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Hogenhuis, Jochem

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Chapter 2

Design and methodology of the COACH study: a multicenter randomized coordinating study evaluating outcomes of advising and counselling in heart failure

Tiny Jaarsma, Martje H. van der Wal, Jochem Hogenhuis, Ivonne Lesman, Marie Louise Luttik,
Nic J. Veeger, Dirk J. van Veldhuisen.

Abstract

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.

Results: The study started in January 2002 and results are expected at the end of 2005.

Conclusions: 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.

Background

In contrast to favourable trends for most cardiovascular diseases in recent years, the number of patients with chronic heart failure (CHF) is still growing. CHF presents a significant and growing public health problem in industrialised countries and is sometimes referred to as an epidemic. Because the incidence of CHF rises with age, its prevalence will markedly increase as our population ages. CHF places a significant economic burden on society, consuming about 1-2% of the health care budget, and a large proportion (approximately 70%) of this is spent on hospitalisations. There is growing evidence that many of these hospitalisations can be prevented by improved patient care. Additionally, CHF is a significant burden to patients themselves. CHF has a high mortality rate and patients experience many adverse effects both from the disease and its treatment. Indeed, symptoms such as breathlessness, fatigue and oedema are frequently present, which can substantially affect quality of life.

To improve patient outcomes, a number of heart failure management programs have been developed and tested over the past twenty years. In these programs, several organisational models have been used. Examples of these models are a heart failure clinic, a home based intervention and a hospital outreach program. Key components of all of these models are education and counselling by a heart failure nurse, accessibility of a health care provider in
case of problems (mostly a nurse), optimization of medication and increased support after discharge.

To address the effectiveness of heart failure management programs, a number of randomised controlled studies have been conducted, some of which have reported decreased readmission rates, increased time to first major event, decreased costs and an improvement in quality of life. Moreover, a higher survival rate was recently reported in a randomised, controlled trial of a home-based management program in Australia. However, several other studies have failed to support these positive findings, either by reporting negative or inconclusive results.

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.

In addition, differences in national health care systems raise questions about the suitability and comparability of heart failure management programs in different countries. To illustrate this, we have previously reported that an educational intervention with one home visit was not enough to significantly reduce re-hospitalization in a group of Dutch CHF patients. In contrast, Stewart and co-workers have reported a lower readmission rate in a CHF population as a result of a single home visit by a cardiac nurse.

It is therefore a major challenge to identify, which program is most effective and the level of intensity required. There are currently no studies that compare the relative effectiveness of different programs.

This background was the rationale for designing the Coordinating study evaluating Outcomes of Advising and Counselling in Heart Failure (COACH). In this multicenter randomised study, advising and counselling at two different intensity levels will be compared to “care as usual” in order to evaluate the level of advising and counselling required. The rationale behind COACH is that if a basic program provides most of the beneficial effect (Figure 1), a much more intensive program is unnecessary, and too costly. In contrast, if the effect can only be gained by intensive advising and counselling (Figure 2) a basic support program may fail to provide that effect. This may indeed explain some of the “negative” studies, which may not have provided enough advising and counselling.

In addition to the discussion on the effectiveness and intensity of interventions, it is vital to identify the mechanisms of action. Some authors state that education, follow up and
availability of a health care provider in case of problems are the most important components of interventions. Others emphasize the importance of compliance to treatment and the early detection and treatment of clinical deterioration, suggesting that these were the key elements in the success of these interventions. Improved knowledge or self-care behaviour of patients are also considered as part of the underlying mechanism for better outcomes.\textsuperscript{11,13,14,17}

### Methods

#### Study hypothesis
The hypothesis of the COACH study is that advising and counselling will be beneficial to CHF patients, as compared to “care as usual”, in terms of prevention of CHF related mortality and morbidity, as well as quality of life and health care costs.

#### Primary objective
To determine the effectiveness of two interventions (basic support vs. intensive support) compared to “care as usual” in CHF patients, on time to first major event (heart failure readmission or death).

#### Secondary objectives
- To determine the effectiveness of two interventions (basic support vs. intensive support) compared to “care as usual” in CHF patients, on quality of life and costs.
- To investigate the role of underlying mechanisms (knowledge, beliefs, self-care behaviour, compliance) in the effectiveness of the 2 interventions.

#### Study design
A multicenter, randomised, controlled design will be used. The aim is to recruit 1050 patients with heart failure, randomised into one control group ‘care as usual’ and two experimental groups’ basic support or intensive support.

The study has been approved by the central Ethics Committee.
**Study population**

All patients will be required to have a hospital admission for CHF (NYHA II-IV). In addition, patients must be at least 18 years of age, with evidence of structural underlying heart disease. Reasons for exclusion from the study are: concurrent inclusion in a study requiring additional visits to research health care personnel; restrictions that make the patient unable to fill in the data collection forms; invasive intervention within the last 6 months (PTCA, CABG, HTX, valve replacement) or planned during the following 3 months; ongoing evaluation for Heart Transplantation; inability or unwillingness to give informed consent.

After confirmation of eligibility according to the above mentioned criteria, patients will be randomised to one of the three intervention strategies, i.e. “care as usual”, basic support, or intensive support.

**Primary endpoint**

The primary endpoint is the time to first event (readmission for CHF or death). A hospitalisation for CHF is defined as an unplanned overnight stay in a hospital (different dates for admission and discharge) due to progression of CHF or directly related to CHF.

Secondly, the proportion of ‘unfavourable days’ during the study will be analysed. A day is considered as ‘unfavourable’ if the patient is hospitalised or dead.

In addition, data will be collected on the number of readmission days, number of readmissions per patient and hospitalisations for CHF. Data will be collected by chart reviews, use of databases and interviews.
Secondary endpoints
The secondary endpoints are quality of life, health care costs, compliance, knowledge, beliefs and self-care behaviour.

Assessment, randomisation and intervention protocol

Assessment and randomisation
Following confirmation of suitability and informed consent, patients’ baseline characteristics will be assessed from the medical chart, patient interview and patient questionnaires (Table 1). After the baseline assessment, patients will be randomised by a central randomisation service on a 1:1:1 basis, to either “care-as-usual”, basic support or intensive support (Figure 3).

Follow-up assessments will take place 1, 6, 12 and 18 months after discharge. Data will be collected at the patients’ home by an independent data collector using a structured interview. Additional data will be collected from the medical chart.

Treatment and care
Two different types of interventions will be tested and compared to a control group as described below (Table 2). The content of the interventions is derived from interventions used in other countries, from interventions that are relevant and realistic in the Netherlands and according to the Dutch Heart Failure Guidelines.
Care-as-usual: Patients in the control group will receive usual treatment and care. After hospital discharge patients assigned to the control group will continue to receive routine management by the cardiologist and, subsequently, by their general practitioner. No extra follow-up by a heart failure nurse or a multidisciplinary team will be provided. Since counselling and advising by a heart failure nurse is not the usual care in the Netherlands, this control situation is (still) ethically feasible. Patients will visit the cardiologist at the outpatient clinic according to a defined schedule. This schedule consists of visits to the outpatient clinic 8 weeks after discharge, 6 months, 12 months, and every 6 months thereafter. Patients will be treated using current guidelines, receiving optimal doses of standard medication.

Table 2: Treatment and care for patients in the ‘care as usual’ group (control), and intervention groups

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Care as usual</th>
<th>Basic program</th>
<th>Intensive program*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 week</td>
<td>Visits by HF Nurse</td>
<td>Visits by HF Nurse Multidisciplinary Advice</td>
<td>Advising</td>
</tr>
<tr>
<td>2 week</td>
<td>Advising</td>
<td>Advising</td>
<td></td>
</tr>
<tr>
<td>3 week</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
<tr>
<td>4 week</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
<tr>
<td>8 week</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>4 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>5 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
<tr>
<td>7 months</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
<tr>
<td>8 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>9 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
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<tr>
<td>10 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
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<tr>
<td>11 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
<tr>
<td>13 months</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
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<tr>
<td>14 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>15 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
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<tr>
<td>16 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
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<tr>
<td>17 months</td>
<td>Visit to HF nurse</td>
<td>Visit to HF nurse</td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>Visit to cardiologist</td>
<td>Visit to cardiologist</td>
<td></td>
</tr>
</tbody>
</table>

* if needed additional visits or phone calls will be made.
**Intervention group 1: basic support:** These patients will receive care from the cardiologist as described above. In addition, the following support will be provided:

- Patient (and family) education according to guidelines and protocol in hospital and during visits to the outpatient clinic. Behavioural strategies will be used to improve compliance.
- A telephone contact will be made within 2 weeks of discharge.
- During their regular visits to the cardiologist at the outpatient clinic patients will also visit the heart failure nurse. In addition, there will be visits to the heart failure nurse after 4 weeks and then 3, 9 and 15 months after discharge.
- Telephone access to a heart failure nurse. Patients and their family/carers will be encouraged to contact the nurse if there is a change in the patients’ condition or if there are any problems or questions. The nurse can be contacted Monday to Friday 0900-1700.

**Intervention group 2: intensive support:** In this group, the most intensive level of advising and counselling will be provided. This means that patients in this group will receive education and counselling similar to that in intervention group 1.

The following extra support is provided:

- A home visit will be made within 10 days after discharge from the hospital. The home visit will allow the nurse to assess how the patient is coping in the home environment, the patients’ CHF status, the patients’ general health status, available medical support, health care and social support and future health care needs based upon this. An additional home visit will be made 11 months after discharge.
- Patients in this group will be contacted each month during the course of the study by the heart failure nurse (and by their cardiologist during usual visits). If needed, additional visits or telephone calls will be made.
- In the first month telephone calls will be made weekly.
- Telephone availability of a heart failure nurse during office hours and 24-hour coverage by a back up system.
- The nurse will consult a multidisciplinary team at least once during hospital admission and once at follow-up to optimise her advice for each patient. This multidisciplinary team will consist of a physiotherapist, dietician and social worker. Other health care professionals will be consulted, as required.

In both intervention groups the heart failure nurses will use a computer program to guide patient education and counselling. This program consists of an assessment form and patient education topics, which are specified for each patient visit (incl. home visit). Additionally, patient progress is reported and the number of patient contacts that are initiated either by the health care provider or by the patients, are registered.

In the training of the HF nurses, the importance of counselling strategies is stressed and explained. In addition to providing information to patients, HF nurses are trained to increase self-efficacy of patients. Material used in the intervention include a patient diary, brochures and samples of sodium restricted seasoning/spices.
Statistical issues

Analysis

All analyses will be conducting according the intention-to-treat principle. To meet the primary objective in the study, the primary variable ‘time to the first hospitalisation for heart failure or death’ will be evaluated using Kaplan-Meier survival analysis. Log-rank testing will be done to compare the different treatment strategies. In addition, a Cox proportional hazard model will be fitted for a multivariate analysis. A p-value below 0.05 will be considered as statistically significant and the incidence curves will be considered to be confirmed different.

Secondly, the proportion of ‘unfavourable days’ during the study will be analysed. A day is considered as ‘unfavourable’ if the patient was hospitalised or dead.

Power calculation

The number of 1050 patients in the COACH study is based on the primary endpoint of time to major event. In previous international studies, event rates (hospital admission and/or death) ranging from 30-54% are reported. It should be noted that several studies only include patients with a low ejection fraction and patients in NYHA III-IV. In patients with NYHA II, a lower event rate can be expected. In a Dutch intervention study, a readmission rate of 50% (control) versus 37% (experimental) within 9 months has been reported. The effect-size of nursing interventions vary from a reduction in readmission rates of 27%, 42% or 44%. In the current study with an 18 months follow-up period, the event rate (readmission or mortality) of control patients is estimated at 40% within 1 year. A 25% reduction of the major events in the basic follow up intervention (A+C) group is considered both realistic and clinically relevant.

It was calculated that 698 subjects (349 in each group) will be needed to detect a 25% reduction in events (power of 90%, alpha of 0.05) in the basic intervention group (A+C). For the additional intervention group, another 349 patients will be included.

Moreover, with 349 patients per group, the study has a 90% power to show that the number of ‘unfavourable days’ reduces by 50% by the intervention - from 60 days to 30 days (SD 120) during the study period of 18 months.

Study organisation

Study centres

In order to include the 1050 patients in 18 months, 17 hospitals in the Netherlands are participating in this study.

Steering Committee

Prof. dr. DJ van Veldhuisen, Chairman and Principal Investigator, dr. T. Jaarsma, Principal Investigator, DJA Lok (on behalf of the Working Group on Heart Failure of the NVVC), Prof. dr. KI Lie, Prof. dr. R Sanderman, Prof. dr. JGP Tijssen, dr. PHJM Dunselman, Prof. dr. WH van Gilst, dr. HJ Hillege, Prof. dr. AW Hoes, dr. JE Speksnijder and dr. MCM. Senten (both on behalf of the NHF)
**Endpoint Committee**

A panel of 2 cardiologists and an internist/geriatrician will judge whether a reported hospitalisation of a study participant is related to heart failure (primary endpoint), cardiovascular death or cardiovascular events. The panel will be blind as to whether the patient was in the control group or one of the intervention groups.

**Support and monitoring**

The study will be supported and monitored by the Trial Coordination Centre (dr HJ Hillege MD PhD, N Veeger MSc) a contract research organization for clinical trials. Both the quality of the research data and of the intervention will be structurally monitored. To address the quality of the intervention the data from the computer program -which is used for the education and counselling- is monitored and discussed monthly with the HF nurses by an on site visit of a research fellow.

**Financial support**

The Netherlands Heart Foundation (NHF) financially supports the study as one of their top down research programs (2000Z003).

**Conclusion**

To obtain an insight into the optimisation of education and counselling of HF patients, this multi-centre randomised trial, aims to include 1050 HF patients. Results from this trial, which recently started recruitment, 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.
References


