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Self-management Counseling in Patients With Heart Failure

The Heart Failure Adherence and Retention Randomized Behavioral Trial

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SUCCESS IN THE CONTROL OF THE heart failure epidemic has come from advances in understanding effective, evidence-based medical therapies.¹ Challenges remain, however, in the delivery of these therapies to patients. Patient nonadherence to heart failure drugs ranges from 30% to 60% and nonadherence to lifestyle recommendations from 50% to 80%, with higher rates occurring in more socioeconomically disadvantaged subgroups.²

To meet the challenge of delivering evidence-based therapies to patients with heart failure, research has turned to the evaluation of disease management, remote monitoring, and patient self-management programs.³⁻⁸ Disease management programs extend medical care in the outpatient setting but keep patients in a passive role and, as

For editorial comment see p 1383.

Context Motivating patients with heart failure to adhere to medical advice has not translated into clinical benefit, but past trials have had methodological limitations.

Objective To determine the value of self-management counseling plus heart failure education, compared with heart failure education alone, for the primary end point of death or heart failure hospitalization.

Design, Setting, and Patients The Heart Failure Adherence and Retention Trial (HART), a single-center, multiple-hospital, partially blinded behavioral efficacy randomized controlled trial involving 902 patients with mild to moderate heart failure and reduced or preserved systolic function, randomized from the Chicago metropolitan area between October 2001 and October 2004 and undergoing follow-up for 2 to 3 subsequent years.

Interventions All patients were offered 18 contacts and 18 heart failure educational tip sheets during the course of 1 year. Patients randomized to the education group received tip sheets in the mail and telephone calls to check comprehension. Patients randomized to the self-management group received tip sheets in groups and were taught self-management skills to implement the advice.

Main Outcome Measure Death or heart failure hospitalization during a median of 2.56 years of follow-up.

Results Patients were representative of typical clinical populations (mean age, 63.6 years; 47% women, 40% racial/ethnic minority, 52% with annual family income less than \$30 000, and 23% with preserved systolic function). The rate of the primary end point in the self-management group was no different from that in the education group (163 [40.1%] vs 171 [41.2%], respectively; odds ratio, 0.95 [95% confidence interval, 0.72-1.26]). There were no significant differences on any secondary end points, including death, heart failure hospitalization, all-cause hospitalization, or quality of life.

Conclusions Compared with an enhanced educational intervention alone, the addition of self-management counseling did not reduce death or heart failure hospitalization in patients with mild to moderate heart failure.

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such, raise questions about optimum duration and cost-effectiveness. Remote monitoring draws on technology or telephone contacts to transfer information on patient status but raises the same questions about duration and cost-effectiveness. Patient self-management programs aim to motivate patients to collaborate in their care by teaching them self-management skills. If skills such as self-monitoring and environmental rearrangement can be learned, maintained, and used to implement medical advice, this is a potentially cost-effective approach to controlling heart failure costs.

Five trials of self-management among patients with heart failure have been published to date.⁹⁻¹³ All were limited by small sample sizes (range, 70-197 patients), short durations (typically 2-3 contacts), and inadequate evaluations of maintenance of treatment effects (typically 0-3 months). One trial showed benefit for a clinical end point (death or hospitalization),¹³ but baseline differences in prognostic factors limit interpretation. Thus, the value of self-management programs for patients with heart failure is questionable.

The Heart Failure Adherence and Retention Trial (HART) is the largest and most rigorous trial of self-management in heart failure to date. It was designed to assess the value of 1 year of self-management counseling on death or heart failure hospitalization in patients with mild to moderate heart failure and reduced or preserved systolic function.

METHODS

Design

The design and methods have been reported.¹⁴ HART was a single-center, multiple-hospital, partially blinded behavioral efficacy randomized controlled trial. We showed previously that self-management counseling plus heart failure education improved self-efficacy at self-management.¹⁵ We thus hypothesized that this benefit would extend to improvement in adherence to drug therapy, sodium restriction, and depression, which would in turn re-

sult in an improvement in the primary end point of death or heart failure hospitalization.

Patients were randomized in a 1:1 ratio into 2 trial groups and underwent follow-up for a minimum of 2 years (1 year of treatment and 1 year of follow-up) and a maximum of 3 years (1 year of treatment and 2 years of follow-up), depending on the timing of recruitment. Sample size was based on the assumption that the self-management intervention would produce a 25% reduction in the primary end point, based on the results of prior self-management trials.^{16,17} The base rate for the primary end point in the control group was assumed to be 15% per year, derived from rates in the treatment groups of positive drug trials with similar patients,¹⁸ because these drugs would likely be the standard of care when HART ended. Losses and withdrawals were estimated to be 15%, and sample size was adjusted by approximately 3% to allow for interim analyses. Assuming a 2-sided α of .05 and 80% power, this led to a sample size of 900 patients, evenly distributed between the 2 treatment groups.

Double-blinding in a behavioral trial is impossible, because patients are aware of the treatment they are receiving. However, HART was a partially blinded trial. All staff, except for the senior investigators, and all patients were blinded to trial hypotheses by providing neutral names for the treatment groups (ie, "skills training" for the self-management group and "enhanced education" for the education control group). All investigators and staff, except for the data management team, were blinded to the randomization status of the patient. Treatment teams within each group had no contact with patients in the other group.

The protocol was approved by the institutional committees on human research at the 10 recruiting hospitals. Patients provided written informed consent.

Trial Patients

Eligible patients had heart failure with reduced or preserved systolic func-

tion. All patients were receiving some form of active heart failure treatment, including diuretics, for the previous 3 months. Heart failure with reduced systolic function was defined as ejection fraction of 40% or less by echocardiography, radiographic ventriculography, or radionuclide ventriculography. Heart failure with preserved systolic function was defined as ejection fraction greater than 40% by 1 of the 3 methods and 1 or more previous hospitalizations for heart failure.

Exclusions were factors that would jeopardize the conduct or rigor of the trial. These included (1) New York Heart Association (NYHA) class IV, owing to low likelihood of benefiting from behavioral treatment; (2) NYHA class I, owing to low likelihood of having a primary end point; (3) heart failure symptoms that may be eliminated by surgery (eg, severe aortic stenosis); (4) uncertain 12-month prognosis (eg, likelihood of cardiac transplantation, symptomatic or sustained ventricular tachycardia); (5) severe medical or psychiatric comorbid condition (eg, cognitive dysfunction, substance abuse, psychotic disorder, or active suicidal ideation); (6) patient unwillingness to make lifestyle changes; (7) logistical barriers (eg, limited mobility, enrollment in a conflicting protocol, non-English-speaking); (8) physician refusal; and (9) patient refusal.

Race/ethnicity was self-reported using investigator-defined categories (white/caucasian, black/African American, Hispanic/Latino, Asian American/Pacific Islander, Native American/American Indian, or other [specify]).

Recruitment and Randomization

Recruitment of patients was conducted between October 2001 and October 2004 at 10 recruiting hospitals located throughout the Chicago metropolitan area. Each recruiting hospital had a cardiologist who served as the local principal investigator (see list at end of article). Patients were recruited through inpatient and outpatient screening and through referrals from cardiologists and internists.

At the conclusion of the baseline examination, the nurse coordinator called the automated randomization service (Moffitt Cancer Center, University of South Florida) and treatment assignment was sent to an unblinded staff member, who mailed a letter of notification to the patient. Follow-up by staff leading the relevant trial group commenced approximately 2 to 5 days after receipt of the letter.

To make group treatment logistically feasible, randomization was conducted using a stratified block design, with strata defined as 3 geographic locations and blocks of size 20. Once 20 patients from the same geographic area were recruited, randomization resulted in 10 patients assigned to a group held within their community.

Treatments

A detailed description of the 1-year treatments tested in HART has been reported.¹⁴ The self-management plus education treatment featured group-based heart failure education plus counseling to help patients develop mastery in problem-solving skills and in 5 self-management skills. Eighteen 2-hour group meetings of approximately 10 patients were spread over the course of 1 year. At each meeting, education in the form of 18 Heart Failure Tip Sheets from the American Heart Association (available at <http://www.hearthis.org/hc-heart-failure.htm>) summarized basic elements of patient management, including medication adherence, sudden weight gain, sodium restriction, moderate physical activity, and stress management. Implementation of this advice was aided by training in 5 self-management skills: self-monitoring, environmental restructuring, elicitation of support from family and friends, cognitive restructuring, and the relaxation response. To foster proactivity, a problem-solving format was used in which patients identified barriers to implementing the tips and used self-management skills to overcome them.

Groups were led by health professionals with advanced degrees, experience in conducting groups, willingness

to follow a protocol, and demonstrated competency after a 2-day training session. Treatment fidelity was ensured by (1) audiotaping all sessions, randomly selecting 5% for review, and providing needed feedback; (2) monitoring data on patients and group leaders to identify and resolve problems; and (3) conducting mandatory monthly group leader meetings.

The education group was conceptualized as an attention control, representative of the standard of care in heart failure education that would be in place when HART ended. An attention control, rather than a usual-care control, minimizes such problems as a placebo effect in which any attention could promote benefit, the inability to mask patients to trial hypotheses, and an “underdog” effect that could promote differential dropout or treatment crossovers.

Patients randomized to receive education received the same 18 Heart Failure Tip Sheets, on the same schedule as the self-management group meetings but delivered by mail. To ensure receipt and check comprehension, a study coordinator contacted the patient by telephone within 2 to 3 days of each mailing. If the tip sheet had not been read, the call was rescheduled. All questions about the tip sheets were answered. For concerns unrelated to the tip sheets, the patient was referred to his or her primary care clinician.

Study coordinators were trained on purpose, structure, content, data reporting responsibilities, and quality control procedures. Training included role playing to simulate phone call interactions. Retraining occurred in response to special problems.

Outcome Measures

The primary end point was assessed in blinded fashion by a team of cardiologists (eAppendix, available at <http://www.jama.com>). All patients, or in the case of death, their family members, were contacted every 3 months by telephone to ascertain occurrence of a death or hospitalization. Reports of death were confirmed by medical record,

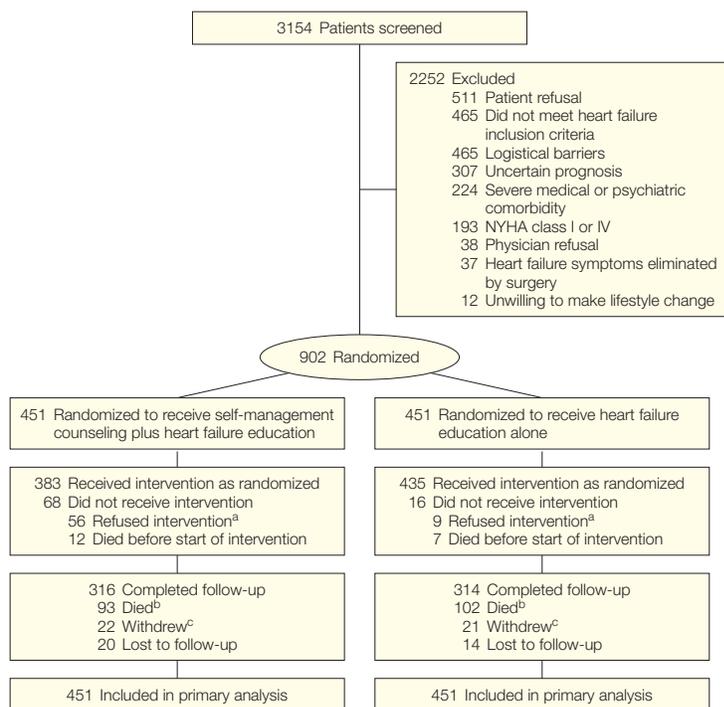
death certificate, emergency medical services record, or queries from the Social Security Death Index. Heart failure admissions were adjudicated by the presence of shortness of breath, peripheral edema, or chest radiographic evidence of pulmonary edema without evidence of another disease process accounting for symptoms or signs. Heart failure admissions were confirmed if the patient responded to heart failure therapy or had a documented decrease in left ventricular function.

Baseline and annual outcome assessments have been described previously.¹⁴ Briefly, examinations consisted of (1) clinical assessment of height, weight, respiratory rate, blood pressure, 6-minute walk, and a blood draw; (2) medical history including medical conditions, medications, sociodemographic status, and risk factors; and (3) questionnaires completed via interview and self-report. The patient was asked to place a month's supply of an angiotensin-converting enzyme (ACE) inhibitor (or β -blocker if the patient was not taking an ACE inhibitor) into a Medication Event Monitoring System electronic pill cap container (MEMS V Trackcap; AARDEX, Zug, Switzerland) and was taught to use it for the ensuing month. Adherence to drug therapy was defined as the percentage of pills taken, relative to pills prescribed, with a cutpoint of 80% or greater.

Sodium intake was assessed as milligrams per day based on the CALS Food Frequency Questionnaire, which was developed to include the main sources of sodium in the diet.¹⁹ Clinically significant sodium intake is 2400 mg/d or less for patients with hypertension²⁰ and 2000 mg/d or less for those with heart failure.²¹ A cutpoint of 2400 mg/d or less was used because too few patients had an intake of 2000 mg/d or less to make statistical analyses feasible.

The Self-Efficacy at Self-Management Scale, developed specifically for HART, included 5 items targeting each of the 5 self-management skills taught in the intervention. Each item had a 10-

Figure 1. Study Flow



NYHA indicates New York Heart Association.

^aPatients who refused intervention were continued in follow-up until they completed, died, fully withdrew, or were lost to follow-up.

^bIncludes patients who died before start of intervention.

^cAll withdrawals were voluntary and patient-initiated.

point scale (the higher the score, the greater the self-efficacy), and the total score was calculated as the average of the scores on the 5 items (range, 1-10). Quality of life was assessed as (1) physical function, using the 10-item subscale from the RAND 36-Item Short-Form Health Survey ($\alpha=0.93$)²²; (2) vitality, using the 4-item subscale from the RAND survey ($\alpha=0.86$)²²; (3) satisfaction with health and function, using the 11-item subscale from the Quality of Life Index–Cardiac ($\alpha=0.93$)²³; and (4) satisfaction with psychological/spiritual function, using the 11-item subscale from the Quality of Life Index–Cardiac ($\alpha=0.89$).²³ Psychosocial function was assessed as (1) major depressive symptoms, using the Geriatric Depression Scale²⁴ (for which a score greater than 10 is a sensitive and specific screen for major depressive symptoms); (2) social support–emotional, using the 8-item subscale of the Medi-

cal Outcomes Study Social Support Scale ($\alpha=0.90$)²⁵; and (3) purpose in life, using the 14-item subscale of the Psychological Well-Being Scale.²⁶ Comorbid conditions were the number of the following: previous myocardial infarction, high blood pressure, diabetes, cancer, stroke, renal disease, arthritis, lung disease, liver disease, depression, asthma, sleep apnea, and Parkinson disease. The range (0-13) was categorized at the median (≤ 3). Family income was dichotomized at the median (\$30 000/y). Six-minute walk was dichotomized at the lowest tertile (≤ 186 m).

Statistical Analyses

Analyses were conducted using SAS version 9.1 (SAS Institute Inc, Cary, North Carolina). In accordance with the analysis plan approved by the data and safety monitoring board, 2-sided tests and an overall significance level of $P=.05$ for

the primary outcome were used. Categorical variables were compared using χ^2 tests. Continuous variables were compared using t tests, except when skewed distributions warranted use of the Wilcoxon rank-sum test.

The effect of the 2 treatment groups on the primary end point and secondary clinical end points was compared using Kaplan-Meier time-to-event curves and analyzed using the Wilcoxon test. The Wilcoxon test was used because the curves clearly indicated that the hazards were nonproportional. Patients who were lost to follow-up or who withdrew consent were included until the time of censoring. Rates during the entire trial period were calculated as events divided by the number of patients at risk minus those censored. Annualized rates were calculated as events divided by person-years. χ^2 Statistics produced P values. Odds ratios (ORs) were the proportion of at-risk patients with an event in the self-management group relative to those in the education group and were accompanied by 95% confidence intervals (CIs).

The effect of treatment on secondary end points was analyzed as a comparison of change between baseline and 1 year posttreatment, adjusting for baseline values. The effect of treatment on behavioral treatment targets was analyzed using repeated-measures mixed-effects regression analyses, with treatment group as the between-subject factor and time (before and after the 1-year treatment) as the repeated within-subject factor. A significant time effect indicated that both groups changed, and a significant time \times treatment group interaction indicated that one group changed more than the other.

The effect of treatment in prespecified subgroups was analyzed by stratifying on the relevant subgroup and comparing treatment group within strata using ORs and 95% CIs. Because of the compromised power in this approach, subgroups were also evaluated by testing for interactions between subgroup and treatment, adjust-

ing for covariates, using a parametric log-logistic accelerated failure time multivariate model, which is appropriate for use with nonproportional hazard data.^{27,28} This model assumes that explanatory variables act multiplicatively on the speed with which a patient proceeds to an event. Acceleration factors greater than 1 indicate faster time to event. A multivariate base model considered all prespecified subgroup variables (ie, age, sex, education, income, race/ethnicity, functional capacity, comorbid conditions, preserved vs reduced systolic function, and baseline drug adherence)¹⁴ and other predictors associated with the primary outcome from the literature (ie, NYHA class, depression, use of ACE inhibitors or angiotensin receptor blockers, and use of β -blockers) and retained only those reaching $P \leq .15$ at each iteration using backward elimination. All prespecified subgroup variables remaining in the base model were tested for their interaction with treatment group.

HART featured a cluster design within the self-management group only, in which patients were treated in 42 groups of approximately 10 patients each. Because the effect of group assignment and group leader on the primary outcome was found to be nonsignificant, clustering was not considered further.

RESULTS

FIGURE 1 presents the trial profile. Of 3154 patients screened during 3 years, 902 were enrolled, resulting in a screening-enrollment ratio of 3.5 patients screened for every patient enrolled. The median (interquartile range) follow-up time was 935 (439-1095) days—918 (464-1095) days in the self-management group and 963 (389-1095) days in the education group. Of the 18 treatment contacts during 1 year, 14 or more (>80%) were received by 46.4% of patients in the self-management group and 53.1% of those in the education group.

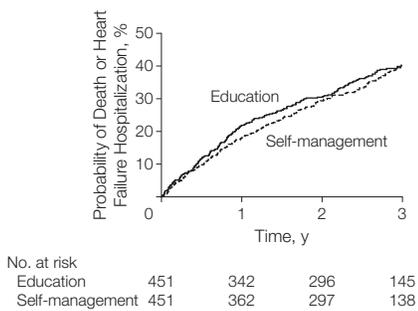
TABLE 1 presents baseline characteristics. On average, the cohort was approximately 64 years of age, 47%

Table 1. Baseline Characteristics in the Total Cohort and by Treatment Group

Characteristic	No. (%)		
	Overall (N = 902)	Self-management (n = 451)	Education (n = 451)
Demographic			
Age, mean (SD), y	63.6 (13.5)	63.8 (13.7)	63.4 (13.3)
Women	427 (47.3)	209 (46.3)	218 (48.3)
Minority race/ethnicity	362 (40.1)	177 (39.2)	185 (41.0)
≤High school education	394 (43.7)	197 (43.7)	197 (43.7)
Annual family income <\$30 000	428 (51.6)	215 (51.9)	213 (51.3)
Unmarried	503 (56.3)	251 (56.3)	252 (56.4)
Medical			
Preserved systolic function	208 (23.1)	107 (23.8)	101 (22.4)
NYHA class III	285 (31.6)	144 (31.9)	141 (31.3)
6-min walk, median (IQR), m ^a	252.9 (149.4-339.0)	264.0 (150.0-349.5)	248.1 (147.0-330.0)
Heart rate, mean (SD)/min	69.7 (14.8)	69.7 (13.9)	69.7 (15.7)
Respiratory rate, mean (SD)/min	15.7 (8.2)	16.0 (7.9)	15.4 (8.5)
Blood pressure, mean (SD), mm Hg			
Systolic	120.7 (20.7)	120.5 (20.1)	120.8 (21.3)
Diastolic	70.2 (11.5)	70.2 (11.1)	70.3 (11.9)
Acute physiology score, mean (SD)	2.6 (2.1)	2.6 (2.0)	2.6 (2.1)
History of hypertension	676 (75.2)	345 (76.8)	331 (73.6)
History of diabetes	362 (40.2)	178 (39.6)	184 (40.9)
Comorbid conditions, mean (SD), No.	3.2 (1.7)	3.2 (1.7)	3.3 (1.7)
Medications, mean (SD), No.	6.8 (3.0)	6.8 (3.0)	6.8 (3.0)
Current medication use			
ACE inhibitor or angiotensin receptor blocker	773 (85.7)	383 (84.9)	390 (86.5)
β -Blocker	636 (70.5)	320 (71.0)	316 (70.1)
Quality of life, mean (SD)			
SF-36			
Physical function ^b	48.1 (25.0)	48.1 (24.9)	48.1 (25.1)
Vitality ^b	46.5 (23.7)	45.9 (23.7)	47.1 (23.6)
Quality of Life Index—Cardiac			
Satisfaction with health and function ^c	4.3 (1.0)	4.3 (1.1)	4.2 (1.0)
Satisfaction with psychological/spiritual function ^c	4.7 (1.1)	4.7 (1.1)	4.8 (1.0)
Adherence			
Nonadherence to drug therapy ^d	274 (36.5)	143 (38.4)	131 (34.6)
Sodium, median (IQR), mg/d ^e	3338 (2654-4273)	3309 (2695-4253)	3342 (2609-4290)
Current smoker	85 (9.4)	39 (8.6)	46 (10.2)
Body mass index, mean (SD)	31.0 (7.7)	31.1 (7.3)	30.9 (8.0)
Self-efficacy at self-management, mean (SD) ^f	7.6 (1.7)	7.6 (1.8)	7.6 (1.6)
Psychosocial			
Major depressive symptoms ^g	265 (29.4)	136 (30.2)	129 (28.7)
Social support—emotional, mean (SD) ^{b,h}	75.2 (22.2)	74.3 (22.5)	76.1 (21.9)
Purpose in life, mean (SD) ^{c,i}	4.5 (0.8)	4.5 (0.8)	4.5 (0.8)

Abbreviations: ACE, angiotensin-converting enzyme; IQR, interquartile range; NYHA, New York Heart Association; SF-36, RAND 36-Item Short-Form Health Survey.
^aRange, 0-780.
^bRange, 0-100; higher scores indicate greater quality of life or emotional support.
^cRange, 1-6; higher scores indicate greater satisfaction or life purpose.
^dTaking less than 80% of prescribed dose of ACE inhibitor or β -blocker.
^eRange, 1250-15 678.
^fRange, 1-10; higher scores indicate greater self-efficacy.
^gMeasured using the Geriatric Depression Scale. A score greater than 10 is sensitive and specific for major depressive symptoms.
^hSubscale of the Medical Outcomes Study Social Support Scale.
ⁱSubscale of the Psychological Well-Being Scale.

Figure 2. Time to Death or Heart Failure Hospitalization by Treatment Group



There was no benefit of self-management compared with education (Wilcoxon $P = .46$). Time indicates time since randomization.

women, 40% self-reported racial/ethnic minority, and 23% with preserved systolic function, making it representative of typical clinical populations. Patients were taking an average of 6.8 medications, and 37% did not adhere to at least 80% of the prescribed dosage of either an ACE inhibitor or β -blocker. Median sodium intake was 3338 mg/d, well more than the recommended 2000 mg/d for patients with heart failure²¹ or 2400 mg/d for those with hypertension.²⁰ Major depressive symptoms were evident in 29%. There were no statistically significant differences between treat-

ment groups for any of the baseline variables.

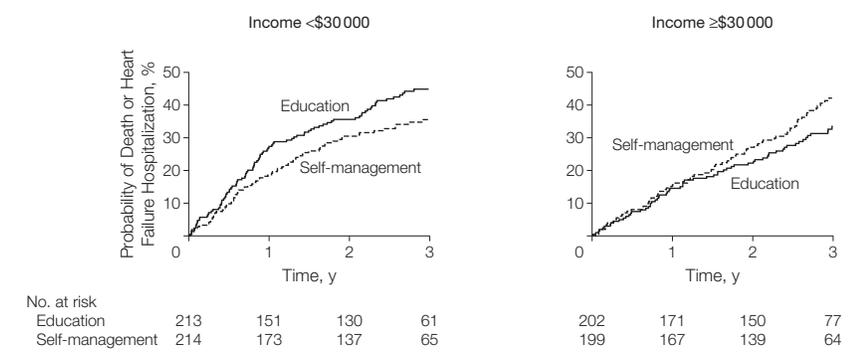
FIGURE 2 presents the Kaplan-Meier estimates of the time to death or heart failure hospitalization by treatment group. There was no benefit of self-management compared with education (Wilcoxon $P = .46$). During approximately 2.56 years of follow-up, there were 163 events (40.1%) in the self-management group and 171 (41.2%) in the education group (OR, 0.95 [95% CI, 0.72-1.26]). The annual event rate was 18.4%, based on 883.84 person-years in the self-management group and 19.2% based on 889.11 person-years in the education group. eTable 1 presents ORs and 95% CIs for the secondary clinical end points (death: OR, 0.87 [95% CI, 0.63-1.21]; heart failure hospitalization: OR, 1.00 [95% CI, 0.72-1.38]; all-cause hospitalization: OR, 0.85 [95% CI, 0.62-1.17]). Both groups had a mean of 0.7 heart failure hospitalizations ($P = .39$). eTable 2 presents change from baseline to the 1-year conclusion of treatment in secondary end points. There were no differences between groups on change in NYHA class, 6-minute walk, heart rate, respiratory rate, blood pressure, body mass index, quality of life, emotional support, or purpose in life. There were no adverse or serious adverse events in either group.

Table 2. Prespecified Independent Predictors of Death or Heart Failure Hospitalization^a

Predictor	Acceleration Factor	Parameter Estimates	P Value ^a
Age ≥ 65 y	1.57	-0.45	.002
New York Heart Association class III	1.92	-0.65	<.001
Major depressive symptoms	1.32	-0.28	.07
≥ 3 Comorbid conditions	1.84	-0.61	<.001
Minority race/ethnicity	1.34	-0.29	.057
Income $\geq \$30\,000$		-0.21	.31
Education treatment		-.036	.056
Treatment \times income interaction		0.64	.02
Self-management			
Income $< \$30\,000$	Reference		Reference
Income $\geq \$30\,000$	1.23		.31
Education			
Income $< \$30\,000$	1.44		.056
Income $\geq \$30\,000$	0.93		NA ^b

Abbreviation: NA, not available.
^aStatistics reported are derived from log-logistic accelerated failure time models.
^bComputationally unobtainable from the accelerated failure time model.

Figure 3. Time to Death or Heart Failure Hospitalization by Treatment Group in Low- and High-Income Subgroups



Accelerated failure time model that included age, New York Heart Association class, depression, comorbid conditions, race/ethnicity, income, treatment, and the income \times treatment interaction resulted in a significant interaction ($P = .02$). Time indicates time since randomization.

The treatments produced variable changes on risk factor targets. Self-efficacy scores improved by 0.2 points in both groups ($P = .008$ for time effect). Major depressive symptoms decreased to 90 (20%) in the self-management group and 99 (22%) in the education group ($P = .008$ for time effect). Restricting sodium to 2400 mg/d or less occurred in 126 (28%) patients in the self-management group and 81 (18%) in the education group ($P = .01$ for time effect), but there was more improvement in the self-management group ($P = .02$ for treatment \times time interaction). However, even in the self-management group, sodium intake remained high, with 325 (72%) having an intake greater than 2400 mg/d. Non-

adherence to the prescribed dosage of ACE inhibitor or β -blocker increased in both groups by 7 percentage points ($P = .01$ for time effect).

The effect of treatment on 9 prespecified subgroups is presented in the eFigure and eTable 3. There were no statistically significant differences between the self-management and education groups within any subgroup. TABLE 2 presents the results of multivariate accelerated failure time modeling. Adjusting for covariates and main effects, the only significant interaction between treatment and a subgroup was for income (parameter estimate, 0.64; $P = .02$). In patients with income less than \$30 000, those randomized to receive education alone had a statistically nonsignificant 44% faster time to event than those randomized to receive self-management (acceleration factor, 1.44; $P = .056$); in patients with income of \$30 000 or greater, there was no difference between treatment groups (FIGURE 3).

COMMENT

Past trials have failed to support the efficacy of motivating patients to manage their heart failure by learning self-management skills,⁹⁻¹³ but these trials have been limited by weak designs. The size, duration, methodological rigor, and representativeness of HART position it well to provide more conclusive results.

We hypothesized that heart failure education, the standard of care, was necessary but not sufficient to affect clinical outcomes. Like any chronic illness, heart failure should be managed collaboratively, such that the clinician prescribes evidence-based therapy and an informed, proactive patient implements it.^{29,30} To enable patients to be proactive, we reasoned that heart failure education should be augmented by training in self-management skills to help patients implement the education. This hypothesis was not supported. Consistent with past trials, self-management training plus education had no benefit compared with education alone in reducing death or heart

failure hospitalization in patients with mild to moderate heart failure.

We believe, however, that the results of HART provide some direction for future trials. In post hoc analyses of prespecified subgroups, we observed a significant interaction between treatment group and income, suggesting that self-management counseling may be beneficial for low-income patients. Others have suggested that low-income patients may need special attention to help them manage chronic illnesses, possibly owing to poor health habits, poor health literacy, and/or limited health insurance.^{13,31} Were future trials to support the value of self-management counseling for low-income patients with heart failure, this would encourage a tailored approach that goes beyond the current standard of care.

Technology-assisted remote monitoring was not evaluated in this trial. However, a recent meta-analysis showed that both telephone monitoring and technology-assisted monitoring achieved a 30% reduction in risk of heart failure hospitalization compared with usual care.⁸ Long-term cost-effectiveness, however, remains to be demonstrated.⁸ It is possible that remote telephone monitoring, such as that used in the HART education group, may enhance patient self-monitoring and thus be an effective way to teach patient self-management skills. Long-term cost-effectiveness of such a joint approach should be studied.

Two limitations of this trial must be considered. First, the education control appeared to have been a more active treatment than expected. Patients in the education group received education tip sheets by mail, and follow-up telephone calls ensured that they were read and comprehended. This enhanced standard of care improved sodium intake, depression, and self-efficacy at self-management.

Second, the assumption that self-management counseling would produce a 25% reduction in the primary end point compared with education may have been overly optimistic. Although the results from early self-

management trials, available when HART was designed, produced an effect greater than 25%,^{16,17} current heart failure trials seek smaller effects (eg, HF-ACTION [Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training]: 11% reduction compared with usual care³²; CHARM [Candesartan in Heart Failure]: 18% reduction compared with placebo³³). Taking these 2 limitations together, one possible explanation for the HART results is that a type II error attributable to small sample size precluded the observation of a treatment benefit.

In summary, the results of HART are consistent with those of past trials. There appears to be no benefit from self-management counseling on important clinical end points in patients with heart failure. However, given the epidemic of heart failure burdening the health care system, identification of innovative and cost-effective approaches to outpatient management is urgently needed. Future trials might evaluate the benefit of self-management counseling in low-income patients.

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Online-Only Material: eTables 1 through 3 and the eFigure are available at <http://www.jama.com>.

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REFERENCES

1. Jessup M, Brozena S. Heart failure. *N Engl J Med*. 2003;348(20):2007-2018.
2. van der Wal MHL, Jaarsma T. Adherence in heart failure in the elderly: problem and possible solutions. *Int J Cardiol*. 2008;125(2):203-208.
3. Kozak AT, Rucker-Whitaker C, Basu S, et al. Elements of nonpharmacologic interventions that prevent progression of heart failure: a meta-analysis. *Congest Heart Fail*. 2007;13(5):280-287.
4. McAlister FA, Stewart A, Ferrua S, McMurray JJ. Multidisciplinary strategies for the management of heart

failure patients at high risk for admission: a systematic review of randomized trials. *J Am Coll Cardiol*. 2004;44(4):810-819.

5. Gwady-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH. A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. *Arch Intern Med*. 2004;164(21):2315-2320.
6. Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR. Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a meta-analysis. *JAMA*. 2004;291(11):1358-1367.
7. Clark RA, Inglis SC, McAlister FA, Cleland JGF, Stewart S. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *BMJ*. 2007;334(7600):942-945.
8. Klersy C, De Silvestri A, Gabutti G, Regoli F, Auricchio A. A meta-analysis of remote monitoring of heart failure patients. *J Am Coll Cardiol*. 2009;54(18):1683-1694.
9. Harrison MB, Browne GB, Roberts J, Tugwell P, Gafni A, Graham ID. Quality of life of individuals with heart failure: a randomized trial of the effectiveness of two models of hospital-to-home transition. *Med Care*. 2002;40(4):271-282.
10. Sethares KA, Elliott K. The effect of a tailored message intervention on heart failure readmission rates, quality of life, and benefit and barrier beliefs in persons with heart failure. *Heart Lung*. 2004;33(4):249-260.
11. Wright SP, Walsh H, Ingley KM, et al. Uptake of self-management strategies in a heart failure management programme. *Eur J Heart Fail*. 2003;5(3):371-380.
12. Prasun MA, Kocheril AG, Klass PH, Dunlap SH, Piano MR. The effects of a sliding scale diuretic titration protocol in patients with heart failure. *J Cardiovasc Nurs*. 2005;20(1):62-70.
13. DeWalt DA, Malone RM, Bryant ME, et al. A heart failure self-management program for patients of all literacy levels: a randomized, controlled trial [ISRCTN11535170]. *BMC Health Serv Res*. 2006;6:30.
14. Powell LH, Calvin JE Jr, Mendes de Leon CF, et al; Heart Failure Adherence and Retention Trial Investigators. The Heart Failure Adherence and Retention Trial (HART): design and rationale. *Am Heart J*. 2008;156(3):452-460.
15. Flynn KJ, Powell LH, Mendes de Leon CF, et al. Increasing self-management skills in heart failure patients: a pilot study. *Congest Heart Fail*. 2005;11(6):297-302.
16. Friedman M, Thoresen CE, Gill JJ, et al. Alteration of type A behavior and reduction in cardiac recurrences in postmyocardial infarction patients. *Am Heart J*. 1984;108(2):237-248.
17. Lorig KR, Sobel DS, Stewart AL, et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. *Med Care*. 1999;37(1):5-14.
18. SOLVD Investigators. Effect of enalapril on survival in patients with reduced left ventricular ejection fractions and congestive heart failure. *N Engl J Med*. 1991;325(5):293-302.

19. DeBusk RF. MULTIFIT: a new approach to risk factor modification. *Cardiol Clin*. 1996;14(1):143-157.
20. Chobanian AV, Bakris GL, Black HR, et al; National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289(19):2560-2572.
21. Hunt SA, Abraham WT, Chin MH, et al; American College of Cardiology Foundation; American Heart Association. 2009 Focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines developed in collaboration with the International Society for Heart and Lung Transplantation. *J Am Coll Cardiol*. 2009;53(15):e1-e90.
22. Ware JE Jr, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36), I: conceptual framework and item selection. *Med Care*. 1992;30(6):473-483.
23. Ferrans CE, Powers MJ. Quality of Life Index: development and psychometric properties. *ANS Adv Nurs Sci*. 1985;8(1):15-24.
24. Yesavage JA, Brink TL, Rose TL, et al. Development and validation of a geriatric depression screening scale: a preliminary report. *J Psychiatr Res*. 1982-1983;17(1):37-49.
25. Sherbourne CD, Stewart AL. The MOS Social Support Survey. *Soc Sci Med*. 1991;32(6):705-714.
26. Ryff CD, Keyes CL. The structure of psychological well-being revisited. *J Pers Soc Psychol*. 1995;69(4):719-727.
27. Collett D. *Modeling Survival Data in Medical Research*. 2nd ed. New York, NY: Chapman & Hall/CRC Press LLC; 2003.
28. Anderson KM. A nonproportional hazards Weibull accelerated failure time regression model. *Biometrics*. 1991;47(1):281-288.
29. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. *Milbank Q*. 1996;74(4):511-544.
30. Von Korff M, Gruman J, Schaefer J, Curry SJ, Wagner EH. Collaborative management of chronic illness. *Ann Intern Med*. 1997;127(12):1097-1102.
31. Wagner EH. Deconstructing heart failure disease management. *Ann Intern Med*. 2004;141(8):644-646.
32. O'Connor CM, Whellan DJ, Lee KL, et al; HF-ACTION Investigators. Efficacy and safety of exercise training in patients with chronic heart failure: HF-ACTION randomized controlled trial. *JAMA*. 2009;301(14):1439-1450.
33. Yusuf S, Pfeffer MA, Swedberg K, et al; CHARM Investigators and Committees. Effects of candesartan in patients with chronic heart failure and preserved left-ventricular ejection fraction: the CHARM-Preserved Trial. *Lancet*. 2003;362(9386):777-781.