with heart failure (HF), other studies have not confirmed these positive findings. Substantial differences in the type and intensity of disease management programs make it impossible to draw definitive conclusions about the effectiveness, optimal timing and frequency of interventions.

Aims:

1. To determine the effectiveness of two interventions (basic support vs. intensive support) compared to 'care as usual' in HF patients, on time to first major event (HF readmission or death), quality of life and costs.

2. To investigate the role of underlying mechanisms (knowledge, beliefs, self-care behaviour, compliance) on the effectiveness of the two interventions.

Methods:

This is a randomised controlled trial in which 1050 patients with heart failure will be randomised into three treatment arms: care as usual, basic education and support or

intensive education and support. Outcomes of this study are; time to first major event (HF hospitalisation or death), quality of life (Minnesota Living with HF Questionnaire, RAND36 and Ladder of Life) and costs. Data will be collected during initial admission and then 1, 6, 12, and 18 months after discharge. In addition, data on knowledge, beliefs, self-care behaviour and compliance will be collected.The study started in January 2002 and results are expected at the end of 2006. This study will help health care providers in future to make rational and informed choices about which components of a HF management program should be expanded and which components can possibly be deleted.

Doel van het onderzoek

1. To determine the effectiveness of 2 interventions (basic support (A&Cb) vs intensive support (A&Ci) compared to care as usual in CHF patients on time to first major event (HF hospitalisations and death), quality of life and costs;

2. To determine the role of underlying mechanisms (knowledge, attitude, skills, behaviour, compliance) in the effectiveness of the 2 interventions (A&Cb vs. A&Ci).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients in the intervention group 1 (A&Cb) will receive extra visits to outpatient clinic where they will visit the HF nurse. Education according to guidelines starts during hospital phase. Behavioural strategies will be used to improve compliance. In addition, patients are instructed to contact the HF nurse if there is a change in the patients condition or if there are any problems related to HF needing assistance of a health care provider.

Patients in intervention group 2, (A&Ci) are provided with more intensive advising and counselling. Patients in this group will receive support similar to this in intervention group 1, to which further support is added: patients in this group will be seen each month during the course of the study by the HF nurse. The first month telephone calls are made weekly and at least one home visit is made within 10 days. The nurse consults a multidisciplinary team at least once to optimise her advice for each patient. This team will consist of a physiotherapist, dietician and social worker.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Hospital admission for symptomatic chronic heart failure, established by the cardiologist;

2. Evidence for structural underlying heart disease;

3. >18 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Are included in medical trials requiring additional visits to research health care personnel;

2. Restrictions that render the patient unable to fill in the data collection materials;

3. Have undergone cardiac invasive intervention the last 6 months (PTCA, CABG, HTC, valve replacement) or planned to have such an procedure the following 3 months;

4. Are evaluated for Heart Transplantation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	1050
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-03-2006
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	NL587
NTR-old	NTR643
Ander register	: N/A
ISRCTN	ISRCTN98675639

Resultaten

Samenvatting resultaten

Jaarsma T, van Veldhuisen DJ, van der Wal MHL. NHF-COACH multicenter trial in The Netherlands: searching for underlying potentially beneficial mechanisms in nurse led heart failure management. Prog Cardiovasc Nurs 2002;17:96-8.

Jaarsma T, van der Wal MHL, Hogenhuis J, Lesman I, Luttik MLA, Veeger N, van Veldhuisen DJ. Design and methodology of the COACH study: a multicenter randomised Coordinating study evaluating Outcomes of Advising and Counselling in Heart failure Eur J Heart Fail 2004;6:227-33.