



Published in final edited form as:

J Appl Gerontol. 2020 February ; 39(2): 181–191. doi:10.1177/0733464817746757.

An Intervention to Improve Physical Function and Caregiver Perceptions in Family Caregivers of Persons with Heart Failure

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Abstract

Objective—This randomized controlled trial was conducted to determine if a 12-week home-based aerobic and resistance exercise program would improve physical function and caregiving perceptions among family caregivers (FCGs) of persons with heart failure.

Methods—127 FCGs were randomized to one of 3 groups: usual care attention control (UCAC), psychoeducation only (PE) and psychoeducation + exercise (PE + EX). Physical function measures (six-minute walk test, handgrip and upper and lower strength) and caregiving perceptions (Bakas Caregiving Outcomes Scale) were obtained at baseline and at 6 months.

Results—FCGs in the PE + EX showed significant improvement in six-minute walk distance ($p = 0.012$) hand grip and lower extremity strength compared to the PE and UCAC groups. The combined group had the greatest improvement in caregiving perceptions ($p < 0.001$).

Conclusions—FCGs in the PE+EX group improved the most in physical function and caregiver perception outcomes. Directions for future research are provided.

Introduction

Heart failure (HF) is the only cardiovascular disease that is increasing in prevalence and this number is expected to rise exponentially over the next several decades in the United States largely due to an aging population, advances in pharmacological and device management and the rise in risk factors that contribute to HF such as obesity, diabetes, and hypertension. Among older adults, HF is the most common reason for hospitalization and is also the most costly Medicare expenditure, currently exceeding 30 billion dollars annually (Heidenreich et al., 2013). Along with the enormous physical, psychological and economic consequences of HF, there is also an increasing recognition of the high burden associated among those providing informal care to this population. Adherence to self-care behaviors such as dietary sodium restrictions, complex medication regimens, and identifying worsening symptoms are essential for optimal disease management and quality of life in HF (Yancy et al., 2013). The ability to participate in and adhere to self-care behaviors becomes more challenging as HF worsens. Physical function decline, depressive symptoms and mild cognitive impairment are common in HF and may further hinder the individual's capacity for performing self-care (Corotto, McCarey, Adams, Khazanie, Whellan, 2013; Freedland et al., 2016; Hadjuk et al., 2013). Informal or family caregivers (FCGs) often take over the responsibilities for managing HF self-care activities when the individual can no longer manage independently (Buck, et al., 2015). Once FCGs engage in caregiving responsibilities, they tend to ignore their own well-being and are less likely to participate in health promoting activities such as exercise, which places them at heightened risk for physical function decline and poor health (O'Connell, Dal Bello-Haas, Crossley & Morgan 2015).

Evidence has shown over the past several decades that caring for a spouse or family member with a chronic and life-threatening illness is stressful and associated with depressive symptoms and emotional distress (Stromberg & Luttk, 2015; Doherty, Fitzsimmons & McIlfattrick, 2016; Adelman, Tmanova, Delgado, Dion & Lachs, 2014). Schulz and Beach (1999), in a landmark study, reported higher mortality rates for chronically stressed FCGs as well as adverse health risks associated with caregiving. Recent studies have also shown that many FCGs have positive perceptions and physical and psychological health benefits from caregiving (Roth, Freedman & Haley 2015). Most of the caregiving literature has focused on dementia, with less known about the challenges associated with life threatening chronic conditions such as HF. The unpredictable nature of HF, symptom variability and increased risk for sudden cardiac death contributes to higher emotional distress among FCGs. In one study, HF FCGs had greater burden than those providing care for advanced cancer and other chronic illnesses (Garlo, O'Leary, Van Ness & Fried, 2010) Unlike other conditions, including dementia, where the disease trajectory is more predictable, HF is typically associated with long periods of stability followed by worsening symptoms, acute exacerbations, and hospitalizations despite optimal self-care management (LeMond, Camacho & Goodlin, 2015; O'Leary, Murphy, O'Loughlin, Tiernana & McDonald, 2009). In addition, prognostic uncertainty and lack of shared decision making to end life sustaining treatments such as implantable devices also increases emotional distress among FCGs (LeMond et al. 2015; Gadoud, Jenkins & Hogg, 2013). Few studies however, have reported

how symptom severity and worsening disease progression contributes to perceptions of caregiving among FCGs of persons with HF.

Studies consistently report that most FCGs do not engage in adequate levels of physical activity (PA) that meet the current recommended guidelines (150 minutes of moderate to vigorous PA weekly) (Nelson et al., 2007; Fredman, Bertrand, Martire, Hochberg & Harris, 2006; Marquez, Bustamante, Kozey-Keadle, Kraemer & Carrion, 2012). Caregiving responsibilities, fatigue, reluctance to leave the home, time constraints and unwillingness to drive are some of the key barriers that limit FCG participation in exercise programs conducted outside of the home (Farran et al., 2008; King, Baumann, O'Sullivan, Wilcox & Castro, 2002; Janevic & McConnell, 2004). Telephone supervised, home-based exercise programs have been successful alternatives for site-based exercise programs in older adults and in chronic conditions (Gary, Cress, Smith, Higgins & Dunbar, 2011; Eyler, Brownson, Bacak & Housemann, 2003). Existing studies indicate that FCGs prefer physical activity programs that are simple, convenient, inexpensive, and incorporate behavioral strategies such as self-monitoring (Farran et al., 2008; Castro, Wilcox, O'Sullivan, Baumann & King, 2002). Moreover, the flexibility and convenience of a home-based program enables FCGs to exercise at a time that does not interfere with caregiving responsibilities or in shorter time frames spread throughout the day. Additionally, home-based programs have been shown to be equivalent to site-based programs in terms of adherence (especially in the long-term) among older adults (Ashworth, Chad, Harrison, Reeder & Marshall, 2005).

The purpose of the current study was to determine if a 12-week home-based aerobic and resistance exercise program would improve physical function among FCGs of persons with HF following a 12-week maintenance period. We hypothesized that FCGs in a combined psycho-education plus exercise (PE + EX) program would show the greatest improvement in physical function compared to psycho-education (PE) alone or to a usual care attention control group (UCAC) from baseline to 6-months. In addition, we hypothesized that the combined group would have the most improvement in positive perceptions of caregiving compared to PE alone and the UCAC groups.

METHODS

Study Design

A randomized controlled repeated measures design was used to enroll and follow participants from baseline to 6-months. Participants were FCGs of persons with HF and were randomized to one of three groups: Group 1 (UCAC), Group 2 (PE) and group 3 (PE + EX). This trial was part of a larger caregiving study that also included FCGs of persons with dementia as a separate investigation; here we report only on FCGs of persons with HF.

Participants

The sample included 127 FCGs, who were defined as a spouse, partner or other adult family member living in the same house or in contact with a HF patient in a caregiver relationship at least 4 times/week for at least one hour or more. Eligibility criteria included FCGs of persons with HF aged 21 years or older, English fluency, ambulatory and physically able to

engage in structured, low impact walking and upper body strength training program and sedentary (not engaging in 30 minutes of moderately strenuous exercise 3 or more times a week). Exclusion criteria included a medical or physical condition precluding participation in the exercise component of the study, psychiatric comorbidity, ischemic or inappropriate blood pressure changes on baseline treadmill test, currently taking corticosteroids or experiencing an acute inflammation or infection. After receiving university affiliated human subject's approval, participants who volunteered to participate in the study were required to provide written informed consent before initial baseline measurements were obtained.

Measures

Caregiver socio-demographic and clinical information was obtained from a self-report demographic record on age, gender, marital status, education, and medications. The Charlson Comorbidity Index (Charlson, Pompei, Ales & McKenzie, 1987) was used to assess the number and severity of comorbid diseases among FCGs using the original scoring version. *Care recipients* were screened using electronic medical records to confirm the presence of a HF diagnosis, New York Heart Association functional class, left ventricular ejection fraction, current medications and comorbidities.

Cardiorespiratory fitness. A modified Balke or Bruce submaximal motorized treadmill test (Balke & Ware, 1959; Pollock & Wilmore, 1990) was used initially to determine maximal oxygen consumption (VO_{2max}) using expired gas analysis to prescribe exercise based on target heart rate for intensity level and screen for cardiac contraindications to exercise according to the American Heart Association/American College of Cardiology guidelines (Gibbons et al., 2002). Because many of our older FCGs were reluctant to complete the VO_{2max} test, an alternative for estimating VO_{2max} was employed using 85% predicted HR. Determination of exercise treadmill protocol was based on the age, BMI and medical history of the participant. Seven percent of participants received the Bruce protocol (n=9; 2 males, 7 females), 14% received the Modified Balke (n=17; females only), 10.5% received the Bruce indirect (estimated VO_{2max}) test (n=13; 2 males, 11 females), and 68.5% received the Modified Balke indirect (estimated VO_{2max}) test (n=85; 6 males, 79 females). Because of the difficulty comparing absolute and estimated values for VO_{2max} , only baseline measures were used for prescribing exercise.

Six-Minute Walk Test (6MWT) was used to measure submaximal endurance. The 6MWT, a frequently used, reliable, and well-validated measure was used to measure submaximal functional capacity and has been previously reported in FCGs (Wakabayashi, Motegi, Yamada, Ishii, Gemma & Kida, 2011). Participants walked for 6 minutes on a level hallway 100-feet in length at baseline and again at 6-months using a standardized protocol (Camarri, Eastwood, Cecins, Thompson & Jenkins, 2006; Mentiplay et al., 2015).

Muscle strength included handgrip, upper (forearm flexion) and lower-extremity strength (knee extension) measured with a hand-held dynamometer (Jamar, Lafayette Instruments, Lafayette, IN) using a standardized protocol (dominant and nondominant) with a precision of 0.1kg. Three trials were performed alternately on each side, with a rest period of at least 1 to 2 minutes between trials.⁴³⁻⁴⁶ The mean value for each hand was used for strength (Roberts, Denison, Martin, Patel, Syddall, Cooper & Sayer, 2011; Alley et al., 2014).

Handgrip and lower extremity muscle measures have been used extensively to determine muscle strength, including FCGs (Winters-Stone, Lyons, Dobek, Dieckmann, Bennett, Nail & Beer, 2016; Gusi, Prieto, Madruga, Garcia & Gonzalez-Guerrero, 2009).

Physical activity level was measured using the Community Healthy Activities Model Program for Seniors (CHAMPS) Questionnaire (revised), a 41-item questionnaire, (Stewart, Mills, King, Haskell, Gillis & Ritter, 2001) was used to measure light, moderate, and vigorous physical activities to which participants reported weekly frequency of participation and duration over the last four weeks. The CHAMPS instrument has strong psychometric properties, is sensitive to change for various activity levels in older adults, and has been used extensively in exercise intervention studies (Stewart et al., 2001; Moore, Ellis, Allen, Cherry, Monrow, O'Neill & Wood, 2008). The CHAMPS has also been validated in culturally diverse groups including African Americans (Resincow, McCarty, Blissett, Wang, Heitzler & Lee, 2003) and in FCGs (Farran et al., 2016; Winters-Stone et al., 2016).

Caregiving perceptions were measured using the revised Bakas Caregiving Outcomes Scale (BCOS), (Bakas, Pressler, Johnson, Nauser, Shaneyfelt, 2006) a 15-item questionnaire that assesses caregivers' perceptions of changes in their lives as a result of providing care for the family member. Social functioning, physical health and subjective well-being are evaluated on a seven-point scale ranging from -3 (changed for the worst) to +3 (changed for the best). Scores > +4 indicate that the caregiver's life has improved, whereas scores < -4 indicate negative perceptions of the caregiving experience. This scale has been used in caregivers of persons with HF (Pressler et al., 2009) and in the current study the reliability for the BCOS was 0.94.

Caregiver strain was measured using 2 questions, "How much of a mental or emotional strain is it on you to either provide the help directly, or to arrange for help to be provided for this activity?" The second question was used to determine level of physical strain using the same phrase. Response options for the questions about strain were "no strain," "some strain," and "a lot of strain" (Ashburner, Cauley, Cawthon, Ensrud, Hochberg & Fredman, 2011). Higher scores reflect greater emotional or physical strain. Caregivers with increased strain have been shown to have higher rates of mortality and adverse health outcomes (Ashburner et al., 2011; Schultz & Beach, 1999).

Intervention

Usual Care Attention Control (UCAC) group received the usual care provided to HF FCGs such as standardized information on HF care. Participants in the UCAC group participated in one group session on nutrition education and returned demonstration of the stretching and flexibility movements. They received a printed manual and DVD that included all of the stretch and flex movements designed by the study team. The stretching and flexibility protocol had previously been piloted in persons with HF and was effective for engaging participants as a placebo condition but not strong enough to influence physical function outcomes (Gary et al., 2011).

Psycho-education group completed four consecutive weekly group sessions consisting of usual care plus the psycho-educational intervention. The goals of the psycho-educational

sessions were to provide FCGs with the recommended self-care management guidelines. In addition, the FCGs focused on communication and strategies that provided motivation, social support, coping skills, and accessing resources. A similar PE protocol had previously been tested in HF family dyads and found to be effective for improving dietary sodium outcomes (Dunbar, Clark, Deaton, Smith, De & O'Brien, 2005; Dunbar et al., 2013). Telephone calls occurred weekly for 12 weeks and then bi-monthly during the remaining 12-week maintenance period.

Psycho-education plus exercise group (PE + EX) had the same four psycho-educational sessions as previously described. In addition, participants performed the combined aerobic and resistance exercise program for 12-weeks followed by a 12-week maintenance period. Progressive low-to-moderate-intensity walking was used for the aerobic exercise component. Based on the modified Balke (Balke et al., 1959) or Bruce (Pollock et al., 1990) treadmill test, participants began their exercise regimen at 50% intensity and progressed to 70% intensity over a 4-week period for a minimum of 30 minutes 3 times per week. They received individualized home-based instruction and a demonstration of how to monitor and record HR using the Polar HR monitor, use of the 6- to 20-point Borg RPE Scale (Borg, 1982) and any symptoms experienced during the walking sessions. The same telephone follow-up schedule was utilized as described above.

Color coded Thera-cords (Hygenic Corp, Akron, OH) were used for the resistance exercise component. All participants began low resistance bands to familiarize with the exercise regimen and for safety reasons. The duration of the resistance exercise sessions was approximately 1 to 1.5 hours, depending on patient 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. Individual progression of resistance training was monitored and adjusted when the participant was able to perform 2 sets of 12 to 15 repetitions or less than 15 on the RPE scale. 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.

Exercise adherence was assessed by using step/cord calendars and pedometers. The number of daily steps walked was assessed indirectly by using the Omron HJ 112 (Omron Healthcare Bannockburn, IL), an important part of the intervention for self-monitoring. A number of studies have shown Omron pedometers to be accurate and reliable in adults and a more valid measurement than self-report questionnaires (Bravata, Smoth-Spangler, Sundaram, Gienger, Lin & Lweis, 2007). For adherence to the resistance exercise component, patients recorded Thera-cord color, exercises completed, and number of repetitions performed on the step/cord calendar. To be considered 100% adherent to the protocol, 3 documented walking sessions and 2 strength training sessions weekly were required.

Data analysis

Descriptive statistics were run for all measures prior to analysis. Baseline group differences were tested using analysis of variance (ANOVA) or chi-square tests (for proportions). To test for the effect of the intervention, a mixed methods model was used for the outcome measures testing for differences between groups, between time points and for group-by-time

effects. Post hoc tests were performed using Sidak error rate adjustment for the multiple pairwise comparisons.

Results

Baseline Characteristics. At baseline, there were no significant group differences in sociodemographic or clinical variables (Table 1). The mean age of participants was 55 ± 11 years, most were female (N=117, 92%), African American (N=74, 58%) and half were obese as indicated by a body mass index (BMI kg/m^2) ≥ 30 (N= 63; 50%). The FCGs were well educated with the majority attending college (N=89, 70%) and most were spouses (N=69, 55%), living with the care recipient in the same household (N=107, 84%). Care recipients were more often NYHA class III (N=47, 38%) followed by Class I, (N=32, 26%), Class II (N=31, 25%), and 12% were Class IV (n=15).

Study recruitment occurred over a 36-month period, and a total of 495 caregivers were screened for study eligibility. Of this number, 335 were excluded (see figure 1) for not meeting eligibility criteria (n=335) and 76 declined study participation. Common reasons for declining participation were too busy, caregiving demands or did not want to exercise. Allocation to the intervention is shown in figure 1, with 0 being lost to follow-up in the UCAC group, 7 in the PE and 15 in the PE+EX intervention. The reason for the higher drop-out rate in the PE + EX was due to 8 deaths among the care recipients compared to 4 in the PE and no deaths in UC; a total of 105 FCGs (82.7%) completed the study. Caregivers were not retained in the study after the death of a recipient.

Direct $\text{VO}_{2\text{max}}$ testing was performed in 26 participants at baseline (Table 1). Peak VO_2 was lower than age- and gender-matched reference values (Edvardsen, Scient, Hansen, Holme, Dyrstad, Anderssen, 2013). Estimated VO_2 values were obtained from ninety-five participants and compared to age-and gender-matched reference values (ACSM, 2014) and were higher than direct measures. Direct $\text{VO}_{2\text{max}}$ among female FCGs (N=24) was 22 ± 5 mL/kg/min compared to estimated values of 30 ± 8 mL/kg/min. As expected, among male FCGs (N=2) who underwent the $\text{VO}_{2\text{max}}$ direct (N=2) and estimated (N=7) both values were much higher than females at 35 ± 8 and 47 ± 18 mL/kg/min, respectively.

Six-minute walk. At baseline, FCGs walked a mean distance of 1264 feet (range 800-1890) on the 6MWT (Casanova et al., 2011). Participants in the PE + E group had the greatest improvement in 6MWT distance at 6 months with a mean increase of 72 feet ($p = 0.005$) (Table 2). Among those in the PE group, the 6MWT improved by 45 feet ($p=0.06$) and there were no differences among the UCAC group in distance walked.

Muscle strength. Women in the study had an average grip strength of 26.5 kg (range 9–54 kg) for both right and left hands. Among the 10 male caregivers, the handgrip strength was 40 kg (range 27–52). The PE+ EX group showed a greater improvement in left hand grip strength ($p=.001$) and lower extremity strength compared to the PE and UCAC groups (Table 2). No significant improvements in handgrip, upper or lower extremity strength were noted in either the PE or UCAC groups at 6 months (Table 2).

Physical activity. Only the FCGs who participated in the PE + EX intervention increased the frequency of moderate intensity activities ($p=0.024$) (Table 2). In addition, this group significantly increased the number of exercise items per week and the number of moderate intensity level activities from baseline. There were no significant improvements on any of the four CHAMPS score components for the PE or UCAC groups.

Caregiver perception. Both the PE and PE+ EX groups showed significant improvements for the Bakas caregiver scores: PE averaged 7.29 ± 13.51 points improvement ($p<.001$) and PE +EX averaged 10.96 ± 15.57 points improvement ($p<.001$) indicating they perceived their life was positively influenced by their caregiving experience (Table 2) compared to no change in perception among controls.

Caregiver strain. Most caregivers perceived their emotional strain to be higher than physical strain as shown in Table 2. The number of FCGs who perceived some emotional strain to a lot of strain ranged from 71–91% at baseline compared to 38–67% those who perceived physical strain, respectively. The PE+EX group had more participants at baseline who said they were experiencing some to a lot of emotional strain ($p=0.036$) as well as physical strain ($p=0.093$). Caregiver strain was measured at baseline only.

Adherence. In the UCAC group, 88.6% attended the group session. Nearly all PE subjects (95.5%) attended 3–4 group sessions, receiving 50% of the allocated intervention. More than three-fourths (77.1%) of the PE+EX subjects attended 3–6 sessions receiving 50% of the allocated intervention. Many FCGs did not complete the exercise logs as instructed, making adherence to the exercise program difficult to determine. Of the 33 participants who did complete the exercise logs, adherence was 80% or higher to the walking and resistance exercise regimen.

Discussion

Interventions examining physical function in FCGs are limited, especially those using objective measures. Previous caregiving studies have primarily targeted psychosocial outcomes in dementia FCGs. To our knowledge, this is one of the first interventions to evaluate physical function outcomes in FCGs and in HF caregivers. We intentionally recruited sedentary FCGs to evaluate the intervention effects of exercise and psychoeducation. Sedentary behavior is defined by engaging in 30 minutes of moderate intensity exercise for three or more times a week. Our hypothesis that the PE + EX group would have the best physical function outcomes was partially supported with greater distance walked on the 6MWT, increased handgrip and lower extremity muscle strength. Importantly, these improvements were sustained during the 3-month maintenance phase following the intervention. Maintaining endurance and strength are essential for FCGs to provide effective care. The 6MWT and strength measures are simple and safe to administer, well-validated, and require little equipment or training which makes them practical in most clinical settings (Salbach et al., 2015; Hogrel, 2015). Both measures also have minimal detectable changes (MDC), a threshold score that is associated with clinical status change and is important for interpreting level of risk for poor health outcomes (Cooper, Kuh & Hardy, 2010; Metter, Yalnot, Schrage & Conwit, 2002). As our study supports, many FCGs

had physical functioning that was well below healthy age matched normative values (ASCM, 2014). Periodic tracking of walk distance and handgrip strength by clinicians at routinely scheduled intervals may identify FCGs at greater risk for health decline and future mobility limitations earlier when they may be more amenable to intervention effects (Salbach, et al, 2015; Cesari et al., 2009; Xue, Beamer, Chaves, Guralnik & Fried, 2010).

The 6MWT and handgrip strength are highly correlated with adverse health outcomes including disability, increased hospitalizations and poorer quality of life in older adults, and includes many FCGs (Fredman et al., 2008; Ashburner et al., 2011). In the current study, there were wide ranges for both the 6MWT and strength measures indicating that some FCGs had very poor physical functioning that may have interfered with their ability to provide care. Mean total distance walked in meters during the 6MWT was lower than previously established normative values (1620 – 1873 feet) in populations aged 20 to 80 years (Enright & Sherrill, 1998; Casanova et al. 2011). Hand grip strength was also significantly lower than age- and gender-matched norms (Hogrel, 2015; Schaubert & Bohannon, 2005). Fried et al (2001) established 21-kg as the cut-off for women with a BMI >29 as one component of frailty. In the current study, many women were well below the 21-kg cut-off point and possibly at risk for frailty and other adverse health outcomes. Notably, the relatively short 12-week intervention increased endurance and strength which were sustained 3 months following the intervention. Whether improvement in six-minute walk distance and handgrip strength are associated with better health outcomes is an area for further investigation.

The reason for the better exercise outcomes in the combined group may have been the focus placed on the walking and resistance exercise in the group sessions. Approximately 30–45 minutes of the group PE + EX sessions were allotted to discussing benefits and barriers of exercise as well as individual strategies that worked to help motivate exercise within the context of caregiving tasks. In addition, walking and resistance exercise logs were reviewed by the group leader weekly and exercise was progressed based on step and band information on the log. Many FCGs reported their confidence for participating in exercise increased over time based on weekly group leader feedback and group discussion. Future interventions that include group discussion and problem solving for caregiver situations and exercise may provide a balance that FCGs find beneficial for improving both mental and physical health.

Both intervention groups perceived their caregiving experience more positively over a 6-month period with the greatest change experienced by the combined PE+EX group. In the group sessions, the FCGs exchanged both positive and negative aspects of caregiving as well as problem solving strategies that worked for them in difficult situations. Care recipient NYHA class, which reflects HF severity, was not correlated with caregiver perceptions or strain. It is unclear if other recipient characteristics may have contributed to the emotional strain the FCGs were experiencing at baseline. In other studies, FCG health has been associated with the HF care recipient experiencing worsening symptoms or mental health issues such as depression (Stromberg & Luttk, 2015; Pressler et al., 2013). We did not monitor recipient mental or physical health in the current study, but future studies should incorporate a dyadic approach that involves the FCG and recipient characteristics (Dunbar et al. 2005; 2013). This would enable change occurring in recipient health to be documented

over time and how these changes influence FCG mental and physical health. This may be particularly important with the rapid changes in health status that often occur in persons with HF. Because of the high rates of emotional distress reported in FCGs, routine evaluation using simple screening instruments may identify those with high depressive symptoms or in need of a mental health referral, particularly as the care recipient health declines or changes.

Strengths and limitations

The strengths of the study included the design, focus on physical function and the diversity of this sample of FCGs. Prior to this study, interventions had primarily targeted Caucasian FCGs of persons with dementia and none to our knowledge were designed to improve physical function outcomes. Use of a home-based approach was flexible, convenient and enabled the FCGs to engage in exercise activities as time and caregiving responsibilities permitted. The group activities were also well-attended by the FCGs and the focus on problem solving and sharing caregiving success stories were well received. An important strength was the physical function improvements that were sustained at 3-months following the intervention. The intervention outcomes would have likely been more robust if the measures had been taken immediately after the intervention and serves to better inform study design and measurement of intervention effectiveness. Adherence to the exercise program was high among the FCGs completing logs and suggests that objective methods are needed to effectively evaluate exercise dose-response. In an ongoing study, we are using an objective monitoring system, Fitabase, that enables our research team to track daily steps, HR and intensity level which has reduced participant burden, increased adherence and serves as a basis for providing ongoing weekly feedback on actual performance.

There were also several limitations which included the relatively small sample size and recruitment from a large, urban academic health sciences center which may have included care recipients who were more ill than the general HF population. Tracking the care recipient characteristics and symptom severity periodically would have provided greater insight on how change in health status influenced FCG physical function. For example, 8 care recipients died in the PE + EX group and how this may have influenced FCG outcomes was not captured. These FCGs may also have had the heaviest caregiving burden and were differentially excluded which may have biased results. Future intervention designs should consider retaining FCGs who experience death of the care recipient over the duration of the trial to better understand how this influences health outcomes.

These FCGs were younger than previously reported and may reflect different caregiver characteristics which may have influenced physical activity responses on the CHAMPS an instrument designed for older adults. In addition, while the CHAMPS does provide an estimate of self-reported physical activity level, it is not a highly accurate measure of the actual number of hours/minutes of activity performed. Participants estimate their time per physical activity item which are then summed together; any activities that overlap are not adjusted so “frequencies per week” may overestimate the actual time spent physically active. Although not statistically significant, there were more FCGs who lived with the care recipient in the PE + EX group which may have provided more time to focus on their physical activity and well-being, potentially introducing positive bias. Finally, many FCGs

were reluctant or unwilling to undergo a VO_{2max} test which changed direct measurement to an estimated THR which is less precise and reliable for exercise prescription and may have underestimated the dose required for change in physical function outcomes.

In summary, the health and well-being of FCGs is of vital importance since nearly 44 million persons in the US are providing informal care for a chronically ill adult. Approximately one-third of that number are reported to experience high caregiver burden that has been shown to have a negative impact on physical function outcomes (Adelman et al., 2014). The home-based exercise approach used in this study was easy to implement, low in participant burden and could be completed around the care recipient's needs. Using multiple types of exercise may be more beneficial to FCGs as well as the ability to tailor exercise according to participant's physical function status. The group psychoeducation sessions enabled FCGs to discuss ways to balance caregiving responsibilities and the importance of caring for their personal health.

Our study indicates that FCGs are willing to attend group sessions and exercise. Lessons learned from studies of effective psychoeducational and health promoting (exercise) interventions suggest these interventions may be effective for improving physical function and caregiver perceptions and provide important future directions for intervening with FCGs not only in HF but in other chronic conditions as well.

Acknowledgments

Supported in part by the National Institutes of Health National Institute of Nursing Research grant no. P01 1P01NR011587 (PI-E. Corwin), Advancing Translational Sciences of the National Institutes of Health under award no. UL1TR000454 (D. Stephens), and the Atlanta Veterans Administration Medical Center. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or the Veterans Administration.

This study is registered at www.clinicaltrials.gov (NCT01188070)

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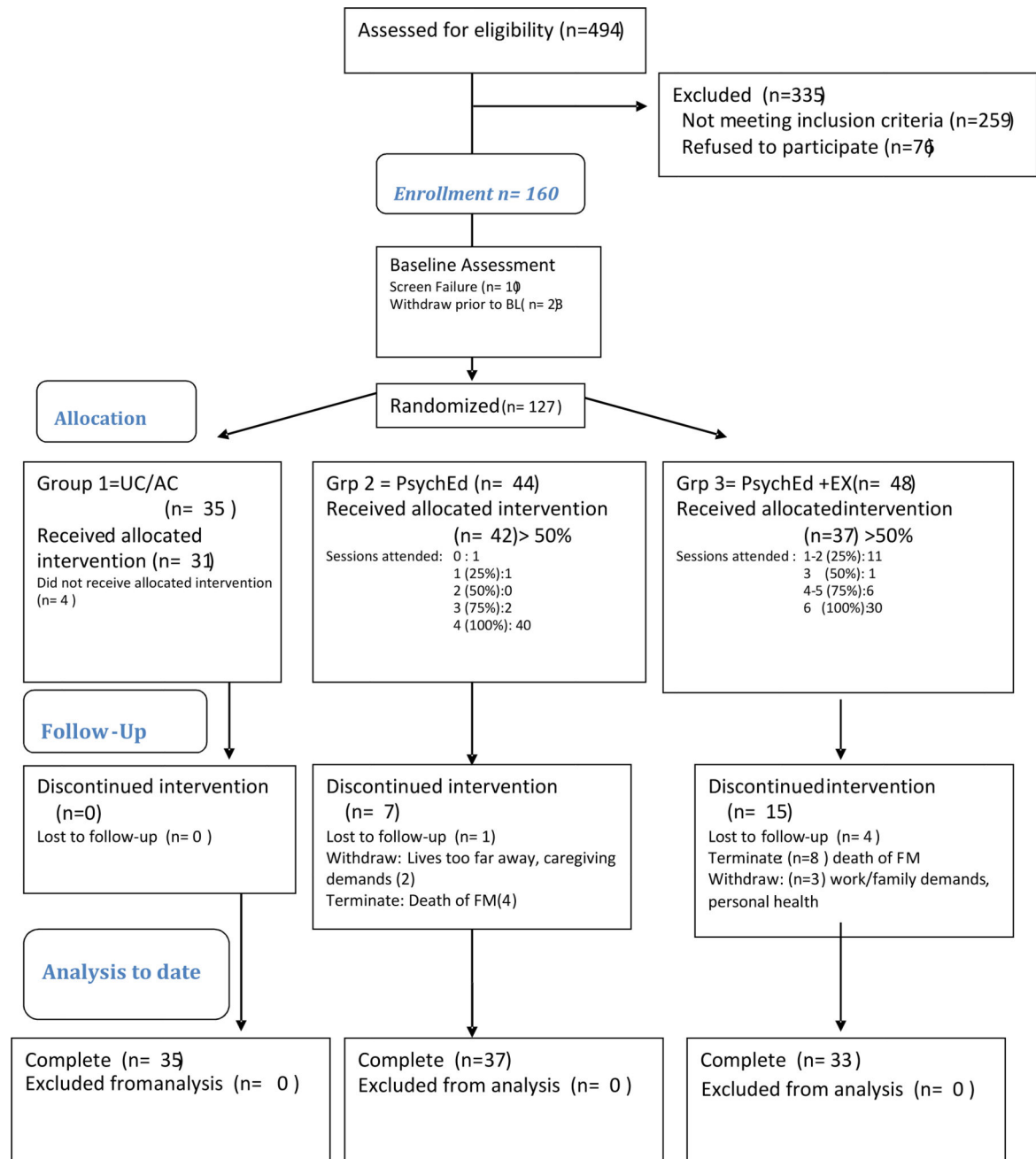


Figure 1.
CONSORT Diagram

Table 1

Baseline sociodemographic and clinical characteristics

Caregiver Characteristic	ALL N=127	UCAC N=35	PE N=44	PE + E N=48	p-value
Age (M ± SD)	55 ± 12	57 ± 14	55 ± 11	54 ± 10	.600
Gender (N, %)					
Male	10 (8)	1 (3)	3 (7)	6 (12.5)	.315*
Female	117 (92)	34 (97)	41 (93)	42 (87.5)	
Race (N, %)					
Black	74 (58)	18 (51)	25 (57)	31 (65)	.473
Relationship to HF patient (N, %)					
Spouse	69 (55)	21 (60)	22 (51)	26 (55)	.737
Live with HF patient (N, %)	107 (84)	30 (86)	39 (89)	38 (79)	.443
Educational Level (N, %)					
College/Post graduate	89 (70)	27 (77)	28 (57)	23 (28)	.424
BMI (M ± SD)	31 ± 7	30 ± 6	31 ± 7	32 ± 8	.459
NYHA Class of HF Patient (N, %)					
I	32(26)	10 (29)	8 (18)	14 (30)	.377
II	31 (25)	8 (23)	15 (34)	8 (17)	
III	47 (38)	13 (37)	18 (41)	16 (35)	
IV	15 (12)	4 (11)	3 (7)	8 (17)	
Comorbidity Index > 0 (N, %)	41 (32)	15 (43)	10 (23)	16 (33)	.161
V02 _{max} (direct) ML/kg/min	23 (4)	23 (3)	23 (5)	23 (8)	.998
V02 _{max} estimated (mL/kg/min)	31 (7)	30 (7)	30 (8)	32 (13)	.403

Table 2

Differences in physical function and caregiving perceptions from BL to 6 months.

Outcome	UCAC (N=35)	PE (N=37)	PE + E (N=33)	RM-ANOVA Effect	p-value
6MWT (feet)					
BL	1293 ± 184	1229 ± 170	1269 ± 212	Time	.001
6 Mos	1323 ± 217	1274 ± 223	1341 ± 231	Time x Group	.497
				Group	.388
Within Group	.218	.059	.005		
Time p-value					
Right handgrip (kg/force)					
BL	26 ± 5	27 ± 8	29 ± 7	Time	.011
6 Mos	27 ± 6	28 ± 8	30 ± 7	Time x Group	.937
				Group	.256
Within Group	.148	.197	.089		
Time p-value					
Left Handgrip (kg/force)					
BL	26 ± 6	26 ± 7	28 ± 7	Time	.003
6 Mos	27 ± 7	27 ± 7	31 ± 7	Time x Group	.065
				Group	.100
Within Group	.177	.712	.001		
Time p-value					
Right knee strength (kg/force)					
BL	21 ± 8	20 ± 9	24 ± 8	Time	.046
6 Mos	22 ± 6	20 ± 8	27 ± 9	Time x Group	.361
				Group	.007
Within Group	.376	.745	.029		
Time p-value					
Left knee strength (kg/force)					
BL	20 ± 9	20 ± 8	23 ± 8	Time	.016
6 Mos	22 ± 7	21 ± 8	27 ± 8	Time x Group	.590
				Time x Group	

Outcome	UCAC (N=35)	PE (N=37)	PE + E (N=33)	RM-ANOVA Effect	p-value
				Group	.013
Within Group Time p-value	.188	.457	.037		
CHAMPS frequency/week All physical activities [LN transformed]				Time Time x Group	.088 .490
BL	2.56 ± 0.59	2.68 ± 0.84	2.65 ± 0.76	Group	.491
6 Mos	2.63 ± 0.72	2.78 ± 0.70	2.91 ± 0.73		
Within Group Time p-value	.784	.437	.061		
CHAMPS frequency/week Moderate activities [LN transformed]				Time Time x Group	.086 .255
BL	1.35 ± 0.97	1.39 ± 1.13	1.55 ± 1.13	Group	.109
6 Mos	1.45 ± 1.00	1.42 ± 1.02	2.01 ± 0.94		
Within Group Time p-value	.608	.894	.024		
Bakas Caregiving outcomes				Time Time x Group	<.001 .008
BL	57 ± 17	52 ± 15	55 ± 18	Group	.266
6 Mos	57 ± 14	60 ± 15	68 ± 21		
	.639	.001	< .001		