Disease Management Produces Limited Quality-of-life Improvements in Patients With Congestive Heart Failure: Evidence From a Randomized Trial in Community-dwelling Patients

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Background: Disease management programs are reported to improve clinical and quality-of-life outcomes while simultaneously lowering healthcare costs.

Objective: To examine the effectiveness of disease management in improving health-related quality of life (HRQL) among patients with heart failure beyond 12 months.

Methods: A total of 1069 community-dwelling patients 18 years and older in South Texas with echocardiographic evidence of congestive heart failure were randomly assigned to disease management, augmented disease management, and control groups. They were followed up 18 months. Patients in the control group received usual care. Patients in the intervention groups were assigned a registered nurse as a disease manager who performed telephonic patient education and medication management. Health-related quality-of-life data (based on the Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36]) were collected 4 times, at 6-month intervals.

Results: Disease management has a limited effect on HRQL. Analysis of the SF-36 health transition measure showed a positive effect of the intervention on self-reported improvement in health at 6 months and at 12 months ($P = .04$ and $P = .004$, respectively). However, no effect of disease management was observed across any of the SF-36 components. Women and patients with diastolic heart failure had poorer HRQL scores.

Conclusions: Participation in disease management has little effect on HRQL outcomes in congestive heart failure. Beneficial effects on the SF-36 scale scores seen at 6 and 12 months were not sustained. Therefore, it is unclear whether disease management can provide long-term improvement in HRQL for patients with congestive heart failure.

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The effects of congestive heart failure (CHF) management on the economics of healthcare systems and on the lives of patients have been well documented.[1,2] As a major component of inpatient and outpatient medical expenditures, the burden and expense of treating the disease are likely to increase further because of extensions in the life spans of patients with CHF and because of the aging of the US population.[3,4]

The prevalence and cost of treating CHF have motivated payers and healthcare policy makers to seek new methods of controlling costs. In the last decade, disease management programs, defined by the Disease Management Association of America as a "system of coordinated healthcare interventions and communications for populations in which patient self-care efforts are significant,"[5] have been reported to reduce the cost of caring for chronically ill patients, while delivering improved outcomes.[6] Given the widespread desire to control costs, disease management programs are rapidly growing in popularity. Recent statistics show that 88% of health maintenance organizations have implemented at least 1 disease management program, and about 150 companies providing this service have been established.[7] Despite the fact that disease management initiatives are increasingly common, there have been few large-scale randomized controlled trials testing the effectiveness of such programs.

The extant evidence on the effectiveness of disease management in CHF programs is mixed.[8,9] Most of the 11 randomized controlled trials reviewed by McAlister and colleagues[10] showed that disease management pro-

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grams in CHF produced modest reductions in different hospitalization measures, but no evidence of a mortality benefit was seen. The effect of disease management programs on health-related quality of life (HRQL) has been less well explored than clinical outcomes. Only 5 of the 11 trials reviewed by McAllister et al included assessments of HRQL, and in only one case was it shown that patients in the intervention group reported significant improvement. More recently, studies[11-18] have shown beneficial and statistically significant effects of participation in disease management on HRQL. This body of research, however, has several important limitations. Some studies[12,14] have been quasi-experimental, other studies[15,18] have had short (3-6 months) follow-up periods, while yet other studies[11,13] implemented narrowly focused interventions (eg, only patient education or weight management). Although some sex differences in HRQL have been noted,[19,20] few studies have examined ways in which the effect of disease management on HRQL outcomes may differ by sex. Still fewer studies have explored differences in HRQL outcomes according to cardiac dysfunction (systolic vs diastolic).

It is unfortunate that HRQL has not been a central focus in studies of disease management given its importance in the treatment of patients with heart failure. The causal relationship between heart failure and HRQL outcomes is bidirectional. Studies have shown that depression and psychological distress are expected sequelae of heart failure,[21,22] due to heightened uncertainty[23] and perceived loss of control.[24] Not only is poor mental health an anticipated comorbidity of heart failure, but also there is strong evidence that HRQL has an important causal link to morbidity and mortality in CHF patients.[25] Further underscoring the importance of HRQL in heart failure is patient opinion. Stanek and colleagues[26] observed that patients place a higher value on symptom reduction vs extended survival. In the present study, we assess the effect of a program of disease management on HRQL in a large, decentralized community-based population of patients with CHF.

METHODS

Patients

The South Texas Congestive Heart Failure Disease Management Project was a single-center randomized controlled clinical trial that ran from 1999 to 2003. It was conducted by The University of Texas Health Science Center at San Antonio, in partnership with Wilford Hall Medical Center, Brooke Army Medical Center, the South Texas Veterans Health Care System, TRICARE Southwest (Region 6), and University Health System, all in San Antonio. Potential patients were identified through lists generated from the databases of partner institutions filtered for an *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis code for CHF. A list of potential participants was also obtained through an academic partnership with the Centers for Medicare & Medicaid Services, Baltimore, Md. These patients were contacted by letter and were offered an opportunity to participate in the study. Congestive heart failure symptoms were determined by a screening questionnaire containing 9 broad items regarding a patient's history of CHF symptoms, such as lower extremity edema and shortness of breath. A positive answer to any of the history questions qualified a patient for further screening through echocardiography. Patients with systolic dysfunction qualified for the study if their ejection fraction was 49% or less; patients with diastolic dysfunction qualified if their echocardiogram showed evidence of left ventricular hypertrophy, defined as a left ventricular wall measurement of at least 1.2 cm in any dimension, an E to A reversal, or an abnormal transmitral flow pattern.

Among the patients who responded to our outreach and had a history of CHF symptoms, we performed or obtained screening echocardiograms on 1874 patients. Of this group, 125 (6.7%) were eligible but refused to participate, 564 (30.1%) did not qualify because of a lack of echocardiogram verification of CHF or the presence of various exclusion conditions, while 116 (6.2%) did not respond to further contact, died after their screening echocardiogram, or were unable to be enrolled before the deadline was reached. In total, the study enrolled 1069 men and women (57.0% of the 1874 patients who were screened) 18 years and older who had symptoms of CHF and had documented systolic or diastolic dysfunction.

Study Design

Approval was obtained from the institutional review boards of all partner institutions. After initial screening for eligibility, informed consent was obtained from each subject. Patients were followed for 18 months and were randomly assigned to 1 of the following 3 study groups: usual care (control group), disease management, and augmented disease management. Given the external nature of the intervention, it was not possible to blind patients or staff to the identity of the group to which they had been randomized. All subjects underwent an echocardiogram at baseline and at 18 months and were assessed every 6 months by medical history, physical examination, 6-minute walk test, and serum chemistries. Subjects in the disease management group were assigned a disease manager, a registered nurse

with specialized cardiac training, who performed telephonic patient education and medication management in conjunction with the patient's primary care provider. Subjects in the augmented disease management group received the same disease management services but also were issued a blood pressure cuff, a finger pulse oximeter, and an activity monitor to provide data for the generation of additional hypotheses. Patients received training on device use at their clinic visits and provided data from activity monitors when the devices were returned to the office. No data from the augmented disease management group were transmitted to patients' personal physicians. Subjects in both intervention arms received bathroom scales and were asked to weigh themselves daily. Subjects in the control group had no contact with disease managers and received only those changes to their care that were ordered by their personal physicians.

Disease management services were provided through a contract with CorSolutions, Rosemont, Ill, a disease management vendor with experience in providing disease management services to patients with CHF. Disease managers followed the MULTIFIT[27-29] disease management proprietary protocol, developed by CorSolutions. Under the MULTIFIT protocol, the patients' care was directed by their physicians, with recommendations made by disease managers in accord with the American College of Cardiology/American Heart Association guidelines for the treatment of CHF.[30,31] The recommendations were part of the study protocol, but because patients were drawn from many different funding sources and healthcare systems, patients' personal physicians were free to implement or to ignore the recommendations. Critical components of the disease managers' recommendations included initiation and upward titration of all recommended drug classes for CHF, including angiotensin-converting enzyme inhibitors, β-blockers, and diuretics. For patients in the New York Heart Association (NYHA) functional classes III and IV, the recommended drugs also included spironolactone. In addition, disease managers recommended the initiation of antihyperlipidemic and antianginal medications as indicated.

Patient education included instruction in appropriate cardiac diet (low fat, low sodium, and fluid restricted), medication compliance, exercise, and proper response to signs of the onset of a CHF exacerbation. In addition to the telephone calls scheduled as part of the protocol, patients had around-the-clock telephonic access to a disease manager who answered questions about CHF management. Reported symptoms were addressed based on the disease management algorithm unless the patient's physician had given other orders. Physicians were telephoned regarding all management issues. The on-call study physician served as a backup in the event that the patient's physician could not be reached within 1 hour.

Outcomes

Clinical and healthcare utilization outcomes of the trial have been reported elsewhere.[32] This article focuses on HRQL as measured by the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The SF-36 is a widely used[31,33,34] generic measure of functional health and well-being that has been shown to perform well among different age and disease groups.[35] Thirty-five of the questionnaire items on the SF-36 comprised the following 8 general dimensions: Bodily Pain, General Health, Mental Health, Physical Functioning, Role-Emotional (perceived disruptions in daily routine due to emotional problems), Role-Physical (perceived disruptions in daily routine due to physical problems), Social Functioning, and Vitality. These 8 scales may be condensed into 2 summary measures representing overall physical (physical health summary measure) and emotional (mental health summary measure) well-being. Analysis was conducted separately on a 36th item, which is not used in the computation of any of the scales or summary measures. The SF-36 health transition measure assesses change in self-reported health and asks: "Compared to one year ago, how would you rate your health in general now: much better, somewhat better, about the same, somewhat worse, [or] much worse?"

Health-related quality-of-life data were collected at randomization and at 6-month intervals during the trial. The amount of data collected from patients made it impossible to complete the entire data collection process while they were on site for a clinic visit, and the SF-36 was completed after the clinic visit. Research staff members collected data by giving patients the option to answer questions through telephone interviews within a week of the clinic visit or to take the SF-36 home and complete it by hand and return it in a postage-paid envelope. Although no comparison of reliability across administration methods is possible regarding the present data, the work of Bennett and colleagues[36] suggests that there should be no appreciable difference across methods of administration. Their study of several HRQL instruments revealed no differences between face-to-face and telephone interview methods of administration. Research staff conducted extensive follow-up via telephone to maximize the response rate at each wave of data collection. Of the 1069 patients who were randomized, 720 (67.4%) completed the protocol. Of the 349 patients who did not

complete the study, 93 (8.7% of the 1069 randomized patients) were deceased, and 256 (23.9%) were unable to complete the study for various reasons (3.5% were lost to follow-up, 15.7% withdrew, and 4.7% were medically disqualified). Although the rates of withdrawal, loss to follow-up, and medical disqualification were higher than expected, they were not statistically distinguishable across the study groups. Of the 651 patients from whom complete data from all 4 clinic visits were available, there was a mean of 420 valid responses across the SF-36 scale and summary measure scores, giving a follow-up rate for the HRQL measure of 39.2%, with a questionnaire response rate of approximately 65%, a reasonable rate for a self-administered at-home questionnaire.[37] We believe that the low follow-up rate was because of the broad scope of the data collection effort, the advanced age of the patients, the severity of illness in the study population, and the duration of the study. Given the low follow-up rate, the conclusions drawn from these analyses should be regarded as suggestive rather than definitive. Nonetheless, we believe that a low follow-up rate does not invalidate our results for several reasons. Although attrition yielded a sample that is not representative of the original 1069 patients, given its idiographic nature the generalizability of the initial sample could be questioned. Furthermore, the final sample size of 420 still represents one of the largest samples in studies of HRQL in CHF patients to date.

Subgroup Analyses

Two subgroup analyses were performed. First, in light of inconsistent findings on the question of whether sex differences in HRQL exist among CHF patients,[19,20,38] sex was used as an additional between-subjects factor. Second, because few studies have assessed differences in HRQL by type of CHF, the effect of the intervention on HRQL was compared between patients with systolic vs diastolic dysfunction.

Statistical Analysis

The efficacy of randomization was assessed by means of *t* tests for continuous variables and χ^2 tests for categorical variables. The SF-36 health transition measure was analyzed with ordinal logistic regression using a set of dummy variables for study group membership as the sole covariates. Repeated-measures analysis of covariance (ANCOVA) was used to assess study group and subgroup differences in HRQL during the trial. For both subgroup analyses, differences in each of the demographic and clinical variables given in **Table 1** were assessed by sex and type of CHF. Variables for which statistically significant subgroup differences were observed were included as controls in the multivariate ANCOVA models. Control variables that consistently failed to predict HRQL were dropped from the final model specification. In their final forms, the repeated-measures ANCOVA analyses for sex were adjusted for initial NYHA class, age, race or ethnicity, and baseline diastolic blood pressure. The analyses for type of CHF were adjusted for initial NYHA class, age, and sex. In general, an overall $\alpha = .05$ was used. For final determinations of significance, the repeated-measures analyses used an adjusted $\alpha = .005$ (.05 divided by 10, the number of separate SF-36 components tested).

RESULTS

Baseline Characteristics

The demographic and clinical characteristics of patients by study group are listed in Table 1. Except for a statistically significant but clinically negligible difference in diastolic blood pressure, the study groups were statistically indistinguishable across an array of demographic and clinical measures. In general, the cohort was older, largely male, and white. The typical patient had systolic dysfunction, had poorly controlled blood pressure (mean systolic blood pressure, > 140 mm Hg), and was only moderately symptomatic (modal category, NYHA class II).

Health Transition Measure

Study group differences on the SF-36 health transition measure at each of the 4 data collection points are shown in the **Figure.** Although there was not a statistically significant difference at randomization, at 6 and 12 months patients in the intervention groups were significantly more likely than patients in the control group to report that their health had improved in the preceding year. However, the magnitude of the intergroup differences was modest. At 6 months, 34.6% (sum of "somewhat better" and "much better" responses) of the patients in the disease management group and 25.6% of the patients in the control group responded that their health had improved in the previous year ($P = .04$). At 12 months, the rates of responses indicating improved health were 36.9% in the augmented disease management group and 26.8% in the control group ($P = .004$). A similar rate of positive responses was observed in the intervention arms through the 18-month mark, with 36.9% and 29.9% of the augmented disease management and disease management groups, respectively, reporting at least some improvement in their health during the previous 12 months. However, the control group patients were approximately equally likely (30.2%) as patients in either of the intervention groups to report

Table 1. Characteristics of the Study Population at Randomization*

Variable	Entire Sample (N = 1069)	Control (n = 359)	Disease Management (n = 356)	Augmented Disease Management (n = 354)	*P*
Age at enrollment, y	70.9 ± 10.3	70.8 ± 9.9	70.6 ± 10.8	71.4 ± 10.1	.62
Female sex	29.0	28.4	28.4	30.2	.78
Race or ethnicity					.69
White	71.6	73.8	71.1	69.8	
Hispanic	22.6	20.1	23.6	24.3	
Other	5.8	6.1	5.3	5.9	
Type of heart failure					.59
Systolic	70.3	68.3	71.4	71.2	
Diastolic	29.7	31.8	28.7	28.8	
Medical history					
Coronary artery disease	62.5	62.8	65.4	59.2	.23
Diabetes mellitus	34.1	33.9	37.4	30.9	.19
Hypercholesterolemia or hyperlipidemia	50.3	49.6	50.7	50.7	.94
Hypertension	71.8	70.9	73.4	71.1	.72
Prior myocardial infarction	38.7	41.2	38.8	36.0	.36
New York Heart Association functional class					.07
I	19.1	21.1	20.8	15.5	
II	57.2	55.1	57.9	58.8	
III	21.2	21.9	20.2	21.5	
IV	2.4	2.0	1.1	4.2	
Ejection fraction, %					
Diastolic heart failure	61.9 ± 6.9	61.6 ± 6.1	61.9 ± 6.2	62.4 ± 8.4	.68
Systolic heart failure	34.9 ± 8.7	34.2 ± 8.8	35.8 ± 7.9	34.6 ± 9.2	.09
Blood pressure, mm Hg					
Diastolic heart failure					
Systolic	154.7 ± 24.9	154.4 ± 24.7	155.2 ± 24.1	154.7 ± 26.1	.97
Diastolic	81.2 ± 14.7	80.5 ± 14.6	81.8 ± 13.2	81.3 ± 16.2	.81
Systolic heart failure					
Systolic	137.8 ± 21.9	136.4 ± 20.2	138.4 ± 22.4	138.6 ± 23.0	.47
Diastolic	78.5 ± 12.1	76.9 ± 11.2	79.7 ± 12.7	78.7 ± 12.1	.04
Heart rate, beats/min	72.7 ± 13.8	73.2 ± 13.3	73.7 ± 14.3	73.5 ± 12.6	.89
Pharmacotherapy					
β-Blocker	47.0	49.9	46.5	45.3	.47
Angiotensin-converting enzyme inhibitor	60.0	59.5	61.3	60.0	.88
Angiotensin II receptor blocker	13.0	13.1	12.4	12.7	.96
Diuretic	75.0	74.1	74.0	76.5	.70

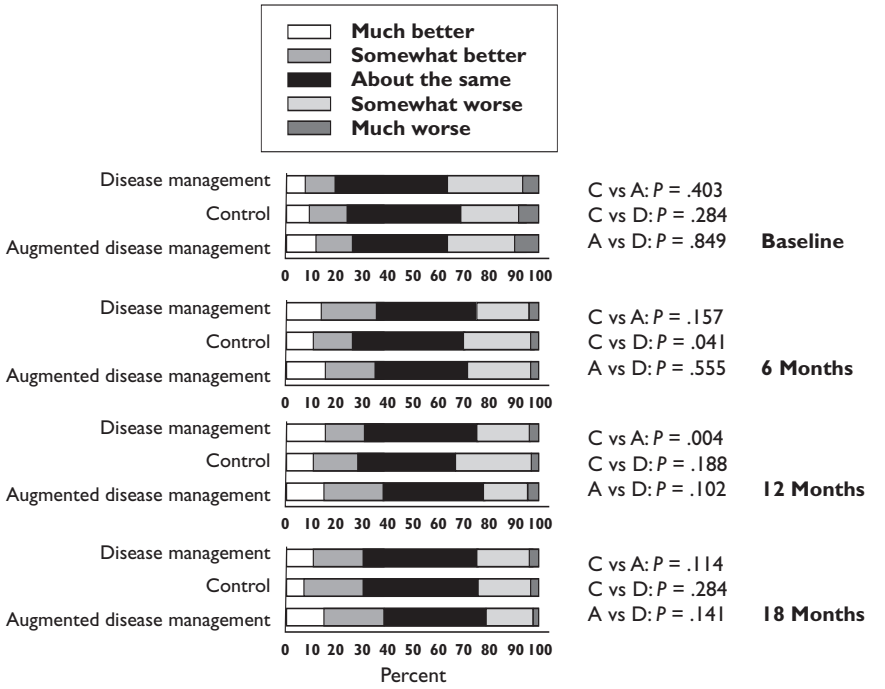
*Data are given as means ± SDs or as percentages unless otherwise indicated.

improvements in self-assessed health during the preceding year.

SF-36 Components

Data from the SF-36 scales and summary measures showed that patients in the control and disease management groups underwent a statistically significant ($P = .002$) decline over time in the Physical Functioning scale (**Table 2**). This decline was of similar magnitude for both groups. Paradoxically, we also observed a statistically significant time trend toward improvement on the Vitality scale. Judging from the pattern of means over time, as well as the nonsignificant group-×-time interaction, the increases appear to have occurred in the intervention and the control arms of the study. No main or interaction effects of study group membership were observed across any of the 8 scales or the 2 summary measures of the SF-36.

Figure. Comparison of Current Health With Previous Health by Study Group



		Percent of Patients Saying Reporting Their Health is				
Time, mo	Group	Much better	Somewhat better	About the same	Somewhat worse	Much worse
0	Control	8.0	17.0	38.6	28.3	8.1
	Disease management	6.6	14.5	38.4	34.0	6.5
	Augmented disease management	10.8	14.3	32.5	33.2	9.2
6	Control	9.1	16.5	44.9	26.8	2.7
	Disease management	13.3	21.3	41.7	19.6	4.1
	Augmented disease management	14.5	19.2	37.9	25.4	3.0
12	Control	9.1	17.7	40.7	29.0	3.5
	Disease management	13.1	15.3	46.0	22.1	3.5
	Augmented disease management	14.1	22.8	42.2	17.0	3.9
18	Control	7.8	22.4	44.8	21.4	3.6
	Disease management	11.3	18.6	44.6	22.6	2.9
	Augmented disease management	15.9	21.0	40.9	19.3	2.9

The pattern of results observed for several of the SF-36 scales suggested that an important short-term benefit of the intervention might have been obscured by a long-term trend in HRQL scores. As summarized in Table 2, for the Bodily Pain, General Health, Role-Emotional, Role-Physical, and Social Functioning scales of the SF-36, one or both of the intervention groups tended to experience a short-term improvement from 0 to 6 months, followed by a return to near initial levels. Despite this trend in the data, a series of repeated-measures ANCOVA analyses conducted separately for the intervals of 0 to 6 months and 0 to 12 months failed to reveal any statistically significant effect of study group membership on HRQL.

Subgroup Analyses

As summarized in **Table 3**, sex differences affect the experience of CHF in the physical domains. Women were at a 5- to 10-point deficit compared with men for the Physical Functioning and the Role-Physical scales, with both differences trending toward statistical significance (P = .009 and P = .03, respectively). A statistically significant (P = .003) sex difference of similar magnitude was observed for the Role-Emotional scale. Health-related quality-of-life outcomes also differed by type of CHF. An unadjusted repeated-measures ANCOVA (data not shown) showed that patients with diastolic dysfunction showed significantly worse HRQL outcomes than patients with systolic dysfunction across several physical dimensions, including pain, poorer physical functioning, and ability to perform physical tasks, and had overall worse scores on the physical health summary measure. However, the adjusted analyses summarized in **Table 4** indicate that these differences were largely accounted for by sex, initial NYHA class, and age. In no case did the subgroup analyses for sex or type of CHF reveal statistically significant main or interaction effects of the intervention.

DISCUSSION

This study shows evidence of a short-term beneficial effect of disease management on HRQL outcomes in patients with CHF among a large sample observed during the longest follow-up period, to our knowledge, in

Table 2. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Scores by Study Group and Time*

SF-36 Component	Study Group	Time, mo				*P*†		
		0	6	12	18	Study Group	Time	Study Group–×-Time Interaction
Bodily Pain	Control	51.2 ± 40.5	51.2 ± 40.2	47.3 ± 42.1	50.8 ± 41.4	.49	.50	.80
	Disease management	50.9 ± 40.4	55.8 ± 40.7	53.0 ± 41.5	52.6 ± 39.8			
	Augmented disease management	48.0 ± 38.6	50.3 ± 41.2	49.4 ± 39.0	46.5 ± 40.5			
General Health	Control	50.2 ± 20.9	51.3 ± 19.9	51.0 ± 22.6	50.4 ± 21.1	.78	.08	.87
	Disease management	50.0 ± 21.0	53.4 ± 20.4	51.6 ± 21.9	51.4 ± 22.1			
	Augmented disease management	49.6 ± 22.4	50.7 ± 23.6	50.3 ± 22.2	49.2 ± 22.9			
Mental Health	Control	75.9 ± 17.4	77.4 ± 19.0	75.0 ± 19.1	76.0 ± 19.2	.14	.06	.22
	Disease management	78.6 ± 15.4	79.8 ± 16.8	79.7 ± 17.3	78.7 ± 18.7			
	Augmented disease management	76.4 ± 19.1	79.7 ± 16.6	80.1 ± 16.7	79.8 ± 16.2			
Physical Functioning	Control	49.9 ± 28.2	49.0 ± 29.0	47.6 ± 29.8	46.1 ± 29.4	.71	.002	.14
	Disease management	47.9 ± 28.1	48.3 ± 27.6	49.2 ± 28.1	45.6 ± 29.7			
	Augmented disease management	44.0 ± 24.6	48.1 ± 27.1	46.3 ± 25.7	44.5 ± 27.3			
Role-Emotional	Control	73.0 ± 38.8	75.4 ± 39.6	73.2 ± 40.7	77.1 ± 37.0	.15	.20	.10
	Disease management	79.1 ± 33.1	80.8 ± 34.6	76.8 ± 38.0	73.1 ± 40.5			
	Augmented disease management	67.2 ± 40.7	72.8 ± 41.0	75.1 ± 38.2	67.2 ± 41.7			
Role-Physical	Control	48.6 ± 41.4	48.8 ± 44.0	44.6 ± 44.4	42.0 ± 40.4	.20	.10	.71
	Disease management	44.8 ± 42.6	47.2 ± 41.9	47.5 ± 43.0	43.7 ± 42.4			
	Augmented disease management	37.1 ± 39.3	42.4 ± 41.7	40.6 ± 42.7	37.9 ± 41.2			
Social Functioning	Control	70.8 ± 29.7	70.8 ± 29.8	70.4 ± 29.5	66.6 ± 31.1	.28	.04	.56
	Disease management	69.9 ± 31.0	73.9 ± 28.3	71.8 ± 29.7	70.6 ± 30.8			
	Augmented disease management	63.6 ± 33.0	70.5 ± 31.6	67.4 ± 30.7	66.5 ± 29.5			
Vitality	Control	46.5 ± 22.3	46.0 ± 23.0	47.2 ± 22.6	48.9 ± 23.5	.75	.001	.10
	Disease management	46.2 ± 23.0	49.6 ± 22.1	50.0 ± 22.5	47.8 ± 23.2			
	Augmented disease management	45.3 ± 24.8	49.3 ± 24.3	51.4 ± 22.5	49.9 ± 23.7			
Physical health summary	Control	34.7 ± 12.4	34.4 ± 13.1	34.1 ± 13.6	33.4 ± 13.4	.49	.08	.78
	Augmented disease management	32.1 ± 11.1	33.3 ± 12.4	32.7 ± 12.0	32.1 ± 12.4			
Mental health summary	Control	52.1 ± 10.1	52.5 ± 10.3	52.4 ± 10.5	53.1 ± 10.1	.25	.05	.40
	Experimental	53.8 ± 8.9	54.9 ± 9.5	54.2 ± 10.3	53.8 ± 11.0			
	Augmented disease management	51.5 ± 12.4	53.7 ± 9.8	54.0 ± 10.1	53.2 ± 10.5			

*Data are given as unadjusted means ± SDs unless otherwise indicated.
†Repeated-measures analysis of covariance for selected main and interaction effects.

Table 3. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Scores by Study Group, Sex, and Time*

SF-36 Component	Study Group	Sex	Time, mo 0	6	12	18	P† Study Group	Sex	Time	Study Group–×-Sex Interaction	Study Group–×-Time Interaction
Bodily Pain	Control	Female	29.5	27.1	19.9	27.9	.22	.15	.71	.09	.87
		Male	42.5	40.9	38.6	41.4					
	Disease management	Female	42.0	41.3	43.7	43.1					
		Male	36.8	42.1	36.9	40.4					
	Augmented disease management	Female	36.7	32.2	35.6	36.1					
		Male	40.1	41.9	38.2	38.3					
General Health	Control	Female	51.5	46.6	45.2	45.0	.92	.19	.20	.54	.39
		Male	41.5	43.0	43.2	41.7					
	Disease management	Female	44.2	47.0	46.0	46.8					
		Male	41.6	44.5	41.8	40.7					
	Augmented disease management	Female	44.9	43.0	43.8	42.2					
		Male	44.4	45.1	43.8	42.3					
Mental Health	Control	Female	67.3	69.4	68.6	70.8	.10	.47	.09	.41	.34
		Male	71.6	71.1	73.1	71.3					
	Disease management	Female	73.7	73.5	76.7	75.7					
		Male	72.0	72.4	75.8	72.8					
	Augmented disease management	Female	68.2	72.6	76.3	73.8					
		Male	73.1	73.9	77.7	76.3					
Physical Functioning	Control	Female	28.9	30.1	28.3	25.4	.32	.009	.006	.47	.45
		Male	43.3	37.2	37.5	36.5					
	Disease management	Female	31.2	30.4	33.9	32.0					
		Male	40.4	37.4	37.9	35.1					
	Augmented disease management	Female	36.5	36.9	35.0	36.3					
		Male	39.3	40.2	40.2	38.0					
Role-Emotional	Control	Female	57.9	51.8	56.5	40.1	.14	.003	.85	.14	.57
		Male	68.3	61.2	72.9	66.3					
	Disease management	Female	70.6	60.3	66.4	61.2					
		Male	71.4	66.2	74.1	54.3					
	Augmented disease management	Female	57.5	54.5	64.7	37.0					
		Male	64.5	61.3	75.4	60.6					
Role-Physical	Control	Female	37.3	23.9	23.3	15.5	.79	.03	.73	.52	.55
		Male	42.1	40.7	38.4	32.3					
	Disease management	Female	34.5	31.8	31.1	31.6					
		Male	37.7	37.2	40.1	30.0					
	Augmented disease management	Female	31.4	30.0	33.0	20.6					
		Male	35.5	37.3	35.2	33.1					
Social Functioning	Control	Female	58.9	52.6	55.7	50.5	.43	.12	.74	.23	.65
		Male	65.8	63.6	67.4	55.9					
	Disease management	Female	61.9	62.9	64.4	62.4					
		Male	62.8	64.0	65.0	55.9					
	Augmented disease management	Female	56.1	56.9	63.5	56.2					
		Male	61.4	66.1	63.7	57.3					

(Continued)

Table 3. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Scores by Study Group, Sex, and Time* *(Continued)*

SF-36 Component	Study Group	Sex	Time, mo				P†				
			0	6	12	18	Study Group	Sex	Time	Study Group–×-Sex Interaction	Study Group–×-Time Interaction
Vitality	Control	Female	41.1	38.9	40.4	42.5	.38	.15	.005	.38	.19
		Male	42.6	44.3	44.7	47.8					
	Disease management	Female	40.1	45.9	47.9	47.5					
		Male	41.7	46.6	45.5	45.0					
	Augmented disease management	Female	38.5	43.9	46.5	44.9					
		Male	44.9	49.7	50.3	51.8					
Physical health summary	Control	Female	28.4	26.4	25.4	25.5	.89	.09	.19	.64	.57
		Male	30.9	30.4	29.5	29.5					
	Disease management	Female	27.4	27.6	28.0	28.3					
		Male	29.4	30.3	28.8	29.1					
	Augmented disease management	Female	28.8	27.9	28.8	28.4					
		Male	29.5	30.7	28.4	29.2					
Mental health summary	Control	Female	47.4	47.0	49.0	46.2	.07	.04	.68	.10	.73
		Male	50.7	50.3	52.8	51.0					
	Disease management	Female	51.8	51.7	52.8	52.2					
		Male	51.0	51.7	53.6	49.7					
	Augmented disease management	Female	47.7	49.4	52.1	47.4					
		Male	50.3	51.4	54.0	51.5					

*Unless otherwise indicated, data are given as means adjusted for age, initial New York Heart Association class, race or ethnicity, baseline diastolic blood pressure, and type of heart failure.
†Repeated-measures analysis of covariance for selected main and interaction effects.

published randomized trials of disease management to date. At 6 and 12 months after randomization, patients receiving disease management were more likely than the control group to report improvement since entering the study. This statistically significant effect did not, however, carry through to the domain-specific HRQL components of the SF-36, with no intervention effect found across the 8 scale or the 2 summary measure scores of the SF-36. The failure to find statistically significant effects of disease management on HRQL is not surprising given that previous investigations have also failed to show improvement in HRQL outcomes, despite significant improvements in clinical and utilization indicators such as mortality and hospital readmission.[39] Somewhat surprising, however, is the disjuncture between the positive outcome observed for the health transition measure and the negative outcomes observed for the specific SF-36 scales.

Several possibilities may account for this paradoxical pattern of results. It is possible that in the present study disease management had little more than a placebo effect on patients. Given the nature of the telephonic intervention, it was impossible to blind patients to the identity of the group to which they had been assigned. By knowing that they were receiving the experimental intervention, patients may have believed that their health had improved since entering the trial, even if there had been no real improvement in their condition. The "effect" of the disease management intervention may then have disappeared when subjected to more careful scrutiny with the domain-specific SF-36 scales. The placebo view is supported by the observation that the percentage of control group patients who reported improved self-rated health at the 18-month mark was statistically indistinguishable from the percentage of patients giving the same response in either of the intervention groups. Also suggesting the possibility of a placebo effect is the statistically significant time trend toward improved responses on the Vitality scale in the intervention and control groups. However, other evi-

Table 4. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Scores by Study Group, Type of Heart Failure, and Time

SF-36 Component	Study Group	Type of Heart Failure	Time, mo 0	6	12	18	$P^{\dagger}$ Study Group	Type of Heart Failure	Time	Type of Heart–Failure- × Study Group Interaction	Time- ×– Study Group Interaction
Bodily Pain	Control	Diastolic	25.4	30.9	28.4	36.5	.26	.02	.88	.06	.76
		Systolic	51.4	49.3	45.2	50.4					
	Disease management	Diastolic	44.7	50.8	40.6	43.7					
		Systolic	42.8	48.1	48.2	50.0					
	Augmented disease management	Diastolic	44.9	45.2	42.2	37.1					
		Systolic	42.4	44.6	44.9	47.8					
General Health	Control	Diastolic	45.2	45.8	44.7	45.3	.97	.92	.03	.76	.44
		Systolic	44.8	45.7	47.0	44.5					
	Disease management	Diastolic	42.8	50.7	46.6	47.4					
		Systolic	43.7	45.8	45.8	44.1					
	Augmented disease management	Diastolic	41.6	44.9	47.8	44.5					
		Systolic	47.2	46.6	45.4	44.6					
Mental Health	Control	Diastolic	67.4	70.8	69.1	71.6	.09	.24	< .001	.65	.27
		Systolic	72.1	74.2	74.4	73.2					
	Disease management	Diastolic	72.0	74.4	76.3	74.1					
		Systolic	73.3	75.5	77.4	75.9					
	Augmented disease management	Diastolic	71.8	73.0	77.8	77.8					
		Systolic	71.2	76.8	77.7	76.5					
Physical Functioning	Control	Diastolic	34.5	30.7	29.1	28.2	.44	.08	.02	.26	.16
		Systolic	43.4	39.1	39.5	36.6					
	Disease management	Diastolic	37.7	38.8	39.6	34.2					
		Systolic	40.8	36.2	38.7	35.5					
	Augmented disease management	Diastolic	37.5	39.5	36.4	34.4					
		Systolic	40.1	40.4	41.2	39.0					
Role-Emotional	Control	Diastolic	64.4	52.3	70.3	62.0	.18	.38	.89	.55	.16
		Systolic	69.3	71.8	65.4	65.2					
	Disease management	Diastolic	70.8	72.3	68.5	69.2					
		Systolic	74.4	70.9	71.4	57.4					
	Augmented disease management	Diastolic	59.7	59.4	70.7	52.8					
		Systolic	65.1	67.0	70.0	57.8					
Role-Physical	Control	Diastolic	35.0	24.5	33.0	26.8	.42	.50	.53	.15	.59
		Systolic	43.1	41.8	41.7	27.6					
	Disease management	Diastolic	35.0	39.4	47.7	41.1					
		Systolic	37.7	34.4	40.5	26.0					
	Augmented disease management	Diastolic	30.2	31.0	36.0	24.6					
		Systolic	34.2	35.8	39.6	29.7					
Social Functioning	Control	Diastolic	57.5	56.5	61.6	52.6	.62	.55	.08	.52	.39
		Systolic	64.1	62.5	62.7	58.8					
	Disease management	Diastolic	59.5	63.9	61.7	61.7					
		Systolic	61.3	63.7	64.1	60.6					
	Augmented disease management	Diastolic	52.9	61.3	66.3	62.6					
		Systolic	59.3	62.6	58.3	57.3					

(Continued)

Table 4. Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Scores by Study Group, Type of Heart Failure, and Time *(Continued)*

SF-36 Component	Study Group	Type of Heart Failure	Time, mo 0	6	12	18	*P*‡ Study Group	Type of Heart Failure	Time	Type of Heart–Failure- × Study Group Interaction	Time- ×– Study Group Interaction
Vitality	Control	Diastolic	40.5	39.6	39.0	44.8	.29	.82	.02	.58	.05
		Systolic	39.6	40.4	43.0	42.7					
	Disease management	Diastolic	37.4	47.2	47.1	44.8					
		Systolic	40.4	42.7	43.7	41.7					
	Augmented disease management	Diastolic	39.2	42.6	45.7	46.4					
		Systolic	42.3	47.2	48.9	47.1					
Physical health summary	Control	Diastolic	27.8	27.6	27.2	27.6	.81	.18	.51	.26	.81
		Systolic	32.8	31.2	31.9	30.2					
	Disease management	Diastolic	29.7	31.7	30.6	29.9					
		Systolic	30.4	30.0	31.0	29.7					
	Augmented disease management	Diastolic	29.8	31.0	30.3	27.8					
		Systolic	30.4	30.2	30.6	30.5					
Mental health summary	Control	Diastolic	48.9	48.8	51.4	50.4	.38	.82	.047	.96	.47
		Systolic	49.7	50.7	50.8	50.4					
	Disease management	Diastolic	50.0	52.2	51.6	52.2					
		Systolic	51.2	52.2	52.8	50.4					
	Augmented disease management	Diastolic	48.2	49.6	53.6	51.6					
		Systolic	49.1	51.8	51.7	50.0					

*Unless otherwise indicated, data are given as means adjusted for age, initial New York Heart Association class, and sex.
†Repeated-measures analysis of covariance for selected main and interaction effects.

dence from the trial suggests that the intervention may indeed have had a positive effect on HRQL. In addition to an observed survival benefit among the sickest patients with systolic dysfunction, patients in the experimental group were more likely than controls to experience an improvement in their NYHA class.[32]

An alternative explanation of this pattern is that differences between the groups in the SF-36 scales and summary measures were not manifest because of inadequately sensitive instruments. It is possible that disease management may have produced an improvement in HRQL among the intervention groups that was detectable by the health transition measure of the SF-36 but not by the non–disease-specific HRQL instruments used in the trial. Among the choices of general HRQL instruments available to CHF researchers, the SF-36 has been deemed to be a valid and reliable measurement tool.[20,40] Nonetheless, several reviews of HRQL measures in CHF suggest that the SF-36 and its variants may be less sensitive than disease-specific measures in detecting changes in disease severity in CHF patients over time.[34,36,40,41] Although typically identified as being superior to generic HRQL instruments for applications in CHF patients, disease-specific instruments such as the Minnesota Living With Heart Failure Questionnaire[42] and the Kansas City Cardiomyopathy Questionnaire[41] have shortcomings as well. The Minnesota Living With Heart Failure Questionnaire, for example, has been reported to inadequately distinguish between levels of CHF severity[34] and to be weaker than the SF-36 series of instruments in detecting change in physical health.[43] Given its focus on fluid retention, the Kansas City Cardiomyopathy Questionnaire is considered by some to be of limited utility in older patients where fluid retention is often not the most important symptom.[44] Given that our sample was older and included a significant subsample of patients with diastolic dysfunction, it is unclear whether either disease-specific instrument would be superior to the SF-36 for the objectives described herein. Nonetheless, the lack

of a disease-specific measure to serve as a comparison to the SF-36 is regrettable.

Another instrument-related concern pertains not to the content but to the timing of administration. A meta-analysis by Riegel and colleagues[45] of several studies that used the Minnesota Living With Heart Failure Questionnaire found that responses to a clinical intervention were most readily observed 3 months after hospital discharge. In the present study, it is possible that we missed important improvement in HRQL in the period before our first data collection visit at 6 months. Although more frequent data collection would have been preferable, the applicability of the findings by Riegel et al to the present study is unclear. It seems unlikely that the timing and nature of any positive effect of an intervention in a sample of community-dwelling CHF patients would necessarily follow the pattern observed in a population of patients who have recently been hospitalized.

This study confirms and extends findings of previous research on CHF, disease management, and HRQL in several important ways. These results significantly expand the body of knowledge on the relationship between the nature of cardiac dysfunction and HRQL among CHF patients. A comprehensive literature search yielded only 2 small sample studies assessing differences in HRQL by CHF type. In a study of 54 CHF patients (25 with diastolic dysfunction and 28 with systolic dysfunction), O'Mahony and colleagues[46] found no statistically significant difference in the SF-36 physical health and mental health summary measures or in 2 other instruments assessing functional status and mental health. Although a study by Jaarsma and colleagues[47] of 186 CHF patients (150 with systolic dysfunction and 36 with diastolic dysfunction) found that patients with systolic dysfunction reported fewer problems with the healthcare system than patients with diastolic dysfunction, they observed no differences in overall well-being by type of dysfunction. In contrast, the present data show a modest difference in HRQL between patients with systolic vs diastolic dysfunction. Patients with diastolic dysfunction reported worse pain-related HRQL outcomes than patients with systolic dysfunction. This contrast in findings, although due in part to small sample sizes and variations in the instruments used in previous studies, suggests that the question of how HRQL relates to the nature of cardiac dysfunction could benefit from additional investigation, and that approaches to managing the effects of CHF on HRQL may need to be tailored differently depending on the type of dysfunction.

The present findings also represent an incremental advance in our knowledge about sex differences in HRQL among CHF patients. Although the variety of instruments used to measure sex differences in HRQL outcomes in previous research confounds a precise comparison,[20,48,49] the present results provide, to our knowledge, the first confirmation in a large sample of patients with CHF that women exhibit poorer physical HRQL outcomes than men. The literature is inconclusive with respect to sex differences in emotional HRQL outcomes. Although some investigations point to significantly worse emotional outcomes among women vs men with CHF,[49] larger and more recent studies by Riedinger et al[48] and Riegel et al[38] failed to reveal sex differences in emotional distress. Although our study found no sex differences in the SF-36 Mental Health scale or mental health summary measure outcomes, statistically significant differences between men and women were observed in the SF-36 Role-Emotional domain. Women were no more likely than men to report being depressed or anxious. However, women were more likely than men to report that emotional distress inhibits their ability to spend time on work and other activities, reduces the amount of those activities that they are able to accomplish, and negatively affects the level of care that they take in performing the activities. Although a test of the hypothesis is beyond the scope of the present research design, the contrast of finding no sex differences in emotional distress with the finding of significant differences in the degree to which emotional distress affects daily activities is indeed perplexing. This may indicate tht the way in which CHF affects emotional well-being may depend on the nature of the patient's daily responsibilities. Although a complete understanding of this complex interaction requires future prospective study, our results suggest that women with CHF may need different kinds of support than men with CHF.

In summary, this study on HRQL outcomes for disease management in CHF helps answer an important question for healthcare policy makers considering the implementation of disease management for patients with CHF. Participation in disease management has only a limited effect on HRQL outcomes in CHF. Although some beneficial effects in self-assessed health were seen at 6 and 12 months after enrollment, these positive effects were not observed on any of the SF-36 scales.

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