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Home care as an option in worsening chronic heart failure— A pilot study to evaluate feasibility, quality adjusted life years and cost-effectiveness

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Abstract

Background: Worsening chronic heart failure (CHF) is largely characterized by frequent hospital admissions and the need for specialist care.
Aim: To evaluate the feasibility of home care (HC) versus conventional care (CC) in relation to health-related quality of life (HRQL) and cost-utility in patients with worsening CHF.
Methods: Thirty-one patients seeking medical attention at hospital for worsening CHF were randomised to HC or CC. Following discharge within 48 hours from the hospital, patients in the HC group were followed-up in their homes by a specialist nurse. Follow-ups were conducted for both groups, 1, 4, 8 and 12 months after inclusion in the study.
Results: There was no significant difference in clinical events, adverse events or in HRQL. The total cost related to CHF was lower in the HC group after 12 months ($p=0.05$).
Conclusion: Reduction in cost of care for selected patients with CHF eligible for hospital care might be achieved by early discharge from hospital followed by home visits. Due to the small number of patients, these results must be interpreted with caution.

Keywords: Heart failure; Congestive; Health care cost; Quality-adjusted life years; Home care; Cost-utility analysis

1. Introduction

Despite advances in treatment, chronic heart failure (CHF) remains a serious health problem [1]. Progressive deterioration with disabling symptoms, diminished health-related quality of life (HRQL) [2] and frequent hospital admissions [3,4], is common. Hospital admissions for HF have doubled during the past two decades and hospital readmission rates of 30–50% within 6 months after discharge have been reported [5].

The annual cost for treatment of CHF in Sweden is about 2% of the Swedish health care budget [6]. Mostly (75%) due to hospital care [6]. A similar trend has been noted in the Netherlands, the UK, Spain, the USA and New Zealand [7]. Previous studies have reported difficulties in providing care for frail elderly patients with CHF when using current hospital-based disease management programmes [8]. However, home-based HF care after initial discharge from hospital may reduce re-hospitalisations and/or mortality [9,10]. Many patients treated for CHF experience worsening symptoms long before seeking medical attention [11] which could be managed at home rather than by hospitalisation.

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Recently, evidence of the feasibility and patient satisfaction with a physician-led "Hospital at Home" model for patients with an exacerbation of CHF or with other diagnoses has been demonstrated [12,13]. However, sending patients with worsening CHF home after being assessed in a hospital setting, with only specialist nurse follow-up, requires careful assessment. Therefore, this study aimed at evaluating the feasibility, HRQL and economic aspects of an alternative care (home care) approach in patients with worsening CHF.

2. Materials and methods

2.1. Design and setting

An open, randomised, controlled pilot study was conducted at Sahlgrenska University Hospital/Östra, a hospital serving 250 000 inhabitants in Göteborg, Sweden. Approval was obtained from the Regional Ethical Review Board and all participants gave written informed consent. The study conforms to the principles outlined in the Declaration of Helsinki.

2.1.1. Subjects

Between April 2004 and May 2006, patients seeking care for deterioration of CHF were identified within 24 h after admission from three medical facilities: an emergency department (ED), a heart failure (HF) outpatient clinic and a medical ward. After one year, the protocol was amended, with an extension of time to 48 h for study inclusion. Eligible patients were those with a prior diagnosis of CHF according to the European Society of Cardiology Guidelines [5], assessed as being in need of hospital care by their consulting physician and complying with all of the inclusion and exclusion criteria (Table 1).

2.1.2. Procedure

After being given oral and written information, patients were invited to participate in the study. Additional blood samples were drawn as necessary according to the study protocol (e.g., N-terminal pro-brain natriuretic peptide, NT-proBNP) if not already ordered by the patient's physician. All data were recorded in a case record form (CRF). The enrolling cardiologist conducted a complete history and physical examination. Four questionnaires were administered while awaiting the blood test results. Echocardiography was considered valid if less than one-year-old; otherwise, a new test was performed.

Patients were randomised using a random number generator to either home care (HC) under the direction of a specialist nurse or to hospital admission/conventional care (CC).

2.2. Intervention

2.2.1. Home care group

Patients in the HC group were initially treated in the ED or in the ward for up to 48 h and subsequently sent home. It was considered medically safe to treat patients at home if they had a *S*-Potassium level between 3.4 and 5.5 mmol/L, systolic blood pressure > 95 mm Hg, *S*-Creatinine < 250 μmol/L and less than a 50% increase from the baseline value during drug adjustment. To ensure medical safety, the specialist nurses responsible for the patients in the HC group followed a written physician directed care plan which included details of when to adjust medications. The nurses could consult a cardiologist if necessary.

All patients were followed-up the day after returning home by a specialist nurse from the HF clinic. The patients were visited at their home daily or every other day by the specialist nurse for the next 5–7 days as determined by the patients' health status. The home visits were terminated when a patient: (1) was symptomatically stable or improving, (2) had stable or falling weight, (3) had no signs of pulmonary rales and (4) had no oedema above the ankle. If necessary, the patients could contact the specialist nurse by telephone during office hours. Nurses at the intensive cardiac care unit (ICCU) could be reached by telephone after office hours. A cardiologist was always available for telephone consultation. Up to 1 month after the last home visit, the specialist nurse was also available for telephone counselling.

Table 1
Inclusion and exclusion criteria used to screen all patient candidates for this study

Inclusion criteria
Earlier diagnosed with chronic heart failure with diastolic or systolic left ventricular dysfunction
Deterioration of HF ≥ 3 days with symptoms of increasing dyspnoea, orthopnoea, weight gain ≥ 2 kg, debuting peripheral oedema or abdominal swelling
Clinical signs, e.g., extended jugular vein, leg oedema, tachypnoea, pulmonary rales, ascites and third heart sound
At least one symptom and one sign should be present
New York Heart Association class II–IV
Exclusion criteria
Unwillingness to participate
Worsening of CHF < 3 days
Newly onset HF
Pulmonary or pre-pulmonary oedema
Need for monitoring of arrhythmia
Other morbidities indicating need for hospitalisation
Living at an institution
Inability to follow instructions
S-Haemoglobin < 100 g/L or a decrease of *S*-Haemoglobin > 20 g/L
S-Creatinine > 250 μmol/L
S-Potassium > 5.5 mmol/L or < 3.4 mmol/L
S-Troponin T > 0.05 μg/L
Creatine kinase-MB > 5 μg/L
ASAT and ALAT > three times above the normal value
Systolic blood pressure < 95 mm Hg
Heart rate < 45 or > 110 beats/min
Systolic heart failure was defined as:
Ejection fraction ≤ 45%.
Heart failure with preserved ejection fraction was defined as:
Ejection fraction > 45% and signs of diastolic dysfunction:
One of the following criteria should be fulfilled:
– Posterior wall thickness + interventricular septum thickness / 2 > 1.3 cm.
– Enlarged left atrium (female > 42 mm, male > 46 mm) in the absence of atrial fibrillation.

After termination of the home visits, patients were referred to the HF clinic for drug up-titration if necessary.

Clinical signs and symptoms were assessed at each home visit according to the study protocol. In addition, blood samples for analysis of *S*-Sodium, *S*-Potassium and *S*-Creatinine were collected. If there was no improvement in dyspnoea, orthopnoea, leg oedema and weight or if pulmonary rales persisted, intravenous diuretics were administered and drug adjustments were performed according to study protocol or after consultation with a cardiologist.

Patients were encouraged to ask questions about medicines and treatment, and information about their condition was provided to each patient. The importance of symptoms in relation to their poor condition was also discussed with the patients. Routines for weighing were established, with the goal that the patients weigh themselves at least twice a week. Other professionals (e.g., physiotherapist and home-help service) were consulted when possible or when it was deemed necessary. After each home visit, the nurse and study physician had a short consultation to discuss the patient's condition.

2.2.2. Conventional care

The patients randomised to the CC group were treated in accordance with hospital treatment guidelines. All data were collected in the same way as in the HC group.

2.3. Data collection

2.3.1. Baseline

Baseline data collection was similar in the two treatment groups (HC and CC), i.e. demographics and baseline characteristics, interviews and questionnaires were performed in the same sequence for all patients in both groups to avoid order effects.

Patients' functional status was assessed according to the NYHA classification system. In addition, weight, blood pressure, heart rate, breathing frequency, jugular venous distension, pulmonary rales, leg oedema, symptoms, blood electrolytes and NT-proBNP were also assessed.

HRQL and symptoms were measured with the disease-specific Kansas City Cardiomyopathy Questionnaire (KCCQ) [14], one global question from the generic Short Form (SF-36) [15], the EuroQol five-dimension questionnaire (EQ-5D) of HRQL with the visual analogue scale (VAS) [16,17] and the utility-based standard gamble (SG) [17].

2.3.2. Follow-up

Patients in both groups completed four follow-up sets of questionnaires at 1, 4, 8 and 12 months. Patients' clinical status was documented and information about clinical events was elicited through patient interviews and complemented by the patients' medical records.

2.3.3. Resource utilization

Information on all health care utilization specific to CHF was elicited by patient interviews and complemented by data from the patients' medical records. Costs for the patients in the CC group were based on compensation charged by the hospital for each patient.

Costs for patients in the HC group included the time costs for the specialist nurses (e.g., home visits and time for pre- and post-visit preparation and transportation). Time costs for physicians included time for consultation, prescriptions, referrals and other practical tasks performed. Further, the laboratory tests and the costs for intravenous diuretics administered to patients in the HC group were also included in the costs for the patients in this group. Information on the number of visits and telephone contacts to the HF clinics, emergency visits and hospitalisations due to HF, was obtained through patient interviews at each of the follow-up visits, and complemented by data from patients' medical records. Since the majority of patients were retired, only direct costs were considered in this study. Costs for the patients in the CC group and readmissions for patients in both groups were obtained from the hospital's financial department.

2.4. Statistical analysis

Statistical analyses were performed using SPSS version 14.0 for windows (SPSS Inc., Chicago, IL, USA). Summary statistics are presented as mean (SD), median (interquartile range) and proportions. Based on previous studies we calculated that 77 patients in each group would be required to detect a 20% difference in hospital days with a two sided α of 0.05.

Wilcoxon signed-rank test was used to determine clinical improvement over time within the two groups (weight, NYHA and NT-proBNP). The non-parametric Mann–Whitney test was used to compare group differences between groups at baseline and follow-ups for ordinal data from the SF-36 (Q. 1), the KCCQ (QoL and symptom domain), the categorical variable NYHA and the continuous data (hospital days, costs, QoL, Quality-adjusted life years [QALYs], weight and NT-proBNP).

The cost-utility analysis (CUA) assessed the HC and CC groups on the basis of monetary costs and QALYs using VAS and SG techniques. Spearman's rank correlation coefficient was used to assess the association between QALYs derived from SG and VAS measurements. Further, Kaplan–Meier non-parametric analysis was utilized to determine whether the probability of re-hospitalisation differed between the two treatment groups [18].

2.5. Sensitivity analysis

Sensitivity analysis was performed for cost and HRQL with last value carried forward (LWCF) for patients who dropped out during the study. Because HRQL might be affected by the choice of technique used to elicit QALYs, the number of QALYs for the patients in each group was calculated using three assumptions: (1) any change in HRQL

between two measurement points occurred immediately after the first measurement point; (2) any change in HRQL occurred immediately before the second measurement point; and (3) any change occurred in HRQL exactly halfway between the two measurement points.

3. Results

Fig. 1 depicts patient flow and data availability. Descriptive statistics are presented in Table 2. The CC group included a larger number of male and more educated patients than the HC group. In the HC group, seven patients were sent home directly from the ED, five were recruited within 24 h, and one within 48 h from the medical ward. Four patients died during the study, two from each group because of stroke and cardiac arrest. Three patients in the CC group withdrew their consent during the study period. Two patients withdrew consent because of fatigue, while one patient did not state any reason for withdrawal.

The patients improved clinically in both groups and there was no significant between-group difference (Table 3). Treatment with beta-blockers, ACE inhibitors and angiotensin receptor blockers (ARBs) was optimized during the study period in both groups.

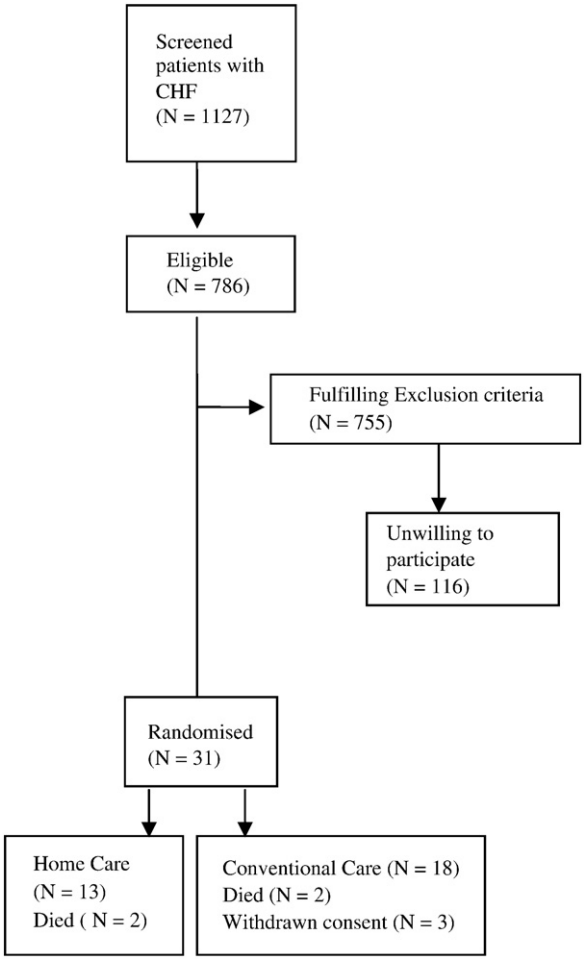


Fig. 1. Patient flow and data availability as a function of treatment group.

Table 2
Baseline demographics and clinical characteristics of the study population

	Home care ($n=13$)	Conventional care ($n=18$)	p-value
Male *n* (%)	6 (46)/7 (54)	15 (83)/3 (17)	0.03
Age (years) mean (SD)	77 (10)	78 (8)	ns
Marital status *n* (%)			
Divorced	2 (15)	3 (17)	ns
Single	1 (8)	2 (11)	ns
Widowed	7 (54)	5 (28)	ns
Education *n* (%)			
≥9 years	1 (8)	8 (44)	0.02
			ns
Weight kg mean (SD)	71 (13)	79 (15)	ns
NT-proBNP pg/ml (median and interquartile range)	4420 (1690–14350)	9335 (3375–13350)	ns
LVEF % mean (SD)	36 (13)	33 (12)	
Preserved ejection fraction CHF *n* (%)	3 (23)	2 (11)	
Systolic CHF *n* (%)	10 (77)	16 (89)	
NYHA class *n* (%)			
II		1 (5.5)	
III	13 (100)	16 (89)	
IV		1 (5.5)	
Signs mean (SD)			
Heart rate beats/min	76 (13)	77 (13)	ns
Breathing rate	21 (7)	20 (6)	ns
Systolic BP mm Hg	130(20)	132 (24)	ns
Pulmonary rales *n* (%)	8 (62)	13 (72)	ns
Leg oedema	8 (62)	14 (78)	ns
Comorbidities *n* (%)			
Total comorbidities ≥3	9 (70)	17 (93)	ns
Ischaemic heart disease	9 (70)	12 (67)	ns
Hypertension	5 (38)	11 (61)	ns
Stroke/TIA	1 (8)	6 (33)	0.09
Diabetes	2 (15)	10 (56)	0.02
Atrial fibrillation	8 (61)	10 (56)	ns
Respiratory disease	4 (31)	7 (39)	ns
Valve disease	5 (38)	2 (11)	0.09
Renal failure	1 (8)	0 (0)	ns

NYHA; New York Heart Association, BP; blood pressure, LVEF; left ventricular ejection fraction, NT-proBNP; N-terminal pro-brain natriuretic peptide.

Resources used, measured in terms of time and monetary units, are presented in Table 4. Health care cost was higher in the CC group ($p<0.001$ after initial intervention, and $p=0.04$ at the end of the study). However, a large variation among patients was observed. Details of the various costs at inclusion and at the follow-ups are displayed in Fig. 2. The difference between groups was still significant after inclusion of costs for the HF clinic visits, which occurred after termination of the home visits ($p=0.05$). Sensitivity analysis with LWCF resulted in group differences: median € 5110 for the CC group versus € 1122 for the HC group ($p=0.05$) at the end of the study and € 5150 for the CC group versus € 2680 for the HC group ($p=0.08$) while including costs from the HF clinic visits.

Table 3
Changes in clinical status and medication for the home care and conventional care groups

Clinical status	HC median (IQR)				
Follow-up	Initial	1 month	4 months	8 months	12 months
N	13	12	12	11	11
Weight (kg)	72(61–83)	67(58–82)	67(60–81)	72(63–81)	68(66–78)
NYHA	3(3–3)	2.5(2–3)	2(2–3)	2(2–3)	2.5(2–3)
NT-proBNP (pg/ml)	4420(1690–14350)	2510(1412–8535)	3430(1400–6500)	3300(980–5515)	2365(777–7088)
Medical treatment (%)					
ACE or ARB	54				64
Beta blockers	69				100
Spironolactone	0				45
Diuretics	92				91
	CC median (IQR)				
N	18	14	13	13	13
Weight (kg)	79(68–90)	78(72–86)	77(66–92)	77(67–92)	78(64–90)
NYHA	3(3–3)	3(2–3)	3(2–3)	3(2–3)	3(2–3)
NT-proBNP (pg/ml)	9335(3375–13350)	4100(2700–8137)	3630(1995–5625)	2450(1425–4290)	4570(1368–13100)
Medical treatment (%)					
ACE or ARB	89				77
Beta blockers	78				77
Spironolactone	23				31
Diuretics	89				100

HC; home care, CC; Conventional care, NT-proBNP; N-terminal pro-brain natriuretic peptide, NYHA; New York Heart Association classification system, ACE; Angiotensin Converting Enzyme, ARB; Angiotensin Receptor Blocker, IQR; Interquartile range.

The mean QALYs generated by SG were 0.71 (HC group) and 0.64 (CC group), whereas the mean QALYs generated by EQ-5D were 0.44 (HC group) and 0.43 (CC group) for patients remaining in the study at the 12-month follow-up. The mean number of QALYs in the CC group was 0.75 (SG) and 0.50 (EQ-5D) when assigning the value "0" to those patients who died and LWCF to patients who dropped out during the study. Spearman's rank correlation between QALYs generated by SG and EQ-5D was 0.70 ($p<0.001$). No differences were observed when QALYs were estimated with different approaches, regardless of method. Cost/QALY was lower in the HC group though this difference did not reach statistical significance.

The groups did not differ in the utilization of unplanned health care related to HF [i.e. number of visits to the emergency ward, HF clinics, hospital days or time to health care utilization after discharge (CC)/last home visit (HC)]. Two (11%) of the patients in the CC group were hospitalised because of hyperkalaemia during follow-up. The Kaplan–Meier analysis, which was used to compare the distribution of time to the first event for the groups, revealed no statistically significant difference between the groups.

4. Discussion

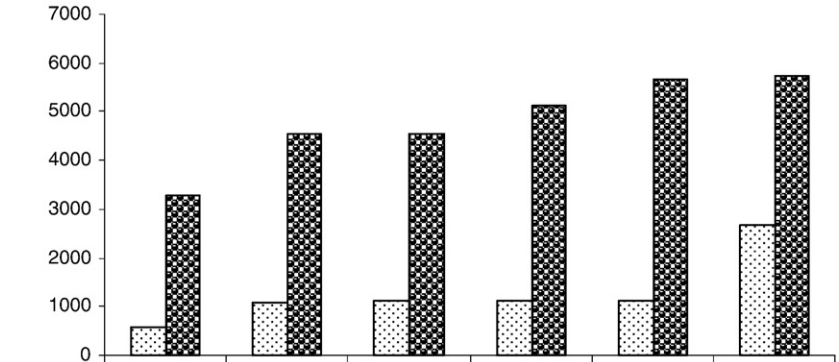
We sought to assess the HC and CC care procedures in relation to medical safety, HRQL and cost-effectiveness in patients with worsening CHF. Although no meaningful differences in HRQL could be identified in our small sample, substantial differences in the costs between the two procedures were found with no indications of increased adverse events with the HC approach.

Previous studies with intense monitoring of patients with CHF following discharge from hospital (i.e. stable patients)

Table 4
Resources (in hours and Euros) used per patient in the CC and HC groups during the study period

Resources used	Home care	Conventional care	*p*-value
*Time consumed for intervention or initial hospitalisation (h)	12 (7–34)	120 (90–192)	0.000
Number of home visits	4 (3,5–4,5)	–	
Total physician time consumed, (h)	0,53 (0,3–1,1)	–	
Number of visits to HF clinic, mean (SD)	7,2 (10)	3,6 (5,2)	ns
Time to the first hospitalisation, (days)	45 (95)	41 (70)	ns
HF-related-ED visits, (*n*)	0,3 (0,6)	0,3 (0,5)	ns
– Hospitalisation	0,5 (0,8)	0,6 (0,8)	ns
– Hospitalisation days	5,6 (9,4)	4,5 (6,2)	ns
Costs			
Nurses cost for intervention	386 (244–1107)	–	
Physician consultation cost	35 (19–74)	–	
Transportation cost for home visit	96 (53–127)	–	
**Total initial cost for intervention or hospitalisation	586 (334–1125)	3277 (2125–5750)	0.000

All values are Median (IQR) if not otherwise indicated. IQR; Interquartile range. *Time for intervention included preparation time before and after home visits and during the home visits, telephone consultation with patient and cardiologist and transportation time). **Included cost for blood samples, i.v. diuretics and consumed nurses and physician's time.



	Baseline***	1 month***	4 months**	8 months**	12 months**	with HFclinic*
cost HC	586	1095	1122	1122	1122	2680
cost CC	3277	4546	4550	5111	5670	5750

Fig. 2. Median cost for the CC and HC groups in Euros. Baseline = cost for initial intervention. Included cost for blood samples, i.v. diuretics and consumed nurses and physician's time. Cost for all events included in the total cost at follow-ups. With HF clinic = cost includes all cost up to 12 months and cost for HF clinic visits. ***$p<0.001$ **$p<0.05$ *$p=0.05$.

have generally shown a decrease in readmission and improvement in survival [10,19–21]]. We wanted to go a step further and examine the effect of HC on patients eligible for hospital care because of worsening CHF. Our study population was at high risk because of their age, severe symptoms and signs and several comorbidities. It is important to note that these patients were assessed as needing hospital care but were nevertheless sent home.

Of 1127 patients screened over two years, only 31 (3%) were included in the present study. Other well-known studies evaluating nurse-led HF programmes [20,22] have also included a low proportion of all screened patients. For example, the hospital-based programme by Strömberg et al. included only 5% of 1964 patients during a 30-month period [22] and Stewart et al. [20] included only 5% of 4055 screened patients during a period of 14 months.

Worsening CHF is often complicated by other serious conditions that require hospital care. The exclusion criteria were devised to exclude only those patients at the highest risk of complications. To ensure the patients' safety and minimize the risks of relapse, a conservative policy was implemented to prevent patients being sent home with electrolyte disturbances [23] that might cause arrhythmias, renal failure [24], ischaemic events [25] and acute HF. Exclusion criteria in our study mirrored those in large CHF studies, i.e. *S*-Potassium ≥ 5.5 mmol/L and *S*-Creatinine ≥ 265 μmol/L [26,27]. The study results show no severe adverse events in the HC group suggesting the strategy may be safe even in severely ill patients.

The patients in the HC group were referred more frequently to the HF outpatient clinic because initially fewer patients were treated optimally with indicated medications in this group.

As expected, the analysis of the breakdown of health care costs showed that hospitalisation of the patients accounted for the largest proportion of the costs. Due to the small sample size, the contribution of a single patient's health care consumption can substantially influence the mean value; therefore, the results are presented as median values. The major portion (96%) of the costs in the HC group was attributable to personnel costs. In contrast, costs for laboratory analyses and medication (intravenous diuretics) were very small (4%) in the HC group. Ekman et al. [8] suggested that patients with CHF could be cared for in their homes because, 29% of the patients in their study were not able to come to the HF clinic mainly due to fatigue. In our study, the impact of place of care had no effect on HRQL and medical safety though HC was found to reduce health care costs. Clinical and economic efficacy and feasibility, as well as greater satisfaction with care for diverse groups have been demonstrated with a "Hospital at home" model that included continuous nursing supervision and daily home visits by a physician [12,13]. A specialist nurse visited most of the patients in our study on alternate days and thus fewer resources were consumed without any serious adverse events. However, information on cost-utility requires further investigation in well-powered studies.

5. Limitations

Despite randomisation, there were differences between groups for some variables (Table 2) which may have affected patients' health, thereby causing differences in health care costs, HRQL, and the probability of a serious event between groups; the study was too small to adjust reliably for the imbalance. Only patients who were willing to return home when they were already seeking help at the hospital were eligible for the study. A further limitation is that this study only explored the impact of the intervention, it did not analyze other variables, such as the quality of care provided by home-help services or relatives. The findings in this study might not be generalisable to health services elsewhere. Our results must be interpreted with caution.

6. Conclusion and clinical implications

This study, with a limited number of patients, shows that it may be possible to care for some patients with worsening CHF administered by a specialist nurse in a home setting, even when the patients are assessed as being in need of hospital care. This nursing outreach support service might be provided by expansion of HF clinic services to appropriately informed patients.

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