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Does Self-management Counseling in Patients with Heart Failure Improve Quality of Life? Findings from the Heart Failure Adherence and Retention Trial (HART)

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Abstract

Purpose—Heart failure (HF) is associated with poor health-related quality of life (HRQOL). The purpose of our study is to determine the effect of a self-management intervention on HRQOL domains across time, overall and in pre-specified demographic, clinical, and psychosocial subgroups of HF patients.

Methods—HART was a single-center, multi-hospital randomized trial. Patients (n=902) were randomized either to a self-management intervention with provision of HF educational information or an enhanced education control group which received the same HF educational materials. HRQOL was measured by the Quality of Life Index, Cardiac Version, modified and the Medical Outcomes Study 36-item Short-Form Health Survey physical functioning scale. Analyses included descriptive statistics and mixed-effects regression models.

Results—In general, overall, study participants' HRQOL improved over time. However, no significant differences in HRQOL domain were detected between treatment groups at baseline or across time ($p>0.05$). Subgroup analyses demonstrated no differences by treatment arm for change in HRQOL from baseline to 3 years later.

Conclusions—We conclude that in our cohort of patients, the self-management intervention had no benefit over enhanced education in improving domains of HRQOL and HRQOL for specified HF subgroups.

Keywords

heart failure; quality of life; self-management

Heart failure (HF) affects 5.7 million Americans, with an excess of 670,000 new cases diagnosed each year in adults ≥45 years [1]. In addition to high rates of mortality [1, 2] and substantial direct and indirect costs [3], HF is associated with poor health-related quality of life (HRQOL). HF patients experience significantly worse physical and mental HRQOL as compared to the United States general population and significantly worse physical HRQOL than patients with other cardiovascular diseases, such as coronary artery disease [4, 5].

Given the effect of HF on patient outcomes, randomized clinical trials have been conducted with the purpose of investigating both pharmacological and non-pharmacological treatments for HF. Many of the non-pharmacological treatments consist of disease management programs that include teaching self-management skills [6]. In general, mortality and hospitalization rates have been the outcomes of interest in these trials, although some researchers have examined the effects of treatment versus usual care on HRQOL outcomes.

The literature is equivocal regarding the influence of a self-management intervention on HF patient HRQOL. Whether study design, characteristics of the intervention (including timing and duration), instrument, or sample characteristics were considered, the evidence for making a strong case of the effect of self-management on HRQOL is not present. We previously reviewed 17 randomized controlled trials (sample size range = 18–338 for all but one trial that had a sample size comparable to HART) for the effect of HF self-care on HRQOL, and reported that only approximately half of the studies demonstrated an improvement in HRQOL [7]. Small to moderate sample sizes were reported in many trials (n=18–338), and descriptions of interventions and usual care were not always fully provided. Furthermore, no single HRQOL measure has been consistently used by researchers, and many researchers used only one tool (each with its own limitations) to study HRQOL, including the Minnesota Living with Heart Failure Questionnaire, Medical Outcomes Study 36-item Short Form Health Survey, and Quality of Life Index [7]. Even meta-analyses that included HF self-management as part of an intervention failed to demonstrate significant differences in HRQOL outcomes between treatment groups [8–13]. Given that instruments used to examine HRQOL differed among studies, pooling of data in these meta-analyses was not possible. Additional information is needed to enhance our understanding of self-management and HRQOL in patients with HF.

The Heart Failure Adherence and Retention Trial (HART) expands upon the existing literature. HART included 902 individuals, which is substantially larger than most of the previous studies. Additionally, the treatment under investigation in HART was a group-based intervention entirely focused on self-management counseling. This study also used two measures that assessed different aspects of HRQOL. In the report of our primary findings from HART, we detected no differences in the primary end point of death or heart failure hospitalization and any of the secondary end points, including overall HRQOL, between patients randomized to the self-management intervention versus the enhanced education control group [14].

The purpose of this report from HART is to determine the effect of the self-management intervention on HRQOL domains across time, overall and in pre-specified demographic,

clinical, and psychosocial subgroups of HF patients. Examination of the effect of our intervention on HRQOL in subgroups is based on the primary outcome results which suggest that the group-based intervention may have benefit for specific HF patients, especially those with limited socio-economic resources [14]. We therefore tested whether the intervention also resulted in more beneficial changes in terms of HRQOL within the same subgroups.

METHODS

Sample and sites

HART was a National Heart, Lung, and Blood Institute funded randomized behavioral clinical trial designed to test whether a self-management intervention improved outcomes (including HRQOL) as compared to a control group in patients with New York Heart Association (NYHA) class II or III [15]. Inclusion criteria were HF for ≥ 3 months and a left ventricular ejection fraction ≥ 40% or on diuretic therapy for ≥ 3 months and one hospitalization for HF. Patients with only diastolic heart failure (n=208 [23%] of enrollees) (i.e., ejection fraction > 40%) were enrolled based on the use of diuretic therapy and rehospitalization. Patients were excluded based on the following criteria: uncertain 1-year prognosis (e.g. NYHA class IV, possibility of heart transplantation, presence of a life-limiting illness, other than HF), NYHA class I, unlikely to benefit from the intervention (e.g. due to severe cognitive dysfunction, substance abuse), surgical candidates (e.g. those with severe aortic stenosis), non-English speaking, enrolled in a competing study, unwilling to make lifestyle changes, and refusal of patient access by a physician. Patients were recruited from 10 hospitals or clinics in a large Midwestern city and surrounding suburbs. HART investigators screened 3,154 patients, and 2,252 patients were excluded. Participants included in the study (n=902) were randomized to self-management (intervention group, n=451) or enhanced education (control group, n=451).

Design and Intervention

HART was a single-center, multi-hospital randomized trial, which used a stratified block randomization protocol [15]. Methods for this trial have been described in detail previously [15]. Patients who were randomized to self-management participated in 18 two-hour group counseling sessions spread over a 1 year time period that coached them in the development of self-management skills and problem solving and were provided with HF educational information intended to improve adherence with their medical regimen and ultimately improve HRQOL, a secondary endpoint [15]. During group meetings, participants received one of the 18 HF educational materials and were taught self-management skills such as self-monitoring (e.g., regarding sodium consumption), environmental restructuring, elicitation of support from family, and cognitive restructuring. The enhanced education control group received the same 18 HF educational materials, per mail, as the self-management intervention group at the same pre specified time intervals during a 1 year time period, followed by a telephone call to ensure receipt, check comprehension, and answer questions about the information. The HF education consisted of American Heart Association materials with information regarding diet, physical activity, stress, medications, sudden weight gain, HF symptoms, and physician appointments.

Instruments

Two self-report instruments were used to measure HRQOL in HART: the Quality of Life Index (QLI), Cardiac Version – IV, modified [16] and the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) physical functioning scale [17]. Since HART was proposed in the late 90's, these two instruments were acceptable measures of HRQOL at that time and continue to be used in HF studies today [18–20]. The QLI measures satisfaction

with various aspects of life. We used two of the QLI subscales that measured satisfaction with (1) health and functioning and (2) psychological and spiritual well-being [16]. The 22 items from these subscales rated satisfaction on a 6-point scale from 1= very dissatisfied to 6 = very satisfied. Scores were calculated for the combined subscales (total score) by averaging scores across all non-missing items. This widely used HRQOL instrument has acceptable reliability and validity in cardiac patient populations [21]. In this patient sample, Cronbach alpha was 0.94 [22].

The SF-36, version 2, physical functioning scale [17] includes 10 items that assess the degree to which poor health limits ability to perform physical activities, including walking, climbing stairs, bathing or dressing, and carrying groceries. Items are scored on a 3-point scale from limited a lot to not limited at all. A raw score is calculated for the scale and transformed into a scale score that converts the lowest possible score to 0 and the highest possible score to 100. Higher scores indicate better functioning. The validity and reliability of the SF-36 has been documented in a variety of patient populations including medical and geriatric patients [23, 24]. In this patient sample, the Cronbach alpha was 0.88 [22].

Depression was also measured with the 30-item Geriatric Depression Scale (GDS) [25]. The GDS measures depressed mood, anhedonia, hopelessness, and negative thoughts, coded as yes/no and summed across items (range = 0–30). The GDS is a reliable and valid measure of depressive symptoms in elderly patients and patients with chronic medical conditions, wherein somatic symptoms are deemphasized [25, 26]. The Cronbach alpha for our patient sample was 0.89 [22].

Procedures

The study was approved by the Institutional Review Boards of all participating institutions. The research project was explained to patients, and those who volunteered to participate were enrolled in the study. After consent, patients underwent a baseline examination, consisting of a clinical examination, medical history, and interview regarding physical functioning HRQOL and depression. Patients were also given written questionnaires to complete via self-report regarding satisfaction with HRQOL and social support, with instructions to return questionnaires by mail. Patients were then randomized to the self-management or enhanced education group. Self-report HRQOL data for HART were subsequently collected via written, self-report with return of questionnaires by mail at the following time periods: after 1 year of treatment and annually up to a maximum of 2 years of follow-up (beginning on November 20, 2001 through June 8, 2007).

Statistical analyses

All analyses were conducted using SAS[®] (SAS, version 9.1.3, Cary, NC). Descriptive statistics included frequencies and measures of central tendency (mean $\pm$ sd). Subscale and total scale scores were calculated for both the QLI and SF-36. Analyses were performed overall and within pre-specified subgroups [8]. The subgroups included age, gender, race, educational level, income level, NYHA class, number of co-morbidities, and depression.

For each HRQOL outcome, mixed-effects regression modeling was used to analyze changes over time. The mixed-effects models employed the following variables: treatment arm, time since baseline (in years), a treatment arm by time interaction, and a random intercept. Analyses were performed first using only available data. Multiple imputation was then employed as a sensitivity analysis to assess the influence of missing data [27–29]. Variables used to impute the missing scores included: non-missing scores, number of co-morbidities, age, body mass index, race (white vs. non-white), survival time, and gender.

RESULTS

Baseline demographic, clinical, and psychosocial characteristics overall and by treatment arm are reported in Table 1. Overall, the majority of the 902 enrolled patients were male, white, with more than a high school education, an earned income of <\$30,000, and on average 64 years of age. Additionally, just under half of patients were married. Patients had an average of three co-morbidities. The vast majority of patients were taking angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs) and beta blockers. Patients were satisfied with HRQOL at baseline, overall as well as within each domain; although patients also reported some physical functional limitations. There were no statistically significant differences in characteristics or HRQOL between treatment arms at baseline.

HRQOL by Domains across Time

Results of the mixed-effects modeling by domains and based only on available data are presented in Table 2. These results indicate a significant increase in QLI scores over time (coefficient = 0.07, $p < 0.0001$). However, the treatment arm by time interaction term (coefficients = 0.003, $p = 0.90$) was not significant, indicating the improvements in QLI scores did not significantly differ by treatment arm. When the two QLI domains were examined separately, the psychological and spiritual well-being domain did not significantly change over time (coefficient = 0.03, $p = 0.14$), while the health and functioning domain improved over time (coefficient = 0.09, $p < 0.0001$), although changes did not differ by treatment group. Analyses using imputed data yielded similar results.

In contrast to the QLI scores, Table 2 indicates a significant decrease in SF-36 physical functioning scores from baseline (coefficient = -1.25 , $p = 0.004$), indicating a decline in physical functioning. Similar to the QLI, however, changes over time did not differ by treatment arm (coefficient = 0.19, $p = 0.59$). Again, analyses using imputed data yielded similar results.

HRQOL by Specified Subgroups across Time

Tables 3 and 4 show results of mixed-effects modeling of QLI and SF-36 scores based on available data, by pre-specified subgroups. These analyses indicate a significant increase in QLI scores over time in almost all subgroups and decrease in SF-36 physical functioning scores over time in many subgroups. However, no significant treatment arm effect or treatment arm by time interaction was observed in any of the subgroups. Sensitivity analyses with imputation of missing data resulted in similar findings.

DISCUSSION

In a diverse group of HF patients, we considered the effect of a self-management intervention on domains of HRQOL relative to an enhanced education control group. We used two distinct instruments to measure HRQOL: the QLI, which measured overall satisfaction with HRQOL and satisfaction with the following domains: (1) health and functioning and (2) psychological/spiritual well-being, and the SF-36, measuring the domain of physical functioning. We observed an improvement in satisfaction with overall HRQOL and health and functioning, but no change in the psychological/spiritual domain and a decline in physical function over time. However, changes in these HRQOL outcomes did not differ by treatment arm, suggesting that both the self-management intervention and the enhanced education contributed to our findings. Given that the enhanced education group received education per mail with follow-up telephone calls, we believe these patients may have received a more active intervention than intended, and thus our study may not have

been adequately powered to detect a treatment benefit for HRQOL. Furthermore, our self-report HRQOL instruments were generic and cardiac-specific and thus may not have been sensitive enough to detect between-group differences in our HF cohort. Our infrequent assessment of HRQOL may also have contributed to null findings.

Subgroup analyses also demonstrated no differences by treatment arm for changes in HRQOL over time. However, our trial was underpowered to test for such interactions in our subgroup analyses. Estimating power for interactions within a longitudinal mixed-model involves several assumptions concerning variability of the scores across individual participants at each time-point as well as within individuals over time. Allowance for missing observations somewhat complicates this estimation. Hedeker et al., [30] provide a useful strategy for power and sample size estimation within this context. Using our study data, we computed variance-covariance estimates and then the sample sizes required to achieve 80% power to detect the treatment group by time interactions presented in this report, by subgroup. As one might expect, the required sample size varies quite a bit; with lower sample sizes being required within subgroups in which the time effect has greater significance. For example, with respect to Table 4 and analyses of the SF-36 Physical Functioning Score, the required sample size for the subgroups of age ≥ 65 , race: white, education $\leq$ HS, # co-morbidities < 3 , and GDS ≥ 10 range from about 750 per group, entered and followed for three years, to about 2200 per group, whereas that required for many of the other subgroups ranged into the tens of thousands per group to adequately detect the interaction. Notably, improvement in satisfaction with overall HRQOL and decline in physical functioning occurred over time in some specific subgroups (e.g., age, gender, and number of co-morbidities). Our subgroup findings may provide direction for future trials that focus on assessing HRQOL in special populations of HF patients with important challenges from a cultural, demographic, and/or clinical perspective.

The lack of group differences in our domain and subgroup analyses is consistent with our previous overall findings [14] and findings of others, specifically for HF patients with NYHA class IV HF, poor health literacy, and older age [31–35]. Also, there are few reports of HF interventions that consider cultural differences, other than one small trial of self-management in Hispanic patients of Mexican origin that did not detect group differences for HRQOL [36]. Interestingly, a recent secondary analysis from a randomized controlled trial of HF patients ($n=317$) did detect between group differences for education and cognitive function, such that patients with lower education and better cognitive functioning benefited from assignment to the self-management intervention versus control group [37]. Our general findings of declining physical function across time, that did not differ by treatment arm, may reflect the physical deterioration associated with progressive HF or worsening deconditioning [38, 39]. Importantly, improvement in physical functioning has been demonstrated in HF clinical trials that include exercise training [40–42].

From a clinical perspective, given that our findings demonstrate similarity of the impact of a self-management intervention and enhanced education on HF patient HRQOL across time, including for specified subgroups, it appears to not be necessary to integrate a more resource intensive program of self-management into heart failure programs to improve HRQOL. Importantly, the decline in physical function in patients with HF across time suggests the need for regular evaluation of this HRQOL domain with subsequent recommendations for therapy. Furthermore, demographic and clinical characteristics may contribute to an increased risk of poor HRQOL outcomes. Knowledge of these risk factors can also guide assessment and treatment.

The scientific rigor, methods, sample size, diversity of our cohort, duration of the study, and use of two HRQOL instruments in HART underscore the relevance of our findings.

Furthermore, while it is impossible to have double-blinding in a behavioral trial, HART was partially blinded, as all staff, except senior investigators, were blinded to trial hypotheses. Also, treatment teams were assigned to one group and did not interact with patients in the other group. However, our analyses indicated that, within some subgroups, data may not have been missing at random, although the missing at random assumption appeared appropriate overall. Thus, we report subgroup findings cautiously and consider them to be exploratory. Lastly, generalizability of our trial was limited by its conduct in one Midwestern city and its suburbs.

CONCLUSIONS

We conclude that in our cohort of patients, the self-management intervention had no benefit over enhanced education in improving domains of HRQOL and HRQOL for specified HF subgroups. Further research on the effect of a self-management intervention on HRQOL by domain and subgroup is needed. Conducting a trial with a less active control condition is recommended to better observe the impact of self-management counseling.

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Abbreviations

HF	heart failure
HRQOL	health-related quality of life
HART	Heart Failure Adherence and Retention Trial
NYHA	New York Heart Association
QLI	Quality of Life Index
SF-36	Short Form 6
GDS	Geriatric Depression Scale
ACE	angiotensin-converting enzyme
ARB	angiotensin-receptor blocker

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Table 1

Baseline Characteristics in the Total Cohort and by Treatment Arm

	OVERALL (N=902)	TREATMENT GROUP	
		Self- Management (N=451)	Education (N=451)
Demographics			
Age, mean(sd)	63.6 (13.5)	63.8 (13.7)	63.4 (13.3)
Age < 65, N(%)	451 (50.0)	221 (49.0)	230 (51.0)
Male, N(%)	475 (52.7)	242 (53.7)	233 (51.7)
White, N(%)	540 (59.9)	274 (60.8)	266 (59.0)
>High School Education, N(%)	508 (56.3)	254 (56.3)	254 (56.3)
Annual Family Income < \$30,000, N(%)	428 (51.6)	215 (51.9)	213 (51.3)
Married, N(%)	399 (43.7)	200 (43.7)	199 (43.6)
Clinical			
NYHA Class III, N(%)	285 (31.6)	144 (31.9)	141 (31.3)
Number of Co-Morbidities, mean(sd)	3.2 (1.7)	3.2 (1.7)	3.3 (1.7)
Number of Medications, mean(sd)	6.8 (3.0)	6.8 (3.0)	6.8 (3.0)
Current Use of, N(%)			
ACE inhibitor or ARB	773 (85.7)	383 (84.9)	390 (86.5)
Beta Blocker	636 (70.5)	320 (71.0)	316 (70.1)
Six minute walk(ft), md (iqr)	843 (632)	880 (665)	827 (610)
Psychosocial			
Major Depressive Symptoms (GDS), N(%)	265 (29.4)	136 (30.2)	129 (28.7)
Geriatric Depression Scale < 10, N(%)	636 (70.6)	315 (69.8)	321 (71.3)
HRQOL			
Quality of Life Index (QLI), mean(sd) [†]	4.4 (1.0)	4.4 (1.0)	4.4 (1.0)
SF-36: Physical Functioning, mean(sd) [‡]	48.1 (25.0)	48.1 (24.9)	48.1 (25.1)
Quality of Life Index (QLI): Psychologic and Spiritual Well-Being	4.8 (1.1)	4.7 (1.1)	4.8 (1.0)
Quality of Life Index (QLI): Health and Functioning	4.3 (1.0)	4.3 (1.1)	4.3 (1.0)

NYHA=New York Heart Association; ACE=angiotensin-converting enzyme; ARB=angiotensin-receptor blocker; GDS=Geriatric Depression Scale; HRQOL=health-related quality of life

[†] Range = 1–6 with 1=very dissatisfied with HRQOL to 6=very satisfied with HRQOL (from the QLI [total scale score])

[‡] Range = 0–100 with higher score= fewer limitations in performing physical activities (from the SF-36 physical functioning scale)

Table 2

Results from mixed-effects modeling, using only available data

Quality of Life Index	Intercept	Time Effect	Group Effect	Group*Time Effect
<i>available-case analysis</i>				
estimate	4.44	0.07	−0.01	0.003
<i>p-value</i>	<.0001	<0.0001	0.8721	0.8983
SF-36 Physical Functioning	Intercept	Time Effect	Group Effect	Group*Time Effect
<i>available-case analysis</i>				
estimate	48.0	−1.25	−1.47	0.19
<i>p-value</i>	<.0001	0.0039	0.972	0.5908
Quality of Life Index: Psychologic and Spiritual Well- Being	Intercept	Time Effect	Group Effect	Group*Time Effect
<i>available-case analysis</i>				
estimate	4.75	0.028	0.0038	0.025
<i>p-value</i>	<.0001	0.1369	0.9582	0.3304
Quality of Life Index: Health and Functioning	Intercept	Time Effect	Group Effect	Group*Time Effect
<i>available-case analysis</i>				
estimate	4.30	0.085	−0.018	−0.007
<i>p-value</i>	<.0001	<.0001	0.7995	0.7609

Table 3

Results from mixed-effects modeling on Quality of Life Index (QLI) scores, based on available data, by indicated subgroup.

Subgroup	Intercept ^I	Time Effect	Group Effect	Group * Time Effect
Age >= 65	4.62	0.01	0.00	0.02
Age < 65	4.26	0.12***	-0.01	-0.01
Annual Income >= \$30,000	4.52	0.07**	-0.02	0.02
Annual Income < \$30,000	4.37	0.07**	0.01	-0.02
Race: White	4.49	0.06**	-0.06	0.02
Race: Non-white	4.35	0.08**	0.08	-0.02
GDS>=10	3.54	0.12**	0.09	0.02
GDS < 10	4.82	0.04*	-0.07	0.00
# of Comorbidities < 3	4.62	0.09***	-0.04	0.01
# of Comorbidities >= 3	4.33	0.05*	0.02	0.00
Female	4.40	0.11***	0.05	-0.02
Male	4.48	0.03	-0.07	0.02
Baseline NYHA Class III	4.18	0.10**	-0.03	-0.04
Baseline NYHA Class II	4.56	0.05**	-0.01	0.02
Education <= High School	4.34	0.06*	0.11	-0.03
Education > High School	4.52	0.07**	-0.10	-0.02

^I All intercept estimates have p-values < 0.001

* "0.01 < p-value ≤ 0.05",

** 0.001 < p-value ≤ 0.01,

*** "p-value ≤ 0.001

GDS=Geriatric Depression Scale; NYHA=New York Heart Association Class

Table 4

Results from mixed-effects modeling on SF-36 Physical Functioning scores, based on available data, by indicated subgroup

Subgroup	Intercept ^I	Time Effect	Group Effect	Group * Time Effect
Age >= 65	45.19	-3.38***	-1.11	1.05
Age < 65	50.93	0.56	0.75	-0.40
Annual Income >= \$30,000	53.31	-0.88	1.61	0.53
Annual Income < \$30,000	42.22	-1.69**	-0.73	0.62
Race: White	50.62	-1.43**	0.26	0.11
Race: Non-white	43.94	-1.01	-0.27	0.66
GDS>=10	37.84	-1.90*	0.11	1.78
GDS < 10	52.33	-0.95	-0.47	-0.23
# of Comorbidities < 3	55.24	-1.57*	3.50	1.17
# of Comorbidities >= 3	43.6	-1.04	-1.53	-0.25
Female	42.94	-1.13	1.53	0.18
Male	52.37	-1.32*	-1.18	0.45
Baseline NYHA Class III	33.61	-0.59	-1.15	0.56
Baseline NYHA Class II	54.71	-1.56**	0.23	0.25
Education <= High School	43.24	-1.77*	-0.56	-0.07
Education > High School	51.70	-0.89	0.35	0.54

^I All intercept estimates have p-values < 0.001

* "0.01 < p-value ≤ 0.05",

** 0.001 < p-value ≤ 0.01,

*** "p-value ≤ 0.001

GDS=Geriatric Depression Scale; NYHA=New York Heart Association Class