European Journal of Heart Failure (2014)
doi:10.1002/ejhf.151

Effects of person-centred and integrated chronic heart failure and palliative home care. PREFER: a randomized controlled study

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Received 4 March 2014; revised 27 June 2014; accepted 11 July 2014

Aims We evaluated the outcome of person-centred and integrated Palliative advanced home caRE and heart FailurE caRe (PREFER) with regard to patient symptoms, health-related quality of life (HQRL), and hospitalizations compared with usual care.

Methods and results From January 2011 to October 2012, 36 (26 males, 10 females, mean age 81.9 years) patients with chronic heart failure (NYHA class III–IV) were randomized to PREFER and 36 (25 males, 11 females, mean age 76.6 years) to the control group at a single centre. Prospective assessments were made at 1, 3, and 6 months using the Edmonton Symptom Assessment Scale, Euro Qol, Kansas City Cardiomyopathy Questionnaire, and rehospitalizations. Between-group analysis revealed that patients receiving PREFER had improved HRQL compared with controls (57.6 ± 19.2 vs. 48.5 ± 24.4, age-adjusted P-value $= 0.05$). Within-group analysis revealed a 26% improvement in the PREFER group for HRQL ($P = 0.046$) compared with 3% ($P = 0.82$) in the control group. Nausea was improved in the PREFER group (2.4 ± 2.7 vs. 1.7 ± 1.7, $P = 0.02$), and total symptom burden, self-efficacy, and quality of life improved by 18% ($P = 0.035$), 17% ($P = 0.041$), and 24% ($P = 0.047$), respectively. NYHA class improved in 11 of the 28 (39%) PREFER patients compared with 3 of the 29 (10%) control patients ($P = 0.015$). Fifteen rehospitalizations (103 days) occurred in the PREFER group, compared with 53 (305 days) in the control group.

Conclusion Person-centred care combined with active heart failure and palliative care at home has the potential to improve quality of life and morbidity substantially in patients with severe chronic heart failure.
Trial registration: NCT01304381

Keywords Heart failure • Integrated care • Palliative care • Person-centred care • RCT

Introduction

Chronic heart failure (CHF) is a serious condition with a prognosis worse than many forms of cancer.[1] Patients with CHF have symptoms as severe and distressing as those of cancer patients, but they do not have equal access to palliative care.[2] The course of CHF is unpredictable, making it difficult to identify a specific time point to introduce palliative care to heart failure management.[3] Recently, we found large differences in the quality of end-of-life care in the Swedish Register of Palliative Care between patients with heart disease and those with cancer.[4] For example, patients with heart disease experience more shortness of breath and have fewer drugs prescribed on demand against the usual symptoms, compared with patients with cancer.[4] In addition, patients with CHF often require frequent hospitalizations and readmissions, suggesting insufficient management of these patients, which may be due to the frequency of concomitant chronic diseases. The European Society of Cardiology (ESC) has pointed out that selected

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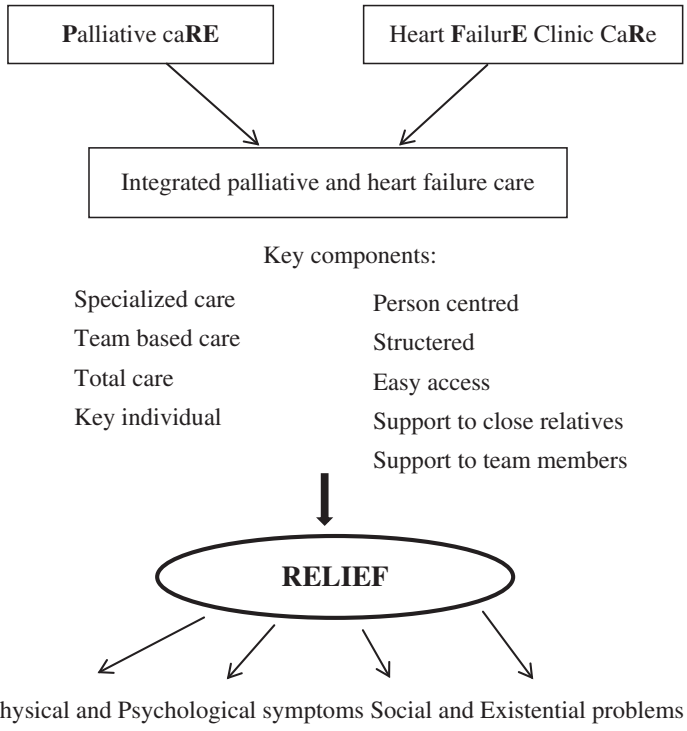

Figure 1 PREFER. A model for person-centred and integrated care of patients with heart failure.[9]

patients require palliative care services in addition to the heart failure management programme.[3] Guidelines[5] have concluded that a great need exists for new models of integrated care, such as active heart failure and palliative care, in order to facilitate care equality for dying patients regardless of diagnosis. This idea is also in line with the World Health Organization's description of palliative care.[6] We found some information in the literature concerning the advantages and effects of an in-hospital specialist heart failure- and home-based palliative care for patients with severe CHF.[7] A Cochrane review showed that home palliative care reduces symptom burden, particularly for patients with cancer, but more research is needed on valid outcomes in populations with non-malignant conditions and powered studies are required to compare different models of home palliative care.[8]

Here, we report the clinical outcome of a new model that integrates Palliative advanced home caRE and heart FailurE caRe (PREFER) for patients with severe CHF (*Figure 1*) as described previously.[9] Our hypothesis was that the combination of key components for delivering heart failure care and palliative care contained in PREFER should reduce the total symptom burden, increase health-related quality of life (HRQL) and functional capacity, and reduce morbidity.

Our primary aim was to evaluate the effects of the PREFER intervention on symptom burden, quality of life (QoL), and functional classes compared with usual care. The secondary aim was to study the effect of the PREFER model on the number of hospitalizations and days spent in hospital.

Methods

Study design and setting

This was a prospective randomized study with an open non-blinded design. Patients were randomized with envelopes in blocks of 20 to the PREFER intervention group ($n = 36$) or to usual care ($n = 36$). Usual care was provided mainly by general practitioners or doctors and/or the nurse-led heart failure clinic at the Medicine-Geriatrics department. After 6 months (± 2 weeks) the patients were transferred to the original care provider following the establishment of an individual care plan. The research context was an advanced home care unit providing services Monday–Friday during the day and based in a county hospital located in northern Sweden. The home visits and the phone calls varied substantially from several times per day to every other week. Diuretic administration also varied substantially between patients due to the severity of heart failure, from none to several times per day. Diuretics were administered s.c. or i.v. at home on demand for worsening symptoms when oral therapy was insufficient. Blood sampling, e.g. for determination of electrolytes, creatinine, and BNP, and transmission of the ECG to the hospital, were performed in the patient's home. No i.v. inotrope was administered at home.

Participants

The Department of Medicine-Geriatrics serves a catchment area of 75 000 inhabitants. The participants in the PREFER trial were

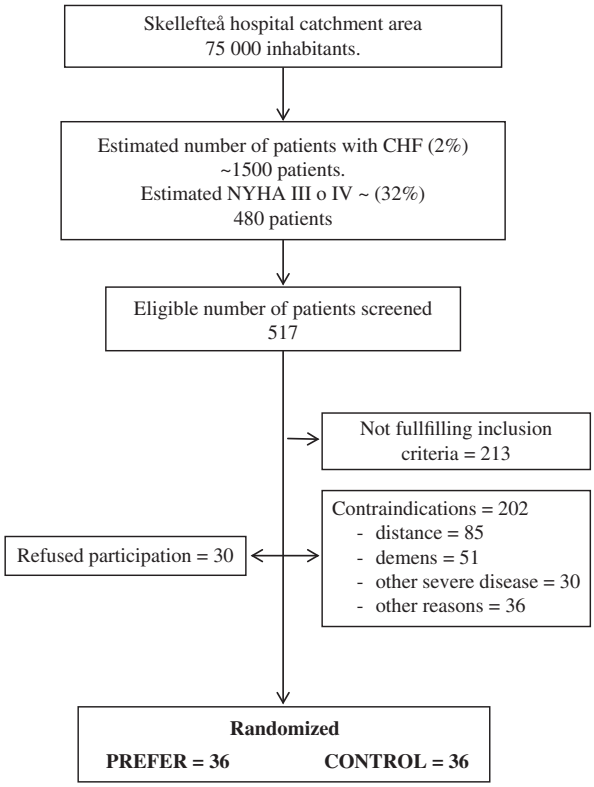

Figure 2 Flow diagram of the study. CHF, chronic heart failure.

inhabitants who had their primary healthcare centre within 30 km of the hospital.

Patients with a confirmed diagnosis of CHF[1] and cared for at the Department of Medicine-Geriatrics or primary healthcare centres and who met the criteria of the ESC[5] were asked to participate in the study. Inclusion criteria comprised CHF with NYHA functional classes III – IV symptoms and at least one of the following: at least one hospitalized episode of worsening heart failure that resolved with the injection/infusion of diuretics or the addition of other heart failure treatment in the preceding 6 months and regarded as being 'optimally treated' according to the responsible physician; need for frequent or continual i.v. support; chronically poor QoL based on a visual analogue scale (VAS) score <50; signs of cardiac cachexia, defined as an involuntary non-oedematous weight loss ≥6% of total body weight within the preceding 6–12 months; and life expectancy of <1 year. Exclusion criteria were patients who did not want to participate in the study; had severe communication problems; had severe dementia or other serious diseases in which heart failure was of secondary importance; with other life-threatening illnesses as their primary diagnosis and an expected short survival time; whose primary care centre responsible for their care was located >30 km from the hospital; and who were already participating in another clinical trial. We estimated a prevalence of CHF of 2% (1500), and ~32% (480) of these would be in NYHA class III–IV according to a Swedish registry study.[10] We identified 517 patients eligible for the study, of whom 72 were finally randomized (*Figure 2*).

Randomization and intervention

Patients ($n = 72$) were randomized into either the PREFER intervention ($n = 36$) or the control group ($n = 36$). Patients in the intervention group were offered a multidisciplinary approach involving collaboration between specialists in palliative and heart failure care, i.e. specialized nurses, palliative care nurses, cardiologist, palliative care physician, physiotherapist, and occupational therapist. The patients were also offered structured, person-centred care (PCC) at home.[11] PCC is one of the key components and cornerstones in the PREFER model. PCC is described as a partnership between patients/carers and professional caregivers, and includes initiating, working on, and documenting the partnership. The starting point is the patient's narrative, which is recorded in a structured manner and from which a mutual care plan is created that incorporates goals and strategies for implementation and follow-up.[11]

The intervention was carried out as follows: (i) after identifying a patient who fulfilled the inclusion criteria and had no exclusion criteria earlier described in the design paper,[12] a responsible physician and nurse were identified for each patient; (ii) the patient was then called for a thorough medical examination by the responsible physician with identification of co-morbidities and assessment of physiological, social, and spiritual needs; followed by (iii) meeting

with nurses who used a model for person-centred palliative care. The model is called the six Ss and consist of the six S key words; self-image, self-determination, social relationships, symptom control, synthesis, and surrender,[12] and continued through; (iv) regular meetings about the patients' conditions within the team twice a month; and, finally, (v) between the meetings brief discussions took place out between the team members ($n = 7$) at the unit and information was shared by the documentation in medical records and phone calls.

The team was responsible for the total care, i.e. including co-morbidities. Assessments of symptoms, QoL, and risks of decubitus, falling, and malnutrition were continually performed in a structured way with validated questionnaires or in the national quality of care registry by the Swedish Association of Local Authorities and Regions (SALAR). Further registrations in the national palliative registry and heart failure registry were performed. The Swedish Palliative Registry is a nationwide quality registry aimed at improving end-of-life care. The goal of the registry is to list and report quality indicators related to care during the last week of life in the case of all expected deaths in Sweden. This was fulfilled by each profession and documented independently, but also in the team in order to support the patient and attain the goals. The structure of care was also based on goals and steps in the process of providing palliative care for patients with CHF as recommended by the ESC[1,5,9] and developed within the PREFER model as described previously.[12]

One of the researchers (M.B.) was not involved in the treatment and care of the patients; the other researcher (K.B.) shared responsibility for cardiac treatment together with a general practitioner specialized in palliative medicine.

Assessments and outcomes

Prospective assessments were made at baseline and 1, 3, and 6 months of follow-up using the Edmonton Symptom Assessment Scale (ESAS), Euro Qol (EQ-5D), and Kansas City Cardiomyopathy Questionnaire (KCCQ). Socio-demographic and clinical characteristics were measured at baseline using a pre-specified protocol. If a categorical variable was denoted as unknown it was registered as a no answer. The questionnaires (Qs) were filled in by the patients themselves, baseline. At and the final 6 month Qs were filled in at the research unit. At the 1 and 3 month visits, Qs were filled in at home and returned in an envelope. The response rate was 100% at baseline and 1 month. At 2 months, four Qs were missing and at 6 months six Qs were missing (one due to dementia).

The ESAS, a valid and reliable tool,[13] was used to measure symptom burden: pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being, and shortness of breath. The severity of each symptom at the time of assessment is rated on a 10-item numerical scale.[13] The item 'other' was not included in the analysis due to very few answers.

The HRQL was measured using EQ-5D, a generic, single index that defines health in the five dimensions of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[14,15] For each dimension, the health of the patient is rated by the patient on a 5-point scale EQ-5D 5 L:[20] no problem, slight problems, moderate problems, severe problems, and impossible or extremely difficult problems. A VAS was also used.[14]

The QoL was also measured using the disease-specific instrument, the KCCQ, which measures physical limitation, symptoms (frequency, severity, and recent change over time), QoL, social interference, and self-efficacy. The KCCQ is a valid and reliable instrument in a Swedish CHF population.[16] Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

Statistical analysis

Patients with CHF (NYHA class III–IV) were considered to have a mean total symptom burden corresponding to 50 points out of 100 according to the ESAS scale and compared with findings by Follwell *et al.*[17] for patients with cancer. The patients in that study had a mean ESAS Distress Score (EDS) of 39.5 at baseline, and a mean improvement in the EDS of 8.8 points. The PREFER model was created to improve the mean symptom burden by at least 25% compared with the control group. With a power of 80%, significance level of $P < 0.05$, and an estimated drop-out rate of 15%, 31 patients were needed in each arm (total 62 patients). Due to patients dropping out, mainly due to deaths (12 patients), the number of participants was increased to 36 in each arm.

Results are presented as the mean ± standard deviation (SD) or frequencies expressed as percentages. Comparisons between the intervention and control groups were made using the χ^2 test for proportions and Student's *t*-test for normally distributed continuous variables. The Shapiro–Wilk statistic was used to test normality. If the distributions were not normal or ordinal, the Mann–Whitney U-test or χ^2 with Fisher's exact test for categorical variables was used. For within-group analysis of non-normally distributed data, the Wilcoxon matched-pair signed-rank test was used. Logistic regression analysis was used to calculate the odds ratio and 95% confidence interval for different variables after adjusting for age differences between the groups. All analyses were performed on an intention-to-treat basis. A *P*-value <0.05 was considered significant. The data were analysed using PASW Statistics 18.

Ethics

Oral and written informed consent was obtained from all participants. The investigation conforms to the principles outlined in the Declaration of Helsinki, 1964. The Regional Ethics Committee for Human Research at Umeå University (reference number 2010-294-31 M) approved the study, which was registered at www.clinicaltrials.gov (registration number NCT01304381).

Results

From January 2011 to October 2012, we randomized 72 patients (36 in the PREFER and 36 as controls, i.e. usual care). The

two groups were balanced with respect to baseline characteristics except for mean age (PREFER 81.9 ± 7.2 years vs. control 76.6 ± 10.2 years, $P = 0.012$; *Table 1*).

All patients were regarded as optimally treated by their physicians, and pharmacological treatment was characterized by a relatively high number of evidence-based therapies with regard to inhibitors of the renin–angiotensin system, beta-blockers, and mineralocorticoid receptor antagonists (*Table 1*). There were a number of serious co-morbidities but there was no statistically significant difference between the two groups (*Table 1*). Twelve patients died during the study; the remaining 60 patients completed the study.

Euro Qol-5D: health-related quality of life

No difference was found between the two treatment groups at baseline for HRQL assessed with the EQ-5D. At 6 months, the PREFER group had an increased HRQL, from 47.7 ± 19.4 to 60.4 ± 20.6, compared with 48.2 ± 23.1 vs. 52.3 ± 23.2 for controls (age-adjusted *P*-value = 0.10). The between-group analysis of the age-adjusted delta-value of HRQL from baseline to 6 months was significantly ($P = 0.02$) better for patients in the PREFER group than for controls.

If the last measurement at 1, 3, or 6 months was analysed, the delta-difference of HRQL, after adjusting for age, was still significantly better ($P = 0.04$) in the PREFER group.

For the five dimensions of the EQ-5D (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), no significant differences were found between the groups (data not shown).

In a paired within-group analysis of the PREFER group, HRQL increased 28% from baseline to 6 months (from 46.9 ± 21.3 to 60.4 ± 20.6, $P = 0.013$). If all measurements of HRQL (1, 3, and 6 months) were included, the increase was 20% (from 48.2 ± 19.8 to 57.6 ± 19.2, $P = 0.026$). Corresponding values for the control group were 3% (from 50.7 ± 24.2 to 52.3 ± 23.2, $P = 0.61$) and 1.0% (from 48.7 ± 24.0 to 49.6 ± 23.8, $P = 0.74$), respectively. For the other dimensions, no significant differences were found.

The Edmonton Symptom Assessment Scale

No significant differences were found between the PREFER and control groups in regard to any item of the ESAS scale or after adjusting for age difference (data not shown). Nausea was significantly improved (2.3 ± 2.7 vs. 1.2 ± 1.7, $P = 0.02$) in the PREFER group, but not in the control group. Numerical improvements were observed in eight out of nine items in the PREFER group compared with four out of nine in the control group. The item 'other' was not included due to very few answers,

Kansas City Cardiomyopathy Questionnaire

No significant differences were found between the two treatment groups for all dimensions of the KCCQ at baseline (data not shown) and 6 months. However, in the PREFER group, we noted an increase in 19 summary scores and a decrease in one. The increase was statistically significant for total symptom burden (18%, $P = 0.035$), self-efficacy (17%, $P = 0.041$), and QoL (24%, $P = 0.047$; *Table 2*).

In the control group, we found no significant difference in any dimension (data not shown). Increases were observed in 11 dimensions and decreases in 9.

Functional classes

Functional classes improved in the PREFER group compared with controls, including a significant difference in mean NYHA class at 6 months (2.9 ± 0.65 vs. 3.3 ± 0.58, $P = 0.012$, baseline 3.2 vs. 3.1; *Table 3*). In the PREFER group, improvement was seen in 11 out of 28 (39%) vs. 3 out of 32 (9%) in the control group ($P = 0.015$). Worsening NYHA functional class was found in 2 out of 28 (7%) vs. 5 out of 32 (16%) patients in the PREFER and control groups, respectively.

Hospitalizations

The mean number of hospitalizations was significantly lower in the PREFER group than in the control group (0.42 ± 0.60 vs. 1.47 ± 1.81, $P = 0.009$; *Table 4*). The total number of hospitalizations was 15 in the PREFER group and 53 in the control group. The total number of days spent in hospital was 408, range 1–46 days, being 103 (range 1–45 days) in the PREFER group and 305 (range 2–46 days) in the control group. The mean number of days was significantly (2.9 ± 8.3 vs. 8.5 ± 12.4, $P = 0.011$) lower in the PREFER group compared with the control group. The number of days spent in hospital was also significantly lower in the PREFER group at the Departments of Medicine-Geriatrics (100, range 1–45 vs. 242, range 2–46 days) and Surgery (0 vs. 56, range 2–21 days) (*Table 3*). Days in other departments did not differ significantly (3, range 1–2 vs. 7, range 1–6 days).

No statistically significant ($P = 0.34$) difference (8 vs. 4 patients) in mortality occurred during 6 months.

Resource utilization

There were significant differences in the utilization of visits and phone calls or prescriptions of physicians and nurses between the PREFER and usual care group at the outpatient clinic of the hospitals and the primary healthcare centres (*Table 4*). Additionally, within the PREFER team there were 158 additional physician visits and 1031 nurse visits at the patient's home, and 36 phone call and/or drug prescriptions by the physician and 225 phone calls and/or prescriptions by the nurses. Summarizing all this, the most striking difference was found between nurse visits in the PREFER group and the usual care group (1075 vs. 230; $P = 0.000$). On the other hand, phone calls and prescriptions by doctors were more common in the usual care group (108 vs. 231), while physician's visits were somewhat similar (194 vs. 201).

Table 1 Baseline characteristics

	PREFER, *n* = 36	Usual care, *n* = 36	*P*-value
Female	10 (27.8)	11 (30.6)	0.80
Age, years	81.9 ± 7.2	76.6 ± 10.2	0.012
Civil status			
Single	14 (39)	14 (39)	1.00
Married/co-habiting	22 (61)	22 (61)	1.00
Smoking			
Never	13 (36.1)	14 (38.9)	0.81
Former	21 (58.3)	17 (47.2)	0.35
Actual/unknown	2 (5.6)	5 (13.8)	0.23
Alcohol			
Never	15 (41.7)	13 (36.1)	0.09
Regular use	16 (44.4)	17 (47.2)	0.41
Unknown	5 (13.9)	6 (16.7)	0.26
History of primary CVD for CHF	26 (77.2)	26 (77.2)	1.00
Ischaemic heart disease	13 (36.1)	13 (36.1)	1.00
Arterial hypertension	9 (25.0)	9 (25.0)	1.00
Valve disease	1 (2.8)	1(2.8)	1.00
Dilated cardiomyopathy	1(5.6)	0 (0.0)	0.10
Other	2(5.6)	3 (8.4)	0.64
Unknown	10 (28.0)	10 (28.0)	1.00
History of atrial fibrillation or flutter	23(63.9)	22 (61.1)	0.81
History of pulmonary disorder	15 (41.7)	18 (50)	0.48
History of stroke	14 (38.9)	12 (33.3)	0.56
History of diabetes	13 (19.4)	8 (16.6)	0.07
History of depression	6 (16.7)	12 (33.3)	0.30
History of renal disorder	10 (27.8)	11 (30.6)	0.57
History of malignancy	6 (16.7)	2 (5.6)	0.13
Creatinine >130 mmol/L	12 (33.3)	12 (33.3)	1.00
GFR <60 mL/min	25 (69.4)	22 (61.1)	0.46
Anaemia <120	19 (52.7)	15 (41.7)	0.29
NYHA III	28 (77.8)	23 (63.9)	0.34
NYHA IV	8 (22.2)	11 (30.6)	0.34
Dyspnoea			
None	1 (2.8)	2 (5.6)	0.56
Mild	8 (22.2)	6 (16.6)	0.55
Moderate	23 (63.9)	22 (61.1)	0.81
Severe	4 (11.1)	6 (16.7)	0.50
Fatigue			
None/missing	3 (8.3)	4 (11.1)	0.69
Mild	10 (27.8)	7 (19.4)	0.41
Moderate	16 (44.4)	15 (41.7)	0.81
Severe	7 (19.4)	10 (27.8)	0.41
Blood presssure			
Systolic, mmHg	124 ± 25.8	120 ± 19.9	0.42
Diastolic, mmHg	70 ± 12.5	74 ± 9.7	0.12
Systolic function			
EF 40–49	13 (36.1)	12 (33.3)	0.80
EF 30–39	16 (44.4)	21 (58.3)	0.36
EF <30	7 (19.4)	3 (8.3)	0.17
Treatment			
RAS blockade	32 (86.1)	33 (91.7)	0.69
Beta-blocker	30 (83.3)	31 (86.1)	0.74
MRA	10 (27.8)	13 (36.1)	0.45
Loop diuretics	32 (88.9)	30 (83.3)	0.50
Digitalis	8 (22.2)	5 (13.9)	0.36

Table 1 Continued

	PREFER, $n = 36$	Usual care, $n = 36$	*P*-value
Nitrates	12 (33.3)	11 (30.6)	0.80
Statins	12 (33.3)	18 (50.0)	0.15
Anticoagulants	17 (47.2)	17 (47.2)	1.00
ASA/Trc.inh.	21 (58.3)	15 (41.7)	0.16
No. of other drug treatments, median	5	6	0.73
Devices, procedures			
CRT without ICD	2 (5.6)	2 (5.6)	1.00
Pacemaker	4 (11.1)	5 (13.9)	0.72
Valve operations	4 (11.1)	3 (8.3)	0.69
History of CABG/PCI	17 (47.2)	13 (36.1)	0.34

Data are given as *n* (%) or mean ± standard deviation.
ASA, acetylsalicylic acid; CABG, coronary artery bypass graft; CHF, chronic heart failure; CVD, cardiovascular disease; GFR, glomerular filtration rate; ICD, implantable cardioverter defibrillator; MRA, mineralocorticoid receptor antagonist; RAS, renin–angiotensin system; Trc.Inh., thrombocytic inhibitor.

Table 2 The within-group analysis of all dimensions of Kansas City Cardiomyopathy Questionnaire in the PREFER-treated patients

KCCQ-12	*n*	Mean ± SD	*n*	Mean ± SD	*P*-value
Physical limitation, bl.–6 m	24	58.5 ± 21.9		60.0 ± 26.2	0.93
Physical limitation, bl., 1–6 m	33	55.1 ± 24.1		55.3 ± 27.3	0.83
Symptom stability, bl.–6	26	51.0 ± 25.0		55.8 ± 24.8	0.60
Symptom stability, bl., 1–6 m	34	51.4 ± 22.1		52.2 ± 23.3	0.97
Symptom frequency, bl.–6 m	25	59.1 ± 22.5		65.8 ± 27.6	0.13
Symptom frequency, bl., 1–6	33	56.4 ± 21.4		58.2 ± 29.6	0.63
Symptom burden, bl.–6	27	58.8 ± 21.4		63.3 ± 28.5	0.15
Symptom burden, bl., 1–6 m	35	59.2 ± 20.2		59.6 ± 26.5	0.67
Total symptom score, bl.–6 m	26	55.9 ± 20.6		65.8 ± 25.8	**0.041**
Total symptom score, bl., 1–6 m	34	56.7 ± 20.2		59.3 ± 27.3	0.37
Self-efficacy score, bl.–6 m	26	50.5 ± 29.0		59.1 ± 25.1	0.24
Self-efficacy score, bl., 1–6 m	33	48.9 ± 28.2		61.7 ± 26.9	**0.041**
QoL, bl.–6 m	27	49.5 ± 24.7		61.3 ± 26.6	**0.047**
QoL, bl., 1–6 m	34	51.8 ± 24.7		58.8 ± 24.9	0.21
Social limitation, bl.–6 m	22	53.9 ± 24.6		59.9 ± 28.1	0.35
Social limitation, bl., 1–6 m	29	56.1 ± 23.1		57.5 ± 27.9	0.76
Overall summary score, bl.–6 m	33	53.3 ± 18.9		51.4 ± 34.3	0.96
Overall summary score, bl., 1–6 m	31	56.7 ± 16.7		59.5 ± 21.9	0.22
Clinical summary score, bl.–6 m	30	54.0 ± 20.7		55.7 ± 30.1	0.47
Clinical summary score, bl., 1–6 m	33	55.5 ± 18.3		57.7 ± 24.9	0.34

The comparison over time within the PREFER arm.
bl.–6 m denotes changes from the baseline value to the value at 6 months and bl., 1–6 m denotes values also at 1 and 3 months in the case of missing values at 6 months.
Scores are transformed to a range of 0–100, in which higher scores reflect better health status.
KCCQ, Kansas City Cardiomyopathy Questionnaire; QoL, quality of life.

Discussion

Our main findings were significant improvements with the PREFER intervention compared with usual care in regards to HRQL, NYHA, and morbidity, with reductions in the number of hospitalizations and days spent in hospital. Moreover, in the within-group analysis of the usual care and the PREFER groups, patients in the PREFER group showed increases in most dimensions of the KCCQ, and were significantly improved in terms of total symptom burden, self-efficacy, and QoL. The symptomatic improvement of patients in the PREFER group was accompanied by a marked reduction in the need for hospitalization.

The PREFER model was developed from the goals and steps in the process of providing palliative care for patients with CHF as recommended by the ESC.[1,5,9] These were: patient features; confirm diagnosis; patient education; establishment of an advanced

Table 3 Distributions, mean values, and changes of functional classes at the end of study, and total number and mean number of hospitalizations per patient during the study

	PREFER *n*	Mean ± SD	Control *N*	Mean ± SD	*P*-value
NYHA					
NYHA I	1		0		
NYHA II	5		2		
NYHA III	19		19		
NYHA IV	3		11		
NYHA		2.9 ± 0.65		3.3 ± 0.58	0.012
NYHA change					0.037
Improved	11		3		
Unchanged	15		24		
Worse	2		5		
Morbidity					
Hospitalizations, *n*, mean ± SD	15	0.42 ± 0.60	53	1.47 ± 1.81	0.009
Numbers, total	15		53		
None	23		15		
1	11		9		
2	2		2		
3	0		5		
4	0		2		
5	0		2		
7	0		1		

care plan; required organization of services; symptom management; identifying end-stage heart failure; breaking bad news to the patient and family; and establishing new goals for care. The PREFER model also includes goals of support to relatives/bereavement and to the team members.[12] The strategy used in the PREFER model goes beyond traditional heart failure management at hospitals by including person-centred and specialized palliative care.

One of the main differences from standard heart failure management is that the PREFER team takes more comprehensive care of the person, taking into consideration symptoms and signs related to accompanying co-morbidities, such as stroke, renal dysfunction, pulmonary disorders, anaemia, and even cancer, which were common in the present study.

In the PREFER group, we used PCC in addition to the identity-promoting care concept applied to palliative care planning.[12] Earlier studies showed that being met as a person (i.e. with trust and a willingness to help) by professional caregivers at home seems to increase feelings of security,[18] and that seeing the patients in their home situation helps the team to tailor care to the persons' way of life.[19] To the best of our knowledge, this is the first study to evaluate a new approach for CHF management by integrating specialized palliative home care and heart failure care. This study provides new information about the PREFER model resulting in improved HRQL, total symptom burden, and NYHA functional class in association with reductions in the number of hospitalizations and days spent in hospital at both the Medicine-Geriatrics and Surgery departments. These findings are in line with the results of the PCC-HF study,[20] which showed that PCC during in-hospital care impacts the length of stay in the hospital and maintained functional performance.

Relapses and rehospitalizations are very common in patients with CHF. This condition has the highest rate of rehospitalization at departments of medicine[21] and is very costly and resource demanding.[22] County councils expend much effort, with limited success, to reduce both the length of stay and rehospitalization for these patients. In line with Kossovsky *et al.*,[23] Clarke,[24] and Ekman *et al.*,[20] we also support the idea that relapses and length of stay and rehospitalization can be reduced by improving the quality of care, and that common practice should be rethought and re-evaluated with regard to shortening of the length of hospitalizations through rapid discharge after symptom relief. Another type of structure of CHF care also seems to be needed.[9] The management of patients with CHF and their co-morbidities is very complex and a challenge to all of the healthcare personnel and systems involved. While CHF is largely managed in primary care in mild to moderate stages, the problems arise in more advanced situations, especially when the syndrome of CHF is accompanied by co-morbidities. This is not easily handled by primary healthcare physicians.[25] A bridge between acute care of CHF at hospitals and primary healthcare has been successfully fulfilled by heart failure clinics,[26] which focus primarily on the management of heart failure. The strategy of PREFER goes beyond traditional heart failure management in clinics by including specialized palliative care as practised for cancer patients. One of the main differences from standard heart failure management is that PREFER also takes more comprehensive care of accompanying co-morbidities. The team is responsible for the total care of the patient. Assessment of symptoms, QoL, and risks of decubitus, falling, and malnutrition is continual. This does not mean that responsibility is removed from the patient's general practitioner or other specialists, but rather that they are included

Table 4 Total number of physician and nurse visits, phone calls, and/or drug prescriptions at the outpatient clinics of the hospitals and at the primary healthcare centres.

	PREFER *n*	Usual care *n*	*P*-value
Hospital outpatient clinic			
Physician visits, *n*	27	133	0.000
Median (min–max)	1 (4–30)	3 (2–11)	
Physician, phs., pres., *n*	42	86	0.012
Median (min–max)	3 (0–8)	3 (0–10)	
Nurse visits, *n*	4	60	0.003
Median (min–max)	1 (0–4)	2 (0–27)	
Nurse, phs., pres., *n*	8	44	0.003
Median (min–max)	1 (0–4)	2 (0–8)	
PHC			
Physician visits, PHC, *n*	9	54	0.027
Median (min–max)	1 (0–3)	2 (0–8)	
Physician, phs., pres., *n*	30	145	0.000
Median (min–max)	1 (0–5)	1 (1–14)	
Nurse visits, PHC, *n*	29	61	0.25
Median (min–max)	1 (0–12)	2 (0–14)	
Nurse, phs., pres., *n*	59	153	0.010
Median (min–max)	3 (0–9)	4 (1–21)	
Physician visits, home, *n*	0	14	
Median (min–max)	0 (0–0)	2, (1–5)	
Nurse visits, home, *n*	11	109	0.032
Median (min–max)	2 (1–3)	5 (1–23)	

PHC, primary healthcare centre; Phs, phone calls; pres, prescriptions.

in the collaboration. PREFER is also organized in close co-operation with out-of-hours palliative advanced home care. This team is fully informed of the identities of the patients and knows how to respond to calls.

On the other hand, PREFER differs from traditional palliative care by including active heart failure treatment with acute heart resuscitation if needed, according to the patient's expressed desire.[19,27] Even more important is the intention to use all modern pharmacological treatments and other types of devices, such as CRT, if necessary, to reduce symptom burden. The decision to include this form of active treatment arises from the difficulty in defining a transition point to palliative care for heart failure patients.[19,27,28] Their lives are sometimes described as 'living near death' or 'a roller coaster life', i.e. an ongoing oscillation between ups and downs.[18] The unpredictable progression of the illness leads to a great risk that these patients and their close relatives will not have access to palliative care.[1,5]

The mechanisms underlying the favourable results are not evident. Several components are probably related to each other, and it could be difficult to separate them to explain the effectiveness of the intervention.[29] In some cases, the recognition of important co-morbidities is more important than the syndrome of CHF *per se*. In other cases, undertreatment of the CHF condition may be an explanation. Despite the participating patients being regarded as 'optimally treated' by their physician before inclusion in the study, a number of patients had their medications re-evaluated, up-titrated, and rigorously checked according to optimal evidence-based therapy for CHF. Nevertheless, the impact of physiological, psychosocial, and spiritual problems should be recognized. The continuity of the team, accessibility, and the possibility of visits and examinations at patients' homes are important measures for lessening the patient's total symptom burden. The confidence, availability, and trust in the PREFER team may have had a substantial impact on patients' HRQL and need for hospital care. Also, the involvement of a wife or husband and other relatives may be important.[30] A number of explanations are possible as the PREFER concept involves different strategies involving specialist competences from different areas: general practitioners and doctors trained in palliative care, cardiologists, nurses, physiotherapists, and occupational therapists. We consider that the PCC has had a substantial impact on the results. One of the main differences between the two strategies was the nurse visits at the patient's home, which were substantially and significantly more frequent in the PREFER group compared with the usual care group. This made it possible to carry out the structured, PCC at home. Moreover, besides the updating of drug treatment according to recent guidelines both for drug treatment and device therapy, we hypothesize that the continuity of the same personnel, being a rather small group, was of importance. The possibility for the patients to reach the personnel easily by phone and that treatment often could take place at the patient's home instead of them being admitted to hospital may have contributed to the achieved results. These steps of the PREFER concept may have created confidence in and reassurance by the care given and reduced patients' anxiety.

Further research is needed to evaluate the separate impact of each component of the PREFER concept, if possible, and its contribution to the beneficial effects found in the present study.

Limitations

Our findings have a number of limitations. First, patients in the PREFER group were significantly older than those in the control group, but this difference was adjusted for in the follow-up analyses. Secondly, the outcome analyses were not blinded; functional class was evaluated by physicians involved in the trial. Questionnaires were filled out by participating patients who knew the group to which they belonged. This may have introduced some bias into the symptom reporting and assessment of NYHA classes. Thirdly, this study was small and at a single centre, which should be considered when interpreting and generalizing the study findings. Although the number of patients was limited, a strength of this study was that we included patients with a high number of severe co-morbidities that are seldom accepted in most randomized clinical trials. The exclusion criteria were mostly for practical or administrative reasons, so we consider the patients in this study to be representative of many elderly patients with moderate to severe CHF treated in hospitals and primary healthcare.

Conclusion

Patient-centred care seemed to relieve the physical, physiological, social, and spiritual problems of patients with severe CHF by improving HRQL, functional class, and total symptom burden, and reduced hospitalizations and the number of days spent in hospital. Our findings also challenge the traditional way of caring for elderly patients with CHF and accompanying co-morbidities.

Acknowledgements

We would like to thank the participants for sharing data about their illness with us, and Claes Lundgren MD, Skelleftea Hospital, Sweden for valuable support in identifying eligible patients for the study.

Funding

This work was supported by the Swedish Association of Local Authorities and Regions, the Swedish Heart and Lung Association, and the Ronnbaret Foundation Skelleftea Municipality.

Conflict of interest: none declared.

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