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Clinical Trials

Effects of the HEART Camp Trial on Adherence to Exercise in Patients With Heart Failure

BUNNY J. POZEHL, PhD, APRN-NP, FHFSA, FAHA, FAAN,[1] RITA MCGUIRE,, PhD, RN,[2] KATHLEEN DUNCAN, PhD, RN,[2] KEVIN KUPZYK, PhD,[1] JOSEPH NORMAN, PhD, PT,[1] NANCY T. ARTINIAN, PhD, RN, FAHA, FAAN,[3] PALLAV DEKA, PhD, AGACNP-BC,[4] STEVEN K. KRUEGER, MD,[5] MATTHEW A. SAVAL, MS, ACSM-RCEP,[6] AND STEVEN J. KETEYIAN, PhD[6]

Omaha, and Lincoln, Nebraska; East Lansing, Michigan; Sioux Falls, South Dakota; and Detroit, Michigan.

ABSTRACT

Background: Few exercise training studies in patients with heart failure (HF) report adherence to guideline-recommended 150 minutes of moderate-intensity exercise per week, and no studies have focused on a primary outcome of adherence.

Methods and Results: This randomized controlled trial evaluated the effect of a multicomponent intervention, Heart Failure Exercise and Resistance Training (HEART) Camp, on adherence to exercise (after 6, 12, and 18 months) compared with an enhanced usual care (EUC) group. Patients (n = 204) were 55.4% male, overall average age was 60.4 years, and 47.5% were nonwhite. The HEART Camp group had significantly greater adherence at 12 (42%) and 18 (35%) months compared with the EUC group (28% and 19%, respectively). No significant difference ($P > .05$) was found at 6 months. The treatment effect did not differ based on patient's age, race, gender, marital status, type of HF (preserved or reduced ejection fraction) or New York Heart Association functional class. Left ventricular ejection fraction (LVEF) significantly moderated the treatment effect, with greater adherence at higher LVEF.

Conclusions: The multicomponent HEART Camp intervention showed efficacy with significant effects at 12 months and 18 months. Adherence levels remained modest, indicating a need for additional research to address methods and strategies to promote adherence to exercise in patients with HF. (*J Cardiac Fail 2018;00:1−7*)

Key Words: Exercise, heart failure, adherence, exercise training.

Adherence to the Heart Failure Society of America (HFSA) 2010 guidelines that recommend 30 minutes of supervised moderate-intensity exercise 5 days per week[1] is difficult for the 6.5 million individuals with heart failure (HF).[2−4] Studies indicate that 40%−91% of patients with HF do not engage in any regular exercise. Patients report fear of exercising[5,6] and lack of opportunity or skills for exercise[7] as reasons for not exercising. Programs designed to teach patients with HF how to exercise and to maintain the behavior of exercise are needed. In 2014 the Centers for Medicare and Medicaid approved reimbursement for cardiac rehabilitation (CR) in beneficiaries with HF with reduced ejection fraction; however, in spite of this favorable step to provide access, very few (2.6%) actually participate in CR.[8] Among those patients that do participate, many do not continue to exercise once the formal program is completed.[9,10]

Studies that focus on adherence to exercise are limited, and as a result we know very little about effective strategies that improve adherence in patients living with chronic HF. Studies that specifically focused on

From the [1]University of Nebraska Medical Center, Omaha, Nebraska; [2]University of Nebraska Medical Center, Lincoln, Nebraska; [3]Michigan State University, East Lansing, Michigan; [4]University of South Dakota, Sioux Falls, South Dakota; [5]Bryan Heart Institute, Lincoln, Nebraska and [6]Henry Ford Hospital, Detroit, Michigan..

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Reprint requests: Bunny J. Pozehl, PhD, APRN-NP, FHFSA, FAHA, FAAN, University of Nebraska Medical Center—College of Nursing 985330 Nebraska Medicine, Omaha, NE 68198-5330. Tel: 402-559-3182; Fax: 402-559-9666. E-mail: bpozehl@unmc.edu

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adherence to exercise considered only short-term (≤6 mo) adherence outcomes.[11−13] The multicenter HF-ACTION trial (Heart Failure—A Controlled Trial Investigating Outcomes of Exercise Training) reported adherence to exercise beyond 12 months, and the results showed adherence levels as low as 34% after 24 months.[14] Adherence to exercise recommendations are not being met and there is need for a paradigm shift to focus on long-term adherence to exercise in the chronically ill population with HF. Therefore, the purpose of the present study was to evaluate the effect of a federally funded (R01-HL112949) multicomponent intervention, Heart Failure Exercise and Resistance Training (HEART) Camp (HC), on adherence to exercise and to explore selected demographic variables (race, gender, age, body mass index, and ejection fraction) as potential moderators of the effect of the HC intervention on adherence. Specific aims of the study were: 1) to evaluate the effect of HC on adherence to exercise; and 2) to explore the effect of the demographic and clinical variables as potential moderators of the HC intervention on adherence. We hypothesized that subjects in the HC intervention group would have significantly greater adherence to exercise than the enhanced usual care (EUC) group at each time point (6, 12, and 18 months), with a maximum difference expected at 18 months.

Methods

Design

A prospective randomized 2-group repeated-measures experimental design with 4 data collection points (baseline and 6, 12, and 18 months) was used. Subjects were randomized to the 2 groups and stratified by site and gender. The 2010 HFSA guidelines recommend moderate-intensity exercise training in a supervised setting; therefore, both groups (EUC and HC) received 9 supervised exercise training sessions during a 3-week run-in period and were instructed to then continue to exercise in the setting of a health care exercise facility. Only subjects who completed ≥6 of the 9 supervised exercise sessions were randomized. The 9 exercise training sessions before randomization included moderate-intensity aerobic (40%−80% heart rate reserve [HRR])[15,16] and resistance (10−15 repetitions to volitional fatigue)[17,18] training. The decision to only randomize individuals who attended ≥6 of the 9 sessions was made to ensure safety of individuals to exercise, because participants in the EUC group would not have close supervision by the exercise coach during the 18 months of exercise. We recognize that this limits generalizability, but we think it is an important first step in investigating adherence to exercise in individuals who have an initial desire to exercise and an informed understanding of exercise expectations. A cardiopulmonary exercise test was also completed on all subjects at the beginning of the study. The study protocol specifically provided the supervision needed to assure safety of all subjects.[15,16,19,20] Access to the exercise training facility was provided for both groups (EUC and HC).

Setting and Sample

Permission to conduct the study was obtained from the Institutional Review Boards at the University of Nebraska Medical Center, Wayne State University, and Henry Ford Health System. Subjects were recruited from 2 urban medical centers: Bryan Heart Institute in Lincoln, Nebraska, and Henry Ford Hospital in Detroit, Michigan. Inclusion criteria for patients were: (a) diagnosis of HF (stage C chronic HF confirmed by means of echocardiography and clinical evaluation) with preserved or reduced ejection fraction; (b) 19 years of age or older; (c) able to speak and read English; (d) telephone access in home; and (e) stable pharmacologic therapy per guidelines for past 30 days. Exclusion criteria were: (a) clinical evidence of decompensated HF; (b) unstable angina pectoris; (c) myocardial infarction, coronary artery bypass surgery, or biventricular pacemaker within the past 6 weeks; (d) orthopedic or neuromuscular disorders preventing participation in aerobic exercise and strength/resistance training; (e) participation in 3-times-per-week aerobic exercise in the past 8 weeks; (f) cardiopulmonary exercise test results that precluded safe exercise training; (g) plans to move >50 miles from the exercise site within the next year; (h) peak oxygen uptake (pVO_2) in women >21 $mL{\cdot}kg^{-1}{\cdot}min^{-1}$ and in men >24 $mL{\cdot}kg^{-1}{\cdot}min^{-1}$; and (i) planned or current pregnancy. All participants gave written informed consents. The numbers of subjects screened and randomized to each study arm are presented in the CONSORT diagram (Fig. 1).

HC Intervention

The HC intervention was based on social-cognitive theory and used group-based (ie, educational sessions) and individual-based (coach trainer) strategies to deliver the intervention. Five components—knowledge, attitudes, self-efficacy, self-management skills, and social support—were emphasized throughout the 3 intervention phases: adoption (baseline to 6 months), transition (months 7−12), and maintenance (months 13−18). In the adoption phase, 6 group-based educational sessions (attitudes toward exercise, pathophysiology of HF and benefits of exercise, HF symptoms and exercise, medications and exercise, sodium/fluid intake, and relationship to exercise and exercising safely) were provided. The coach trainer met with individuals on a weekly basis during the adoption and transition phases. This meeting included review of the exercise diary, discussion of exercise prescriptions, goal setting, monitoring, relapse prevention, and self-management strategies for exercise. Coaches contacted participants if they did not attend this weekly meeting. During the maintenance phase (13−18 months) participants submitted weekly exercise diaries; if a diary was not submitted, the exercise coach followed up with a telephone call to the participant. The intervention protocol has been described in detail previously.[21]

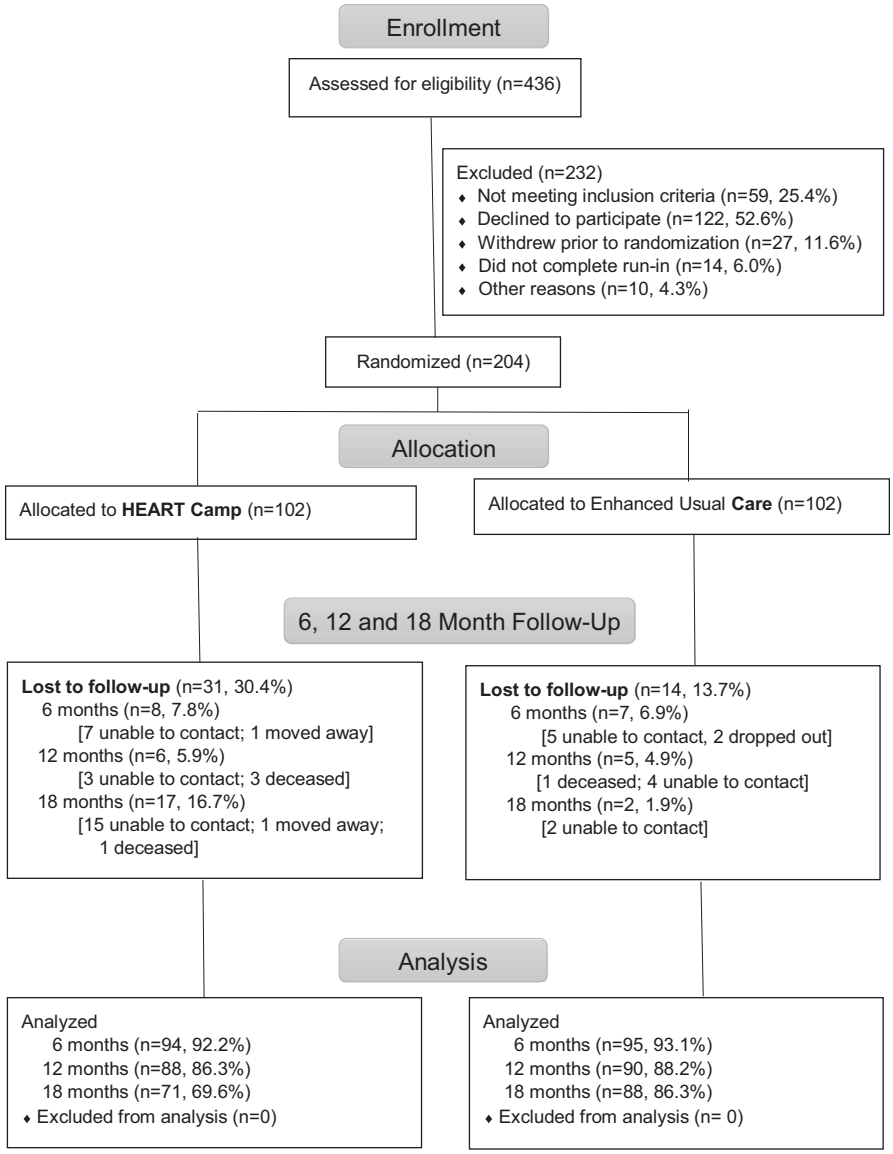

Fig. 1. CONSORT diagram.

Measures

Demographic data (age, race, gender, and marital status) were obtained at baseline. Clinical information (body mass index, left ventricular ejection fraction [LVEF], type of HF [preserved or reduced ejection fraction], and New York Heart Association [NYHA] functional classification) was obtained from the subject's record.

Adherence is defined as the extent to which a person's behavior corresponds to the recommendations of a health care provider.[22] Adherence behavior has been defined as meeting 80% of the recommended behavior,[23,24] and this definition has been used in exercise trials to date.[20,25] Consistently with the literature, this study defined adherence as achieving ≥80% of the recommended 150 minutes (ie, >120 minutes) of moderate-intensity aerobic activity per week. Participants were directed to complete their exercise diaries on a daily basis, which included information on date, duration of exercise (minutes), and average HR (intensity). Only minutes of exercise in the moderate-intensity range (40%−80% HRR) were counted in measurement of adherence. Weekly adherence data were obtained from participants self-reported exercise diaries and verified with the use of data obtained from a heart rate (HR) monitor. The 6-, 12-, and 18-month adherence levels were computed as the averages across the 4 weeks before each measurement time point.

An HR monitor (Polar RS400; Polar Electro, Lake Success, New York) was used to guide intensity of exercise and to validate self-reported diary data. Subjects were instructed to wear the Polar RS 400 to record each exercise session. The Polar RS400 provided adequate storage of data and could be programmed with target HR ranges (THRRs) with the use of the Polar Pro Trainer software. The THRR for each subject was determined by the core laboratory from the cardiopulmonary exercise (CPX) tests done at baseline using 40%−80% HRR

for each participant. Each participant was provided with the THRR and asked to regulate the intensity of their exercise to keep their HR within this range. Data from the monitor was downloaded via the Polar Pro Trainer software to obtain a breakdown on date, time spent in exercise, average HR, and amount of exercise time within the THRR. Exercise coaches collected diaries and downloaded the stored HR monitor data from HC intervention participants during weekly coaching sessions. Research personnel collected these data for the EUC subjects by appointment every 2 months. Exercise duration data from the self-reported exercise diaries were validated and considered in the calculation of exercise adherence minutes if it was within 10% of the objective data from the Polar RS400 on exercise time spent above the minimum THRR (≥40% HRR). Exercise time spent below the THRR (<40% HRR) was not considered in calculation of adherence minutes.

Statistical Analysis

A power analysis was completed with the use of levels of adherence from HF-ACTION[14] and our own pilot study data. An adherence level of 25% was the level of crossover in HF-ACTION for the control group, and reported adherence in the exercise group was 38% at 12 months and 0.36 at 18 months. Our pilot study data achieved adherence of 86% at 3 months in the intervention group, so we expected to achieve adherence of ≥50% at 18 months. A 1-tailed z test of the difference in proportions of 50% would have power of 0.90 ($\alpha = 0.05$) with a total sample size of 126 subjects. We recruited 246 patients (123 subjects from each study site) to allow for the following attrition rates: 10% not meeting medical criteria for safe participation in the study, 30% failing to attend ≥6 of the 9 planned sessions during the run-in period, and an additional 15% attrition over the 18 months of the study), resulting in the final desired sample size of 63 per group (total n = 126).

Descriptive statistics were calculated on adherence and all study variables. To assess adherence between groups at 18 months (primary aim), a chi-square test was used to test group differences in the proportion of the sample that adhered to ≥80% of the 150 minutes per week recommendation. Significance level was set at $P < .05$. Tests were carried out at 6, 12, and 18 months, the primary data collection points in the study. The analysis included all participants according to the condition to which they were assigned and was based on all available data. To assess the possible effect of attrition on outcomes, sensitivity analyses were performed. Attrition or "lost to follow-up" (n = 45) is depicted on the consort diagram (Fig. 1) and included unable to contact (n = 36), died (n = 5), moved (n = 2), and dropped out (n = 2). Chi-square tests at 6 and 12 months were analyzed both with and without participants who were lost to follow-up at 12 months. Furthermore, a sensitivity analysis with generalized estimating equation (GEE) analysis was performed with both complete cases and all available data to test whether attrition had an impact on the group differences in adherence over the course of the study.

To explore effects of selected demographic variables on adherence, potential moderators of the effect of the intervention on adherence were tested. Logistic regression models were performed with adherence at 18 months as the dependent variable. The moderators tested were gender, age, race (white vs nonwhite), body mass index, and LVEF. For continuous moderators, the raw scores were used in the analysis, and median splits were performed to create interaction plots only if significant interactions were found. Significant moderator−-group interactions indicate that the

Table 1. Descriptives of Sample: Demographic and Clinical Variables.

Descriptor	Intervention	Enhanced Usual Care	*P* Value
N	102	102	
Demographic variables			
Age, y	59.8 ± 12.6	60.9 ± 10.3	.482
Female	45 (44.1%)	46 (45.1%)	.888
Married	52 (51.0%)	61 (59.8%)	.205
Nonwhite	51 (50.0%)	44 (43.1%)	.326
Clinical variables			
HFrEF	85 (83.3%)	80 (78.4%)	.373
HFpEF	17 (16.7%)	22 (21.6%)	
(i) NYHA functional class			
I	5 (4.9%)	11 (10.8%)	.248
II	54 (52.9%)	59 (57.8%)	
III	42 (41.2%)	31 (30.4%)	
IV	1 (1.0%)	1 (1.0%)	
Beta-blocker medication	99 (97.1)	100 (98.0)	.651
ACEI/ARB medication	92 (90.2%)	83 (81.4%)	.071
LVEF, %	39.3 ± 12.1	40.5 ± 14.0	.504
BMI, kg/m^2	35.0 ± 8.6	34.7 ± 7.8	.828

Values are presented as mean ± SD or n (%). HFrEF, heart failure with reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; NYHA, New York Heart Association; ACEI, angiotensin-converting enzyme inhibitor; ARB, Angiotensin receptor blocker; LVEF, left ventricular ejection fraction; BMI, body mass index.

intervention effect varies as a function of participants' levels of the moderating variables.

Results

Descriptive statistics for the primary outcomes of the study are presented in Table 1. Of the 204 patients included in the analysis, there were 113 men (55.4%) and 91 women (44.6%), with an overall average age of 60.4 years (SD 11.5). There were 165 subjects (80.9%) with HF with reduced ejection fraction and 39 with HF with preserved ejection fraction. Ninety-one of the 95 (19.1%) non-white subjects were African-American. The majority of subjects were NYHA functional class II or III (n = 186; 91.2%). Pharmacologic management included 97.5% (n = 199) on beta-blocker medications and 85.7% (n = 175) on angiotensin-converting enzyme inhibitor or angiotensin receptor blockers. No significant differences were found between groups for any of the demographic or clinical variables.

The HC group had significantly greater adherence at both 12 (42%) and 18 (35%) months compared with the EUC group (28% and 19%, respectively). No significant difference was found at 6 months (Fig. 2).

The total attrition at the end of the 18-month study was 45 participants (22.1%), with 159 participants completing data collection at 18 months. Fifteen participants (7.4%) were lost by 6 months, an additional 11 (5.4%) were lost by 12 months, and 19 (9.3%) more were lost by 18 months. Additional analyses were performed to examine attrition rates by group. Comparing the proportion of the sample present at 12 months (subjects had completed the 6-month data collection), no difference was found; 10.8% of the EUC group was not present at 12 months, compared with 13.7% of the intervention group ($P = .539$). At 18 months, however, there was a significant difference in dropout status between the groups ($P = .002$). More participants in the intervention group had either dropped out or did not provide adherence data (30.4%) compared with the EUC group (13.7%).

Owing to the difference in dropout rate between 12 and 18 months, a sensitivity analysis was performed to determine if excluding those subjects who dropped out of the study between 12 and 18 months affected the analysis. We excluded subjects from the 6- and 12-month analyses who were not present at 18 months and found no change in the effects at 6 and 12 months (Fig. 2). There was no difference in adherence rates between groups at 6 months ($P = .242$), and the intervention group had a significantly higher adherence rate than the EUC group ($P = .017$) at 12 months.

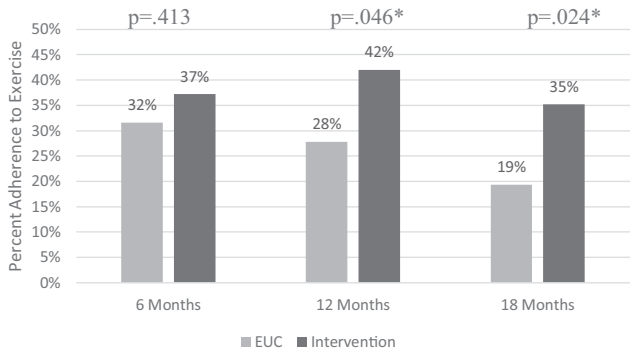

Fig. 2. Adherence to exercise by group over time (all available data). EUC, enhanced usual care.

To assess the effect of participant dropout on group differences in adherence, GEE models were performed as well, once with all available data and again with completers only (ie, sensitivity analysis; Table 2). The group effect was estimated at the last time point (18 months), because GEEs use the last time as the referent category. The group effect in both models showed significant differences in adherence at 18 months, indicating that attrition did not bias the group differences observed in adherence to exercise.

Demographic and clinical variables were tested for moderation effects of the intervention on adherence. Moderator variables are variables that affect the relationship between the independent (group) and dependent (adherence) variables. Results of the group−moderator interactions from logistic regression models testing moderators of group effects on adherence are presented in Table 3 (1 model was performed for each moderator). The treatment effect did not differ, or was equally effective, based on a patient's age, site, race, gender, marital status, or NYHA functional class. LVEF significantly moderated the treatment effect. The effect on adherence was greater at higher levels of LVEF. There was less of an effect for those with low LVEF (Fig. 3).

Discussion

Using the multicomponent HEART Camp intervention, this was the first randomized controlled trial to examine adherence in a diverse sample of patients with HF and showed efficacy with significant effects at 12 months (42% adherent compared with 28% in EUC) and at 18 months (35% adherent compared with 19%). There was no difference in adherence between the HC (37% adherent) and EUC (32% adherent) groups at 6 months. This finding at 6 months suggests that giving patients access to a facility and providing 9 sessions of supervised exercise training can be equally effective in promoting short-term adherence to exercise.

Table 2. Sensitivity Analysis (Generalized Estimating Equations)

Sample	Term	$\chi 2$	*(ii) df*	*(iii) P* Value
Completers (n = 159)	Intercept	22.83	1	(iv) <.001
	Group	4.84	1	.028
	Time	8.60	2	.014
	Group × time	1.67	2	.434
All available (c = 204)	Intercept	34.66	1	*(v)* <.001
	Group	3.85	1	.049
	Time	7.93	2	.019
	Group × time	2.00	2	.367

Last time point is the referent category, so group effect is estimated at 18 months.

Table 3. Moderators of the Intervention Effect on Adherence

(vi) Moderator	B	SE	(vii) *P* Value	OR	95% CI
Treatment by age	0.007	0.033	.835	1.007	(viii) 0.943−1.075
Treatment by nonwhite	(ix) −1.122	0.745	.132	0.326	(x) 0.076−1.403
Treatment by female	(xi) −1.383	0.856	.106	0.251	(xii) 0.047−1.343
Treatment by married	0.780	0.767	.309	2.182	(xiii) 0.485−9.811
Treatment by BMI	0.100	0.054	.066†	1.105	(xiv) 0.994−1.230
Treatment by LVEF	0.079	0.032	.013*	1.082	(xv) 1.017−1.152
Treatment by NYHA functional class	0.609	0.955	.524	1.838	(xvi) 0.283−11.960

OR, odds ratio; CI, confidence interval; other abbreviations as in Table 1.
*Significant at $P < .05$; †marginal effect.

The highest percentage of subsequent adherence was 42% at 12 months, which is modest but must be considered as successful behavior change in these patients with chronic HF. This level of adherence compares favorably with the HF-ACTION trial, in which ~30% or more of the patients in the exercise training group trained at or above the target of 120 minutes of exercise per week at each of the time points.[14]

Comparison of adherence across studies is complicated by lack of consistent measurement.[26] Studies that have reported long-term exercise adherence often report only adherence to number of sessions per week and not minutes of moderate-intensity or above exercise. In the Exercise Rehabilitation Trial (EXERT) with HF patients, 43% of patients attended >80% of scheduled program sessions at 3 months, with a noted decline over the 12 months of the study.[27] Belardinelli et al reported 88% adherence to 2 exercise sessions per week over a 10-year period.[28] Poor adherence continues to be the "Achilles heel" of exercise programs.[23]

Testing for moderation effects demonstrated that the treatment effect did not differ based on a patient's age, race, gender, marital status, or NYHA functional class. This provides assurance that the HEART Camp intervention was equally effective for these different subgroups. The significant moderating effect of LVEF attenuated the effect of the intervention for those with low LVEF compared with those with higher LVEF. Although there was nothing in the methods or strategies of the intervention that would explain the moderating effect of LVEF, it is not surprising that subjects with higher LVEF might respond better in terms of adherence. Exercising may not be as difficult for subjects with higher LVEF, which could explain the intervention's effect on adherence for these subjects.

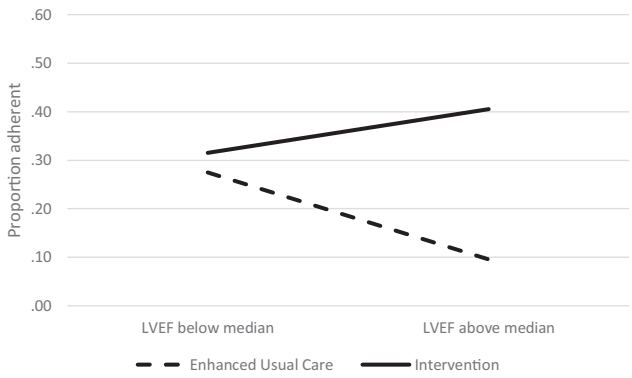

Fig. 3. Moderator analysis of left ventricular ejection fraction (LVEF). Note: A median split was performed to create an interaction plot for the significant interaction.

Findings from this study should not be generalized beyond this sample because this trial involved only two sites in the United States. Although participants were from only 2 sites, the sample was sufficiently diverse regarding race and gender. The lack of moderation effects for race and gender demonstrated that this intervention worked equally well regardless of race or gender. This finding was of particular importance given our baseline findings of fewer minutes of moderate and vigorous physical activity (MVPA) per day for women and nonwhite participants.[29]

Although this trial demonstrated the efficacy of a multicomponent intervention on adherence, there remains a need for additional research addressing methods and strategies to promote adherence to recommendations for exercise in patients with HF. Cost-effective and innovative programs are needed to assist patients with HF to gain the knowledge, skills, and motivation needed for long-term adherence to exercise.

Disclosures

None.

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