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A Combined Aerobic and Resistance Exercise Program Improves Physical Functional Performance in Patients With Heart Failure:

A Pilot Study

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Abstract

Background—Recent guidelines for exercise in patients with heart failure (HF) recommended aerobic and resistance exercise as being safe and effective; however, the clinical and functional significance of these combined training modalities has not been established. In this pilot study, combined aerobic and resistance training was hypothesized to improve physical function, muscle strength, and health-related quality of life (HRQOL) compared with an attention control wait list (ACWL).

Methods—The 10-item Continuous Scale Physical Functional Performance Test (CS-PFP10), which simulates common household chores; muscle strength (handgrip and knee extension); and HRQOL (Kansas City Cardiomyopathy Questionnaire) were evaluated at baseline (T1) and at 12 weeks (T2). The home-based moderate-intensity walking and resistance training program was performed 5 days a week.

Results—Twenty-four New York Heart Association class II to III HF patients (mean [SD] age, 60 [10] years; mean [SD] left ventricular ejection fraction, 25% [9%]) were randomized to a

combined aerobic and resistance exercise program or to an ACWL group. Of the total group, 58% were New York Heart Association class III HF patients, 50% were white, and 50% were female. The CS-PFP10 total scores were significantly increased in the exercise group, from 45 (18) to 56 (16). The Kansas City Cardiomyopathy Questionnaire overall summary score was significantly improved ($P < .001$) at T2 in the exercise intervention group compared with the ACWL group.

Conclusions—Participants provided the home-based, combined aerobic and resistance exercise program had significantly improved physical function, muscle strength, symptom severity, and HRQOL compared with the ACWL group. The findings of this study must be interpreted cautiously owing to the limitations of a small sample, data collection from a single center, and differences between control and interventions groups at baseline. A combined aerobic and resistance exercise approach may improve physical function in stable HF patients, but further study in a larger, more diverse population is recommended. However, in this study, the CS-PFP10 instrument demonstrated its ability to identify functional health status in HF patients and thus warrants further testing in a larger sample for possible use in clinical practice.

Keywords

daily activities; exercise; health-related quality of life; heart failure; physical performance

Background

Heart failure (HF) is a leading cause of cardiac-related disability and is the only cardiovascular disorder that is increasing primarily because of an aging society, earlier diagnosis, and advances in the treatment of coronary artery disease (CAD).^{1–5} However, diminished aerobic capacity and skeletal muscle myopathy often contribute to the progressive exertional intolerance, loss of muscle strength, physical function decline, and poor health-related quality of life (HRQOL) experienced by many HF patients.^{6–8} Numerous studies,^{9,10} including the largest and recently completed Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF ACTION),¹¹ supported the safety and improved cardiovascular outcomes associated with aerobic exercise in stable systolic HF patients. Some studies, however, suggested that aerobic training alone may not optimally address the loss of muscle strength, functional decline, and progressive disability that occur in HF patients.^{12–17} The most recent guidelines for exercise in patients with HF recommended dynamic resistance exercises as being safe and effective and, in conjunction with aerobic exercise,^{18–22} may be the most beneficial strategy for optimizing physical function, thus reducing the deleterious peripheral maladaptations, such as endothelial dysfunction and increased inflammatory cytokine release, and enhancing HRQOL in patients with HF.²³

Findings from several studies revealed that progressive exertional intolerance associated with performing physical activities of daily living (PADLs) is a major reason that patients with HF have a lower HRQOL and experience considerable psychological distress,^{24–29} which substantially increase their risk for institutionalization, further escalating the economic burden of HF.^{30–32} An important component of HF management is the prevention not only of the progression of HF (secondary prevention) but also of secondary conditions and disabilities (tertiary prevention), such as decline in physical function and decrease in

overall quality of life. Surprisingly, despite the well-established loss of physical function, few studies have examined tertiary prevention strategies in patients with HF. Among those who studied this issue, very few have used performance-based measures that directly assessed PADLs but have rather relied upon self-report questionnaires or single-task performance measures such as the 6-minute walk test (6MWT) that indirectly assess PADLs from only 1 perspective, that is, endurance.^{33,34} In addition, self-report questionnaires may be influenced by depression and other emotions, are less sensitive to change, and often miss subtle clinically important changes that performance-based assessment can detect.^{35,36} However, very few instruments simulate and quantify tasks performed in daily life. One such measure, the Continuous Scale Physical Functional Performance Test (CS-PFP),^{37–39} was originally developed to assess physical function among ambulatory older adults with a wide range of physical abilities but has had very limited use in patients with HF. The purpose of this study, therefore, was to determine if a 12-week home-based aerobic and resistance exercise program would improve objective physical functional performance, muscle strength, and HRQOL in stable New York Heart Association (NYHA) class II and III patients compared with an attention control wait list (ACWL) group. The investigators in this study hypothesized that patients in the exercise intervention group would have greater objective improvement in physical function, muscle strength, and HRQOL compared with the ACWL group, who only received instructions and home visits on HF education and how to perform stretching movements. At the conclusion of the 12-week study period, the control participants received the same exercise equipment and instructions as the exercise group.

Methods

Design

A randomized controlled repeated-measures design was used to enroll and follow participants from baseline (T1) to 12 weeks (T2). This design is particularly beneficial for establishing causality by minimizing extraneous factors that may influence, bias, or confound study outcomes by using techniques such as randomization, a control condition, protocols to ensure intervention fidelity, and adjusting for baseline covariates such as gender and NYHA class. Controlling for these potentially competing explanations for the proposed hypothesis better ensures that the exercise regimen is what made the difference in the study outcomes among the intervention participants.⁴⁰

Participants and Setting

The target population for the study consisted of 30 patients diagnosed with stable NYHA II and III systolic HF who were 40 years or older and lived within 100 miles of Emory Healthcare, a large academic health sciences center located in Atlanta, Georgia. Twenty-four patients (12 men and 12 women; mean [SD] age, 60 [10] years) completed the trial and were included in the analyses. Half of the sample were white (n = 11, 50%) and well educated (n = 12, 46% had some college), the majority were categorized as NYHA class III (58%, n = 14), the mean (SD) left ventricular ejection fraction percentage was 25 (9), the majority (n = 19, 79%) had an implanted cardiac defibrillator, and most were obese (mean [SD] body mass index, 34 [7] kg/m²). The mean (SD) comorbidity score was 2.5 (1), with diabetes being the most common medical noncardiovascular disorder. Hyperlipemia (n = 22, 92%)

and hypertension ($n = 12$, 50%) were the most common cardiovascular comorbidities. More than 54% of the participants in the current study also reported having a history of depression and 35% ($n = 9$) were currently taking an antidepressant. The majority ($n = 18$, 75%) had been diagnosed with HF for greater than 2 years and had an ischemic HF etiology ($n = 16$, 62%). After Emory university-affiliated human subjects approval was obtained, participants were screened at 2 outpatient clinics at Emory Healthcare using a large HF database of approximately 3500 patients. Eligibility criteria included (a) a left ventricular ejection fraction of 15% or higher, (b) a diagnosis of systolic HF for a minimum of 6 months, and (c) clearance to enroll in the study given by an attending cardiologist in one of the Emory university-affiliated HF outpatient clinics. Exclusion criteria included the following: (a) hospitalization for an acute HF exacerbation within the last 2 months; (b) aortic aneurysm; (c) valvular disease; (d) uncontrolled angina; (e) renal failure; (f) inability to ambulate; (g) uncontrolled hypertension (resting blood pressure ≥ 160 mm Hg systolic or ≥ 90 mm Hg diastolic); (h) current participation in an exercise program; (i) recent (< 3 months) participation in a cardiac rehabilitation program; (j) inflammatory diseases such as hepatitis and rheumatoid arthritis; (k) dementia, psychological disorders, or substance abuse problems that would interfere with participation in exercise; (l) noncompliance with medication regimen; (m) renal failure; and (n) absence of a telephone line for a telemonitoring device. If eligibility criteria were met, a letter was sent to the potential candidate, and if interested, they were contacted by telephone, the study was explained, and an appointment was made for obtaining informed consent and initial baseline measures.

Study recruitment occurred over a 6-month period, and a total of 615 patients were screened for study eligibility. Of this number, 463 (75%) were screen failures. Common reasons for screen failure included long distance from the enrolling institution, Emory Healthcare; renal failure; NYHA class I or IV HF; documented nonadherence with medication regimen; or psychosocial issues that would affect adherence ability. The 152 (25%) eligible participants were sent a maximum of 2 letters over a 6-month period explaining the study details. Of this number, 21 participants were recruited by letter; 6, by flyers posted in the HF clinics; and 1, by word of mouth. Because of time commitments, 3 participants dropped out before baseline measures were taken, and 1 participant was excluded during baseline measures (not included in the analysis) because of uncontrolled hypertension. Twenty-four patients were randomized in a 1:1 ratio allocating participants to either the exercise or the control group after collection of baseline measures. None of the participants dropped out of the study after baseline measures were taken.

Instruments

10-Item Continuous Scale Physical Functional Performance Test—The 10-item CS-PFP (CS-PFP10) is a shortened, modified version of the original instrument and retains 10 of the 16 items as shown in Table 1.^{37,38} Participants are required to perform household tasks in a serial manner at maximal effort within the judgment of personal comfort and safety. All household tasks for both the original and shortened versions of the CS-PFP are quantified by time, distance, or weight. The battery of tests includes routine tasks, ranging from “easy” to “difficult” (see Table 1). Both the 16-item CS-PFP (CS-PFP16) and the CS-PFP10 yield a possible total score of 100 (range, 0–100), which is the average of the 5

domain scores: (a) upper body strength, (b) lower body strength, (c) upper body flexibility, (d) balance and coordination, and (e) endurance. Scores are scaled from 0 to 100 using a formula based on lower and upper extremes of performance^{37,38}: observed score = (observed score – lower limit)/(upper limit – lower limit) × 100. The total physical functional performance score (CS-PFP total) is the average corrected score of all tasks. Both the CS-PFP16 and the CS-PFP10 are administered using the same protocol and scripted dialogue for each household task. The 16-item instrument was validated in 148 older adults 70 years or older with a broad range of physical function abilities. Of the 148 participants, 78 resided in the community independently, 31 lived in assisted living facilities, and 39 lived in a long-term care facility and had some level of physical dependency. Higher scores on the CS-PFP16 and on the CS-PFP10 reflect better functional health, and both versions have been shown to discriminate between levels of physical function performance. For example, in the validation study of the original 16-item instrument, those who lived independently in a community setting had significantly higher total ($P < .0001$) and domain ($P < .0001$) CS-PFP scores than did those residing in an assisted living facility or with some level of dependency.³⁷ The CS-PFP has been used to measure and distinguish physical function in patients with cardiovascular disease (ie, CAD and stroke),^{41,42} Parkinson's disease,⁴³ and other chronic illnesses^{44,45} and to document change after exercise programs^{37,38} but has had very limited use patients with HF.^{46,47} In a previous study, we reported significant differences between NYHA class II and III patients with HF using the CS-PFP10.⁴⁶ Savage et al⁴⁷ also reported that CS-PFP10 scores were 30% lower among patients with HF compared with healthy age- and physical activity-matched controls. The CS-PFP16 has been validated against standard exercise capacity measures (ie, peak oxygen consumption [peak $\dot{V}O_2$], $r = 0.65$; knee extensor strength, $r = 0.68$; step reaction time, $r = 0.65$), which may be used to gain further insight into underlying physical impairments contributing to functional limitations.³⁷ The CS-PFP16 total and domain scores were also highly correlated with the Medical Outcomes Short Form physical function component subscales ($r = 0.75$) but not the mental component subscale ($r = -0.15$). Reports for internal consistency of the CS-PFP16 range from .74 to .97 for the total and 5 domain scores. Test-retest correlations range from 0.85 to 0.97. Administration of the CS-PFP16 and CS-PFP10 requires training and certification. Interrater reliability for both instruments has ranged from 0.92 to 0.99. The CS-PFP16 also has good sensitivity to detect effect sizes in the range of 0.5 to 0.7 with sample sizes of 15 or fewer per group.³⁷ A score of 57 (range, 48–59) units or lower has been established in previous studies as the threshold for having an increased probability of losing independence.⁴⁸ This CS-PFP threshold has been validated against a peak $\dot{V}O_2$ threshold of 20.1 mL kg⁻¹ min⁻¹ and maximal voluntary muscle torque threshold of 2.5 N m/(kg m⁻¹), which accurately predicted functional limitations in 192 older adults (mean [SD] age, 76 [7] years).⁴⁸

The CS-PFP16 requires a designated laboratory space, equipment, and approximately 1 hour to administer, which makes it impractical in many settings. A major advantage of the CS-PFP10 is that it takes approximately half the time to administer, is portable, can be used in a variety of settings, and reduces participant burden.³⁸ The CS-PFP10 has been validated against the original 16-item version in a series of studies conducted by Cress et al.³⁸ In a study comparing the relationship between total and domain scores performed on the CS-

PFP16 and the CS-PFP10, correlation coefficients were high, ranging between 0.86 and 0.95, with the lowest correlation demonstrated for upper body flexibility ($r = 0.86$). Internal consistency was high for 4 of 5 domains (upper body strength, $\alpha = .83$; lower body strength, $\alpha = .87$; balance and coordination, $\alpha = .90$; and endurance, $\alpha = .91$) and moderate for upper body flexibility ($\alpha = .69$). To establish the portability of the CS-PFP10, total scores were compared between test administrations that took place in a community setting and those that took place in an established laboratory. Mean total scores were similar for both locations: mean (SD), 44.9 (17.9) in the community setting compared with 42.7 (19.0) in the laboratory. In addition, correlations between the total and 4 of the 5 domains were $r > 0.90$ when administered in the 2 different locations, except for upper body flexibility, which was 0.74. Sensitivity to change for the CS-PFP10 was also established after a 12-week exercise program, with statistically significant improvement in the total and 4 of the 5 domains (Bonferroni adjustment $P < .01$), except for upper body strength. These findings suggest that compared with the original 16-item version, the CS-PFP10 is valid, has adequate reliability, and is also sensitive to change. Because a score of 57 on the CS-PFP10 is essentially the same as a score of 57 on the CS-PFP 16, the underlying thresholds for peak $\dot{V}O_2$ (20 mL $\text{kg}^{-1} \text{ min}^{-1}$) and knee extensor peak torque adjusted for body height and weight (2.5 N m/kg m^{-1}) remain comparable.³⁷ These data suggest that the CS-PFP10 can be substituted for the CS-PFP16 without losing important information. At the conclusion of the CS-PFP10, participants were instructed to assess the rate of perceived exertion (RPE) using the Borg scale (range, 6–20).⁴⁹ The Borg scale is a measure of perceived exertion based on the physical sensations that a person experiences during physical activity ranging from 6, which signifies their his/her of exertion at rest, to 20, which indicates his/her maximal level of exertion. The Borg scale is very useful for prescribing exercise intensity, especially among participants prescribed β -blockers. An RPE of 12 to 14 is usually well tolerated by stable HF patients and has a correlation of $r = 0.70$ with peak $\dot{V}O_2$ when performing exercise at a moderate intensity level.^{9,50}

Muscle Strength

Handgrip: Handgrip is one of the measures used to assess muscle strength. Handgrip strength was measured with a Jamar handgrip dynamometer (Jamar, Bolingbrook, Illinois) using a standardized protocol on both sides (dominant and nondominant hand) with a precision of 0.1 kg. Participants were asked to self-adjust the dynamometer to fit comfortably with their hand size to achieve optimal performance. For the 3 serial measurements, the participants were seated with both arms resting on a table at a comfortable level with elbows flexed at a 90° angle with support with the dynamometer facing outward from the body. A warm-up session to familiarize participants with the dynamometer was conducted to choose the best adjustment. Participants were instructed by voice command to grip the dynamometer with maximum strength.⁵⁰ During the grip strength measures, heart rate (HR) was monitored using the Polar HR monitor (Polar USA, Lake Success, New York) and blood pressure was taken immediately before and after for safety reasons. Three trials were performed on each side, alternately, with a rest period of at least 1 to 2 minutes between trials. The mean value for each hand was used for handgrip strength.^{51,52} Muscle strength testing was conducted by 2 data collectors for each measurement to ensure adequate reliability. For both the intervention and control groups, the

interrater reliability of handgrip measures for both the dominant and nondominant hand was 0.92 or higher.

Upper Body (Forearm Flexion) and Lower Body (Knee Extension) Muscle Strength:

Upper and lower body strength was measured using a handheld Jamar dynamometer (Jamar). For forearm flexion, the person sat at a table with elbow at a 90° angle, palm up, with the dynamometer placed 2 in above the wrist. Participants were instructed by voice command to pull upward with maximum strength against the dynamometer. For knee extension, participants were instructed to sit on a bed with knees at a 90° angle to floor. The bed was raised so feet were 10 to 12 in off the floor. The dynamometer was placed 2 in above the ankle, and when prompted, participants were instructed to kick their foot outward at a 90° angle. The mean force (kilograms) of 3 trials was calculated, with rest in between each of the 3 contractions. Muscle strength testing was conducted by 2 data collectors for each test to ensure reliability. If a difference of 0.1 kg was documented for any strength measure, another reading was taken and the mean force (kilograms) was calculated as the strength for that testing procedure.^{53,54} The interrater reliability for the intervention and control groups for the forearm flexion for the dominant and nondominant arms was greater than 0.90. For the knee extension measures, interrater reliability was 0.90 or higher for both the intervention and control participants.

Kansas City Cardiomyopathy Questionnaire—The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a 23-item, self-administered disease-specific questionnaire that quantifies physical function, symptoms (frequency, severity, and recent change), social function, self-efficacy and knowledge, and quality of life for patients with HF. Scores range from 0 to 100, in which higher scores indicate better function. The KCCQ overall summary score includes the scales for physical limitations, symptom summary, social limitations, and quality of life.⁵⁵ The validity and reproducibility of this measure have been previously established for HF patients.^{55–57} For the current study, the internal consistency for the intervention group and for the control group participants was 0.88 and 0.92, respectively.

Beck Depression Inventory—The Beck Depression Inventory (BDI-II)⁵⁸ was used to measure depressive symptoms in HF patients. The BDI-II is a 21-item instrument with scores ranging from 0 to 63; higher scores reflect greater depressive symptoms over the past 2 weeks. This instrument has been used extensively in patients with cardiovascular disease and HF to measure depressive symptoms.^{59–61} For the current study, the internal consistency was 0.92 for the intervention participants and 0.90 for the controls.

Charlson Comorbidity Index—The Charlson Comorbidity Index⁶² is a well-established instrument and was used to assess the severity of comorbid diseases such as diabetes, cancer, and hypertension. At baseline, internal consistency for both the intervention and control participants was greater than 0.90. Participants' medical records were reviewed to obtain information about the number and type of comorbid conditions.

Procedures

Exercise Program Overview—Participants performed the combined aerobic and resistance exercise in a 12-week home-based program. Participants received individualized instruction and demonstration on how to monitor and record HR using a Polar HR monitor (Polar USA).⁶³ The reliability and validity of Polar HR watches have been compared with those of the Holter monitor, with correlation coefficients ranging from $r = 0.93$ to 0.99 .^{64,65} Participants also were instructed and practiced using the Borg RPE 6–20 scale^{49,66} and were told to monitor and record any symptoms experienced during the walking or strength training sessions on their exercise calendars. Eight consecutive weekly supervised exercise sessions were held at the participant's home; these sessions were used for the resistance training. The investigators reviewed the participants' walking progress weekly using their exercise calendars and talked with participants during the resistance training visits. Participants were instructed to document the number of steps displayed on their pedometer after each walking session. After 8 weeks of supervised resistance training at home, participants were followed weekly by telephone, and 1 additional face-to-face home visit was provided at 10 weeks. Participants in the exercise group also received a DVD and exercise booklet demonstrating the resistance exercises to use as a reference when they performed resistance exercises alone.

Aerobic Exercise—Progressive low-to-moderate-intensity walking was used for the aerobic exercise component. Before beginning their exercise regimen, participants were instructed to use warm-up using stretching and flexibility exercises for 5 to 10 minutes. Based on the 6MWT, the investigators estimated the intensity level of participants using the HR reserve (HRR) method,⁶⁷ beginning at 50% intensity (based on HR and feelings of exertion) and progressing to 70% intensity for a minimum of 30 minutes and a maximum of 1 hour, 3 times per week. Both resting and exercise HRs are influenced by β -blockers, which are considered optimal therapy for HF patients.^{68,69} The HRR method takes into account the patient's resting HR, thereby reducing the effect of β -blockade. Participants were provided with an exercise prescription and were instructed to maintain their RPE between 12 and 15, which is well established to reflect a moderate intensity level of exercise.^{9,50} Participants were also instructed to keep their HR range initially at 50% intensity based on their individualized exercise prescription. For example, using the HRR method,⁶⁷ if the participants' resting HR was 70 beats/min and their maximal HR on the 6MWT was 130 beats/min, the prescription was calculated as $[(130 - 70) \times 0.50] + 70$ or 100 beats/min at 50% intensity. All participants were initially started at 50% intensity using this formula and then progressed to 60% and to 70% based on HR, RPE, and any symptoms experienced during the walking sessions. For example, when participants were able to walk at 50% intensity for 30 minutes for 2 consecutive weeks within the prescribed HR and RPE range, they were increased to 60% intensity. The same process was then followed before progression to 70% intensity. When participants were able to walk at 70% intensity for 30 minutes 3 times per week, the duration of walking was increased in increments of 5 to 10 minutes until they were able to walk for 1 hour, 3 times per week. At the conclusion of each walking session, participants were instructed to use a cool-down period of 5 to 10 minutes of walking at a slower pace and stretching movements.^{9,11,50,68,69}

Resistance Exercise—Color-coded Thera-cords (Hygenic Corporation, Akron, Ohio) were used for the resistance exercise measurement; each color represented a different level of resistance. The first session used low-intensity resistance (yellow elastic tubes) to establish familiarization with elastic resistance. Before starting the resistance exercise program, participants warmed up using stretching and flexibility movements for 5 to 10 minutes.^{9,50} The duration of the resistance exercise sessions was approximately 1 to 1.5 hours, depending on participant tolerance, and included a 5-minute warm-up (low-intensity stretching/flexibility) and a 45- to 60-minute lower and upper body resistance training session. Lower body resistance training integrated exercises for the following: (a) ankle plantar flexion and dorsiflexion; (b) knee extension and flexion; (c) hip extension, abduction, and adduction; and (d) leg extensions. The upper body resistance training integrated exercises for (a) shoulder abduction, flexion, and rotation; (b) elbow extension and flexion; and (c) wrist extension and flexion. Individual progression of resistance training was monitored and adjusted when the participant was able to perform 2 sets of 12 to 15 repetitions and had a rating of less than 15 on the RPE scale, which indicates moderate intensity. Participants were asked to perform the resistance exercises 2 or 3 times per week, but not on 2 consecutive days to avoid muscle fatigue and soreness. Several participants who were unable to perform standing exercises used a sitting protocol using the same exercise routines developed by the investigators. Most participants progressed over the 12-week study period to 3 sets of 15 repetitions 2 times weekly. Theraballs (Hygenic Corporation) are also color coded by level of resistance and were used to improve handgrip strength. As the participant's grip strength improved, Theraballs were progressed to those that had greater elastic resistance. Participants were asked to do hand exercises a minimum of 5 minutes per day in each hand and not to squeeze the ball continuously to avoid potential adverse hemodynamic responses. At the end of the resistance exercises, participants cooled down with range of motion, light stretching, and flexibility movements.

Exercise Adherence—For each walking session, the participant recorded the number of steps walked, the duration, maximum HR and RPE, and any symptoms experienced on the exercise calendar. The number of daily steps walked was indirectly assessed using the Omron HJ 112 pedometer (Omron Healthcare Inc, Bannockburn, Illinois). The pedometer device resets at midnight automatically, so the investigators were able to compare steps recorded by participant's documentation on the step calendar and pedometer data to validate their documentation during the weekly visits. A number of studies have shown the Omron pedometers to be accurate and reliable in adults and in patients with HF⁷⁰ and to be a more valid measurement than self-report questionnaires.^{71–73} Stride length was measured according to manufacturer's recommendations to ensure a more accurate step count. For patients to be considered 100% adherent to the protocol, 3 documented walking sessions and 2 strength training sessions were required. Average weekly adherence rates were calculated as follows: (number of exercise sessions recorded/number of sessions prescribed) × 100. A total summary adherence score was calculated by summing and dividing weekly adherence scores by total number of weeks walked, resulting in a percentage of the total expected.

Exercise Progression—For the walking sessions, participants were asked to write the following on the exercise calendar: number of steps walked during the aerobic session,

maximum HR, and RPE during each walk. The primary method of progressing exercise was based on RPE for both aerobic and resistance exercises because most participants were prescribed β -blockers. As described earlier, participants were required to walk at the prescribed level of intensity for 2 consecutive weeks for 30 minutes before they were progressed to the next intensity level. For the resistance exercise, the participant was asked to record the tube color and the number of repetitions after each session, maximum HR, and RPE. Participants were instructed to keep their RPE below 15 for both modes of exercise because moderate intensity is correlated with a score between 12 and 15 on the Borg RPE scale.⁴⁹ When participants were able to complete 2 sets of 12 repetitions, they were progressed to the next tube color.

Attention Control Wait List Group—Control participants were provided with instruction on stretching and flexibility movements in the home; no additional written materials were provided. After the T2 measures were taken at 12 weeks, the control participants received the same instruction, equipment, and 2 supervised home visits for the resistance exercises; no additional measurements were taken. Participants in the ACWL group received a total of 5 to 6 home visits over the 12-week period to control for attention and the confounding effect of social support and researcher contact between groups.

Daily Home Telemonitoring—The Cardiocom Commander (Cardiocom, Inc, St Paul, Minnesota) was used to monitor and track each participant's daily HR, blood pressure, weight, and symptom severity for 12 weeks. A disease management algorithm was used for all questions that were related to HF and to guide the automated cues based on physiological data recorded and the participant's responses to cues. If any of the set parameters were abnormal, such as weight gain, blood pressure change, or increased symptom severity, the participant was flagged for follow-up. Telemonitoring has been used successfully to improve adherence to a home-based exercise program in patients with HF.⁷⁴

Statistical Analysis—Values are presented as descriptive statistics (mean and standard deviation). Baseline differences for sociodemographic and outcome measures were tested using independent-samples *t* tests. Paired *t* tests were used to determine within-group changes. Analysis of covariance was used to determine group differences at 12 weeks on study outcomes adjusting for baseline scores. Pearson *r* correlation coefficients were used to determine relationships among the key variables. Cohen *d* statistic was used to calculate effect size for the intervention. Statistical analyses were carried out using the Statistical Package for Social Science (SPSS/-PC+, version 16.0; SPSS Inc, Chicago, Illinois). A level of significance of $P < .05$ was used for hypotheses testing.

Results

Baseline Characteristics

At baseline, there were no group differences in sociodemographic characteristics (Table 2), total and domain scores for the CS-PFP10, muscle strength, or HRQOL (Table 3). However, there were a significantly greater number of insulin-dependent diabetic patients in the ACWL group, as shown in Table 2. In addition, although all patients were receiving what is

considered optimal medication therapy for HF according to guidelines,^{68,69} there were a significantly greater number of ACWL patients receiving angiotensin-converting enzyme inhibitors and a higher proportion of patients on angiotensin receptor blockers in the intervention group. All patients were receiving one or the other, and therefore, outcomes were unlikely influenced by these medication differences. Only 2 participants (1 exercise, 1 control) were above the CS-PFP10 cutoff range (48–59) of having a higher probability of losing independence. At baseline, the mean (SD) CS-PFP10 score was 42 (16) (range, 8–76); at 12 weeks, the mean (SD) score was 47 (17) (range, 15–78). There was greater improvement among NYHA class III patients from baseline to 12 weeks for the CS-PFP10 total scores, increasing from 37 (13) to 49 (15) as compared with 62 (16) to 68 (10) in NYHA class II patients (not shown). There were no serious adverse events among any of the study participants and baseline medication changes were stable throughout the study period.

Exercise Intervention Group

Participants in the combined aerobic and resistance exercise program experienced significant increases in muscle strength and most of the CS-PFP10 domains (Table 3). The total CS-PFP10 score significantly increased, on average (post-pre change), by 10.3 (9.3) ($P = 0.003$) in the exercise group compared with the ACWL group. Domain scores for upper body strength, upper body flexibility, lower body strength, balance/coordination, and endurance all increased significantly. There was greater improvement among NYHA class III patients from baseline to 12 weeks for the CS-PFP10 total scores, increasing from 37 (13) to 49 (15) as compared with 62 (16) to 68 (10) in NYHA class II patients (not shown). For the 6MWT, distance increased, on average, by 46.4 (46.9) ($P = .027$). The self-report questionnaire, KCCQ, was also sensitive to the exercise intervention, with significant changes observed for the clinical and overall summary scores. The mean number of steps increased by 1500 per session ($P < .001$) during the first 8 consecutive weeks of the intervention. Adherence was 83% and 99% for the walking sessions and resistance exercises, respectively.

Response to Attention Control Stretching and Flexibility Placebo

Within the control group, the changes for the CS-PFP10 and muscle strength were small and nonsignificant (average changes post-pre were small and close to zero compared with their standard deviations). The total CS-PFP10 score increased, on average, by only 1.4 (12.7), which was not significant ($P = .71$). None of the 5 domain scores changed significantly from baseline (Table 3). No improvement was seen in the KCCQ subscale or overall summary scores in this group. In fact, the KCCQ overall scores decreased, on average, by 10.7 (17.0), which was significantly different from baseline ($P = .05$). Depression scores were lower at T2 but remained above the BDI-II cutoff score of 10 that indicated persistence of mild depressive symptoms.

Group Differences

Upper and lower body strength and the total CS-PFP10 score and the domain scores for upper body strength, lower body strength, balance and coordination, and endurance were significantly increased in the exercise group compared with the ACWL group (Table 3).

Large effect sizes (0.64–0.96) were found for all of the muscle strength measures, and a very large effect also was found for the CS-PFP10 total score (1.10). Finally, significant improvements in overall HRQOL were found among the exercise participants but not in the ACWL group (Table 3).

Discussion

The findings from this study demonstrate that a combined aerobic and resistance exercise program improved physical function for a wide range of daily physical activities among stable NYHA class II and III patients in a home setting. Compared with the control group (ACWL), participants in the combined exercise group had significant improvements in muscle strength, CS-PFP10 total and domain scores, and perceived HRQOL. Because functional performance improved in the exercise group to near threshold levels, a program that targets both muscle strength and endurance may be important for slowing and possibly delaying the further functional decline experienced by many HF patients. For example, in a previous study, we found that aerobic exercise alone did not significantly improve CS-PFP10 scores in 74 patients with HF, but improved endurance was noted by an increase in distance walked on the 6MWT.⁴⁶ Savage and colleagues⁴⁷ recently compared a resistance program in patients with HF with that in healthy age and physically active matched controls and found similar improvements in muscle strength and CS-PFP10 total and domain scores, but aerobic capacity was not significantly altered in either group. A combined approach of aerobic and resistance exercise, therefore, may be superior to either approach alone for improving ability to perform PADLs in patients with mild to moderate HF. The current study also demonstrated that complex HF patients, many with implanted cardiac defibrillators, multiple comorbidities, and numerous medications, were able and willing to exercise at a level that positively influenced physical function performance. The finding that muscle strength improved after a combined aerobic and resistance exercise was similar to that in previous studies.^{20,75,76}

Similar baseline values and the substantial gains made after incorporating resistance exercise in the current study and among older women with CAD⁴⁰ suggest that the CS-PFP10 may be a useful measure to evaluate routine physical functional performance in patients with cardiovascular disease. Most participants in the study had CS-PFP10 total scores of less than 57 units, which indicated an increased probability for loss of independence.⁶⁷ Participants (mean [SD] age for women, 55.8 [3.4] years; mean [SD] age for men, 65.0 [1.8] years) in the current study had lower CS-PFP10 total scores than previously reported in healthy older adults 75 years or older (54 [11] units)⁴³ and older women (mean [SD] age, 70.6 [4.5] years) with CAD (49.5 [11.0] units).⁴⁰ In fact, the total CS-PFP10 total scores among female participants, in particular, were the most similar to those of older adults (>80 years) residing in an assisted living community (42 [15] units).³⁷ These findings have important implications for women in the current study who had similar physical function and a probability for losing independence that was similar to those of adults 2 to 3 decades older than participants in this study. Hence, strategies to maximize physical function and reduce further declines in functional performance may be particularly important for younger patients with HF.

Patients often complain that performing routine physical activities becomes increasingly difficult as HF severity progresses or as NYHA class advances.^{1,2,17} Our findings also support that baseline performance of simulated household tasks was lower among NYHA class III than class II patients. Petrella and Cress⁷⁷ found that older adults scoring below the threshold of independence take fewer steps and modify more tasks than do individuals above the threshold. They identified performance of older adults 9.6 units below the threshold (57–47.4) as an indicator of preclinical disability. In our sample, participant scores were, on average, well below this threshold, with scores of 46.6 and 38.0 for NYHA class II and III patients, respectively, indicating that the CS-PFP10 was able to detect levels of functional performance that reflected worsening disease severity and which domains were most compromised. Therefore, the CS-PFP10 may provide additional information to supplement traditional exercise tests for a more comprehensive evaluation of physical function. Also, domain scores may help clarify the nature of self-reported functional limitations. For example, in 2 patients with similar CS-PFP10 total scores, the domain subscales might show that one adult had problems with upper body strength and balance, whereas the other had problems with lower body strength and endurance.^{37,39} With this type of information, clinicians would be able to prescribe more tailored and appropriate exercise by targeting training to improve physical function for domain-specific areas.

Studies have shown that depressed patients perceive worse physical function than do nondepressed patients, despite similar clinical characteristics and objective physical function.^{59–61} Although our findings did not show significant differences between groups in relation to depressive symptoms, the control participants continued to have persistent mild depressive symptoms at 12 weeks. Routine depression screening may help identify patients who are more likely to perceive poorer physical function, curtail activity levels, and benefit from counseling, support groups, or psychotherapy techniques such as cognitive behavioral therapy that may help them think differently about their limitations, set goals that are more appropriate for their functional level, or perceive their physical changes less negatively.⁷⁸

The length of the program and the exercise approach were well received by participants. Very few participants required follow-up for telemonitoring alerts during the study. The most common reasons for follow-up were elevated symptom scores such as increased dyspnea that occurred in the previous 24 hours. Participants enjoyed having the telemonitoring unit to monitor their vital signs and symptoms, and it provided a sense of greater safety for some patients. Owing to careful participant screening before enrollment, telemonitoring appeared not to provide any advantage in terms of identifying those who were at higher risk of experiencing a cardiovascular event or hospitalization. However, it may have prevented attrition among control participants and may be useful for exercise studies that enroll more advanced HF patients (NYHA class IV).

Limitations

This study had several limitations that may influence generalization of the results. First, the sample size was small and prevented the use of tests to evaluate change across time between groups using a comprehensive statistical procedure. In addition, data were collected primarily from 1 academic center and may have lacked general representation of patients

with HF from other settings or geographic locations. Also, the investigators were unable to blind the groups to the intervention, which may have introduced bias in the study. The large number of patients in the target population who were screened ($n = 615$) and eligible ($n = 152$) to reach the sample size of 24 highlights the difficulty of recruitment in this patient population, which suggests the potential challenges of conducting this study in a larger scale trial. The HF ACTION study¹¹ also demonstrated poor adherence in the aerobic exercise arm, so whether a replication of a combined approach would result in higher adherence remains uncertain. A standard protocol was adhered to during administration of the CS-PFP10, and enough time lapsed that familiarity was not a significant factor concerning study outcomes. Another possible limitation might have been the duration of each exercise expected of HF patients, such as 1 hour 3 times a week, which may have produced either fatigue of muscles or lack of adherence, although reports of fatigue were minimal and adherence rates were high in the exercise group. The combined aerobic and resistance exercise program may have been too difficult an expectation for class II and II NYHA patients, suggesting that shorter or less intense exercise may obtain similar outcomes and with increased adherence and more practical clinical usefulness.

Conclusions

Our findings suggest that a combined aerobic and resistance program of exercise improves muscle strength, improves the ability to perform a wide range PADLs, and enhances self-reported HRQOL. Therefore, an exercise program that combines resistance with aerobic exercise may provide additional benefits in functional performance of HF patients, but further study with a larger sample is needed. Finally, more studies are needed to determine whether early interventions for subtle changes in the total and domain-specific CS-PFP10 scores would slow or delay HF-related complications, disability, or functional decline.

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What Is New and Important

- Few trials have used objective physical performance measures to document simulated daily physical function tasks in patients with heart failure (HF).
- This study shows that most patients in this trial were below the physiological threshold (48–57 units) for New York Heart Association (NYHA) class II and III, respectively, on the Continuous Scale Physical Functional Performance Test (CS-PFP), which indicates greater risk for physical function decline and loss of independence.
- A combined aerobic and resistance exercise program improved physical function to near threshold levels among NYHA class II and III HF patients for independent living.
- A program that targets both muscle strength and endurance may be important for slowing and possibly delaying further functional decline experienced by many HF patients.
- The CS-PFP10 tool may have practical utility for assessing physical function in HF patients but needs to be tested in a larger study.

TABLE 1**Continuous Scale Physical Functional Performance Test Household Tasks**

Performance Tasks	Included in CS-PFP10
Low difficulty	
Pot carry test: transfer weighted pan approximately 1 m	Yes
Jacket test: don and remove a light jacket	Yes
Jug pour: pour water from jug into cup	No
Reach test: place a sponge and remove it from an adjustable shelf	Yes
Moderate difficulty	
Floor sweep test: sweep floor with broom and dustpan	Yes
Scarves test: pick up 4 scarves, one at a time, from the floor	Yes
Laundry test 1: transfer clothes from washer to dryer	Yes
Laundry test 2: unload clothes from dryer to a laundry basket	Yes
Fire door: open and pass through a fire door	No
Bed make-up: make a bed	No
Shoe strap: place a strap over a shoe	No
Vacuum: vacuum designated space	No
High difficulty	
Floor down/up test: from a standing position, sit on the floor, and then stand up	Yes
Stair climb test: climb 1 flight of stairs.	Yes
Grocery test: carry bag(s) of groceries for 70 m	Yes
Bus stop: carry weighted bag up and down simulated bus stop	No
6-min walk test: walk a maximal distance in 6 min	Yes

Abbreviation: CS-PFP10, 10-item Continuous Scale Physical Functional Performance Test.

TABLE 2

Baseline Sociodemographic and Clinical Characteristics for Total Group, Intervention, and Control Participants

	Total (N = 24)	Intervention (n = 12)	Control (n = 12)	P
Age, y	60 ± 10	59 ± 11	61 ± 10	.56
Gender				.41
Male	12 (50)	7 (58)	5 (42)	
Female	12 (50)	5 (42)	7 (58)	
Ethnicity				.10
Black	11 (46)	3 (25)	8 (67)	
White	12 (50)	8 (67)	4 (33)	
Other	1 (4)	1 (8)		
NYHA class				.41
II	10 (42)	4 (33)	6 (50)	
III	14 (58)	8 (67)	6 (50)	
LVEF%	25 ± 9 (n = 22)	23 ± 8 (n = 12)	27 ± 9 (n = 10)	.24
Weight, kg	99 ± 18	95 ± 19	102 ± 18	.34
Height, cm	171 ± 14	171 ± 16	171 ± 12	.96
BMI, kg/m ²	34 ± 7	32 ± 7	36 ± 8	.20
HR, beats/min	72 ± 9	72 ± 9	73 ± 9	.31
Systolic BP, mm Hg	114 ± 17	109 ± 19	116 ± 12	.18
Diastolic BP, mm Hg	72 ± 10	70 ± 11	74 ± 12	.67
Implanted device	19 (79)	11 (92)	8 (67)	.13
Comorbidity score	2.5 ± 1 (1–5)	2 ± 1	3 ± 1	.46
Hypertension	12 (50)	4 (33)	8 (67)	.10
Myocardial infarction	11 (46)	5 (42)	6 (50)	.68
Diabetes	12 (50)	4 (33)	8 (67)	.10
Depression history	13 (54)	7 (58)	6 (50)	.68
Dyslipidemia	22 (92)	11 (92)	11 (92)	1.00
Medications	11 ± 3 (3–16)	11 ± 3	11 ± 4	.86
ACEI	13 (54)	4 (33)	9 (75)	.04
ARB	16 (67)	10 (83)	6 (50)	.08
β-Blocker	19 (79)	9 (75)	10 (83)	.62
Diuretic	21 (87)	11 (92)	10 (83)	.54
Insulin	8 (33)	1 (8)	7 (58)	.01 ^a
Oral hypoglycemic (n = 22)	7 (32)	3 (25)	4 (40)	.45
6MWT, m	335 ± 105	364 ± 80	307 ± 121	.18

Data are presented as mean ± SD, mean ± SD (range), or n (%).

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; BP, blood pressure; HR, heart rate; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; 6MWT, 6-minute walk test.

^a*P* < .01.

TABLE 3

Muscle Strength, 10-Item Continuous Scale Physical Functional Performance Test, and Health Status Changes From Baseline to 12 Weeks in the Intervention and Control Participants

	Control (n = 12)				Exercise Intervention (n = 12)				Between Groups		Post Cohen <i>d</i> , Effect Size
	Pre	Post	Change: Post-Pre	Paired <i>t</i> Test, <i>P</i>	Pre	Post	Change: Post-Pre	Paired <i>t</i> Test, <i>P</i>	Pre <i>t</i> Test, <i>P</i>	Post ANCOVA, <i>P</i> ^a	
Muscle strength											
R handgrip	28.4 (11)	24.2 (16)	−4.2 (13.4)	.30	28.1 (9)	35.1 (9)	7.1 (8.9)	.02	.936	.024	0.87
L handgrip	24.8 (10)	25.4 (10)	0.6 (4.7)	.69	26.6 (10)	32.0 (9)	5.4 (9.2)	.07	.675	.063	0.69
R FA flexion	24.9 (9)	17.1 (18)	−7.8 (20.4)	.21	23.2 (8)	27.7 (4)	4.3 (5.0)	.01	.626	.063	0.96
L FA flexion	22.3 (9)	21.8 (8)	−0.4 (4.5)	.76	23.1 (6)	27.1 (4)	4.0 (5.0)	.02	.781	.005	0.88
R knee extension	31.5 (10)	31.0 (9)	−0.5 (7.4)	.83	31.3 (9)	37.8 (10)	6.5 (8.7)	.03	.952	.036	0.72
L knee extension	31.1 (12)	30.6 (10)	−0.4 (7.3)	.84	30.8 (9)	36.7 (9)	4.9 (8.6)	.07	.943	.086	0.64
CS-PP10											
Total	37.8 (13)	39.2 (15)	1.4 (12.7)	.71	45.4 (18)	55.7 (16)	10.3 (9.3)	.003	.252	.025	1.10
UBS	37.1 (16)	39.2 (17)	2.1 (13.8)	.61	46.9 (16)	58.5 (17)	11.6 (10.2)	.002	.146	.032	1.10
LBS	31.3 (14)	33.5 (16)	2.4 (12.3)	.52	39.4 (18)	50.7 (17)	11.3 (10.1)	.003	.215	.035	1.00
UBF	61.0 (14)	61.5 (15)	0.5 (17.6)	.93	59.8 (20)	69.4 (19)	9.6 (8.4)	.002	.868	.107	0.46
BALCOR	38.8 (13)	39.8 (17)	1.1 (14.7)	.80	46.2 (21)	55.8 (17)	9.7 (10.1)	.007	.310	.047	0.94
ENDUR	37.2 (13)	38.1 (17)	0.9 (13.2)	.81	45.4 (20)	55.2 (17)	9.8 (9.3)	.004	.244	.029	1.00
KCCQ											
Summary score	65.0 (23)	54.3 (23)	−10.7 (17.0)	.05	60.5 (24)	73.0 (19)	12.5 (11.1)	.003	.641	<.001	0.89
Clinical score	64.0 (24)	55.1 (20)	−9.0 (18.4)	.12	67.7 (21)	77.6 (16)	10.0 (8.0)	.001	.701	<.001	1.30
6MWT	306.0 (121.3)	305.6 (131.4)	−1.02 (67.2)	.959	364.3 (79.7)	411.0 (110.4)	46.4 (46.9)	.027	.182	.074	0.94
BDI	15.9 (10.0)	12.9 (9.0)	−3.0 (11.6)	.389	10.5 (7.3)	8.9 (6.2)	1.6 (8.4)	.529	.143	.401	0.53

Data are presented as mean (SD). Cohen *d* = (mean group 1 – mean group 2)/average (SD group 1, SD group 2).

Abbreviations: ANCOVA, analysis of covariance; BALCOR, balance and coordination; BDI, Beck Depression Inventory; CS-PFPI0, 10-item Continuous Scale Physical Functional Performance Test; ENDUR, endurance; FA, forearm; KCCQ, Kansas City Cardiomyopathy Questionnaire; L, left; LBS, lower body strength; R, right; 6MWT, 6-minute walk test; UBS, upper body strength; UBF, upper body flexibility.