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A PILOT TEST OF AN INTEGRATED SELF-CARE INTERVENTION FOR PERSONS WITH HEART FAILURE AND CONCOMITANT DIABETES

Sandra B. Dunbar, RN, DSN, FAAN, FAHA[a], **Brittany Butts, RN, BSN**[a], **Carolyn M. Reilly, RN, PhD, FAHA**[a], **Rebecca A. Gary, RN, PhD, FAAN, FAHA**[a], **Melinda K. Higgins, PhD**[a], **Erin P. Ferranti, RN,MPh, PhD**[a], **Steven D. Culler, PhD**[b], and **Javed Butler, MD, MPh, FACC, FAHA**[c]

[a]Emory University, Nell Hodgson Woodruff School of Nursing, Atlanta, GA

[b]Emory University, Rollins School of Public Health and Nell Hodgson Woodruff School of Nursing, Atlanta, GA

[c]Emory University, School of Medicine and Nell Hodgson Woodruff School of Nursing, Atlanta, GA

Abstract

Studies show 30-47% of persons with heart failure (HF) have concomitant diabetes mellitus (DM). Self-care for persons with both of these chronic conditions is conflicting, complex and often inadequate. This pilot study tested an integrated self-care program for its effects on HF and DM knowledge, self-care efficacy, self-care behaviors and Quality of Life (QOL). Hospitalized HF-DM participants (n=71) were randomized to usual care or intervention using a 1:2 allocation and followed at 30 and 90 days after intervention. Intervention was an integrated education and counseling program focused on HF-DM self-care. Variables included demographic and clinical data, knowledge about HF and DM, HF and DM specific self- efficacy, standard HF and DM QOL scales, and HF and DM self-care behaviors. Analysis included descriptive statistics, multilevel longitudinal models for group and time effects, post-hoc testing and effect size calculations. Sidak adjustments were used to control for Type 1 error inflation. The integrated HF-DM self-care intervention conferred effects on improved HF knowledge (30 days, p=.05), HF self-care maintenance (30 and 90 days, p<.001), self-care management (90 days, p=.05), DM self efficacy (30 days, p=.03; 90 days, p=.004), general diet (30 days, p=.05), HF physical QOL (p=.04) and emotional QOL scores (p=.05) at 90 days within the intervention group. UC also reported increased total and physical QOL. Greater percentages of participants in the intervention group improved self reported exercise between 0-30 days (p=.005 and moderate effect size ES=.47), and foot care between 0-90 days (p=.03, small ES=.36). No group differences or improvements in DM specific QOL were observed. An integrated HF-DM self-care intervention was effective in improving essential components of self-care and had sustained (90 day) effects on selected self-care behaviors. Future studies testing HF-DM integrated self-care interventions in larger samples, with longer follow-up, and on other outcomes such as hospitalization and clinical markers are warranted.

Keywords

Heart Failure; Diabetes; Intervention; Self-care

Introduction

Heart failure (HF) is a serious epidemic affecting over 5.7 million persons in the United States (Roger et al., 2012). The societal and patient burden of HF is enormous, partially due to the high rate of rehospitalizations, reported to be 30% by 90 days (Butler & Kalogeropoulos, 2012) and 45% within 6 months (Ross et al., 2010). A striking 40-60% of rehospitalizations are believed to be preventable by greater provider attention to standards of care and better patient self-care (Heart Failure Society of America, 2010). An estimated 25.6 million adults have diabetes, and the national Medicare claims reflect that the annual incidence in the U.S. increased 23% between the years of 1995 and 2004 with prevalence increasing by 62% (Centers for Disease Control and Prevention, 2011; Sloan, Bethel, Ruiz, Shea, & Feinglos, 2008). Nearly one-third to one-half of people with HF have concomitant DM (Adams et al., 2005; Greenberg et al., 2007; Masoudi & Inzucchi, 2007; Sarma et al., 2013). There is a 40% to 80% increased risk of mortality among HF patients with DM, and a reported 1.6 fold increase in the relative risk for rehospitalization over those without DM (Bobbio et al., 2003; De Groote et al., 2004; Domanski et al., 2003; Dries, Sweitzer, Drazner, Stevenson, & Gersh, 2001; From et al., 2006; Gorelik et al., 2005). This is due to both worsening HF and higher burden of other co-morbidities, such as ischemic heart disease. Therefore, patients with concomitant HF and DM represent an increasing population with greater adverse outcomes, prompting us to intervene in this high-risk group.

HF-DM patients are confronted with intense, and often conflicting, expected self-care. Self-care behaviors for HF patients include following a low sodium diet, taking HF medications, performing and interpreting daily weights, physical activity, and monitoring symptoms of dyspnea, fatigue and edema (Heart Failure Society of America, 2010). DM patients are taught to manage a diabetic diet, take DM medications, monitor blood glucose, perform daily physical activity, and monitor symptoms of hypoglycemia and foot problems (Kerr et al., 2007). HF patients with the comorbidity of DM are at greatest risk of being readmitted due to fluid overload, inadequate glycemic control and other problems that might be preventable with better self-monitoring, self-care, and problem-solving. In addition to knowledge about self-care, self-efficacy has been associated with greater self-care behaviors in HF and DM (Cha et al., 2012; Dickson, Buck, & Riegel, 2013; Wu et al., 2013). Little evidence exists to guide the integration of HF and DM patient teaching or support patients' understanding of their co-morbid self-care, such as how to follow a low sodium, diabetic diet, managing HF and DM medications and interactions, self monitoring of HF-DM symptoms, or which provider to contact for changes. The presence of HF may actually lead to less DM self-care prioritization and ability (Kerr et al., 2007; Piette & Kerr, 2006). Thus, tested processes and tools for co-morbidity self-management and care do not exist and are important to improve the quality of care and outcomes. The purpose of this pilot study (IMPROVE HF-DM) was to develop and test an integrated self-care education and counseling program for its short term effects on self-care antecedents and behaviors, and to examine the feasibility of such an integrated intervention. The hypothesis tested was that the HF-DM patients randomized to the intervention group would experience greater improvements in HF and DM specific knowledge, self-care efficacy, self-care behaviors and QOL.

Methods

Theoretical Framework

This study was designed around an integrated theoretical framework developed to guide HF self-care studies (Dunbar, Clark, Quinn, Gary, & Kaslow, 2008). The framework synthesizes concepts from patient self management theories and adult patient education concepts for learning and retention. The theoretical relationships of the variables are organized around antecedents and outcomes of self-care behaviors. Antecedents are individual and family factors and include sociodemographic, clinical, knowledge and skills, and behavioral factors. Within behavioral factors, self efficacy is noted as a powerful indicator of self-care performance and predictor of heart failure hospitalization (Riegel, Lee, Albert, Lennie, Chung, Song, Bentley, Heo, Worrall-Carter, Moser, 2011; Sarkar, Ali, Whooley, 2009). The interventions designed for this study targeted the selected antecedents of self-care behaviors of knowledge and self-efficacy through an integrated comorbidity self-care education and counseling intervention. Short term reinforcement, follow up and support were also designed to foster HF and DM knowledge and self efficacy. The framework suggests that improved self-care and simultaneous adherence to multiple self-care behaviors leads to improved outcomes in terms of health status and quality of life and lower resource utilization (Dunbar, Clark, Quinn, Gary, & Kaslow, 2008; Marti, Georgiopoulou, Giamouzis, Cole, Deka, Tang, Dunbar, Smith, Kalogeropoulos, Butler, 2013). We examined the primary effects of the intervention by indicators of HF and DM specific knowledge, self-efficacy, self-care or self-management behaviors and perceived QOL. The intervention also incorporated the chronic care model’s concepts of self-management support (patient education) and systems design (follow up care) (Wagner, 1998).

Design, Setting and Sample

Participants were recruited during an inpatient HF exacerbation at one of three participating hospitals. All were large tertiary care facilities with HF outpatient clinics. Inclusion criteria and exclusion criteria are presented in Table 1. Research nurses screened patients for eligibility through chart reviews, patient interviews, and assessments of depressive symptoms (Patient Health Questionnaire, PHQ-9) (Kroenke et al., 2001). HF-DM patients who were experiencing their first hospitalization for either disease were also excluded. All study procedures were approved by the Institutional Review Board of Emory University and each participating institution, and all participants provided written informed consent.

Demographic and clinical variables were collected from each patient and the medical record, and consisted of age, gender, marital status, education, ethnicity, left ventricular ejection fraction (LVEF), NYHA classification, body mass index (BMI), perceived health rating, and discharge medications. These variables, considered antecedent factors influencing self-care, were used to fully describe the sample and to compare treatment groups.

Participants were randomized into the study groups of usual care (UC) or usual care plus intervention (I). The randomization procedure was generated using a random sorting algorithm with a maximum allowable deviation of 10% (PASS 2008, NCSS LLC, Kaysville, Utah) for a final ratio of 1 UC to 2 Intervention. This allowed for greater efficiency in testing the intervention in a larger sample than if a 1:1 randomization had been used. Data were collected at baseline and at 30 and 90 days after the intervention. The time frames were selected for their importance to usual follow up care and to improve clinical feasibility and relevance of the study. Additionally, measurement of variables were timed to coincide with the expected intervention effects. All variables were measured at baseline, and Ouality of Life was measured again at 90 days as an overall outcome; the interim measurement point of 30 days was used for tracking short term change closer to the intervention for those variables targeted by the intervention - knowledge, self efficacy, and self-care behaviors and the 90 day measurement point was to examine for sustained change.

Variables and Instruments

Knowledge—The Atlanta HF Knowledge Test (AHFKT) was used to measure HF self-care knowledge (Reilly et al., 2009). The thirty item multiple-choice instrument was developed to measure aspects of heart failure understanding, medications, dietary sodium, fluid restriction and symptom recognition. Reliability was demonstrated in a study of HF patients by Cronbach's alpha of .84 (Reilly et al., 2009), and this same study demonstrated construct validity. Knowledge of diabetes was tested by the Michigan Diabetes Knowledge Test (MDKT), which consists of a 14-item measurement of general diabetes knowledge. The test has adequate reported reliability, with a Cronbach's alpha of .71 (Fitzgerald et al., 1998). Both measures are scored according to the percent of questions answered correctly.

Self-Efficacy—The self-care confidence scale of the Self-Care in Heart Failure Index Version 6.2 (SCHFI) (Riegel, Carlson, Moser, et al, 2004; Riegel, Lee, Dickson, Carlson, 2009) was used to assess self-efficacy in heart failure and is comprised of six items reflecting confidence in recognizing symptoms and taking HF actions. The responses range from 1="Not Confident" to 4="Extremely Confident", and higher scores indicate more confidence in managing HF (Riegel et al., 2004). Internal reliability consistency is acceptable for the scale (alpha= .82), (Riegel et al., 2009). The Perceived Diabetes Self-Management Scale (PDSMS) is an eight-item instrument designed to test diabetes self-efficacy. The responses for the PDSMS items range from 1="Strongly Disagree" to 5="Strongly Agree". The total score can range from 8 to 40, with higher scores indicating more confidence in managing diabetes; an acceptable Cronbach's alpha was reported at .83 (Wallston, Rothman, & Cherrington, 2007).

Self-care Behaviors—Two scales of the SCHFI V6.2 (self-care maintenance, Cronbach's alpha = .60 and self-care management, Cronbach's alpha= .70) were used to assess self-care in heart failure. The self-care maintenance scale is comprised of 10 items that examine the frequency of performance of adherence and symptom monitoring behaviors and include activities such as daily weighing, following a low sodium diet, performing physical activity, and taking medications. The responses range from 1="Never or Rarely" to 4="Always or Daily". The alpha in the self-care maintenance scale is acceptable in that the scale reflects disparate activities. The self-care management scale assesses the HF patient's ability to recognize and respond appropriately to symptoms, including interpreting symptoms and contacting the provider, and the 6 items are scored only if symptoms are reported. Higher scores on all SCHFI scales reflect higher self-care within the domain of the scale. (Riegel et al., 2004, 2009) The Summary of Diabetes Self-Care Activities (SDSCA) scale has a core set of 11 items used to assess 5 diabetes self-management behaviors of diet, exercise, smoking, foot checks, and blood glucose testing. A series of seven studies (Toobert, Hampson, & Glasgow, 2000) has demonstrated adequate internal (.70) and retest reliability, with sensitivity to change. Patients report how many days in the previous week they have engaged in a certain activity, and scores are calculated for each of the 5 areas.

Quality of Life—The Minnesota Living with Heart Failure Questionnaire (MLHFQ) has 21-items which are rated on the extent to which various physical and emotional symptoms of HF have prevented them from living as they wanted in the past month (Rector et al., 1995). High scores indicate poorer quality of life. Total, physical and emotional subscale scores can be determined. Construct, convergent and discriminant validity of the MLHFQ has been established, with Cronbach's alpha of .94 for the total scale and test-retest reliability was high after a 7- to 21-day period (weighted kappa reliability coefficients .84)

(Bennet et al., 2002; Rector et al., 1995). A 5-point change on the total score demonstrates a clinically significant difference as validated by Middel et al. (2001) against the Hospital and Anxiety Depression Scale (HADS) and the Short Form Health Survey (SF-36). For DM specific QOL, the ADDQoL was used which consists of 19 items that measure physical functioning, symptoms, psychological well-being, social well-being, role activities, and personal constructs (Wee, Tan, Goh, & Li, 2006; Woodcock et al., 2004); it has been found to be sensitive to the changes in DM treatment and complications of diabetes (Bradley & Speight, 2002; Speight & Bradley, 2000). A 5-point scale measures the impact of diabetes by asking patients how particular aspects of their life would be if they did not have diabetes. The importance of these aspects on their life is rated on a 4-point scale. The two ratings are multiplied and summed for a final impact score that ranges from −9 to +9, where more negative scores indicate more negative impact of diabetes (Sundaram et al., 2007; Wee et al., 2006). Strong reliability (Cronbach's alpha=0.94) and validity have been reported (Wee et al., 2006).

Intervention and procedures

After consenting to participate, a packet of questionnaires was completed with assistance by the research nurse. Participants received usual care or usual care plus the integrated intervention involving HF-DM education and self-management support. Usual Care was provided by the participants' HF and DM health care providers, and two brochures, one each on overall HF (Heart Failure Society of America) and DM (American Diabetic Association) self-care, were given to the participants to assure equivalent access to information across enrolling sites. The I group received usual care from their providers and the same brochures, plus an educational and self-management intervention delivered initially by research nurses trained and retrained periodically to meet criteria reflecting their ability to deliver the protocol equivalently. Two 30-45 minute individual education/counseling sessions prior to discharge from the hospital were provided at the patient's bedside. The intervention was developed to address the themes of self-care dilemmas identified through prior focus groups with HF-DM patients, and the intervention approach as well as materials were reviewed by experts and HF-DM patients, and refined. The intervention nurse uses a flip chart and a script for the educational session with the purpose of increasing knowledge and skills related to diet, medication taking, symptom monitoring, physical activity, and recognition of the interaction between self-management strategies for HF and DM. Participants were given an intervention resource notebook (Healthy Living with Heart Failure and Diabetes) developed for this project with all presented information in written form and additional materials to which they could refer in the home setting. These included integrated dietary sodium, fat, and carbohydrate content charts of common foods and fast foods, quick nutritional reference guides for appropriate snacks, restaurant dining tips, sample meal plans appropriate for low sodium and low carbohydrate goals, recipes, tailored medication informational sheets, an integrated monitoring diary/log for recording daily weight, HF-DM symptom and symptom management information, and schedules for medications, foot and eye care. Smoking cessation referrals were made for those who reported smoking or tobacco use. All materials were printed in large type and prepared at a 4th grade reading level with ample graphics and attention to culturally and regionally relevant information, particularly in dietary information. The discharge education intervention incorporated the individual patient's medication and follow up care reconciliation.

Additional follow-up education and counseling for integrated self-care was provided with a 15 minute telephone call at approximately 48-72 hours after discharge during which verification of the medication regimen, filling of prescriptions, and daily self monitoring were emphasized. During a clinic visit 2-4 weeks after discharge, the research nurse assessed for difficulty in performing self-care behaviors of diet, physical activity, symptom and self monitoring, and provided reinforcing information and guidance, once again guided by a protocol and script. For intervention fidelity monitoring, research nurses performing the intervention recorded their activities at baseline, telephone calls and follow up visits, to document subjects' receipt of the notebooks, time required for the intervention, and to document specific questions or issues raised by the participant. Participants completed a brief intervention evaluation form at the end of their participation in the study.

Around 30 and 90 days following the enrollment date, the participants were mailed the same questionnaire packet as completed at baseline and were provided with a stamped return addressed envelope. The exception was that QOL was only measured at baseline and 90 days. The research nurse met the participants on their return follow-up visit to the HF clinic at the study time frames if assistance was needed to collect or complete the packet.

Data Analysis

All data were reviewed for data entry errors, potential outliers, missing data as well as any differences between groups on demographic and clinical variables using t-test and chi-square tests. Fewer participants in the UC group were African American (AA) (41.2%) compared to the I Group (68.2%, p=.05) (Table 2). Thus race was included as a covariate in the models. Distributions were also assessed for deviations from normality. No differences were noted in missing data between groups over time. However, due to a minor amount of intermittent missing items in the MLWHF (5 items of less) substitutions were made using the average response across items within a given subscale within each individual with missing items. SCHFI exercise, blood glucose and foot care were significantly skewed and were dichotomized (SCHFI exercise = 0 versus >0; SCHFI Blood Glucose and Foot care <7 versus =7). Multilevel mixed (MLM) longitudinal models (SPSS Statistics, version 20, copyright IBM Corporation, 2011 [SPSS v.20] MIXED) were used for testing group, time and group-by-time effects after adjusting for covariates for outcomes measured at all 3 time points (AHFKT, MDKT, three SCHFI scales, PDSMS, SDSCA General and Specific Diet). In addition to age, NYHA class, gender, education, ejection fraction, and BMI were also considered as potential covariates. Only those with p<.05 were included as covariates in the models. For the dichotomized SDSCA exercise, blood glucose and foot care scales, multilevel mixed longitudinal models for a binomial response function with a logit link function (e.g. logistic regression) was used (SPSS v.20 GENLINMIXED) to test for time effect after adjusting for age within each group and included planned contrasts for time using baseline as the reference. Repeated measures analysis of covariance (RM-ANCOVA) (SPSS v.20 GLM) was used for the quality of life outcomes measured at only 2 time points (baseline and 90 days for MLWHF total, physical and emotional scores and ADDQOL) after adjusting for age. All planned post hoc pairwise tests were performed using Sidak alpha adjustment, which is slightly more powerful than Bonferroni (DeMuth, 2006). All effect sizes (ES) for significant post hoc comparisons are noted throughout and were calculated as the ratio of the mean difference divided by the standard deviation which is Cohen's d (d=0.30 is considered a small ES, d=0.5 a moderate ES and d=0.8 a large ES), and for the multiliel logistic regression models, Cohen's d was calculated as a function of the test statistic for the corresponding effect's test (Cohen, 1988). To test the internal consistency reliability of the instruments in this sample, Cronbach's alpha was determined and is reported in the relevant table describing results for the appropriate instrument. The Cronbach's alpha before and after substitutions for MLWHF were the same on this instrument (reported in Table 9).

Results

A total of 540 individuals were assessed for eligibility, and 65 participants were enrolled, with 19 individuals allocated to the UC group with 16 completing baseline and 46 allocated to I group with 44 completing baseline (Figure 1). Of the 475 excluded from the study, 110 people declined to participate, and 365 did not meet inclusion criteria or were not enrolled for reasons such as living too far from the research center. Those declining to participate gave reasons of feeling too uncertain about their future, too busy, feeling too sick, and in rare cases, already knowing the information. Throughout the course of the study, six individuals were lost to follow-up, nine participants withdrew, and two participants were lost due to death for an overall 25% attrition rate (16/65) (37% for UC (7/19) and 20% (9/46) for I, no significant differences by group: $X^2_{(1)}=2.19$, p=.14).

In spite of the randomization procedures, comparison of the demographic and clinical variables of the UC and I groups (Table 2) revealed a significant group difference in the proportion of African Americans with the I group having a greater percentage than the UC group. There were more men and a lower education level in participants from one clinical site, however this did not affect randomized group composition. There was also a borderline but not significant group difference in age (UC slightly older than I) and ejection fraction (LVEF) with participants in UC having slightly lower values than I. There were no group differences in any other variables.

The mean age of participants was 59.7 years old, and while the majority were male, the characteristics reveal good representation overall of women (32.8%) and African Americans (60.7%). Forty-six percent were married with most were fairly well educated with around a third having a high school or less level of education. The majority were NYHA class III with mean LVEF of 32.7%. The overall body mass index was in the obese range (mean 37), and 44.8% considered their health to be poor. Regarding their DM status and glycemic control, all were Type II on oral agents as specified in the inclusion criteria, and the average HgA1c level was 8.1%. The onset of DM preceded the onset of HF in 64.9% of participants by a mean of 5.8 ± 8.9 years.

Knowledge

On average, HF knowledge was 78% or higher for both groups baseline (Table 3). Race and education were found to be significant or near significant covariates for assessment of knowledge on both tests (AHFKT race p=0.035, education p=.06); MDKT race p=0.001, education p=.002) where AA scored significantly lower than White participants, and participants with higher formal education had higher HF or DM knowledge scores. For the I group, AHFKT scores improved on average by 4.3 percentage points from baseline to 30 days (Table 4, p=.05, small ES=0.38), although this improvement was mostly lost by 90 days (Figure 2). Diabetes knowledge scores averaged 58% or higher and tended to be lower than HF knowledge scores overall (Table 3). The MLM longitudinal model for diabetes knowledge did not result in significant change (Table 4). Cronbach's alpha obtained n this study for both instruments were acceptable as noted in Table 3.

Self-Efficacy

The SCHFI-Confidence scores were not significantly different between the groups at baseline (Table 5). After adjusting for race (which was a significant covariate, p=.03, with lower scores obtained in AA versus White participants), no effects (group, time, group x time) were significant for SCHFI confidence scores (Table 6). Age (p=.01) and LVEF (p<.001) were significant covariates for the PDSMS score where older participants and those with lower LVEF had higher PDSMS scores. For both groups, PDSMS scores increased from baseline with a significant time effect (p<.001) in the MLM longitudinal model after adjusting for age, LVEF, and race (Table 6). Post hoc tests revealed significant PDSMS improvements from baseline to 30 days for the I group (p=.03, small to moderate ES=0.42) and from baseline to 90 days for both UC (p=.05, large ES=0.73) and I (p=.004, moderate to large ES=0.61).

Self-Care Behaviors

Self-care maintenance and management scores were not significantly different between the groups at baseline (Table 7). After adjusting for race and education, the time effect for SCHFI-Maintenance was significant (p<.001, Table 8) with significant improvements in the I group from baseline to 30 days (p<.001, very large ES=1.08) and from baseline to 90 days (p<.001, large ES=0.93). Usual Care group also showed a increase from baseline to 30 days but this was not sustained at 90 days. Self-care management scores were calculated only on a subset of participants who answered yes to item 11 "In the past month, have you had trouble breathing or ankle swelling?" After adjusting for race and LVEF, there was a significant improvement in SCHFI-Management scores for the I group from baseline to 90 days (p=.05, moderate ES=0.56) (Table 8).

The SDSCA-General and -Specific Diet scores were very similar between usual care and intervention groups at baseline (Table 7). After adjusting for race, there were significant *increases* in SDSCA-General Diet scores for the I group from baseline to 30 days (p=.05, small to moderate ES =.39) and significant *decreases* for UC from 30 to 90 days (p=.05). Group, time, or group x time effects were not significant for SDSCA Specific Diet scores after adjusting for race (Table 8).

The dichotomized SDSCA-Exercise scores split participants into those that scored 0 versus >0, and generalized MLM longitudinal models were run for a binomial response function with a logit link function (e.g. logistic regression) to test the group, time, and group x time effects after adjusting for race (Table 8). Sixty-four percent of UC group had SDSCA-Exercise scores >0 at baseline which increased to 75% at 30 days and 77% at 90 days, however these changes were not significant (Table 8). Fifty-five percent of I group had SDSCA- Exercise scores >0 at baseline which was not significantly different from UC at baseline. However, by 30 days 85% of the I group had SDSCA-Exercise scores >0 (p=.005, moderate ES=.0.47, Table 8) and 76% trended toward still having scores >0 at 90 days (p=. 06). For SDSCA-Blood Glucose, fewer usual care participants (46.7%) had scores =7 at baseline than intervention participants (62.8%) but this was not significant. For UC, by 30 days, 75% had SDSCA-Blood Glucose scores =7 but this dropped back to 46.2% by 90 days. For I group, SDSCA-Blood Glucose scores =7 dropped slightly from 62.8% at baseline to 53.8% at 30 days and 51.5% at 90 days. However, these changes were not significant over time after adjusting for race (Table 8). Both UC and I had only about one-third of the participants with SDSCA-Foot Care scores =7 at baseline. Although both groups increased the percentage of participants with SDSCA-Foot Care scores =7 by 90 days, the change in UC was not significant whereas I increased to 43.6% at 30 days and 63.6% at 90 days (p=.03, small ES=0.36) after adjusting for race (Table 8).

The SDSCA has a self-report measure of smoking, and a yes to whether they have smoked any cigarettes in the past 7 days prompts for a report of how many cigarettes they smoke on an average day. At baseline, three participants acknowledged smoking in the past week, with all smoking three cigarettes per day. All were in the I group, and all subsequently answered no to this question at 30 and 90 days. There were too few participants who smoked to track the effect on this behavior, however the self-report data revealed some positive trends.

Quality of Life

Descriptive statistics for HF failure QOL (MLWHF total, physical and emotional subscales) and diabetes QOL (ADDQOL) at the baseline and 90-day time points for both groups are provided in Table 9. Acceptable Cronbach's alphas were obtained as reported in Table 9. Significant improvements from baseline were seen for overall heart failure quality of life (MLWHF total) for both UC (p=.03, large ES=0.69) and I (p=.001, moderate to large ES=0.65) after adjusting for race and age (Table 10). This improvement was also seen for both the I group for the MLWHF physical subscale (p=.01, ES=0.47) and UC group (p=.01, ES=.77) after adjusting for race. There was a small improvement in MLWHF Emotional subscale scores the I group (p=.05, small ES = .35). No significant changes were seen for ADDQOL scores after adjusting for race.

Participants in the intervention group rated the intervention as very positive overall, and expressed that they had not received integrated information in prior patient education sessions. In particular, information viewed as new and useful related to the integrated diet, role of exercise in improving outcomes in both HF and DM, impact of ankle edema from HF on diabetic feet and importance of foot care, and how to interpret overall symptoms of HF and DM and their interaction.

Discussion and Conclusions

The data revealed that the integrated HF-DM self-care intervention conferred effects on HF knowledge at 30 days, improved HF self-care maintenance at 30 days and sustained to 90 days, improved self-care management at 90 days, improved DM but not HF self efficacy at 30 and 90 days, improved self-reported general diet and exercise at 30 days, and improved foot care by 90 days. These results indicate that important self-care antecedents of knowledge and self-efficacy as well as actual self-care behaviors are modifiable in this HF-DM population with intervention, and the change in self-care management reflects the important ability to take action upon detection of HF symptoms. It also suggests that an integrated co-morbidity approach to self-care education such as focusing on behaviors important to both conditions such as exercise, diet and foot care may be effective. Specific DM diet behavior was moderately high at baseline and may have required longer or a larger sample to affect a change. Although within the intervention group, an improvement in physical and small improvement in emotional HF QOL were observed, the UC group also improved overall and physical QOL, and no overall between group differences in overall HF or DM specific QOL were observed. This may be due to the attention received from being in a study or that more time is needed to observe the impact of improved self-care on symptoms and perceived QOL. Importantly, the trend for increased perceived physical QOl in the intervention group corresponds with the trend for increased self-reported exercise for that group.

As with other studies (Mercier, Âeladeau, & Tempier, 1998; Netuveli & Blane, 2008), older participants reported better QOL as measured by the MLWHF scale at each time point. At baseline, participants in both groups reported overall poor perceived quality of life related to both HF and DM, thus any improvement was deemed important. Because groups were different in race, it was included in the models but was not significant in comparing group change on QOL.

Participants demonstrated moderate self-care knowledge. Although the onset of DM preceded HF in most participants, both UC and I groups performed better on the assessment of HF knowledge (AHFKT) than on the assessment of DM knowledge (MDKT). All participants in this study were recruited from a HF exacerbation requiring a hospital stay. Thus, HF education should have been occurring for both groups during the hospital stay whereas DM education may have occurred in the more distant past. Regardless, the study reflects the need to develop strategies for retention of knowledge concerning both conditions. The integrated comorbidity HF-DM intervention was useful for improving HF knowledge, and while knowledge alone is not sufficient for behavior change, it is an imperative factor for self-care (Clark, AM, et al 2009). We only measured HF- and DM-specific knowledge, and the acquisition of integrated HF-DM knowledge and clinically meaningful change would be important for future studies.

The SCHFI-Confidence scale and the PDSMS reflected low to moderate levels of both HF and DM self-efficacy. HF self-efficacy was not improved through the intervention which was surprising and may reflect the impact of confronting lack of knowledge with HF self-care. African American participants did report lower HF and DM self-efficacy than White participants which has implications for design of culturally relevant self-care interventions. Although the intervention group improved DM self-efficacy at 30 and was sustained to 90 days as reflected by changes on the PSMDS, an increase was also observed in the UC group. This may have been due to unknown changes in clinical practice or the fact that the study refocused attention on their DM care since most had had DM for a longer period. The relationship of age to DM self-efficacy but not to HF self-efficacy scores possibly reflects the longer time living with DM versus HF in this sample.

Improving self-care behaviors, even at a modest level has the potential to improve important outcomes in HF and DM. The intervention increased overall HF self-care maintenance activities at the early (30 days) and sustained (90 days) time points, and improved symptoms interpretation and self-care by 90 days. Additionally the intervention improved self-reported exercise across time, efforts to improve general diet, and improved foot care. The addition of the reinforcing education and counseling after discharge from the hospital and in the early follow up visit were important to sustaining the change. Importantly, at baseline, both groups demonstrated low to moderate HF and DM self-care activities with some reporting zero days of participation in exercise or glucose monitoring. There is an opportunity to make a difference in this population through continued development and strengthening of the integrated self-care intervention

The study has several limitations, including the small sample size, numerous analyses, and the total attrition rate which was 25%. Attrition rates were consistent with other separate HF and DM studies reported to be 20-28% and 20-33%, respectively (E.Stull & Houghton, 2013; Heisler et al., 2013; Tang, Funnell, Noorulla, Oh, & Brown, 2012). Retention in longitudinal behavior change studies with patients who have HF alone, and HF complicated by a comorbidity is challenging, and although all efforts were exerted to make participation convenient for participants, retention was lower than desired due to progression of HF severity and death. Of the 534 individuals assessed for eligibility, a large portion were excluded primarily for not meeting inclusion criteria for the study (other comorbitidies, age outside the specified range, inadequate renal function, and presence of a neurological or psychological diagnosis preventing participation). Some were also excluded due to living too distant from the enrolling center to return for follow-up, thus the sample may represent a more urban population. The criteria were selected to reduce confounding with the study variables, however, this rigor excluded a large portion of the overall HF-DM population such as those with more severe renal problems. Nevertheless, the sample size was adequate to identify important trends and effect sizes which will be essential to inform future studies. While the sample size of usual care was small, the combined results from the three time points increased the apparent sample size for most models, and allowed calculation of effect sizes as noted throughout. Additionally the sample was diverse which increases the generalizability.

The intervention materials were prepared at a level below the standard 6th grade level used in low health literacy studies (Baker et al, 2011; Rothman et al., 2004), and around one third of participants reported a high school education or less. Education was found to be a significant covariate for assessment of knowledge on both tests, with the higher the formal education, the higher the HF or DM knowledge score. Studies have shown that patients who demonstrate low health literacy are less likely to have a high school education, however substituting education level for health literacy has proven to be an insufficient measure. In fact, health literacy is associated with adverse outcomes, independent of level of education (Peterson et al., 2011). In older individuals, education level does not account for lifelong learning or age-related declines in reading ability (Baker et al., 2007). In persons with heart failure, memory and learning deficits often arise due to decreased cerebral flow. Moreover, 27% - 54% of patients with heart failure have low health literacy (Evangelista et al., 2010). It is likely that low health literacy among some participants affected both HF and DM knowledge. Attention to health literacy in future studies of educational interventions for those with HF and DM is warranted. As more internet and media based formats are developed and made available, it is likely that future studies might test different methods of delivering this integrated co-morbidity patient education at varying health literacy levels.

This pilot study provided insight into the many issues of recruitment, retention as well as positive trends data on the intervention effect, and effect sizes for determining appropriate samples for future work. This study reveals the potential to be gained from teaching integrated self-care in this population with multiple chronic conditions, and with further study, the intervention could be adapted to other patient populations with intensive recommended self-care such as persons with HF and concomitant chronic obstructive pulmonary disease or renal dysfunction. With the current changes in Medicare reimbursement rates for readmissions and with HF having the highest readmission rate, this small nurse-led intervention could be a great benefit to patients. Considering the current health care environment, and the growing numbers of people with both HF and DM, this intervention could be quite translatable into current practice. More research is needed to fine tune the approach to providing integrated comorbidity self-care patient education. Future studies testing HF-DM integrated self-care interventions in larger samples, with longer follow-up, and on other outcomes such as hospitalization and clinical status, are warranted.

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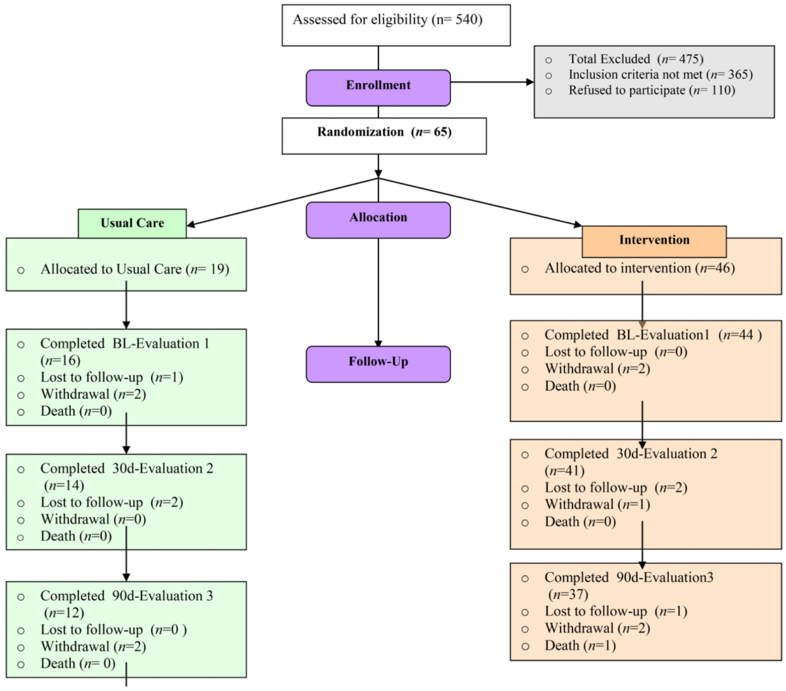

Figure 1.
IMPROVE HF-DM Consort Chart. BL, baseline.

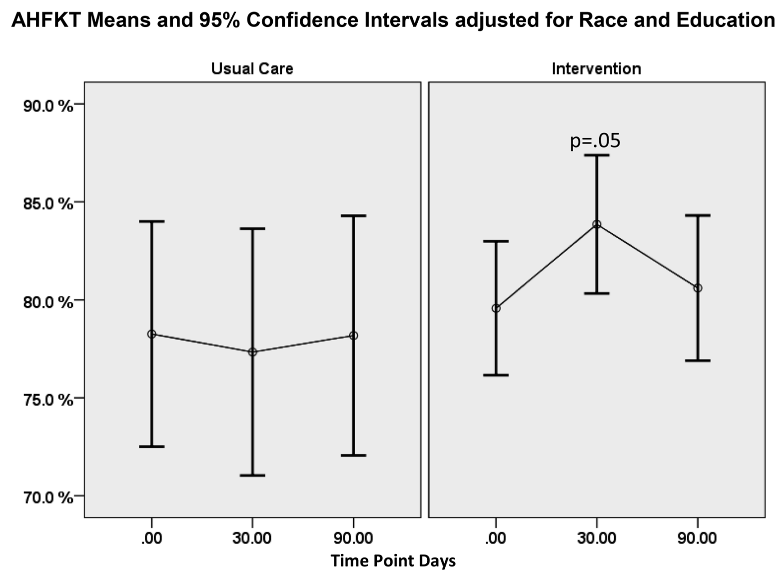

Figure 2.
AHFKT Test Means and 95% Confidence Intervals Adjusted for Race and Education.

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Table 1

Participant inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
• Admitting diagnosis of HF with LVSD	• Hemodynamically significant angina pectoris
• Concomitant DM Type II treated with oral agents	• Renal failure
• Aged 21-80 years	• HF secondary to untreated medical condition
• Planned discharge from hospital to home setting	• Planned cardiac surgery
• English fluency	• Impaired cognition due to neurological comorbidity
• Without cognitive impairment	• Psychiatric diagnosis
	• Uncorrected visual or hearing problem
	• Insulin therapy
	• Depressive symptoms (PHQ-9 > 10)
	• Evaluation for transplant or ventricular assist device

LVSD, Left Ventricular Systolic Dysfunction

Table 2

Demographic and Clinical Variables

	All (n=61)	Usual Care (n=17)	Intervention (n=44)	Group Differences (p-value)
Age years (mean (SD))	59.7 (10.6)	63.8 (9.5)	58.2 (10.7)	.064*
Gender (% male)	67.2 %	70.6 %	65.9 %	.727**
Race (% AA)	60.7 %	41.2 %	68.2 %	.053**
Married (% married)	45.9 %	29.4 %	52.3 %	.108**
Education (% hs or less)	36.7 %	29.4%	39.5%	.463**
NYHA Class II (%)	31.7 %	17.6 %	37.2 %	.319**
Class III (%)	56.7 %	70.6 %	51.2 %	
Class IV (%)	11.7 %	11.8 %	11.6 %	
LVEF % (mean (SD))	32.7 (14.9)	29.1 (12.3)	34.1 (15.8)	.394[c]
BMI (mean (SD))	37.0 (8.8)	36.2 (9.6)	37.3 (8.5)	.688*
Health rating (% poor)	44.8 %	46.7 %	44.2 %	.868**
HgA1c (mean (SD))	8.1 (1.8)	8.3 (2.1)	8.0 (1.7)	.581[c]
Prior MI (% yes)	53.3 %	50.0 %	54.5 %	.755**
PVD (% yes)	11.9 %	11.8 %	11.9 %	1.00[d]
Renal Disease (% yes)	31.1 %	29.4 %	31.8 %	.856**

Abbreviations: SD, Standard Deviation; AA, African American; HS, High School; NYHA, New York Heart Association; LVEF, Left Ventricular Ejection Fraction; BM, Body Mass Index; MI, Myocardial Infarction; PVD, Peripheral Vascular Disease.

*Student's t-test

**Chi-square test

[c]Mann Whitney test

[d]Fisher's Exact Test (2-sided)

Table 3

Knowledge of HF and Diabetes (Unadjusted Means and SDs)

Measure	Baseline		30d		90d	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
AHFKT (Cα=0.83)	60	78.8 (12.0)	52	81.5 (13.4)	48	79.0 (14.7)
Usual Care	16	81.0 (12.9)	12	80.8 (8.9)	13	81.0 (15.1)
Intervention	44	78.0 (11.6)	40	81.7 (14.6)	35	78.2 (14.7)
MDKT (Cα=0.74)	60	58.6 (19.9)	51	59.7 (16.5)	48	61.1 (18.9)
Usual Care	16	64.6 (20.9)	12	62.8 (16.7)	13	69.2 (16.2)
Intervention	44	56.4 (19.4)	39	58.8 (16.5)	35	58.1 (19.1)

Abbreviations: AHFKT, Atlanta Heart Failure Knowledge Test; MDKT, Michigan Diabetes Knowledge Test; SD, standard deviation; Cα, Cronbach’s alpha reliability.

Table 4

Multilevel Longitudinal Models and Planned Contrast Tests for Knowledge

Outcome Measure Model Effect	F(df1,df2)	p-value	Planned Pairwise Post Hoc Contrasts (Sidak adjusted p-value < .10)
AHFKT			
Race	F(1,54.954)=8.939	.004	
Education	F(1,55.420)=3.711	.06	
Group	F(1,55.704)=1.383	.25	
Time	F(2,100.648)=0.448	.64	
Group-x-Time	F(2,100.629)=1.108	.33	
Time within Usual Care	F(2,101.068)=0.050	.95	
Time within Intervention	F(2,99.195)=3.077	.05	BL – 30 days (p=.05) Δ=4.28 (SD 11.13) ES 0.38
MDKT			
Race	F(1,56.217)=12.575	.001	
Education	F(1,56.406)=10.276	.002	
Group	F(1,56.622)=0.024	.88	
Time	F(2,101.715)=1.037	.36	
Group-x-Time	F(2,101.732)=0.603	.55	
Time within Usual Care	F(2,102.119)=1.026	.36	
Time within Intervention	F(2,100.356)=0.240	.79	

Abbreviations: BL baseline; Δ, mean difference; SD; standard deviation; ES, effect size

Table 5

Heart Failure and Diabetes Self-Efficacy (Unadjusted Means and SDs)

Measure	Baseline		30 Days		90 Days	
	n	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
SCHFI–Confidence (Cα=0.85)	56	70.5 (19.9)	48	75.4 (17.1)	45	75.2 (16.5)
Usual Care	16	67.8 (19.2)	11	73.3 (16.5)	13	71.9 (20.5)
Intervention	40	71.6 (20.3)	37	76.0 (17.5)	32	76.6 (14.7)
PDSMS (Cα=0.77)	54	27.3 (6.2)	50	29.8 (5.5)	42	31.5 (5.7)
Usual Care	12	27.4 (5.9)	12	31.0 (5.9)	11	32.7 (4.7)
Intervention	42	27.2 (6.3)	38	29.4 (5.4)	31	31.0 (5.9)

Abbreviations: SD, standard deviation; Cα, Cronbach's alpha reliability

Table 6

Multilevel Longitudinal Models and Planned Contrast Tests for Self-Efficacy

Outcome Measure (Model Effect)	F(df1,df2)	p-value	Planned Pairwise Post Hoc Contrasts (Sidak adjusted p-value < .10)
SCHFI – confidence			
Race	F(1,57.297)=5.261	.03	
Group	F(1,58.169)=1.748	.19	
Time	F(2,95.071)=2.705	.07	
Group-x-Time	F(2,94.995)=0.038	.96	
Time within Usual Care	F(2,94.996)=1.025	.33	
Time within Intervention	F(2,94.898)=2.207	.11	
PDSMS			
Age	F(1,51.739)=6.368	.02	
Ejection Fraction	F(1,53.706)=13.931	<.001	
Race	F(1,53.318)=0.281	.60	
Group	F(1,54.823)=0.378	.54	
Time	F(2,93.707)=7.548	.001	
Group-x-Time	F(2,93.609)=0.106	.90	
Time within Usual Care	F(2,94.904)=3.062	.05	BL – 90 days (p=.05) Δ=4.50 (SD 6.19) ES 0.73
Time within Intervention	F(2,89.995)=6.367	.003	BL – 30 days (p=.03); BL – 90 days (p=.004) Δ=2.55 (SD 5.99) ES 0.42; Δ=3.52 (SD 5.75) ES 0.61

Abbreviations: BL, baseline; Δ, mean difference; SD, standard deviation; ES, effect size

Table 7

HF and Diabetes Self-care (Unadjusted Means and SDs or Frequencies and Percents)

Measure	Baseline		30 Days		90 Days	
	n	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
SCHFI–Maintenance (Cα=0.77)	53	67.1 (19.4)	44	82.9 (12.5)	39	79.1 (14.9)
Usual Care	15	67.8 (23.7)	9	83.0 (18.4)	11	76.1 (18.0)
Intervention	38	66.8 (17.9)	35	82.8 (10.9)	28	80.3 (13.6)
SCHFI–Management* (Cα=0.73)	53	68.4 (23.7)	29	76.7 (18.4)	26	76.9 (19.9)
Usual Care	15	65.3 (23.1)	4	80.0 (4.1)	6	72.5 (17.0)
Intervention	38	69.6 (24.1)	25	76.2 (19.8)	20	78.3 (20.9)
SDSCA–General Diet (Cα=0.80)	57	4.94 (1.9)	50	5.76 (1.2)	48	5.22 (1.5)
Usual Care	14	5.07 (1.3)	12	6.17 (1.0)	13	4.73 (1.9)
Intervention	43	4.90 (2.1)	38	5.63 (1.2)	35	5.40 (1.3)
SDSCA-Specific Diet (Cα=0.06)	59	4.41 (1.6)	50	4.84 (1.4)	48	4.74 (1.5)
Usual Care	15	4.43 (1.4)	12	5.13 (1.0)	13	4.35 (1.4)
Intervention	44	4.40 (1.7)	38	4.75 (1.5)	35	4.89 (1.5)
	count/n	(%)	count/n	(%)	count/n	(%)
SDSCA–Exercise [%>0]† (Cα=0.78)	33/58	(56.9 %)	42/51	(82.4 %)	35/46	(76.1 %)
Usual Care	9/14	(64.3 %)	9/12	(75.0 %)	10/13	(76.9 %)
Intervention	24/44	(54.5 %)	33/39	(84.6 %)	25/33	(75.8 %)
SDSCA–Blood Glucose [%=7]† (Cα=0.87)	34/58	(58.6 %)	30/51	(58.8 %)	23/46	(50.0 %)
Usual Care	7/15 T	(46.7 %)	9/12	(75.0 %)	6/13	(46.2 %)
Intervention	27/43	(62.8 %)	21/39	(53.8 %)	17/33	(51.5 %)
SDSCA–Foot Care [%=7]† (Cα=0.53)	21/59	(35.6 %)	21/51	(41.2 %)	27/46	(58.7 %)
Usual Care	5/15	(33.3 %)	4/12	(33.3 %)	6/13	(46.2 %)
Intervention	16/44	(36.4 %)	17/39	(43.6 %)	21/33	(63.6 %)

Abbreviations: SD, standard deviation; Cα, Cronbach's alpha reliability

* SCHFI-Management scores calculated only on subjects who answered yes to item 11, "In the past month, have you had trouble breathing or ankle swelling?"

† SDSCA – Exercise, -Blood Glucose and –Foot Care were dichotomized since the underlying distributions were highly skewed with the majority of the scores either zero and non-zero for exercise and <7 or =7 for Blood Glucose and Foot Care.

Table 8

Multilevel Longitudinal Models and Planned Contrast Tests for Self-Care

Outcome Measure Model Effect	F(df1,df2)	p-value	Planned Pairwise Post Hoc Contrasts (Sidak adjusted p-value < .10)
SCHFI–Maintenance			
Race	F(1,56.568)=8.997	.004	
Education	F(1,58.340)=3.744	.058	
Group	F(1,58.730)=2.353	.13	
Time	F(2,85.952)=16.991	<.001	
Group-x-Time	F(2,86.182)=0.542	.58	
Time within Usual Care	F(2,86.460)=3.910	.02	BL – 30 days (p=.05); BL – 90 days (p=.09) Δ=11.23 (SD 13.69) ES 0.82; Δ=9.43 (SD 14.31) ES 0.66
Time within Intervention	F(2,84.527)=22.642	<.001	BL – 30 days (p<.001); BL – 90 days (p<.001) Δ=16.11 (SD 14.95) ES 1.08; Δ=13.52 (SD 14.52) ES 0.93
SCHFI–Management			
Race	F(1,51.309)=2.347	.13	
Ejection Fraction	F(1,48.272)=8.927	.004	
Group	F(1,65.692)=3.349	.07	
Time	F(2,68.000)=2.318	.11	
Group-x-Time	F(2,67.939)=0.677	.51	
Time within Usual Care	F(2,68.713)=0.874	.42	
Time within Intervention	F(2,64.353)=3.152	.05	BL – 90 days (p=.05) Δ=11.22 (SD 20.12) ES 0.56
SDSCA – general diet			
Race	F(1,46.569)=0.144	.71	
Group	F(1,48.431)=0.020	.89	
Time	F(2,94.843)=5.046	.09	
Group-x-Time	F(2,94.794)=1.346	.27	
Time within Usual Care	F(2,96.252)=3.285	.04	30 days – 90 days (p=.05) Δ=1.34 (SD 1.98) ES 0.67
Time within Intervention	F(2,90.599)=2.947	.05	BL – 30 days (p=.05) Δ=0.73 (SD 1.86) ES 0.39
SDSCA – specific diet			
Race	F(1,57.937)=1.484	.23	
Group	F(1,59.768)=0.099	.75	
Time	F(2,107.552)=1.893	.15	
Group-x-Time	F(2,107.539)=1.132	.33	
Time within Usual Care	F(2,108.478)=1.516	.22	
Time within Intervention	F(2,104.798)=1.421	.25	

Outcome Measure Model Effect	F(df1,df2)	p-value	Planned Pairwise Post Hoc Contrasts (Sidak adjusted p-value < .10)
SDSCA–Exercise > 0†			*[planned time contrasts using baseline as reference]*
Race	F(1,148)=2.105	.15	
Group	F(1,148)=0.127	.72	
Time	F(2,148)=2.522	.08	
Group-x-Time	F(2,148)=0.436	.65	
Usual Care: BL-30d	F(1,148)=0.449	.51	
Usual Care: BL-90d	F(1,148)=0.605	.44	
Intervention: BL-30d	F(1,148)=8.319	.005	T=−2.884 (df=148), ES=0.47
Intervention: BL-90d	F(1,148)=3.557	.06	
SDSCA– Blood Glucose = 7†			*[planned time contrasts using baseline as reference]*
Race	F(1,148)=2.350	.13	
Group	F(1,148)=0.059	.81	
Time	F(2,148)=1.234	.29	
Group-x-Time	F(2,148)=1.726	.18	
Usual Care: BL-30d	F(1,148)=2.800	.10	
Usual Care: BL-90d	F(1,148)=0.019	.89	
Intervention: BL-30d	F(1,148)=0.655	.42	
Intervention: BL-90d	F(1,148)=1.561	.21	
SDSCA–Foot Care = 7†			*[planned time contrasts using baseline as reference]*
Race	F(1,149)=0.161	.69	
Group	F(1,149)=0.328	.57	
Time	F(2,149)=2.109	.13	
Group-x-Time	F(2,149)=0.078	.93	
Usual Care: BL-30d	F(1,149)=0.000	.99	
Usual Care: BL-90d	F(1,149)=0.875	.35	
Intervention: BL-30d	F(1,149)=0.381	.54	
Intervention: BL-90d	F(1,149)=4.768	.03	t=−2.184 (df=149), ES=0.36

Abbreviations: BL, baseline; Δ, mean difference; SD, standard deviation; ES, effect size

†SDSCA-Exercise>0, SDSCA-Blood Glucose=7 and SDSCA-Foot Care=7 were analyzed using generalized multilevel longitudinal models for a Binomial distribution with a Logit link function using planned contrasts to test for changes from baseline to 30days and baseline to 90 days for each group.

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Table 9

HF and Diabetes QOL Unadjusted Means and SDs

Measure	Baseline		90d	
	n	Mean (SD)	n	Mean (SD)
MLWHF (Cα=0.93)	57	63.9 (23.4)	46	47.1 (25.9)
Usual Care	16	61.3 (20.5)	11	41.8 (19.7)
Intervention	41	64.9 (24.6)	35	48.8 (27.5)
MLWHF Physical	57	27.3 (9.9)	46	20.9 (12.0)
Usual Care	16	26.9 (8.0)	11	19.0 (10.7)
Intervention	41	27.5 (10.6)	35	21.6 (12.4)
MLWHF Emotional	57	12.0 (7.7)	45	9.5 (7.7)
Usual Care	16	10.5 (6.9)	11	8.8 (7.3)
Intervention	41	12.6 (8.1)	34	9.8 (7.9)
ADDQOL (Cα=0.92)	56	−3.61 (2.3)	47	−3.24 (2.6)
Usual Care	16	−2.85 (1.8)	12	−2.04 (1.9)
Intervention	40	−3.91 (2.5)	35	−3.66 (2.7)

Abbreviations: SD, standard deviation; Cα, Cronbach’s alpha reliability.

Table 10

Repeated Measures Models for QOL

Outcome Measure Model Effect	F(df1,df2)	p-value
MLWHF total		
Race	F(1,41)=0.932	.34
Race-x-Time	F(1,41)=0.082	.78
Age	F(1,41)=5.680	.02
Age-x-Time	F(1,41)=0.001	.98
Group	F(1,41)=0.882	.35
Time	F(1,41)=15.380	<.001
Group-x-Time	F(1,41)=0.033	.86
Time within Usual Care	F(1,41)=5.302	.03 [Δ=18.94 (SD 27.27) ES 0.69]
Time within Intervention	F(1,41)=14.269	.001 [Δ=17.19 (SD 26.53) ES 0.65]
MLWHF physical		
Race	F(1,42)=0.670	.42
Race-x-Time	F(1,42)=0.964	.33
Group	F(1,42)=0.622	.44
Time	F(1,42)=12.999	.001
Group-x-Time	F(1,42)=0.793	.38
Time within Usual Care	F(1,42)=6.468	.02 [Δ=9.83 (SD 12.82) ES 0.77]
Time within Intervention	F(1,42)=7.375	.01 [Δ=5.82 (SD 12.50) ES 0.47]
MLWHF emotional		
Race	F(1,41)=0.035	.85
Race-x-Time	F(1,41)=0.054	.82
Group	F(1,41)=0.643	.427
Time	F(1,41)=1.873	.18
Group-x-Time	F(1,41)=0.373	.55
Time within Usual Care	F(1,41)=0.169	.68
Time within Intervention	F(1,41)=4.020	.05 [Δ=2.68 (SD 7.66) ES 0.35]
ADDQOL		
Race	F(1,42)=4.864	.03
Race-x-Time	F(1,42)=0.443	.51
Group	F(1,42)=1.842	.18
Time	F(1,42)=2.739	.11
Group-x-Time	F(1,42)=0.138	.71
Time within Usual Care	F(1,42)=1.330	.26
Time within Intervention	F(1,42)=1.485	.23

Abbreviations: SD, standard deviation; Δ, mean difference; ES, effect size