Quality of Life of Individuals With Heart Failure

A Randomized Trial of the Effectiveness of Two Models of Hospital-to-Home Transition

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Background. The growing number of patients with congestive heart failure has increased both the pressure on hospital resources and the need for community management of the condition. Improving hospital-to-home transition for this population is a logical step in responding to current practice guidelines' recommendations for coordination and education. Positive outcomes have been reported from trials evaluating multiple interventions, enhanced hospital discharge, and follow-up through the addition of a case management role. The question remains if similar gains could be achieved working with usual hospital and community nurses.

Methods. A 12-week, prospective, randomized controlled trial was conducted of the effect of transitional care on health-related quality of life (disease-specific and generic measures), rates of readmission, and emergency room use. The nurse-led intervention focused on the transition from hospital-to-home and supportive care for self-management 2 weeks after hospital discharge.

Results. At 6 weeks after hospital discharge, the overall Minnesota Living with Heart Failure Questionnaire (MLHFQ) score was better among the Transitional Care patients (27.2 ± 19.1 SD) than among the Usual Care patients (37.5 ± 20.3 SD; $P = 0.002$). Similar results were found at 12 weeks postdischarge for the overall MLHFQ and at 6- and 12-weeks postdischarge for the MLHFQ's Physical Dimension and Emotional Dimension subscales. Differences in generic quality life, as assessed by the SF-36 Physical component, Mental Component, and General Health subscales, were not significantly different between the Transition and Usual Care groups. At 12 weeks postdischarge, 31% of the Usual Care patients had been readmitted compared with 23% of the Transitional Care patients ($P = 0.26$), and 46% of the Usual Care group visited the emergency department compared with 29% in the Transitional Care group ($\chi^2 = 4.86$, $_{df\ 1}$, $P = 0.03$).

CONCLUSIONS. There were significant improvements in health-related quality of life (HRQL) associated with Transitional Care and less use of emergency rooms.

Key words: Heart failure; transition; hospital-to-home.   (Med Care 2002;40:271–282)

Individuals with congestive heart failure (CHF) are one of the fastest growing and challenging complex health populations requiring care in both the hospital and community sectors. The incidence of CHF increases dramatically with age, and there is a 50% mortality after 5 years.[1,2] CHF is reported to be the only cardiovascular condition that is increasing in incidence, prevalence, morbidity, and mortality.[2–5] Heart failure may be an even greater public health problem than the statistics reveal. Estimates rely on ICD codes for primary and secondary diagnosis, and these have been reported to exclude one third of patients with clinical evidence of acute CHF.[6]

For individuals and families dealing with heart failure, the condition poses significant challenges in terms of day-to-day living and the burden of care. Frequent hospital admissions are common.[7,8] There is a fragile balance between coping with this long-term condition at home and the exacerbations, often life-threatening, which require hospitalization. Considering the illness trajectory of individuals with heart failure and the therapeutic limits of drug therapies, the effectiveness of non-pharmaceutical, adjunctive interventions has become a clinical and research priority. These interventions include enhancing self-management and symptom control through knowledge, diet, rest and exercise, and proactive symptom monitoring. The former Agency for Health Care Policy and Research (AHCPR) guidelines[4] for CHF, for example, make eight specific recommendations related to hospital discharge and counseling, and self-management. Professional bodies agree that effective management of this condition requires collaborative, proactive vigilance of medical therapies by health care providers and active support for self-management before and after hospitalizations.[4,9] Recommendations about incorporating a comprehensive approach across sectors of care (hospital, ambulatory, and home care) have followed closely on the international efforts with clinical practice guidelines about heart failure.[9] Recent randomized trials[7,10–12] have begun to rigorously evaluate the effectiveness of delivery models emphasizing supportive care for self-management (telephone outreach, patient education and information), and indi-

rect care activities (coordination, case managing and communication). Both hospital-based[7,10,12] and community-based approaches[11,13,14] have shown that an enhanced discharge process and follow-up, with the addition of a clinical nurse specialist, case manager, or cardiac nurse, produces positive patient benefit, reduces hospital readmission and health services utilization, or both. Characteristic themes are innovative delivery strategies, multiple interventions that add a component of comprehensive patient education and counseling, proactive nurse follow-up, and increased access to providers. However, these studies are limited by small sample size,[11] interventions requiring addition of new providers,[7,10–12] and primary outcomes focusing exclusively on system-related endpoints eg, readmission and emergency visits.[7,10–12,14] In summary, the trials are evaluating health services designed to 'case manage' a population with CHF by maintaining provider contact with patients through intensive assessment and education techniques to prevent disease exacerbation.[15] However, Ferguson and Weinberger[15] found equivocal results in their review of case management studies about the benefits in the health care system compared with the putative advantages. Thus, the question remains as to what can be done to stave off CHF exacerbations within the normal organization of services with the usual nurse providers, who are typically generalists. Cook et al[16] argue that complex systems can have gaps between people, stages, and processes. A key aspect for improvements is through the reinforcement of a practitioner's normal ability to bridge these gaps. In the case of heart failure, our premise was that adding a new provider might not be the most effective, feasible, or efficient solution. Could the gap be bridged another way? Rather, by focusing on the activities of usual providers, and the structure and process of transition from hospital-to-home, could continuity with support for self-management be enhanced to improve patient outcomes and reduce health service utilization?

We conducted a prospective, randomized trial to evaluate whether the use of usual providers, and a reorganization of discharge planning and transition care with improved intersector linkages between nurses, could improve quality of life and

health services utilization for individuals admitted to hospital with heart failure. It was hypothesized that the enhanced transition process would improve quality of life and reduce emergency room visits and hospital admissions for individuals discharged from hospital with heart failure.

Materials and Methods

Study Patients and Setting

All individuals admitted to two general medical units of a large urban teaching hospital in Ottawa, Ontario, Canada, with a diagnosis of congestive heart failure, were screened for the study. The two units were similar in size (35–37 beds), occupancy rates (90–94%) and RN staffing (49–51% full time, 29–33% permanent part-time). A centralized department admitted patients to either unit, based solely on bed availability. Study inclusion criteria included: residing in the regional home care radius (60 km); expected to be discharged with home nursing care; English or French speaking; admitted for more than 24 hours to the nursing units; and, not cognitively impaired (score <8 on Short Portable Mental Status Exam).[17,18] The study received approval from the institutional Ethics Review Board of the Ottawa Civic Hospital and Loeb Health Research Institute.

Randomization

Using a computer-generated schedule, consenting patients were randomized by the research coordinator, within 24 hours of hospital admission, to receive either Usual Care or Transitional Care. Prepackaged, consecutively numbered, sealed, opaque envelopes containing the group allocation were prepared for each nursing unit and administered from the research office. Neither the patients, nor the members of the study team, were aware of treatment assignment until after randomization. During hospitalization, the staff physicians established the medical regimen. Other usual providers included hospital and community primary nurses and the home care coordinators. Usual discharge procedures are described and compared with Transitional Care in Table 1. With respect to usual discharge planning and postdischarge care, patients in the control group received optimal usual care in that the timing and number

of home nurse visits were scheduled to match those received by Transitional Care group. The similar number of home visiting and provider contacts during the intervention period (2 weeks after hospital discharge) controlled for the effect of attention alone.

On admission to hospital, the research coordinator flagged the patient's chart as a signal to the patient's primary nurse to follow a checklist of activities for Transitional Care. The protocol was implemented from admission to 2 weeks after hospital discharge, after which the patient received usual care by community nurses while on home care. During the pilot study for this trial, the 10 to 14 days after hospital discharge was identified as the critical 'settling in' period after hospitalization. It was also a typical length of stay for home care follow-up after hospitalization. Eleven individuals were readmitted to hospital within 2 weeks of discharge (the intervention period). Timing for outcome measures then began on the second discharge and followed for 3 months.

Usual Care and the Transitional Care Intervention

Usual care for hospital-to-home transfer involves completion of medical history, nursing assessment form, and, in ideal circumstances within 24 hours of hospital admission, a multidisciplinary discharge plan. Weekly discharge planning meetings further identify patient needs. A regional home care co-coordinator consults with the hospital team as required and may meet directly with patients and families. Immediately before discharge, a physician completes a referral for home care, and necessary services and supplies are communicated to the home nursing agency. Usual home nursing care for CHF patients includes assessment and monitoring, health teaching, provision of direct care, eg, administration of medications, and managing equipment and treatments.

Patients in the Transitional Care (TC) arm received the standard discharge planning and care, plus a comprehensive program, adding supports to improve the transfer from hospital to home. To develop this program, hospital and community nurses met to focus on the 'outreach' from the hospital and 'in-reach' from the community during the transition. An intersectoral continuity of care framework[19] guided their efforts in identifying gaps to specifically address 3 major aspects of a

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TABLE 1. Description of Usual Care and Transitional Care Intervention by Group as Tracked by Protocol Checklist

Transitional Care	%	Usual Care	%
Hospital primary nurse assigned on admission*	99	Hospital primary nurse assigned on admission*	
Home care notified of study participation*	98	Home care notified of study participation*	91
Evidence-based education program (PCCHF) initiated[20]†	97		
Written referral to Home Care on discharge*	66	Written referral to Home Care on discharge*	59
Nursing transfer letter received by Home RN*	92		
Phone Outreach within 24 hours of discharge*	78		
Phone advice from hospital nurse*	20		
Education booklet used at home*	97		
Education map†	97		
Community RN consult with Hospital RN*	9		
Community nurse visits minimum 2 visits in first 2 weeks post-discharge†	94	Community nurse visits minimum two visits in first 2 weeks post-discharge†	93

*Linkage activity.
†Care activity.

hospital-to-home transition: (1) supportive care for self-management; (2) linkages between hospital and home nurses and patients; and (3) the balance of care between the patient and family and professional providers. The defining characteristics of TC were the use of a structured, comprehensive, evidenced-based protocol for counseling and education for heart failure self-management, plus additional and planned linkages to support individuals in taking charge of aspects of their care. An evidence-based intervention is defined as care based by current research or, in the absence of strong empirical findings, on expert consensus. This may involve the use of professional practice standards and practice guidelines, if available.

The education-counseling protocol entitled, Partners in Care for Congestive Heart Failure (PCCHF), was developed in response to AHCPR guideline recommendations.[4] PCCHF has two clinical components: (1) the patient workbook, and (2) an education map that provided the overall education plan, and serving as a patient-held documentation tool.[20–22] The workbook, a comprehensive resource for self-management, provides a structured approach for patient education, yet allows for tailoring to individual needs.[20,21] It covers the basics of heart function and self-monitoring—what CHF means, management of medications, diet, exercise, stress, support systems, and community resources. There is a pocket for insert-ing patient-specific information (eg, medication, dietary handouts). Linkages, additional to usual practice, were created among providers and the patients including: a nursing transfer letter to the home care nurse detailing clinical status and self-management needs; a telephone outreach from the hospital nurse within 24 hours of discharge; notification to home care as to whom hospital primary nurse was for follow-up consult if necessary; and a patient-held documentation tool.

Data Collection and Outcomes Measures

The primary outcome was health-related quality of life, symptom distress and function at 6- and 12-weeks postdischarge, as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), a condition specific instrument.[23–25] Secondary outcome measures included: quality of life measured with a generic measure, the Medical Outcome Study Short Form (SF-36),[26–29] and the number of all-cause emergency room visits and hospital readmissions.

Hospital and home care clinical nursing staff delivered care to both the Usual Care and the TC groups. Two nurse research coordinators, reporting through the Clinical Epidemiology Unit, managed this trial. They were not connected in any way to either the hospital or home care departments, and wore research ID badges to avoid being mistaken

for clinical nursing staff. The coordinators screened and recruited the participants and collected baseline data. On admission, profile information was collected through chart audit using standardized forms for demographic and circumstance of living data and clinical data, including previous admissions, comorbidities, and severity of medical problems from admitting notes and history. Outcome data were collected within 24 hours of discharge (T1) and at two (T2), six (T3), and 12 weeks (T4) after hospital discharge. Appointments in the home were made independent of scheduled home care visits. Patients had the option to complete the forms themselves or partake in a structured interview with the research staff. The majority (>90%) preferred the structured interview.

Analysis

The sample size was based on detecting a clinically important difference in the Minnesota Living with Heart Failure Questionnaire. From changes in function and well-being experienced by patients in placebo controlled angiotensin converting enzyme inhibitor (ACE) trials, the developers of the scale determined that 5 points (4.8%) was the minimally clinically important difference (MCID) in score.[23,25,30,31] With the probability of a type I error set at 0.05 and power of 80%, 50 patients per group were required to detect a 5-point difference in the MLHFQ score, assuming a SD of 9 for the change scores (personal communication, Thomas Rector, May 1996). Allowing for 30% withdrawal because of death or study dropout, and an additional 20% for sufficient statistical power to perform physical and emotional dimension subscale analysis, 75 participants per group were required.

Descriptive statistics (means, SD, proportions) were used to determine the characteristics of those completing the trial and the study dropouts. The success of randomization was determined by comparing the intervention group with the Usual Care group profile on demographic and clinical variables at baseline (T1) using χ^2 test for categorical variables or the Student t test for continuous variables.

Participants in the study were followed for 12 weeks after hospital discharge. All those completing outcome measures, whether they received the intervention, were included in the analyses to conduct an intention-to-treat/completer analysis.

The primary analysis tested the mean difference in the condition-specific quality of life outcome (MLHFQ) between baseline and 6 and 12 weeks postdischarge with the 2 study groups. Mean differences were compared using the independent t test with either the pooled or separate variance estimate as appropriate. To assess trends over time, a two-way analysis of variance (ANOVA) compared each outcome across two factors: the cohort (usual care or TC) and time (baseline and after hospital discharge repeated measures). The clinical importance was assessed using a minimally clinical importance difference (MCID). The MCID was defined as a 5-point or greater change in the total MLHFQ score and 5% change in the physical and emotional dimension scores (2 points on the physical dimension score, 1.25 points on the emotional dimension score). The scores are calculated in whole numbers on a 5-point scale; therefore, the MCID for the emotional dimension was rounded upward to 2 points. Thus, a change of ± 2 points was classified as 'no change'. This had the conservative effect of requiring a 12% deterioration in score to be in the 'worse' category.

Results

Baseline Characteristics

Trial Participants. In the 18 months of study (June 1996 - January 1998), 483 patients with heart failure were admitted to the two study units. Once screened, 212 of these admissions were deemed eligible, and 200 individuals consented to participate (5.6% refusal). Reasons for patient ineligibility included: coming from or being discharged to a long-term care facility (n = 104, 38%); living outside the catchment area for home care (n = 63, 23%); too ill, or deceased, shortly after admission (n = 40, 15%); first language other than French or English (n = 33, 12%); being discharged <24 hours (n = 16, 6%); diagnosis changed (n = 8, 3%); other (n = 7, 3%). After hospital admission and baseline assessment, 8 of 200 consenting participants (5 Transitional Care, 3 Usual Care) did not subsequently enter the study after being randomized (4 because of death/becoming too ill, 2 refusing home care, 1 change in diagnosis, 1 discharge to long-term care). The 'too ill' category included being on life support, in palliative care or in intensive care. Of the 192 remaining patients, 100 were randomly allocated to Usual Care and 92

to the TC group. Before the 12-week study completion, 20 people (11 Usual Care, 9 TC) died or became too ill before the 12 weeks of study completion, 8 withdrew (7 Usual Care, 1 TC), and 7 were a loss to follow-up (5 Usual Care, 2 TC). Most of those randomized (81%, n = 157) completed the study. The 'intent to treat/completer' analysis was conducted on 157 participants who completed the outcome measures, whether they received treatment.

The baseline profile (T1) of the study population after randomization (n = 192) was one of a fairly elderly group. Less than 7% were under 60 years of age and the mean age was 76 years (median 77 years, range 33–93 years). Most participants (91%) were retired or on disability pension, and nearly half lived alone. Most (76%) had at least some high school education. Nearly 80% had NYHA Functional Class[4] III or IV as assessed by the nurse research coordinator on admission. On average, individuals took six prescription medications daily (Table 2).

Comparability of Experimental and Control Participants.

Profiles of those completing the study to 12 weeks (n = 157) and those who did not complete (n = 35) were similar, with no statistically significant differences on any of the demographic or clinical variables. A comparison of the clinical, social and demographic characteristics of the Usual Care and TC groups revealed well-balanced groups with no statistically significant differences in the baseline characteristics between the experimental and control participants (Table 2). A further comparison was made with these characteristics and the 157 participants who completed the study, and again, no differences were found.

Quality of Life

With the primary outcome measure, the ML-HFQ, a lower score indicates less disability from symptoms (range 0–105). The trend over time with the total MLHFQ score is one of continued improvement for the TC group (Fig. 1). The effect of hospitalization and the intervention are intertwined at 2 weeks (T2). As expected, quality of life for participants in both groups improved at the

2-week point (T2) as a hospital admission indicates a pressing need for medical intervention. Alleviation of the exacerbation precipitating the hospitalization would be expected to result in improvements, regardless of the group assignment. While those receiving usual care showed no further improvement at 6 and 12 weeks, the TC group showed both clinical and statistically significant improvements in their reported health-related quality of life (HRQL) (Table 3). The pattern was similar with the MLHFQ physical dimension score (Table 3). With the emotional dimension of the MLHFQ, TC group the scores improved significantly at T3 compared with baseline and were sustained at 12 weeks, compared with Usual Care participants who had no improvement in this score at 6 or 12 weeks.

Clinical Importance of the Quality of Life Improvements

Relative changes in score between baseline and T4 (T1-T4, divided by T1) provide an indication of the clinical importance of the change in MLHFQ scores (Table 3). For instance, in the total MLHFQ scores at 12 weeks, the improvement from baseline for the TC group was 43% compared with 14% for Usual Care group. With the physical dimension, the TC group improved 42% from baseline compared with 9% for Usual Care participants. Although having only borderline statistical significance, the relative change in score was greatest with the MLHFQ emotional dimension where improvement was 36% for the TC group, compared with less than 1% with Usual Care.

To further understand the clinical importance of the differences in MLHFQ scores, the proportion of individuals in each group with a predefined MCID score at 6 and 12 weeks were tabulated. Classifying scores into 'worse,' 'same,' or 'better' revealed that, at 6 weeks, greater than 5 times the number of Usual Care patients had deteriorated (total MLHFQ) compared with the TC participants. At 12 weeks, statistically significant differences were seen in status, with TC improving in both the total MLHFQ and the physical and emotional dimensions (Table 4).

The SF-36, the secondary quality of life outcome, included physical and mental component scales and a general health subscale (five items). A higher score indicates a better status with the SF-36 scales. Table 5 illustrates the scores at base-

TABLE 2.   Comparison at Baseline of Characteristics of The Study Population and Those Allocated to Usual Care and Transitional Care Groups

Characteristics	Total (N = 192)		Usual Care (n = 100)		Transitional Care (n = 92)		Statistic	
	n	(%)	n	(%)	n	(%)	χ^2	P
Gender: females	87	(45)	44	(44)	43	(47)	0.15	0.70
Marital status: married	81	(42)	43	(43)	38	(41)	0.06	0.81
Living arrangements: alone	93	(48)	47	(47)	46	(50)	0.17	0.68
Education	(n = 188)		(n = 98)		(n = 90)		3.51	0.32
Grade school	44	(24)	21	(22)	23	(26)		
High school	104	(55)	54	(55)	50	(55)		
College	10	(5)	8	(8)	2	(2)		
University	30	(16)	15	(15)	15	(17)		
Employment status							1.62	0.44
Employed	7	(4)	2	(2)	5	(5)		
Unemployed	11	(6)	6	(6)	5	(5)		
Retired/disability	174	(90)	92	(92)	82	(90)		
NYHA Functional Class	(n = 191)		(n = 99)				2.87	0.41
Class I (less severe)	2	(1)	2	(2)	0	(0)		
Class II	41	(22)	20	(20)	21	(23)		
Class III	129	(67)	69	(70)	60	(65)		
Class IV (most severe)	19	(10)	8	(8)	11	(12)		
Admitted in last 6 months (n = 191)	70	(37)	41	(41)	29	(32)	1.71	0.19

	Mean	(SD)	Mean	(SD)	Mean	(SD)	t	P
Age (y)	75.64	(9.87)	75.74	(9.40)	75.52	(10.41)	0.15	0.88
Length of hospital stay (days)	7.63	(8.15)	7.67	(7.99)	7.59	(8.36)	.07	0.94
Severity of Illness								
No. comorbidities	3.76	(1.87)	3.59	(1.80)	3.95	(1.94)	−1.32	0.19
No. medications daily (n = 188)	6.36	(3.36)	6.47	(3.60)	6.23	(3.08)	0.48	0.63

The 'other' category under Marital Status includes single, divorced, and widowed. Additional admission(s) other than the one at time of entering study.

line, 6, and 12 weeks after hospital discharge for the physical and mental component scales and the general health subscale. No statistically significant differences were noted in general health or the physical component. On the physical component scale, poor scores are seen in both groups across
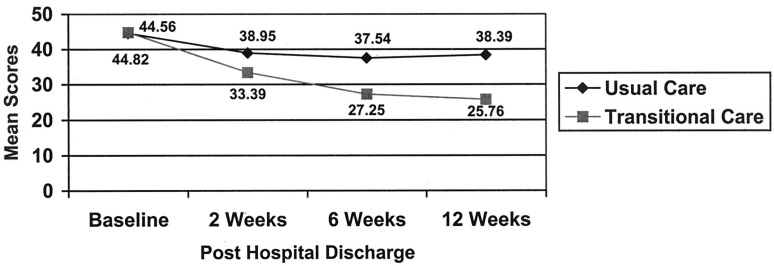

FIG. 1. MLHFQ Mean Total Score (n = 157).

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TABLE 3. Comparison of Mean Total MLHFQ Score and Physical and Emotional Dimension Scores at Baseline, 6 Weeks and 12 Weeks After Hospital Discharge

		Usual Care		Transitional Care		Statistic	
		Mean	(SD)	Mean	(SD)	t	P
MLHFQ total score (physical + emotional dimensions + 8 items) range 0–105	Baseline	44.56	(19.50)	44.82	(18.50)	−0.08	0.933
	2 Weeks	38.95	(19.54)	32.39	(19.71)	N/A	N/A
	6 Weeks	37.54	(20.27)	27.25	(19.07)	3.26	0.002*
	12 Weeks	38.39	(18.24)	25.76	(19.44)	4.16	<0.001*
Physical dimension (8 items) range 0–40	Baseline	25.45	(9.77)	25.46	(9.55)	−0.01	0.996
	2 Weeks	22.53	(10.19)	18.85	(10.87)	N/A	N/A
	6 Weeks	21.46	(11.15)	16.37	(11.04)	2.86	0.01*
	12 Weeks	23.21	(10.66)	14.89	(11.13)	4.75	<0.001*
Emotional dimension (5 items) range 0–25	Baseline	6.98	(5.89)	7.78	(6.38)	−0.82	0.416
	2 Weeks	6.83	(6.03)	6.18	(6.17)	N/A	N/A
	6 Weeks	7.25	(6.15)	4.52	(5.17)	3.00	0.006*
	12 Weeks	6.92	(5.54)	4.97	(5.76)	2.14	0.068*

(n = 157).
*Bonferroni correction made for two tests.

time, with the Usual Care participants showing no improvement and TC participants displaying modest improvement, with the difference at 12 weeks approaching significance (P = 0.07). A similar pattern of improvement for TC participants occurs in the mental component scales with differences between the two groups significant at 6 weeks (P = 0.05).

Hospital Readmission and Emergency Room Visits

The number of emergency room visits by the study group (n = 157) was calculated during the 12-week follow-up period and differed by group with significantly fewer visits being made by the TC participants. The rate of first visits was 46% in

TABLE 4. Proportion of Usual Care and Transitional Care Participants With a Minimally Clinically Important Changes on MLHFQ From Baseline to 6 and 12 Weeks After Hospital Discharge

	6 weeks				12 weeks			
	Usual Care	Transitional Care	Statistic		Usual Care (n = 76)	Transitional Care (n = 79)	Statistic	
			χ	P			χ	P
MLHFQ total score (MCID = 5 points)								
Worse	17 (22%)	3 (4%)	12.34	0.002	22 (29%)	6 (8%)	13.69	0.001
Same	17 (22%)	18 (23%)			10 (13%)	7 (9%)		
Better	42 (55%)	58 (73%)			44 (58%)	65 (83%)		
Physical dimension (MCID = 2 points)								
Worse	19 (25%)	16 (20%)	1.04	0.595	26 (34%)	8 (10%)	13.52	0.001
Same	11 (15%)	9 (11%)			6 (8%)	6 (8%)		
Better	46 (61%)	54 (68%)			44 (58%)	65 (82%)		
Emotional dimension (MCID = 2 points)								
Worse	24 (32%)	13 (17%)	8.18	0.017	32 (42%)	13 (17%)	13.28	0.001
Same	26 (34%)	22 (28%)			18 (24%)	21 (27%)		
Better	26 (34%)	44 (56%)			26 (34%)	45 (57%)		

(n = 157).

TABLE 5. Comparison of Mean Total Scores for the SF-36 Physical and Mental Component Scales and General Health Subscales at Baseline, 6 Weeks, and 12 Weeks After Hospital Discharge

		Usual Care		Transitional Care		Statistic	
		Mean	(SD)	Mean	(SD)	t	P
Physical component							
	T1	28.35	(9.11)	28.63	(9.46)	−0.19	0.850
		(n = 78)		(n = 78)			
	T2	28.67	(10.16)	30.03	(10.15)	N/A	N/A
		(n = 78)		(n = 78)			
	T3	29.35	(10.98)	30.86	(11.72)	−0.83	0.820*
		(n = 76)		(n = 79)			
	T4	28.31	(10.00)	32.05	(11.81)	−2.13	0.070*
		(n = 74)		(n = 77)			
Mental component							
	T1	49.81	(11.36)	50.49	(12.45)	−0.35	0.727*
		(n = 78)		(n = 78)			
	T2	49.31	(11.86)	52.26	(12.18)	N/A	N/A
		(n = 78)		(n = 78)			
	T3	49.53	(11.29)	53.46	(10.50)	−2.25	0.052*
		(n = 76)		(n = 79)			
	T4	51.03	(11.51)	53.94	(12.32)	−1.52	0.262*
		(n = 78)		(n = 78)			
General health							
	T1	55.42	(23.86)	54.74	(24.00)	0.18	0.859
		(n = 78)		(n = 79)			
	T2	52.62	(24.45)	55.10	(23.83)	N/A	N/A
		(n = 78)		(n = 79)			
	T3	48.49	(22.91)	56.34	(23.63)	−2.11	0.072*
		(n = 77)		(n = 79)			
	T4	49.31	(25.05)	54.48	(26.93)	−1.24	0.434*

*Bonferroni correction made for two tests.

the Usual Care group compared with 29% in the TC group (χ^2 = 4.86, $_{df\ 1}$, P = 0.03). Of those accessing the emergency room multiple times (range 1–5 visits), 50% of the Usual Care participants had more than one visit, compared with 32% of the TC group.

During the 12-week trial there were fewer TC participants admitted to hospital (23%), compared with 31% of the Usual Care group (χ^2 = 0.28, $_{df\ 1}$, P = 0.26). The sample size was inadequate to detect this administratively and economically important reduction in hospital readmission associated with TC.

Discussion

Transitional Care resulted in improved CHF-specific quality of life for individuals hospitalized with heart failure and fewer subsequent visits to emergency rooms. This study demonstrated that with modest reorganization of discharge pro-

cesses, and the provision of an evidence-based structure for patients and nurse providers to use for counseling and education,[20–22] significant gains can result. At 12-weeks after hospital discharge, compared with baseline TC participants were 13 points more improved in HRQL than Usual Care participants, ie, a 68% greater improvement. Given the severity of illness of the participants, this is a clinically important gain for those receiving TC. Readmissions to hospitals were showing a trend to lower rates but the study was not powered to detect significant reductions in this area. Not only was TC effective, but these gains were achieved with no additional providers. Other trials[7,10–12,14] have reported positive findings from innovative, interdisciplinary, nurse-led approaches for discharge with the CHF population but, in these studies, a case management role was added.

This trial is unique in that it was designed and powered using a HRQL measure as the primary

outcome. Previous studies have focused on health service utilization as the primary outcome.[7,10–12,14] Feeling better, as assessed by a specific HRQL measure (MLHFQ), was associated with significant changes in the use of emergency services. This highlights the importance of evaluating health services use in the context of self-reported well-being. The impact of "emotional symptoms" of individuals hospitalized with CHF is beginning to be recognized.[13] This factor may be one of the most important in understanding and intercepting emergency room and hospital use by those with heart failure.

Clinical practice guidelines offer one strategy to provide continuous, evidence-based care. Using a guideline across various health sectors provides a common script. With the CHF population, coordination and supportive assistance for self-management with education are key recommendations,[4] and improving hospital-to-home transition for patients with heart failure is a logical step in responding to current practice guidelines.[4,9,13,32] This trial has demonstrated that with an aid, namely a patient booklet and education map, usual providers can deliver evidenced-based education and counseling across sectors of care.

The experience in this study indicates the need for both a generic and specific HRQL outcome measure, an issue of continuing debate[34–37] The condition-specific HRQL measure (MLHFQ) was more sensitive to changes in this study than the generic measure (SF-36). A possible explanation is the difficulty for individuals to separate the contribution of particular co-morbidities to perceived deficits. For instance, is the lack of mobility or ability to assume normal social roles caused by CHF or to arthritis? This trial was focused on an intervention specific to CHF care; thus, alleviation of symptoms would be more evident with a condition-specific measure.[33] Theoretically, because of the nature of complex health populations having more than one prolonged condition, the use of a generic instrument is helpful in determining overall HRQL. However, the potential improvements on general quality of life with a CHF intervention in an elderly group, having more than three comorbidities, may have been diminished by the severity of their other conditions. More work on the application of condition-specific and generic HRQL instruments with complex health populations is required. However, having a generic measure aids in the comparison of those with CHF to other complex populations receiving supportive interventions. Using both instruments in this trial did not present an undue burden of administration with a fairly ill study population.

Limitations of this trial relate to conducting the study in a naturalistic manner in the usual setting of care with usual providers. Hospital nurses provided both experimental and control interventions. This was unavoidable and the only feasible means to conduct such a trial in the clinical setting, and not unduly disrupt service organization. There is a possibility of contamination with the hospital nurses providing Usual Care (control group) for, if the nurses were doing more than Usual Care, it would bias the results by decreasing the observed difference with TC. To assess the possible impact of this limitation, verification that the intervention happened and that the number of events in the TC differed from Usual Care was undertaken. Usual Care was likely made better by the study protocol, eg, early after hospital admission, the process of assessment and home care notification was rigorously adhered to in both groups. Two home visits within the first 2 weeks after hospital discharge were ordered and provided in both groups to account for attention effect. Consequently, Usual Care clients may have received extra care than may have been normally provided. Nevertheless, the effect from these acknowledged limitations would tend to minimize the difference in groups. Thus, any difference would be a true and underestimated difference attributable to the experimental maneuver. Blinding was not 100% assured. Patients may have inadvertently alerted the research coordinators of their assignment to Usual Care or Transitional Care either verbally or through the conspicuous presence of the PCCHF patient booklet. However, because the standardized outcome assessment (MLHFQ, SF-36) were standardized self-reports, we were reasonably confident that, even if assignment was exposed, there was little chance for impact on outcome results. Lastly, with multiple interventions it is not easy to assess the relative contribution of each component, nor the synergistic effect of the sum of the parts. With TC, the linkage aspects and supportive care for self-management were inextricably intertwined.

A note on generalizability of the study is pertinent. This trial was conducted in an urban center after discharge from a teaching hospital. The general medical units served a wide range of heart failure admissions including the elderly. The intervention was acceptable to most whom the pro-

gram applied (94%), and 81% completed the protocol. The length of follow-up (3 months) was comparable to other trials. The patients in the trial were ill with 77% having Stage III or IV NYHA class, and most being elderly (median 77 years). It is not known if similar results would be found with a younger, less advanced CHF population.

Further research is needed. From a health services perspective, guideline-driven interventions are an important strategy to provide evidence-based care and improve continuity. As seen in this study, the impact of such an intervention had no effect on general HRQL, yet demonstrated dramatic results on condition-specific HRQL. The next step will be in evaluating ways to tailor standard approaches to patients by considering their full range of comorbid conditions and social circumstances. Secondly, future trials of CHF hospital transition interventions should address the long-term care sector. Nearly 40% of those not eligible for this trial were from long-term care settings. Implications about outcome measurement in health service trials of reorganization of supportive care fall into two areas: (1) greater use of self-reported measure versus measures previously considered more objective, ones such as clinical endpoints or health services utilization; and (2) use of both a condition-specific and generic HRQL instrument. Ultimately, the examination of economic data in the context of self-reported, well-being data will greatly enhance our understanding of health service utilization. Lastly, components of the TC intervention, particularly the PCCHF educational-counseling approach, should be evaluated in settings other than a teaching facility eg, primary care, community programs, and with individuals at earlier stages of heart failure.

Conclusion

In conclusion, Transitional Care has an important role to play in altering the course of patients hospitalized with heart failure. Our results suggest that with modest adjustments to usual discharge and transition from hospital-to-home, patients with CHF can experience improved quality of life, and decreased use of emergency rooms, for 3 months after hospitalization. This approach will provide the needed adjunct to current management of heart failure. It may also have application in the management of other complex medical populations associated with frequent hospital use.

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