


Original Investigation

Primary Results of the Patient-Centered Disease Management (PCDM) for Heart Failure Study

A Randomized Clinical Trial

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IMPORTANCE Heart failure (HF) has a major effect on patients' health status, including their symptom burden, functional status, and health-related quality of life.

OBJECTIVE To determine the effectiveness of a collaborative care patient-centered disease management (PCDM) intervention to improve the health status of patients with HF.

DESIGN, SETTING, AND PARTICIPANTS The Patient-Centered Disease Management (PCDM) trial was a multisite randomized clinical trial comparing a collaborative care PCDM intervention with usual care in patients with HF. A population-based sample of 392 patients with an HF diagnosis from 4 Veterans Affairs centers who had a Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score of less than 60 (heavy symptom burden and impaired functional status and quality of life) were enrolled between May 2009 and June 2011.

INTERVENTIONS The PCDM intervention included collaborative care by a multidisciplinary care team consisting of a nurse coordinator, cardiologist, psychiatrist, and primary care physician; home telemonitoring and patient self-management support; and screening and treatment for comorbid depression.

MAIN OUTCOMES AND MEASURES The primary outcome was change in the KCCQ overall summary score at 1 year (a 5-point change is clinically significant). Mortality, hospitalization, and depressive symptoms (Patient Health Questionnaire 9) were secondary outcomes.

RESULTS There were no significant differences in baseline characteristics between patients randomized to the PCDM intervention ($n = 187$) vs usual care ($n = 197$); baseline mean KCCQ overall summary scores were 37.9 vs 36.9 ($P = .48$). There was significant improvement in the KCCQ overall summary scores in both groups after 1 year (mean change, 13.5 points in each group), with no significant difference between groups ($P = .97$). The intervention was not associated with greater improvement in the KCCQ overall summary scores when the effect over time was estimated using 3-month, 6-month, and 12-month data ($P = .74$). Among secondary outcomes, there were significantly fewer deaths at 1 year in the intervention arm (8 of 187 [4.3%]) than in the usual care arm (19 of 197 [9.6%]) ($P = .04$). Among those who screened positive for depression, there was a greater improvement in the Patient Health Questionnaire 9 scores after 1 year in the intervention arm than in the usual care arm (2.1 points lower, $P = .01$). There was no significant difference in 1-year hospitalization rates between the intervention arm and the usual care arm (29.4% vs 29.9%, $P = .87$).

CONCLUSIONS AND RELEVANCE This multisite randomized trial of a multifaceted HF PCDM intervention did not demonstrate improved patient health status compared with usual care.

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Heart failure (HF) remains a leading cause of disability, hospitalization, and death in the Veterans Affairs (VA) system and the United States as a whole.^{1,2} It has a major effect on patients' health status, defined as their symptom burden, functional status, and health-related quality of life. To date, few HF interventions have specifically targeted these critical patient-centered outcomes.²⁻⁴

Disease management, variously defined,⁵ has been promoted as a strategy to improve outcomes of patients with HF. It usually refers to multidisciplinary efforts to improve the quality and cost-effectiveness of care for selected patients with chronic conditions. These programs involve interventions designed to improve adherence to scientific guidelines and treatment plans.⁶ However, the association between HF disease management and outcomes is inconsistent.^{4,7-12} Heart failure disease management interventions have often relied solely on nurse case management.

We developed the Patient-Centered Disease Management (PCDM) intervention to address these shortcomings by combining multidisciplinary collaborative care, home telemonitoring, and depression management. Multidisciplinary collaborative care has been shown to be effective in diabetes mellitus, hypertension, lipid level, and depression management.^{13,14} Home telemonitoring in isolation has not improved outcomes.¹⁵ However, integrating home telemonitoring with multidisciplinary collaborative care team management may improve outcomes through the provision of actionable, guideline-based treatment recommendations tailored to individual patients. To date, no studies have targeted improving patient health status as a primary outcome or addressed key barriers such as comorbid depression. It is important to assess and manage depression in HF because depression is associated with poor treatment adherence, health status, and other outcomes.^{4,16,17} Finally, to our knowledge, the effectiveness of disease management for HF has not previously been evaluated in the Department of Veterans Affairs, the largest integrated health care system in the United States.

The multisite PCDM trial evaluated the combination of multidisciplinary collaborative care, telemonitoring, and joint HF and depression management. The primary aim was to determine whether the intervention resulted in better patient health status (ie, symptom burden, functional status, and quality of life) than usual care. The secondary aims were to determine whether the disease management intervention resulted in reduced hospitalizations, depressive symptoms, or mortality.

Methods

Setting and Population

The methods of the PCDM trial have been previously described.¹⁸ The study was conducted at the VA medical centers in Denver, Colorado, Palo Alto, California, Richmond, Virginia, and Seattle, Washington, as well as at their affiliated community-based outpatient clinics. All patients with an assigned VA primary care physician and at least 1 primary care visit during the prior 12 months with a HF diagnosis code in the VA elec-

tronic health record were screened for eligibility to participate. Following previously described case finding methods,¹⁹ the study was designed to target all patients with a diagnosis of HF, irrespective of the type of HF (eg, including those with and without preserved left ventricular systolic function). Therefore, the diagnosis of HF was defined as meeting any 1 of the following 5 criteria: (1) a primary inpatient hospital discharge diagnosis of HF (*International Classification of Diseases, Ninth Revision [ICD-9]* code 428.XX); (2) at least 2 secondary inpatient hospital discharge diagnoses of HF (*ICD-9* codes 428.XX) and a primary inpatient hospital discharge diagnosis related to heart disease (*ICD-9* codes 410.XX, 412.XX, 413.XX, and 414.XX); (3) at least 3 secondary inpatient hospital discharge diagnosis codes related to HF; (4) at least 2 outpatient visit diagnoses of HF, excluding emergency department visits; and (5) at least 2 secondary inpatient hospital discharge diagnoses of HF and at least 1 outpatient HF diagnosis.¹⁹

Potentially eligible patients were screened with the Kansas City Cardiomyopathy Questionnaire (KCCQ) to identify patients with a diagnosis of HF and reduced health status. Individuals scoring less than 60 on the KCCQ overall summary score (indicating significant HF symptoms, limited functional status, and poor quality of life) were invited to an enrollment visit if they did not have any exclusion criteria. Exclusion criteria were (1) severe cognitive or psychiatric impairment; (2) current residence in a nursing home; (3) irreversible, noncardiac medical conditions likely to affect 6-month survival or ability to execute the study protocol (eg, metastatic cancer); (4) prior heart transplantation; and (5) alcohol abuse as indicated by the Alcohol Use Disorders Identification Test²⁰ score of at least 7.

At enrollment, eligible patients provided written informed consent, completed baseline survey measures, and were then randomized to the PCDM intervention or to usual care. The study database was used to create the randomization sequence using block randomization, with stratification by study site and 1:1 randomization of patients to the intervention and to usual care. The randomization sequence was concealed from the study personnel. Randomization occurred after baseline survey information was entered into the database. The study was approved by the institutional review boards at each of the study sites. The full study protocol can be found in the trial protocol in the Supplement.

PCDM Intervention

The intervention included 3 components. These were multidisciplinary collaborative care HF disease management, screening for and treatment of depression, and telemonitoring with patient self-care support.

Collaborative Care

Each site had a collaborative care team consisting of a nurse coordinator (registered nurse), a primary care physician, a cardiologist, and a psychiatrist. For each intervention patient, the team reviewed the electronic health record and baseline depression scores from the Patient Health Questionnaire 9 (PHQ-9). The team recommended care changes for a given patient in accord with the American College of Cardiology and American Heart Association Guidelines for the Diagnosis

and Management of Heart Failure in Adults²¹ and the collaborative depression care intervention as described herein. In addition, the team met weekly to recommend care changes based on review of telemonitoring data and the follow-up PHQ-9 scores. Collaborative care team recommendations were entered into a progress note and written as unsigned orders in the electronic medical record for review and signature by the patient's primary care physician. This method was successfully used in a prior VA intervention study²² for angina, with a high rate of acceptance of the recommendations by VA primary care physicians.

Screening and Treatment of Depression

Intervention patients who screened positive for depression (PHQ-9 score, ≥ 10) received the depression care component of the intervention, adapted from a successful collaborative depression care intervention.²³ This included (1) up to 11 sessions of behavioral activation and antidepressant management, provided by the nurse coordinator and supervised by the team psychiatrist; (2) a depression educational video; and (3) depression assessment and self-management education via telemonitoring. Before enrollment began, the nurse coordinator from each site participated in a 2-day training on depression and behavioral activation by the lead study psychiatrist (M.D.S.) and 4 weekly follow-up calls with the lead study psychiatrist. Thereafter, the nurse was supervised by the site psychiatrist via as-needed calls with the lead psychiatrist and Dr Bekelman. The depression care component of the nurse intervention was standardized in a treatment manual that described detailed procedures for what to discuss with patients.

Telehealth Telemonitoring and Patient Self-care Support

Intervention patients received daily telemonitoring using home-based equipment that tracked signs and symptoms of HF and depression. The system collected daily measures of blood pressure, pulse, weight, and self-reported symptoms (eg, shortness of breath and edema). Patients with depression were asked questions about their mood and behavior. The telemonitoring system assigned a risk to each response on the system. The nurse reviewed medium risk indicators and decided whether an action needed to be taken (eg, for patients unable to understand a low sodium diet, the nurse provided counseling). The nurse acted on all of the high risk indicators by contacting the patient for assessment and then, if necessary, contacted the care team for any changes in medications or tests to be written in the electronic medical record. For example, the collaborative care team could set and change an individual patient's dry weight and recommend a diuretic dosing guideline to primary care physicians.

The self-care programs included medication reminders to promote adherence, education about HF and depression, medication monitoring, and dietary advice. Patients were taught the importance of daily self-weighing, adherence to a low sodium diet and medication regimens, and recognition of early signs and symptoms of HF decompensation. Adherence of nurses and the collaborative care team to the study protocol was not formally measured.

Usual Care

Patients randomized to the usual care arm continued to receive care from their regular health care professionals and regular telehealth nurses (if enrolled in telemonitoring), with no involvement of the study collaborative care team. Care was fully at the discretion of the patient's regular health care professionals and may or may not have included cardiology or mental health clinic care in addition to primary care. Usual care patients were given information sheets at the enrollment visit that described self-care for HF and were provided with a weighing scale if needed. Primary care physicians were notified if usual care patients screened positive for depressive symptoms based on the initial study surveys. From then on, patients' primary care physicians assumed responsibility for depression care.

Outcome Measures

The primary outcome, patient-reported HF-specific health status, was measured using the KCCQ. This questionnaire is valid, reliable, and sensitive to clinical change and predicts hospitalization and mortality.²⁴⁻²⁶ For the secondary measures, depression was measured using the PHQ-9. This questionnaire is a valid and reliable instrument that provides a continuous measure of depressive symptoms.²⁷ Baseline survey measures were collected in person. A research assistant (who was blinded to the randomization arm) collected 3-month and 6-month follow-up study outcome measures by phone or in person. The nurse coordinator collected measures at 12 months by phone or in person. Mortality and hospitalizations were assessed through VA databases, supplemented by patient self-report. Vital status was also ascertained via the VA Vital Status File, which has a sensitivity of 98.3% and a specificity of 99.8% compared with the National Death Index.²⁸

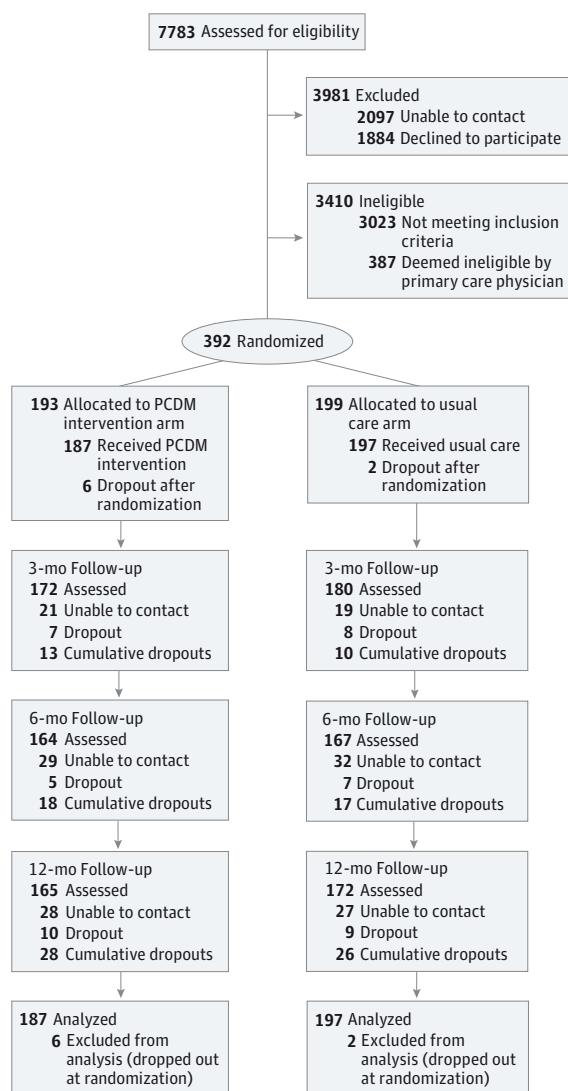
Sample Size and Enrollment Targets

The primary hypothesis of this study was that patients with HF receiving the PCDM intervention would have greater improvement in health status over a 12-month follow-up period compared with those receiving usual care. The minimal clinically meaningful difference in the KCCQ overall summary scores is 5 points,²⁶ and the SD of change in the KCCQ overall summary scores was estimated to be 15 to 20 points based on previous work.^{25,26} With an estimated attrition rate of 30%, we originally estimated that enrollment of 600 patients would yield greater than 80% power to detect a difference in the KCCQ overall summary scores of at least 5 points, assuming an SD of 18. A lower than expected enrollment was partially offset by a greater than expected retention rate (attrition, <20%). The KCCQ SD was 15 points. Hence, the study recruitment concluded with enrollment of 392 patients, with an estimated greater than 80% power to detect a 5-point difference in the KCCQ overall summary scores between groups.

Statistical Analysis

All primary and secondary analyses were conducted using an intent-to-treat approach. Baseline characteristics of patients were assessed by study group using *t* tests for continuous variables and χ^2 tests for categorical variables. For the primary out-

Figure 1. Consolidated Standards of Reporting Trials Diagram of the PCDM for HF Trial



HF indicates heart failure; PCDM, patient-centered disease management.

come, change in the KCCQ overall summary scores from baseline to 1 year between the intervention and usual care groups among patients who had both baseline and 1-year KCCQ overall summary scores was compared using a paired *t* test. In addition, a likelihood-based random-effects model was performed to compare change in the KCCQ overall summary scores over time between arms to account for missing data and longitudinal trends.²⁹ The magnitude and patterns of missing data were analyzed to confirm the validity of model assumptions. Model parameters were estimated using the MIXED procedure (SAS, version 9.3; SAS Institute Inc). Changes in depressive symptoms (PHQ-9 scores) were analyzed among patients who screened positive for depression (PHQ-9 score, ≥ 10) using the same mixed modeling approach. The numbers of all-cause hospitalizations and deaths at 12 months were com-

pared between study arms using a χ^2 *t* test. Log-rank tests were used to analyze time to death and time to hospitalization.

Results

In total, 392 patients were randomized between May 2009 and June 2011 (Figure 1). The study population was mostly male (96.6%) and of white race/ethnicity (81.8%), with a mean age of 68 years, typical of the US veteran population (Table 1). Participants had comorbidities common in HF, including diabetes mellitus (50.0%), prior myocardial infarction (40.6%), chronic obstructive pulmonary disease (30.2%), and obstructive sleep apnea (43.8%). Thirty-eight percent had ejection fraction of less than 40%. At baseline, the mean KCCQ overall summary scores were 37.9 in the intervention group and 36.9 in the usual care group ($P = .48$), indicating high symptom burden and poor functional status and quality of life. Follow-up rates were good, with primary outcome assessments completed in 89.8% (352 of 392) of participants at month 3, in 84.4% (331 of 392) of participants at month 6, and in 86.0% (337 of 392) of participants at month 12.

The individual patient KCCQ overall summary score trajectories for patients in the intervention and usual care arms over the study period are shown in Figure 2. After 1 year, the mean KCCQ overall summary score had increased by 13.5 points for both the intervention and control groups ($P = .97$). The intervention was not associated with greater improvement in the KCCQ overall summary scores when the effect over time was estimated using the 3-month, 6-month, and 12-month data ($P = .74$). Model-estimated KCCQ overall summary scores in the intervention and usual care arms, respectively, were 43.8 (95% CI, 42.3-45.4) and 43.7 (95% CI, 42.1-45.2) at 90 days, 47.2 (95% CI, 45.5-48.9) and 46.9 (95% CI, 45.2-48.6) at 180 days, and 54.2 (95% CI, 51.7-56.6) and 53.6 (95% CI, 51.1-56.0) at 365 days. There were no harmful adverse events attributed to the intervention.

Among secondary outcomes, there were significantly fewer deaths at 1 year in the intervention arm (8 of 187 [4.3%]) than in the usual care arm (19 of 197 [9.6%]) ($P = .04$); the number needed to treat was 20 (95% CI, 10-307). Fewer patients died in the intervention arm over time ($P = .04$, log-rank test). There was no significant difference in 1-year hospitalization rates between the intervention arm and the usual care arm (29.4% vs 29.9%, $P = .87$) or in time to hospitalization between groups. Among those who screened positive for depression, there was greater improvement in the PHQ-9 score after 1 year in the intervention arm than in the usual care arm (2.1; 95% CI, 0.43-3.78 points lower; $P = .01$). Of the recommendations made by the collaborative care teams, 75.7% were accepted by primary care physicians (Table 2).

Discussion

In this multisite randomized clinical trial of 392 patients with HF and poor health status, we found that the multifaceted PCDM intervention did not significantly improve the primary

Table 1. Baseline Characteristics of 384 Participants Enrolled in the Patient-Centered Heart Failure Trial^a

Characteristic	Intervention Arm (n = 187)	Usual Care Arm (n = 197)
Demographics		
Age, mean (SD), y	67.3 (9.6)	67.9 (10.6)
Male sex, No. (%)	178 (95.2)	193 (98.0)
White race/ethnicity, No. (%)	149 (79.7)	165 (83.8)
Medical History, No. (%)		
Myocardial infarction	71 (38.0)	85 (43.1)
Percutaneous coronary intervention	31 (16.6)	48 (24.4)
Coronary artery bypass graft	44 (23.5)	64 (32.5)
Atrial fibrillation	73 (39.0)	70 (35.5)
Implantable cardiac defibrillator	37 (19.8)	42 (21.3)
Biventricular pacemaker	7 (3.7)	14 (7.1)
Other pacemaker	21 (11.2)	26 (13.2)
Diabetes mellitus	99 (52.9)	93 (47.2)
Hypertension	158 (84.5)	159 (80.7)
Chronic obstructive pulmonary disease	57 (30.5)	59 (29.9)
Obstructive sleep apnea	85 (45.5)	83 (42.1)
Peripheral vascular disease	22 (11.8)	26 (13.2)
Heart Failure Characteristics		
Nonischemic etiology, No. (%)	97 (51.9)	96 (48.7)
Left ventricular ejection fraction, No. (%) ^b		
Normal	78 (45.6)	84 (47.5)
Mildly reduced	34 (19.9)	34 (19.2)
Moderately reduced	46 (26.9)	32 (18.1)
Severely reduced	13 (7.6)	27 (15.3)
New York Heart Association classification, No. (%) ^c		
1	16 (8.9)	16 (8.5)
2	77 (42.8)	85 (45.0)
3	82 (45.6)	82 (43.4)
4	5 (2.8)	6 (3.2)
6-min Walk, median (IQR), yd	765 (510-1125)	822 (356-1140)
Medications, No. (%)		
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	122 (65.2)	117 (59.4)
β-Blocker	132 (70.6)	129 (65.5)
Eplerenone	5 (2.7)	5 (2.5)
Spironolactone	49 (26.2)	46 (23.4)
Health Status and Depression		
Kansas City Cardiomyopathy Questionnaire score, mean (SD)	37.9 (13.3)	36.9 (14.6)
Positive depression screen, No. (%)	78 (41.7)	77 (39.1)
Patient Health Questionnaire 9 score, median (IQR)	9 (4-13)	8 (4-11)

Abbreviation: IQR, interquartile range.

^a There were no statistically significant differences between groups at baseline.

^b Left ventricular ejection fraction was available for only 177 usual care patients and 171 intervention patients. Normal is at least 50%, mildly reduced is 40% to 49%, moderately reduced is 30% to 39%, and severely reduced is less than 30%.

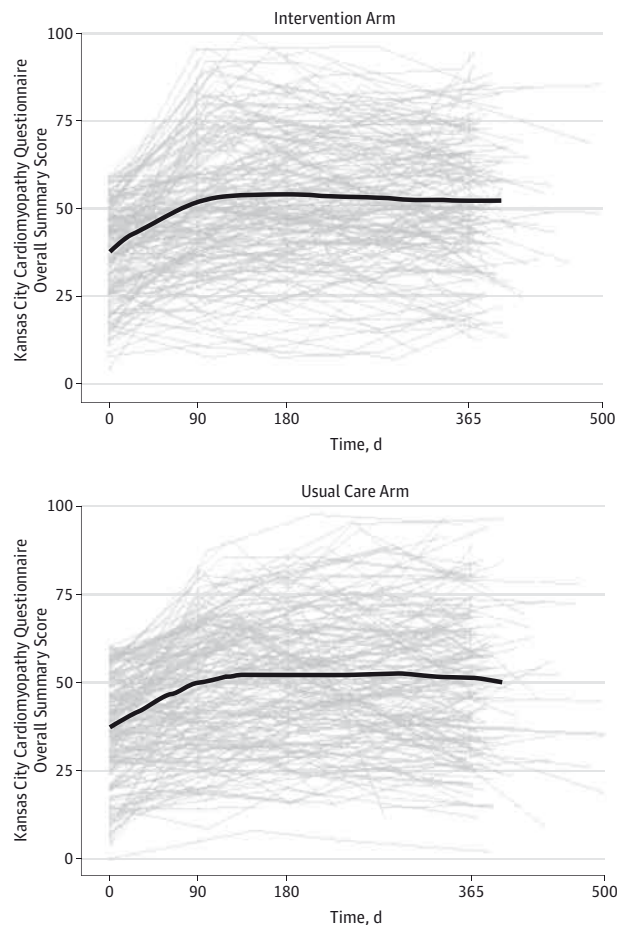
^c New York Heart Association classification was available for only 189 usual care patients and 180 intervention patients.

outcome of patient-reported health status in HF compared with usual care. Patient health status significantly improved over time in both the intervention and usual care cohorts. Among secondary outcomes, there were fewer deaths among the intervention group and reduced depressive symptoms among those who screened positive for depression. With the PCDM intervention, no differences were observed in hospitalization rates.

The PCDM intervention was unique among disease management interventions because of its primary outcome focus on patient health status and because it added depression care to other typical disease management components and used multidisciplinary collaborative care combined with telemoni-

toring. Prior studies³⁰⁻⁴¹ evaluating the effect of HF disease management programs on health status or quality of life have yielded mixed results, and health status was often a secondary outcome. While we cannot determine why the PCDM intervention was unsuccessful in improving patient health status compared with usual care, several reasons are possible. First, the intervention may simply not be effective against the background of current usual, or standard, HF care in the VA system. Second, while the intervention was structured and fully specified for implementation, it was not possible to guarantee strict implementation of all components. For example, we did not audio record and review the nurse counseling sessions for fidelity to the intervention. While many of the col-

Figure 2. Kansas City Cardiomyopathy Questionnaire Scores Over the Study Period in the Intervention and Usual Care Arms



Shown are individual patient trajectories. The darkened lines show the mean KCCQ over time using locally weighted scatterplot smoothing.

laborative care team recommendations were accepted, some were not, and this may have limited the effectiveness of the intervention. Third, because several recommendations were for consultations and diagnostic testing, it may take longer than the 1-year study period to see changes in health status. Fourth, while the depression intervention resulted in an improvement in depressive symptoms, the improvement may have been too small to improve the health status. An improvement of 2.1 points in the PHQ-9 score is below the minimally important difference of 5 points. Future studies of disease management interventions could consider additional implementation process data to capture aspects of implementation such as the number and quality of contacts with the care coordinator, physiological monitoring, medication adherence, or self-management.

This study raises questions about the effectiveness and cost-effectiveness of disease management interventions in the current health care environment. While systematic reviews and meta-analyses have shown reduced hospitalizations and occasionally reduced mortality from disease management, there is heterogeneity in the results, and many of

Table 2. Implementation of Collaborative Care Team Recommendations in the Intervention Arm

Type of Recommendation	Total Recommendations	Accepted Recommendations, No. (%)
Medication	286	215 (75.2)
Consult, such as physical therapy, medical specialty	116	86 (74.1)
Laboratory test	69	59 (85.5)
Other test, such as imaging	40	27 (67.5)
Total	511	387 (75.7)

the original studies were small, single-center trials.^{42,43} Disease management interventions are heterogeneous and complex, and it can be difficult to distinguish the effect of intervention components from the effect of the skilled and motivated staff who conduct the intervention. Telemonitoring, a key component of many HF disease management interventions, was shown in a 2010 study¹⁵ to be ineffective, contradicting the findings of a prior meta-analysis. It may be that different disease management components are needed for different outcomes (eg, health status, hospitalization, and mortality).

The reduction in mortality associated with the intervention has been found in other studies of disease management interventions.⁴³ However, because mortality was a secondary outcome herein, we believe that it would be inappropriate to infer that the PCDM intervention led to reduced mortality. Rather, we view this finding as hypothesis generating, implying the need for future studies adequately powered to detect a difference in mortality as a primary outcome.

The improvement in health status in both arms of the trial has some implications. First, this finding shows the importance of examining the efficacy of disease management interventions using a randomized study design. Evaluating this intervention using a pre-post study design would have found an improvement in health status more than twice the minimal clinically meaningful change, the same improvement observed in the usual care arm. Second, it underscores challenges in studying a population with poor health status because some of the improvement in health status in both arms may have been due to natural variance or regression to the mean.

There are several limitations to this study. We were unable to blind participants to the intervention. Because the study was conducted among the population of US veterans, the results may not be generalizable to other health systems and populations. Additional data on aspects of implementation of the intervention may have informed why the intervention did not improve health status compared with usual care.

Conclusions

In conclusion, the multifaceted PCDM intervention for patients with HF did not improve HF health status compared with usual care. This study adds to the existing literature by

leaving open questions about the effectiveness and cost-effectiveness of disease management and telemonitoring interventions for patients with HF. Fewer deaths were observed in the intervention arm of this trial, and this find-

ing may merit further study in another investigation. While there is significant enthusiasm for disease management programs in HF, rigorous evaluation of these programs continues to be necessary.

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Author Contributions: Drs Bekelman and Rumsfeld had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Sullivan, Heidenreich, Rumsfeld.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Bekelman.

Critical revision of the manuscript for important intellectual content: All authors.

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Study supervision: Bekelman, Sullivan, Hattler, McBryde, Lehmann, Gianola, Heidenreich, Rumsfeld.

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