ELSEVIER

Patient Education and Counseling 58 (2005) 27–34

Patient Education and Counseling

www.elsevier.com/locate/pateducou

Effect of behavioral management on quality of life in mild heart failure: a randomized controlled trial

Martha Shively[a,b,*], Mary Kodiath[a], Tom L. Smith[a,c], Ann Kelly[a], Patricia Bone[a], Lizz Fetterly[a], Nancy Gardetto[a], Ralph Shabetai[a,c], Samuel Bozzette[a,c], Kathleen Dracup[d]

[a]*Veterans Affairs San Diego Healthcare System, Department of Nursing (118), 3350 La Jolla Village Dr., San Diego, CA 92161-4189, USA*
[b]*San Diego State University, San Diego, CA, USA*
[c]*University of California San Diego, San Diego, CA, USA*
[d]*University of California San Francisco, CA, USA*

Received 22 December 2003; received in revised form 16 April 2004; accepted 4 June 2004

Abstract

There has been a lack of research regarding nonpharmacologic interventions in heart failure. The objective was to determine the effect of behavioral management on health related quality of life (HRQL) in patients with heart failure. Participants ($N = 116$) were randomly assigned to one of two groups: usual care for heart failure ($n = 58$) and the 15-week behavioral management program ($n = 58$). Outcomes included exercise performance (6-min walk), physical and mental functioning (SF-36), general health perceptions (SF-36), and disease specific HRQL (Minnesota Living with Heart Failure Questionnaire—MLHF). Outcomes were assessed at baseline, 4, 10 and 16 months. Participants were mostly male (95%) and Caucasian (75%), with a mean age of 67 years (S.D. = 10). Intervention patients showed significantly improved self-reported disease specific HRQL (MLHF physical dimension scores) over time compared to control patients. There were no group differences in exercise performance, physical functioning, mental functioning or general health perceptions.

Keywords: Chronic heart failure; Behavior; Patient; Health behaviors; Quality of life

1. Introduction

It is well known that heart failure is a significant and growing health care problem with high mortality, reduced quality of life and significant economic burden on society [1]. Patient management and guideline recommendations include encouraging patients to be more active in their own care, patient and family education, symptom management, exercise training, dietary modification, and adherence to the prescribed medications [1–3]. Behavioral self-management in patients with heart failure may help to control symptoms, maintain function, avoid preventable re-hospitalization, and ultimately decrease morbidity and mortality. One desired outcome from behavioral self-management is enhanced health related quality of life (HRQL); however, only a few groups have reported behavioral interventions specific to heart failure [4,5]. Evaluation of behavioral interventions is still lacking and interventions to improve HRQL in patients with heart failure still need to be tested. The primary objective of this study was to determine the effect of a nurse-led behavioral management intervention on HRQL in patients with mild heart failure. It was hypothesized that patients who participated in a nurse-led behavioral management intervention as compared to usual care over a 16-month follow-up period (baseline, 4, 10, and 16 months) would have improved exercise performance, physical functioning, mental functioning, and general health perceptions.

* Corresponding author. Tel.: +1 858 642 3493; fax: +1 858 552 7422.
E-mail address: martha.shively@med.va.gov (M. Shively).

0738-3991/$ – see front matter © 2004 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.pec.2004.06.007

2. Methods

2.1. General design

This was a randomized clinical trial design (Fig. 1). Following eligibility screening and consent, 116 patients were randomly assigned to one of two treatment groups to evaluate the clinical impact of the intervention. A stratified blocked randomization approach based on the Specific Activity Scale (SAS) was used to assure that patients were equally distributed based on functional performance. The control group received usual care for patients with heart failure ($n = 58$). The intervention group received usual care plus the 15-week (4-month) behavioral management program ($n = 58$).

2.2. Setting and sample

The study was done at a single site, the Veterans Affairs (VA) San Diego Healthcare System. Patients seen in outpatient clinics with a primary diagnosis of heart failure were screened and enrolled over a period of 27 months in 11 successive groups of 8–13 patients each. To be included, the patient had to be 18 years of age or older, have a primary care provider, have stable heart failure symptoms for at least 1 month, and be able to walk. Exclusion criteria were unstable angina, myocardial infarction, or cardiac surgery within the past 3 months; hypertrophic cardiomyopathy; areas of reversibility greater than 10% on the catheterization report; major surgery within the last 3 months; a co-existing acute medical problem; life expectancy less than 2 years; and current acute

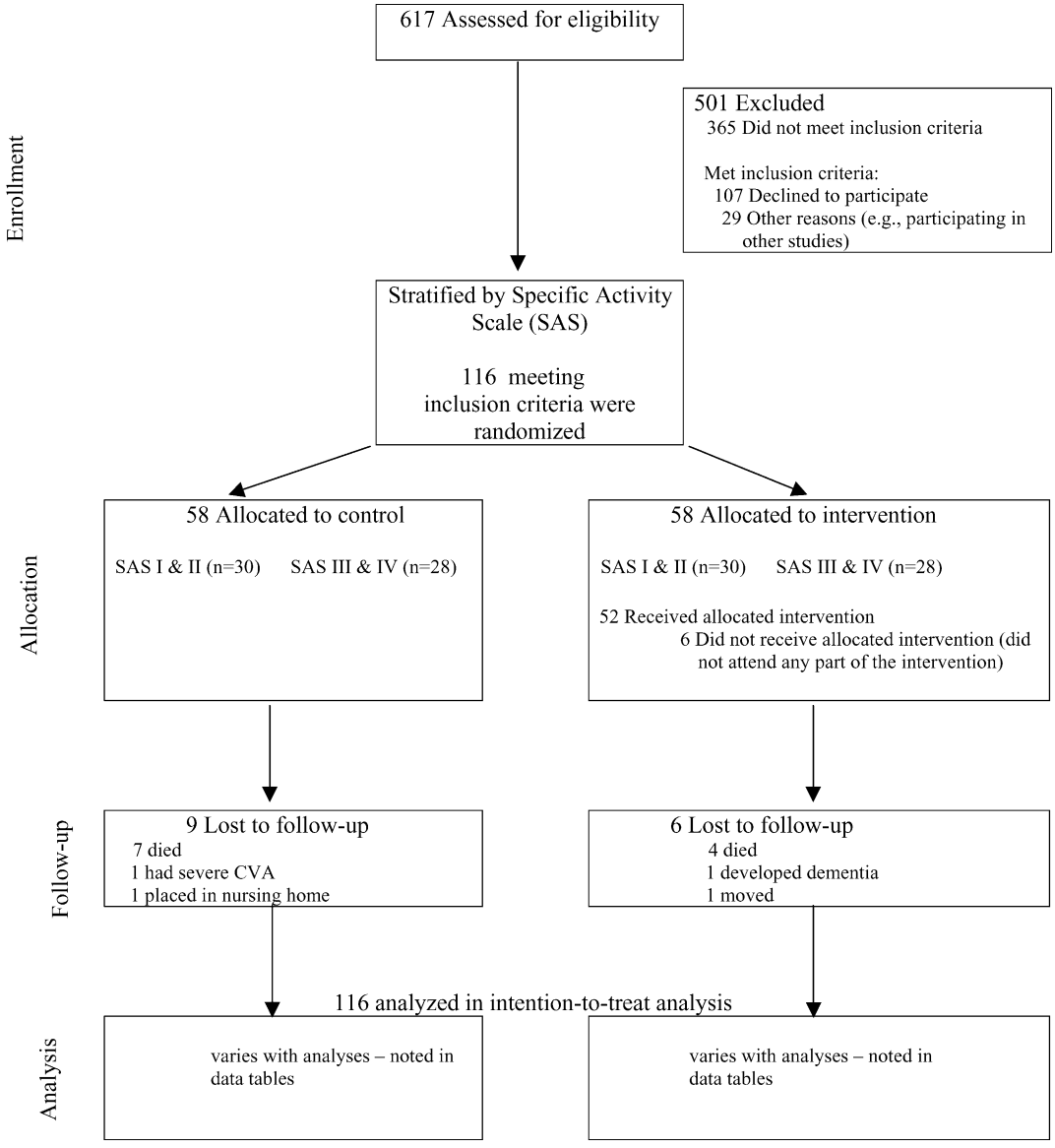

Fig. 1. Clinical trial flow diagram.

psychiatric problems, including substance abuse and homelessness.

The final sample consisted of 116 patients. Enrollment began in September 1998 and was completed in December 2000; the 16-month longitudinal assessments were completed March 2002. The average attendance for the behavioral program (class and phone follow-up) was 70%. The attrition rate was 13%; patients were lost to follow-up in both the control (n = 9) and intervention (n = 6) groups (Fig. 1).

2.3. Protection of human subjects

The appropriate Institutional Review Boards approved the study. All participants gave written informed consent. Participants were given US$ 5 at each data collection time (baseline, 4, 10, and 16 months) and their names were entered in a lottery that paid US$ 50 at the end of the data collection period.

2.4. Protocol

Following consent and randomization, patients were given information regarding their follow-up schedule and assigned treatment group: usual care or behavioral management. Usual care was not manipulated in this study and consisted of clinic visits every 3 months and more frequently as needed. The clinic visit included medication regulation and informal teaching about heart failure and medications. Referrals may have been made to a dietitian for low salt and low fat diet counseling, to a pharmacist for cholesterol lowering agents, to the smoking cessation program, and to home care for those patients needing nursing assessment and teaching in the home. Significant others were encouraged to participate in clinic visits. Patients with heart failure typically are told to engage in regular exercise and advised that it is safe to exercise up to the level of moderate discomfort (e.g., fatigue of the leg muscles or dyspnea). Patients are told not to exceed this level of exercise, and are told to avoid maximal effort. The usual care provided to each patient was not monitored.

The behavioral management program consisted of four classes and three phone calls over a 4-month period. Classes were 2 h in length. The program leaders were two master's prepared nurses who were not involved in randomization or data collection. A standard protocol for the behavioral management intervention was followed and audiotaping of the nurse-led groups was done to monitor the group leaders for standardization of procedures and effective group process. The investigators reviewed the audiotapes to check for significant protocol deviations. The tapes were destroyed after this review. Subjects were aware that the group session was being audiotaped.

The behavioral management program consisted of establishing specific goals with patients related to healthier diet, increased quality and amount of exercise, smoking cessation, alcohol cessation, and increased social and interpersonal activities. The information–behavior–motivation model [6,7] was used to develop the behavioral management program. This model goes beyond education or information giving alone and helps patients set individual goals and develop behavioral skills for change. The focus of the intervention was on goal setting and individualizing health life-style changes for each participant. Cognitive and behavioral skills were taught to help patients manage symptoms and change selected health behaviors. Self-monitoring techniques (e.g., recording daily weight) and positive verbal feedback were also a part of the intervention. The behavioral management program content is shown in Table 1. The program is described in detail in another paper [8].

2.5. Measures

For this study, HRQL was defined as ''the uniquely personal perception of one's own health status'' [9]. HRQL was operationalized by measuring the multiple dimensions of the construct (demographic/clinical variables, symptom status, functioning, general health perceptions) [10]. The major dependent or outcome variables were exercise performance, physical functioning, mental functioning, general health perceptions, and disease specific HRQL. Outcome measures were used to evaluate the differences over time between the usual and behavioral management groups.

Exercise performance was measured with the 6-min walk (distance walked) [11]. Physical functioning was measured with the Medical Outcomes Study Short-Form Health Survey, Veterans adapted version (SF-36V) physical component summary score [12,13]. Mental functioning was measured with the SF-36V mental component summary score [12]. General health perceptions were measured with the SF-36V general health scale score [14]. Disease specific HRQL was measured with the Minnesota Living with Heart Failure (MLHF) Questionnaire, which is designed to examine physical and emotional impairments specific to heart failure [15].

Clinical information included medical diagnoses, cardiac functional class, comorbidities, ejection fraction, and medication profile. Functional class was assessed using the New York Heart Association (NYHA) classification system [16]; functional performance was measured with the Specific Activity Scale (SAS) [17]. Comorbidities were self-reported by patients using the Charlson Weighted Index of Comorbidity adapted by Katz et al. [18]

2.6. Statistical analyses

The study used a two (group: intervention versus control) by four (time: baseline, 4, 10, and 16 months) mixed design with time as the repeated measure. The distributions for all dependent variables/outcome measures were checked for normality and log transformations were used as appropriate for non-normally distributed variables. The primary interest

Table 1
Behavioral management program content outline

Week 1: Class
Introduction to the program, schedule, research (information/motivation)
Discuss heart failure symptoms and their effects on life (information)
Discuss personal behaviors related to heart failure (information/motivation)
Participants given *Learning to Live with Heart Failure*[a] handbook (information)
Participants agree to monitor diet and weight for 1 week (behavior)
Week 2: Class
Discuss *Learning to Live with Heart Failure* handbook (information)
Identify health behaviors that increase quality of life for patients with heart failure (motivation)
Discuss thoughts and feelings related to behavior change (motivation)
Review diet and weight monitors (behavior)
Participants identify and choose one or two behaviors to monitor (behavior)
Week 3: Phone call
Clarify questions, concerns (information/motivation)
Assist participants to increase or decrease activity level per specific increment (information/motivation/behavior)
Provide praise for positive behavior changes made (motivation)
Set new goals, review homework for next 2 weeks (behavior)
Week 5: Phone call
Content same as Week 3 phone call
Week 7: Class
Review previous goals, monitoring and progress towards goals (motivation)
Discuss support systems (information)
Continue to set goals for monitoring, maintenance, and change (behavior)
Week 11: Phone call
Clarify questions, concerns (information/motivation)
Assist participants to increase or decrease activity level per specific increment (information/motivation/behavior)
Discuss support systems (information)
Set goals, review homework for next 4 weeks (behavior)
Week 15: Class
Reinforce behavior changes made throughout program and steps used for behavior change (information/motivation/behavior)
Reinforce strategies for maintaining support systems (motivation)
Identify whom to call for ongoing assistance (information)

[a] Source: *Learning to Live with Heart Failure*, self care handbook (1997). South Deerfield, MA: Channing L. Bete Co., Inc. Phone: 800-628-7733.

in the analyses was with the group by time interactions and, since we expected linear effects, we evaluated the group by time linear contrasts. Initial analyses included all subjects who were randomized to treatment and completed all four data collection time points (intention-to-treat). A second set of analyses used subjects who were randomized to treatment and returned for at least one of the intervention classes (n = 52).

For the full sample (N = 116, n = 58 in each group), for setting alpha at .05 there was more than sufficient statistical power (>.98) to detect medium effects for group by time interactions (f = .25) and sufficient power (>.80) to detect small to medium effects (f = .18). Even for our worst case sample size scenario of missing data for the 6-min Walk (34 intervention and 37 control patients), there was more than sufficient power (>.87) to detect medium effects for group by time interactions (f = .25) and sufficient power (>.80) to detect medium effects (f = .23). Hence, we can say with reasonable confidence of not committing a Type II error that, in the absence of significant ($P > .05$) results, there is no medium size effect present.

Analyses were also run using the missing value analysis module of SPSS v. 10 that uses an iterative expectation and maximization (EM) procedure. The EM module forms a missing data correlation matrix for the partially missing data, finds the conditional expectation of the missing data, then substitutes these expectations for the missing data. The maximization step performs maximum likelihood estimation to generate imputed values [19,20]. The distribution of missingness met the criteria for ''missing at random.''

The frequency of missing data was examined for the outcomes. Missing data were greatest for the 6-min walk. Only 71 patients (61%) completed all four walks, 37 from the control group and 34 from the intervention group. Reasons why patients did not walk at one or more assessments were the following: moved or did not attend appointment, declined, medical status, pain, and dyspnea. The walk distances ranged from 41 to 607 m across all assessments. For patients who started the walk, major reasons for walking less than 6 min were dyspnea and fatigue. Patients who had complete walk data were significantly younger than those patients with missing walk data (66 ± 10.4 versus 70 ± 9.1, t = 2.07, d.f. = 114, and P = .04). There were no other significant differences between those patients with and without missing data.

3. Results

3.1. Patient characteristics

A total of 116 patients enrolled in the study. Participants were primarily male (n = 110, 95%), reflecting the VA population, and Caucasian (n = 87, 75%). The mean age of the entire sample was 67 years (S.D. = 10); ages ranged from 41 to 90 years. The median ejection fraction for both groups was 40%; these data were available in 69 (60%) of the participants from the total sample. Heart failure etiology was available for 88 (76%) of the 116 participants. The most frequently reported etiologies were an ischemic cardiomyopathy and dilated cardiomyopathy. The majority of participants were SAS classes II and III, and New York Heart Association classes I and II. There were no significant differences between the groups at baseline on the demographic or clinical characteristics (Table 2).

Table 2
Demographic and clinical characteristics by group at baseline

Variables	Control (n = 58)	Intervention (n = 58)
Age, mean (S.D.)	69.0 (9.09)	65.8 (10.74)
Gender (male), % (n)	94.8 (55)	94.8 (55)
Income < US$ 25,000, % (n)	68.4 (39)	57.4 (31)
Lives with spouse, % (n)	50.0 (29)	36.2 (21)
Lives alone	32.8 (19)	32.8 (19)
Years education, mean (S.D.)	13.1 (2.49)	13.9 (2.33)
Ethnicity, % (n)		
Caucasian	79.3 (46)	70.1 (41)
African American	3.4 (2)	15.5 (9)
Hispanic	8.6 (5)	6.9 (4)
Asian/Pacific islander	6.9 (4)	3.4 (2)
Mixed	1.7 (1)	3.4 (2)
Not employed, % (n)	81.0 (47)	67.2 (39)
Insurance source		
VA or tricare, % (n)	89.7 (52)	96.6 (56)
Medicare, % (n)	44.8 (26)	37.9 (22)
Specific Activity Scale (SAS), % (n)		
SAS I	5.2 (3)	1.7 (1)
SAS II	46.6 (27)	50.0 (29)
SAS III	48.3 (28)	46.6 (27)
SAS IV	0.0 (0)	1.7 (1)
New York Association (NYHA), % (n)		
NYHA I	37.9 (22)	36.2 (21)
NYHA II	44.8 (26)	50.0 (29)
NYHA III	17.2 (10)	13.8 (8)
NYHA IV	0.0 (0)	0.0 (0)
Etiology, % (n)	n = 43	n = 45
Ischemic cardiomyopathy	30.2 (13)	24.2 (11)
Dilated cardiomyopathy	11.6 (5)	26.7 (12)
Valvular heart disease	4.7 (2)	2.2 (1)
Idiopathic cardiomyopathy	4.7 (2)	4.4 (2)
Hypertensive	9.1 (3)	11.1 (5)
Alcohol intake	2.3 (1)	0.0 (0)
Other	10.3 (6)	10.3 (6)
Ejection fraction, mean (S.D.)	n = 33	n = 36
	40.3 (15.88)	43.2 (16.16)
Comorbidity, % (n)		
Myocardial infarction	46.4 (26)	43.5 (20)
Heart failure[a]	93.1 (54)	87.9 (51)
Peripheral vascular disease	6.9 (4)	10.3 (6)
Cerebrovascular accident	15.5 (9)	5.2 (3)
Hemiplegia	0.0 (0)	1.7 (1)
Chronic pulmonary disease	27.6 (16)	25.9 (15)
Ulcer	12.1 (7)	8.6 (5)
Diabetes	51.7 (30)	53.4 (31)
Renal	19.0 (11)	12.1 (7)
Connective tissue	0.0 (0)	0.0 (0)
Dementia, liver, etc.	3.4 (2)	0.0 (0)
Depression	17.2 (10)	15.5 (9)
Comorbidity category, % (n)[b]		
1	27.6 (16)	37.9 (22)
3	36.2 (21)	41.4 (24)
5	36.2 (21)	20.7 (12)

[a] All patients had a diagnosis of heart failure confirmed by their physician or echocardiogram.
[b] Charlson Comorbidity Index, adapted by Katz et al. (1996).

Table 3
Outcomes by group

Outcomes	Control (n = 58)	Intervention (n = 58)
6-min walk, mean (S.D.)[a]	n = 37	n = 34
Time 1	327.1 (79.31)	330.5 (83.42)
Time 2	323.7 (78.79)	329.8 (88.25)
Time 3	318.4 (79.77)	337.4 (85.76)
Time 4	309.1 (78.14)	331.8 (94.42)
SF-36V, mean (S.D.)[b]	n = 45	n = 47
Physical		
Time 1	40.5 (6.89)	39.2 (7.17)
Time 2	39.0 (6.01)	39.3 (7.17)
Time 3	39.6 (5.94)	38.8 (7.30)
Time 4	38.4 (6.18)	39.1 (7.46)
Mental		
Time 1	41.6 (5.31)	41.4 (3.95)
Time 2	41.2 (6.21)	41.1 (3.65)
Time 3	41.1 (5.16)	41.1 (4.79)
Time 4	41.9 (5.48)	41.0 (3.84)
General		
Time 1	38.3 (28.20)	34.1 (23.80)
Time 2	39.8 (20.05)	39.6 (22.03)
Time 3	43.2 (20.99)	38.8 (23.28)
Time 4	40.3 (20.67)	36.8 (22.18)
MLHF, mean (S.D.)[c]	n = 49	n = 50
Physical		
Time 1	15.0 (10.92)	18.3 (11.72)
Time 2	15.0 (10.22)	16.8 (11.08)
Time 3	15.3 (10.46)	16.9 (11.51)
Time 4	17.0 (10.82)	16.3 (11.67)
Emotional		
Time 1	6.8 (6.43)	8.7 (7.28)
Time 2	6.6 (7.03)	8.2 (6.39)
Time 3	5.7 (6.39)	8.2 (6.75)
Time 4	7.3 (6.73)	8.4 (7.43)
Total		
Time 1	33.2 (22.11)	39.3 (24.79)
Time 2	32.6 (23.47)	37.5 (23.30)
Time 3	31.5 (21.56)	37.0 (25.20)
Time 4	36.1 (24.79)	35.6 (23.51)

[a] 6-min walk: the missing data analyses yielded a significant group by time interaction [$F(3, 342) = 3.13$, $P = .04$] and linear interaction contrast [$F(1, 114) = 6.76$, $P = .01$].
[b] SF-36V, medical outcomes study short-form health survey, Veterans version.
[c] MLHF, Minnesota Living with Heart Failure Questionnaire. MLHF: significantly improved physical dimension scores over time compared to control patients [group by time interaction: log transformed scores, $F(3, 291) = 3.27$, $P = .03$; linear interaction contrast, $F(1, 97) = 7.04$, $P = .009$]. The missing data analyses showed the same results, i.e., a significant group by time interaction with log transformed scores [$F(3, 342) = 3.42$, $P = .02$; linear interaction contrast, $F(1, 114) = 7.05$, $P = .009$].

3.2. Health related quality of life outcomes

Results for the outcomes are presented in Table 3. The outcomes assessed were exercise performance (6-min walk), physical functioning (SF-36V), mental functioning (SF-36V), general health perceptions (SF-36V), and disease specific HRQL (MLHF). There were no group differences

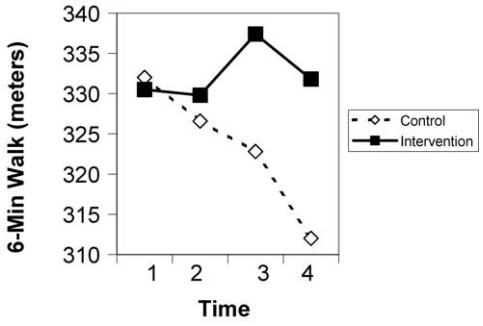

Fig. 2. Six-minute walk distances (raw data; higher numbers indicate greater walk distances) by group and time.

in raw data exercise performance, physical functioning, mental functioning or general health perceptions. However, the missing data analyses using EM yielded a significant group by time interaction [$F(3, 342) = 3.13$, $P = .04$] and linear interaction contrast [$F(1, 114) = 6.76$, $P = .01$] for the 6-min walk. Fig. 2 shows the raw data for the 6-min walk.

Intervention patients showed significantly improved MLHF physical dimension scores over time compared to control patients [group by time interaction: log transformed scores, $F(3, 291) = 3.27$, $P = .03$; linear interaction contrast, $F(1, 97) = 7.04$, $P = .009$]. Fig. 3 shows the raw data. The missing data analyses showed the same results, i.e., a significant group by time interaction with log transformed scores [$F(3, 342) = 3.42$, $P = .02$; linear interaction contrast, $F(1, 114) = 7.05$, $P = .009$]. These differential changes over time on this self-report assessment of physical impairments specifically due to heart failure were parallel to the differential changes over time in exercise performance (6-min walk). For each outcome, the intervention group improved over time while the control group became worse over time. Also for each outcome, the results were the same when excluding the six intervention participants who had not attended any classes.

The MLHF physical dimension scores were compared between patients who completed the 6-min walk and those who did not complete the walk. There were no significant differences in MLHF scores between completers of the walk and non-completers. There were also no significant differences in MLHF scores between the intervention and control group patients based on walk completion.

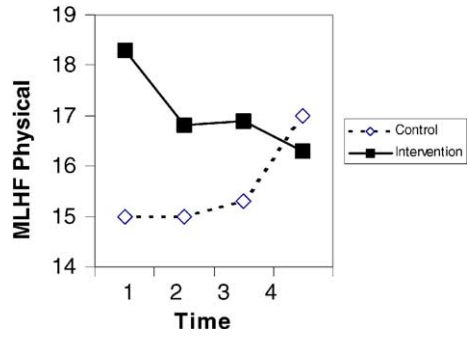

Fig. 3. MLHF physical dimension scores (MLHF—Minnesota Living with Heart Failure Questionnaire raw data; higher scores indicate more impairment) by group and time.

4. Discussion

The important results from this study are in the domain of physical functioning. The physical functioning measures included an objective measurement of exercise performance (the 6-min walk) and a self-report measure of impairment due to heart failure (MLHF physical functioning score). The MLHF self-report measure demonstrated a better outcome in the participants randomized to the behavioral management intervention compared to the control group. The 6-min walk was significantly better only with the missing data analysis. The generic measure of physical functioning, the SF-36V physical component score, did not show any significant changes in physical functioning.

Interestingly, the patterns of change over time for the two groups for the 6-min walk reflect the patterns of change over time for the two groups for MLHF physical functioning. Participants in the intervention group reported less impairment in MLHF physical functioning over time compared to the control group.

These findings of an effect of the behavioral management intervention on physical functioning are consistent with those of Kostis et al. [5] who found improved exercise capacity with their multidimensional intervention. However, our findings in the area of psychosocial functioning differ from those of Kostis et al. [5] and Moser et al. [21] who found a positive impact on mood state. Differences in results related to mood may be due to the differences in interventions and outcome measures between the studies.

The effects of the intervention on exercise performance and MLHF physical functioning may be a function of age. However, given the sample size in this study, direct evaluations of age as a potential moderator were not possible. Age needs to be considered as an independent factor in planning future research and clinical interventions. Other investigators have not reported the impact of age on their intervention and outcomes. It may be that younger patients have differential responses to their illness and to interventions.

Limitations of this study include the small sample size, functional status of the sample, and the intensity of the intervention. However, even with a small sample and some attrition, we found significant results with a conservative intention-to-treat analysis. Regarding the statistical power available in this study, for those instances of a nonsignificant interaction effect, we can state with some assurance of not committing a Type II error that there were no interaction effects at a medium effect magnitude.

The majority of participants were NYHA I or II classes. The relatively mild severity class of patients in this sample may limit the generalizability of these results.

Intervention intensity was considered to be moderate but validity and study comparability of intensity determination is lacking [22]. This study did not use an individual's readiness to change his/her behavior or perceived control for a targeted intervention so the effect may not have been maximized.

Missing data for the 6-min walk is a limitation. However, there was not a differential drop out rate as a function of treatment group assignment. Also, there were no differences in MLHF physical functioning scores based on walk completion status. The statistical procedure used in this study for handling missing data is supported as state of the art for missing data problems [20]. Other recent approaches to missing-data problems include the multiple imputation method [20] and the use of mixed-effects models for which complete data are not required for every subject [23]. Mixed-effects analyses are increasingly used in the research literature and there are new software programs becoming available for running these analyses. However, it should be noted that implementation of these analyses are computationally complex.

Despite the limitations there are several strengths of this study. This was a longitudinal, randomized controlled trial with primary HRQL outcomes. This study is unique in its patient-centered focus on HRQL outcomes. The investigators were able to assess the impact of the intervention using multiple generic and specific HRQL measures. Longitudinal follow-up was 16 months with four time points. Participant retention was excellent and patients were willing to commit to a 4-month group intervention and 16-month follow-up.

The results raise several questions/issues for further study. One area is the intensity and delivery of the intervention. The intervention tested in this study may be only one important part of a comprehensive self-management program for heart failure and more effective when combined with other features. Baseline assessment of a patient's readiness to change health behaviors and targeting the intervention to readiness level may maximize the intervention effect. Adding a measure of ''perceived control'' [24,25] for participants may be useful to detect any mediator/moderator effects on mental and physical functioning. Using multiple objective measures of physical ability should be considered; this addition to a protocol would increase the validity of the physical ability assessment/domain.

Other recommendations for future research would be incorporating a qualitative component to the design to elicit the meaning of ''quality of life'' in persons with heart failure. Quantitative studies should be designed to study the efficacy of this behavioral management intervention with other interventions and to monitor usual care as well as interventions. The effect of age as an independent factor should be examined in future trials. Effectiveness studies are also needed using the intervention reported here. The delivery method for behavioral interventions (e.g., individual, group, use of information technology) should also be considered and tailored to the individual.

5. Conclusions and practice implications

This study demonstrates efficacy of the behavioral management intervention on a self-reported disease specific physical functioning. This study is unique in that it focused on HRQL as a primary patient outcome, used both generic and disease-specific questionnaires for measuring HRQL, tracked HRQL longitudinally, and examined optimal timing of the behavioral management intervention, as well as measurements to evaluate the intervention. The major practice implication suggested by this study is the need to consider behavioral intervention as a component of chronic illness care and disease management for patients with heart failure. Clinicians and health care systems should also track selected HRQL outcomes in heart failure and elicit the patient's perspective on HRQL. Further research should examine the efficacy of the intervention used in this study with other interventions as well as the effectiveness of behavioral interventions in patients with heart failure.

Acknowledgements

We gratefully acknowledge the work of research associates Debbie Dugan, MS, RN, Malinda Fox, MS, RN, Joan Hall, MS, RN, Mary Jane Hoban, MS, RN, Lien Khuat, MS, RN, Vicki McCalmont, MS, RN, Kimberly Newell, MS, RN, Beth Schanke, MS, RN; database management specialist Jo-Anne Toomey, MBA; quality control consultant Ann Bryant, MS, RN; data review board members Kirk Peterson, MD, Barbara Riegel, DNSc, RN; intervention advisors Sheri Pruitt, PhD and Allen Gifford, MD; and general support of the VA Center for Research in Patient Centered Care. We also thank Barbara Riegel for her review of a previous draft.

This study was presented at the Eighth Joint Southern California Chapters Sigma Theta Tau International Nursing Research Conference, October 2002.

The research reported here was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service, Project #NRI-95244-1.

References

[1] Konstam M, Dracup K, Baker D et al., Heart failure, evaluation and care of patients with left-ventricular systolic dysfunction. Clinical Practice Guideline No. 11. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services; 1994.

[2] Grady KL, Dracup K, Kennedy G et al., Team management of patients with heart failure: a statement for healthcare professionals from The Cardiovascular Nursing Council of the American Heart Association. Circulation 2000;102:2443–56.

[3] Hunt SA, Baker DW, Chin MH et al., ACC/AHA guidelines for the evaluation and management of chronic heart failure in the adult: executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

(Committee to revise the 1995 Guidelines for the Evaluation and Management of Heart Failure),. J Am College Cardiol 2001;38: 2101–13.
[4] Moser D, Nelson S. Impact of biofeedback-relaxation training on hemodynamics, neuroendocrine function and rehospitalizations in advanced heart failure (abstract). Am J Crit Care 1999;8:202.
[5] Kostis JB, Rosen RC, Cosgrove NM, Shindler DM, Wilson AC. Nonpharmacologic therapy improves functional and emotional status in congestive heart failure. Chest 1994;106:996–1001.
[6] Fisher JD, Fisher WA. Changing AIDS-risk behavior. Psychol Bull 1992;111:455–74.
[7] Fisher JD, Fisher WA, Misovich SJ, Kimble DL, Malloy TE. Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population. Health Psychol 1996;15:114–23.
[8] Kodiath M, Kelly A, Shively M. Improving quality of life in heart failure patients: an innovative behavioral intervention, J Cardiovasc Nurse, in press.
[9] Gill TM, Feinstein AR. A critical appraisal of the quality of quality-of-life measurements. JAMA 1994;272:619–26.
[10] Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. JAMA 1995;273:59–65.
[11] Guyatt G. Use of the six-minute walk test as an outcome measure in clinical trials in chronic heart failure. Heart Failure 1987;3:211–7.
[12] Ware Jr JE, Kosinski M, Bayliss MS, McHorney CA, Rogers WH, Raczek A. Comparison of methods for the scoring and statistical analysis of SF-36 health profile and summary measures: summary of results from the Medical Outcomes Study. Med Care 1995;33:AS264–79.
[13] Kazis LE, Ren XS, Lee A et al., Health status in VA patients: results from the Veterans Health Study. Am J Med Qual 1999;14:28–38.
[14] Ware JE. SF-36 health survey manual and interpretation guide. Boston: The Health Institute, New England Medical Center; 1993.
[15] Rector TS, Kubo SH, Cohn JN. Validity of the Minnesota Living with Heart Failure Questionnaire as a measure of therapeutic response to Enalapril or placebo. Am J Cardiol 1993;71:1106–7.
[16] American Heart Association. Revisions to classification of functional capacity and objective assessment of patients with diseases of the heart: scientific statement; 1994.
[17] Goldman L, Hashimoto B, Cook EF, Loscalzo A. Comparative reproducibility and validity of systems for assessing cardiovascular functional class: advantages of a new specific activity scale. Circulation 1981;64:1227–34.
[18] Katz JN, Chang LC, Sangha O, Fossel AH, Bates DW. Can comorbidity be measured by questionnaire rather than medical record review? Med Care 1996;34:73–84.
[19] Tabachnick B, Fidell LS. Using multivariate statistics. Boston: Allyn and Bacon; 2001.
[20] Schafer JL, Graham JW. Missing data: Our view of the state of the art. Psychol Methods 2002;7:147–77.
[21] Moser DK, Kim KA, Baisden-O'Brien J. Impact of a nonpharmacologic cognitive intervention on clinical and psychosocial outcomes in patients with advanced heart failure (abstract). Circulation 1999; 100: I–99.
[22] Riegel B, Moser DK, Glaser D et al., The Minnesota Living with Heart Failure Questionnaire: sensitivity to differences and responsiveness to intervention intensity in a clinical population. Nurs Res 2002;51: 209–228.
[23] Gueorguieva R, Krystal JH. Move over ANOVA progress in analyzing repeated-measures data and its reflection in papers published in the archives of general psychiatry. Arch Gen Psych 2004;61:310–7.
[24] Moser DK, Dracup K. Psychosocial recovery from a cardiac event: the influence of perceived control. Heart Lung 1995;24:273–80.
[25] Dracup K, Westlake C, Erickson VS, Moser DK, Caldwell ML, Hamilton MA. Perceived control reduces emotional stress in patients with heart failure. J Heart Lung Transplant 2003;22:90–3.