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Randomized Clinical Trial of an Integrated Self-care Intervention for Persons with Heart Failure and Diabetes: Quality of Life and Physical Functioning Outcomes

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Abstract

Aims—Persons with concomitant heart failure (HF) and diabetes mellitus (DM) have complicated, competing, self-care expectations and treatment regimens that may reduce quality of life (QOL). This randomized controlled trial tested an integrated self-care intervention on outcomes of HF and DM QOL, physical function and physical activity (PA).

Methods—Participants with HF and DM (n=134, mean age 57.4 ± 11 years, 66% men, 69% minority) were randomized to usual care attention control (control) or intervention groups. The control group received standard HF and DM educational brochures with follow up phone contact; Intervention received education/counseling on combined HF and DM self-care (diet, medications, self-monitoring, symptoms, and PA) with follow up home visit and phone counseling. Measures including questionnaires for HF and DM-specific, and overall QOL; Physical activity frequency; and physical function (6 minute walk test; 6MWT) were obtained at baseline, 3 and 6 months. Analysis included mixed models with a priori post-hoc tests.

Results—Adjusting for age, body mass index, and comorbidity, the intervention group improved HF total (p=.002) and physical (p<.001) QOL scores at 3 months with retention of improvements at 6 months, improved emotional QOL scores compared to control at 3 months (p=.04), and improved health status ratings (p=.04) at 6 Months compared to baseline. The intervention group improved 6MWT distance (924 feet vs 952 feet, p=. 03) while control declined (834 vs 775 feet) ($F_{1, 63}$=6.86, p=.01). The intervention group increased self-reported PA between baseline and 6M (p=.01).

Clinical Trial Registration– http://www.clinicaltrials.gov:NCT01606085

Disclosures

None

Conclusions—An integrated HF and DM self-care intervention improved perceived HF and general QOL but not DM QOL. Improved physical functioning and self-reported PA were also observed with the integrated self-care intervention. Further study of the HF and DM integrated self-care intervention on other outcomes such as hospitalization and cost is warranted.

Keywords

Heart Failure; Diabetes; Self-care; Quality of Life; Intervention

The growing prevalence of patients with concomitant heart failure (HF) and diabetes mellitus (DM), and the complex interaction of the two conditions, risk factors and treatments require additional attention to improve patient outcomes. Patients with HF and DM show specific metabolic, neurohormonal and structural heart abnormalities which potentially contribute to worse outcomes compared to each condition individually.[1, 2] Approximately 40% of patients hospitalized with HF and reduced ejection fraction have DM,[3] and recent trials have noted increased risk for mortality,[45] a potentially differential response to medications with greater side effects,[6] and increased rehospitalizations[7, 8] compared to HF patients without DM. The prevalence of both diseases is increasing worldwide with the aging of the population: 1.5 to 2% of individuals over the age of 65 have both HF and DM, and the prevalence is expected to grow exponentially in the next decades.[9] Additionally, self-care for this comorbid group is complex and competes in recommendations for diet, medications, and symptom management.[10] Multi-morbidity is associated with substantially worse health related quality of life (QOL), especially in persons with HF and DM.[11] These adverse clinical, behavioral, and economic outcomes warrant new approaches.

Self-care of either HF or DM alone requires focused daily activities and problem solving to incorporate these behaviors into life routines. Improved knowledge and self-care in patients with either HF or DM alone has the potential to a reduce rehospitalizations, reduce adverse sequelae, and improve QOL.[12] To address the complexity of *comorbid* HF-Diabetes self-care, we conducted a randomized clinical trial of an integrated self-care education and counseling intervention versus a usual care attention control condition in persons rehospitalized or recently rehospitalized for a HF exacerbation [Quality HF-DM ClinicalTrials.gov NCT01606085]. This study was informed by a pilot test of a portion of the intervention in which improved HF knowledge and self-efficacy, and improved selected self-care behaviors for both HF and DM were observed.[13] We developed a more robust clinical trial and hypothesized that an integrated HF and DM self-care intervention would demonstrate improved QOL, improved physical functioning, and reduced cost outcomes than usual care. This paper reports the QOL and physical function outcomes.

Methods

Design

A 2-group randomized design was used with data collected at baseline (entry into the study), and after 3 and 6 months. HF-diabetes patients were enrolled during hospitalization or within 3 months of discharge for a HF exacerbation and randomly assigned to either an integrated HF-DIABETES self-care intervention group (INT), or usual care attention control

group (control). A table of random numbers was used to create group assignments which were placed in sealed envelopes until baseline data were collected. The intervention was delivered after baseline data collection and occurred in several sessions (immediately after enrollment, and after 48–72 hours, 7 days, 14 days, 1 and 2 months, and 4.5 months after study entry). The INT group also received usual care from their primary and specialty care providers. Participants were enrolled from one of 4 large urban tertiary care hospitals that had multidisciplinary outpatient HF clinics. The protocol and informed consent were approved by the Institutional Review Board and all participating institutions.

Participants

The inclusion criteria for this trial included current or recent hospitalization for HF within the past three months, ages 21–80 years, New York Heart Association class II–IV symptoms, type II DM, planned discharge to home and not to an assisted living or skilled nursing facility, English language fluency, baseline guideline derived medical therapy unless there was documented contraindication, ambulatory and eligible for a walking physical activity (PA) program, and eligible for a low-sodium and low carbohydrate diet. Patients with newly diagnosed or first HF admission were excluded as were those with positive screens for depressive symptoms (≥10 on PHQ-9)[14] and cognitive difficulty (>11 Blessed Cognitive Screening tool) [15] which would interfere with ability to participate in the intervention or perform adequate self-care. [1617] Patients were excluded for any of the additional following conditions: uncorrected hearing or vision problem, undergoing cardiac transplant or mechanical circulatory assist device implantation or evaluation at the time of enrollment, renal failure requiring renal replacement treatment, and lack of telephone access. We also excluded patients with severe COPD and prior stroke if they impeded ability to ambulate. Participants were enrolled during 2010 – 2013.

Overview of the Intervention

Usual Care Attention Control Group (Control)—Participants in the control group received routine care from their providers, and after randomization, were provided with informational brochures on “Taking Control of Your Heart Failure” (developed by the Heart Failure Society of America) and “Four steps to Control your Diabetes for Life” (developed by the National Diabetes Education Program). They received the standard hospital discharge patient teaching from staff in the enrolling institutions and follow-up clinic appointments who include family members if present. A brief review of the HF educational materials and procedures implemented in the 4 enrolling hospitals revealed strong similarities, and none had strategies to intentionally integrate HF and DM self-care in their approach or patient education materials. Control group participants received “attention control” phone calls at the same schedule as the intervention participants described below (at 7–10 days, and 1,2, and 4 months) with information about the trial, number of participants enrolled to date, and a reminder of their next set of study activities.

Integrated HF-diabetes Self-Care Group (Intervention)—*After baseline data collection***,** participants in the intervention group participated in an individualized educational and counseling session. Family members were encouraged to attend. A trained research nurse provided an overview of the content using a semi-structured script and

coordinated set of Powerpoint™ illustrations viewed on a laptop computer. Corresponding written materials were developed at a 6th grade reading level and provided in the form of a "HF-diabetes tool kit" to be used at home. The initial content included an overview of HF and DM in lay language, how the conditions interact, and possible influences on fluid balance, glucose utilization, and insulin resistance. Positive and motivational messages focused on the HF-diabetes patients' role in daily self-care, self-monitoring of glucose, body weight and symptoms, and approaches to ameliorating symptoms. Strategies for following an integrated low sodium and low carbohydrate diet, medication-taking behaviors and ways to promote adherence, oral and foot care, and when to take action or call the provider were discussed. (Table 1). HF and DM knowledge questionnaires were used as part of the pre-teaching assessment which allowed the nurse to tailor the information to the patient's need. The content for the patient-centered intervention was derived from data obtained through previously conducted focus groups with HF-diabetes patients. The content and format of presentation were then reviewed by HF-diabetes patients and clinicians, revised, and pilot tested for effects on HF and DM knowledge, self-efficacy and selected outcomes.[13] Time was allowed for individual questions, and goal setting in each category of self-care.

At *48–72 hours*, a home visit by the research nurse was made to review initial material and self-monitored glucose and weight information along with the participant's interpretation of these data, to provide repetition of information, and to ascertain that diet and medication-taking behavior were congruent with discharge instructions. A scripted phone call at *7–10 days* reviewed self-monitoring of glucose, weight and symptoms, reviewed the self-monitoring log and patients' interpretation of the data, and queried about diet and medication-taking behavior. The benefit of PA was introduced in the initial session, however the in-depth PA counseling occurred at the *2 week visit* when participants routinely returned to the clinic and after the 6MWT (see measurement of variables). The research nurse met the participant at the clinic and extended the PA counseling (using a script and illustrations) to include emphasis on why PA was helpful to both HF and DM, information on a walking protocol, safe walking, expected length, duration, self-monitoring of walking with a pedometer and activity log and how to use this information, and problem solving for issues such as hypoglycemia, location and weather to promote self- efficacy for PA. Examples of appropriate chair exercises were provided as an alternative on days when walking was not possible. Additional scripted phone calls occurred at 1 and 2 months and 4 months to review and promote self-monitoring of glucose, weight and symptoms, patients' interpretation of the data, diet, physical activity, and medication-taking behavior.

Measurement of Variables

Participant characteristics—Demographic and clinical characteristics were collected form self-report and the medical record. Variables of interest were age, gender, marital status, education, ethnicity, left ventricular ejection fraction (LVEF), NYHA classification, body mass index (BMI), diagnosis year for HF and DM, perceived health rating, and comorbidities. The Charlson Comorbidity Index (CCI) was used to quantify the combined burden of these other chronic conditions.[18] Medications and dosages intended for post-hospitalization were recorded. These variables were used to fully describe the sample and to compare treatment groups.

Quality of Life—Quality of life was measured with disease-specific and general instruments. HF specific QOL was measured with the well-established Minnesota Living with Heart Failure Questionnaire (MLHFQ) completed by participants at entry, 3 and 6 months. The MLHFQ has 21-items which are rated on the extent in the past month to which various physical and emotional symptoms of HF have prevented them from living as they wanted,[19] and total, physical and emotional subscale scores can be calculated. High scores indicate worse perceived HF quality of life. Construct, convergent and discriminant validity of the MLHFQ has been established, as well as internal consistency reliability and test-retest reliability.[1920, 21] A 5-point change on the total score demonstrates a clinically significant difference.[22]

The Audit of Diabetes-Dependent Quality of Life (ADDQOL), used to measure DM specific QOL, consists of 19 items that measure physical functioning, symptoms, psychological well-being, social well being, role activities, and personal constructs.[23, 24] It is sensitive to the changes in DM treatment and complications.[25, 26] A 5-point scale measures the impact of DM by asking patients how particular aspects of their life would be if they did not have DM. 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.[27] Strong reliability (Cronbach's alpha=0.94) and validity have been reported.[23]

General QOL was assessed since there is no integrated HF-diabetes QOL measure at present. The EuroQol 5-Dimension (EQ-5D) is a standardized instrument used to measure of health outcome and generate Quality Adjusted Life Years (QALYs).[28] The EQ-5D is a self-administered, multi-attribute, preference-based measure of health status in which patients are asked to rate the severity of their illness for five dimensions health: mobility, self-care, daily activities, pain/discomfort, and anxiety/depression. Each dimension comprises three levels (no problems, some/moderate problems/extreme problems), providing a unique EQ-5D health index by combining 1 level from each of the 5 dimensions. The EQ-5D VAS is a visual analogue scale on which the participant marks their perceived health status. The EQ-5D has been used in a wide range of health conditions including HF[29, 30] and DM.[31]

Six Minute Walk Test (6MWT)—Considered a reflection of submaximal physical function, [32, 33] the 6MWT is viewed as reproducible and responsive to exercise and medication interventions.[34] Distance walked in the 6 minute time frame correlates moderately with symptom score ($r = -0.385$, $p < 0.001$) and NYHA class ($r = -0.468$, $p < 0.001$), and independently and strongly predicts one year mortality and hospitalization in patients with HF.[35–37] The 6MWT was conducted when the participant returned for their 2 week follow-up clinic visit and at 6 months. Participants were asked to walk as far as possible at their self-determined speed during 6 minutes, and the distance was calculated in total feet as well as dichotomized into greater than and lower than 984 feet (300 meters). The test was conducted along a level, well-lit hallway in the clinical research unit of the CTSA. Staff conducting the 6MWT were trained in standard procedures to instruct the participants and avoid making comments with the potential to influence motivation. Fidelity and inter-rater reliability for the protocol were assessed periodically. Heart rate, blood

pressure and respiratory rate, and perceived exertion were monitored immediately before and after the 6MWT.

Community Healthy Activities Model Program for Seniors (CHAMPS)—To quantify self-reported daily PA, the well-validated CHAMPS Questionnaire (revised) was completed at baseline and 3 and 6 months.[38] Respondents report typical weekly participation and duration in light, moderate, and vigorous physical activities over the last 4 weeks. Scoring yields estimated kcal per week and frequency per week spent in both moderate-intensity (or greater) and "all" physical activities. The CHAMPS has strong psychometric properties, is reported to be sensitive to change for various activity levels in both younger and older adults. Concurrent validity has been established with other exercise questionnaires, and the CHAMPS has been validated with objective measures of physical function including peak exercise oxygen consumption.[39, 40] The CHAMPS has also been validated in culturally diverse groups including African Americans.[41] We examined scores on the frequency domain and also examined the specific reported activities at baseline, 3 and 6 months.

Data Analysis

All data were reviewed for completeness, potential outliers, distribution, and missing data as well as any differences between groups on demographic and clinical variables using t-test for normally distributed continuous measures, chi square tests for categorical measures, Mann Whitney nonparametric tests for non-normally distributed measures and Fisher's Exact Test (2 sided) for low numbers in cells. While there was no significant difference by group in the proportion of participants who completed the study ($\chi^2_{(1)}$=1.118, p=.290), the 26 subjects who left the study before the final 6 months were significantly younger ($t_{(132)}$=3.804, p<.001). For this reason, age was considered as a possible covariate in each model used herein.[42] Only 66 subjects completed the 6MWT at both baseline and 6 months, however out of the 108 subjects who completed the study, there were no significant differences in the proportion of participants with missing 6MWT data between the 2 groups ($\chi^2_{(1)}$=2.494, p=.114), and no variables were significantly associated with the missing 6MWT. Descriptive statistics were also run for all outcome measures for all participants and by group at all 3 time points for QOL (MLHFQ, ADDQOL, EQ-5D, EQVAS), perceived PA (CHAMPS), and at baseline and 6mo for physical functioning (6MWT). Reliability for MLHFQ, ADDQOL, and EQ-5D were calculated using Cronbach's alpha. For the outcomes measured at 3 time points (baseline, 3m, 6m), multilevel mixed models were conducted (using SPSS v.21 MIXED Procedure) to adjust for the attrition amounts over time. For the 6MWT which was measured at only 2 time points, repeated measures ANOVA was performed. For the CHAMPS measures, the majority of the participants had zero to very low levels of PA. Because the CHAMPS scores were highly right skewed and zero-inflated, we dichotomized the data (for the 28 exercise items) and examined the frequency of performance of the 28 items using a median split at baseline and compared the percent of each group who were >6 across time using Chi Square. These data were analyzed using generalized linear multilevel mixed models for a binomial response with logit-link function (using SPSS v.21 GENLINMIXED). In addition to age being considered as a covariate relative to missing data due to attrition[42] the covariates of gender, race, NYHA class,

education, BMI, CCI were all also evaluated for possible inclusion to increase statistical power and improve precision for estimating treatment effects given their expected association with the outcomes.[43] Only significant covariates were retained in the final models. For all models, post-hoc comparisons between the 2 groups and between the 3 time points were performed using Sidak error-rate adjustment for multiple pair wise comparisons.[44] All post hoc tests that yielded p-values < 0.10 are reported with effect sizes (ES) using Cohen's d.

Results

Sample Characteristics

The recruitment, screening and enrolling procedures resulted in 134 consented and randomized participants, and the CONSORT chart (Figure 1) presents the randomization and attrition from the two groups. Overall 741 HF-diabetes patients were screened with 606 excluded due to inclusion/exclusion criteria or refused participation. The most common reasons included other serious comorbidities and living too far from enrolling institution; 108 of these were excluded due to mobility issues, or perceived barrier to a potential walking intervention. Thus 135 were enrolled, however due to a change in meeting inclusion criteria between consent and beginning of the study, one person was dropped. Of the 134 HF-diabetes patients, 64 were randomized to control and 70 to intervention groups. Six-month evaluations yielded 54 control and 54 intervention participants who completed the study. A total of 4 deaths occurred, two in each group. Overall study attrition including deaths was 19.4% which was less than our pilot study and other behaviorally focused intervention studies with HF patients in these institutions.[13, 45] While age was significantly associated with attrition (subjects who left the study before the end of 6 months were significantly younger, p<.001), there was no difference between the two groups for this association.

Comparison of the demographic and clinical data by group is presented in Table 2. No group differences were found at baseline. The age range was 29–81 years, and women comprised 34% of the sample with women significantly younger than men (52.4 ± 10.89 versus 59.9 ± 9.6 years; t=4.073, p=.001). One participant was age 80 years at screening and consent, turned 81 prior to baseline data collection, but was retained in the study. Overall, 69.4% were African American reflecting the population receiving care in the study settings. Of the women, 87% were African American compared to 60.2% of the men. Around half of the sample was married, and 22% lived alone. Only 37% had an educational level of high school or less. Nine-two percent of the participants had symptoms of NYHA class II and III, and mean LVEF was 33.3% ± 17.6. LVEF ranged from 10–60%, and approximately 30% of the total sample had LVEF ≥ 50% (HfpEF) [46] with no difference in the percent by group. The mean body mass index (BMI) was 37 ± 9 reflecting overweight and obese status. Baseline HgA1c levels ranged widely.

Comorbidities were numerous, and 70% had other chronic conditions besides HF and DM. Other comorbidities such as prior myocardial infarction, peripheral vascular disease (PVD) and renal disease were prevalent, although PVD was not as prevalent as expected because of

exclusions (i.e. able to walk without claudication). Close to 25% rated themselves as in poor health. Most (67.4 %) had DM prior to HF and had lived with DM for a range of 1–41 years.

Quality of Life

The unadjusted means for the MLHFQ, ADDQOL, and EQ-5D and EQVAS scores are presented in Table 3. Older age was associated with lower MLHFQ scores (better QOL), whereas greater BMI and higher CCI sores were associated with higher scores (worse QOL). There were no differences at baseline, however the INT group showed improvements in their MLHFQ Total ($p<.001$), and Physical scale ($p<.001$) scores at 3 months with moderate effect sizes (ES > 0.5) after adjusting for age, BMI and CCI (Figure 2 a & b). Especially important was the significant reduction in the MLHFQ total scores by more than 12 points (Table 3) from baseline to 3 months ($p<.001$) which was maintained at 6mo ($p=.002$). There was a small within INT group improvement in MLHFQ Emotional scale scores from baseline to 3 months ($p=.08$), however the improvement was significant compared with control ($p=.04$) at that time point (Figure 2 c). The control group demonstrated no improvements in total or emotional scores over time however did show improvement in their MLHFQ Physical Scale score from baseline to 6 months ($p=.01$).

The ADDQOL scores remained stable with no significant changes observed for either group (Table 3). For the EQ-5D, the group by time analysis adjusted for age, BMI and CMI, and the post hoc tests revealed significant decreased scores (worse QOL) for the control group from baseline to 3m ($p=.01$) with no significant change in the INT group, although the scores were slightly lower at the 3 month period. (Table 3). However, for the EQ-5D VAS, the INT group did show a significant increase in perceived health status from baseline to 6mo ($p=.04$, small ES=0.34).

Physical Functioning (6MWT)

The data for the 6MWT are presented in Table 4. In addition to the overall attrition, 40 participants had missing 6MWT data at BL or 6 months for issues such as rehospitalization, being out of town, arthritic pain, other problem in the foot, hip, knee or back, or unavailable to come for the 6 month visit. We examined the reasons (other than rehospitalization) in depth to ascertain that they were not related to other HF or DM exacerbations, and as noted in the data analysis section, there was no difference by group in the number/percent missing, nor were any covariates or baseline characteristics significantly associated with the missing 6MWT data.

For the 66 participants who completed the 6MWT at both baseline and 6 months, less than half of the participants (43.9%) walked 984 feet at baseline with slightly more walking this distance in the intervention group at baseline (51.7%) compared to 37.8% of control, however, this was not significantly different between the 2 groups ($p=.259$, Table 4). By 6 months, after adjusting for BMI, there was a main effect for Group ($F_{1, 63}=6.86$, $p=.01$) for the two-time point RM-ANOVA. Post hoc tests revealed that by 6mo, the INT group walked 189 feet further than control ($p=.01$) for a moderate ES=0.49. Similarly, at 6mo, a significantly higher percentage of INT participants walked more than 984 feet than control ($p=.002$, Table 4).

Perceived Physical Activity (CHAMPS)

The intervention group showed significant increases in self-reported PA from baseline to 3 months, and between baseline and 6 months. The control group showed non-significant change in the percent > 6 from 48.4% at baseline to 59.6% at 3 months and 56.6% at 6 months whereas the percent >6 in INT changed from 50% at baseline to 74.5% at 3 months (p=.01) and maintained at 74.1% at 6 months (p=.01). Participants in INT reported adding the following activities by 3 months: light work around the house, walking uphill, walking to do errands, walking leisurely for exercise or pleasure, and stretching or flexibility exercises. Upon examination of specific activities which demonstrated an increase in frequency from baseline to three months, INT participants reported a significant increase (p<.05 Wilcoxon Rank Sum Test) in frequency of “light gardening”, “walk to do an errand”, “walk leisurely for exercise or pleasure”, and “do general conditioning exercises such as light calisthenics or chair exercises.” At 6 months, the frequency of the activity, “Walk uphill” was increased (p<.05) in both control and intervention over baseline, and intervention also sustained the increase in “do general conditioning exercises such as light calisthenics or chair exercises” from baseline.

Discussion

Based on the changes in the MLHFQ and the EQ-5D VAS, the integrated HF and DM self-care intervention was effective in improving total and physical components of HF QOL and overall general QOL. This effect was demonstrated as early as 3 months after entry into the study, and sustained at the 6 month time frame. Although the control group improved their physical QOL scores by 6 months, the intervention group demonstrated improved total and physical quality of life earlier in the study by 3 months with the emotional component showing a greater improvement than control at that time as well. Of importance is the concordance of the change in QOL scores, the objective physical function measure (6MWT), and self-reported increase in physical activity observed in intervention group compared with these data in control. The increase in HF QOL with an integrated intervention at 3 and 6 months is important in that our separate pilot study with only 71 participants revealed a trend in improvement but no statistically significant change in QOL over a usual care group.[13] Differences may be related to the increased focus on physical activity in the intervention of this study, a larger sample size, longer follow up time frames to allow the intervention to affect a change, and increased intervention contacts providing support. The change in overall HF QOL scores of 12 points is considered clinically important as well as statistically significant.[22] For most participants, the discussion of HF and DM self-care in an integrated fashion was novel and appreciated as indicated on evaluation surveys of the benefits at the end of the study. This approach may also inform testing of comorbidity care for other conditions frequently accompanying HF such as COPD or renal disease.

Diabetic specific QOL did not change based on the ADDQOL scores. This may be due to the fact that the participants had been living with DM for a mean of 10 years, thus changing perceptions about DM QOL may have required a stronger intervention and/or dose, greater length of time to observe an effect, or a more sensitive instrument. It is highly likely that the

frequency or intensity of exercise for diabetic impact was not achieved. Although considered a valid and reliable instrument with sensitivity for change, many of the questions on the ADDQOL ask how ones' life would be without DM. In this sample, the length of time living with DM may have influenced ability to respond. Additionally, the intervention did not address several of the domains on the instrument including family life, social life, vacations, finances, relationships, and living conditions. A more sensitive diabetic QOL instrument as well as greater intervention focus on diabetic QOL issues are warranted for future studies.

In this study, older participants reported better QOL which has been described previously in HF patients.[47–49] The decline in quality of life associated with an additional condition in people with multiple chronic conditions was less for older people than for younger people.[11] Younger age was also related to increased attrition which may have stemmed from lower QOL, or the greater life demands in this age group competing with study activities. It was not surprising to observe the relationships between both higher BMI and greater comorbidities with lower HF and overall QOL. The factors of younger age, greater comorbidity, and greater BMI may be important to consider to when identifying HF-diabetes patients at greater risk for lower QOL.

Importantly, the intervention group demonstrated improved physical functioning in those for whom the 6MWT was available compared with usual care attention control, although this observation must be cautiously interpreted given the amount of missing data on the 6MWT resulting in a small sample size. Additionally, comparing groups on both continuous (total distance walked) and dichotomous (<984 feet representing risk for frailty and adverse events),[32, 37, 50] revealed group differences. The increased total walk distance and the percent of the group who could walk beyond risk level suggest compelling improvements in physical function, however we want to acknowledge that a higher number of the intervention group was able to walk the 984 feet at baseline, and although not statistically significant by group, it is possible that the intervention group was more fit. The improvement in physical function was also concordant with the time frames for improved self-reported frequency of performing physical activity. A strength of the intervention content and timing was that the importance of PA was introduced early with the more specific education/counseling on PA delayed until after hospitalization recovery, a time when participants were likely to be receptive and have reduced symptoms. Although older patients with heart failure reported better QOL in spite of significant functional limitations and comorbidities, they are at risk for worsening physical and emotional aspects of QOL with further decline in functional status. These results underscore the potential of focused comorbidity treatments aimed at improving functional status and other outcomes in persons with heart failure and DM.

Efforts to improve PA and physical functioning may be an important strategy for improving overall QOL in this comorbid population. Many barriers to physical activity such as walking are present in the HF-diabetes patient population including ankle edema, lower extremity skin problems, diabetic neuropathy, peripheral vascular disease, poor muscle strength, frailty, poor balance, and low personal value, motivation and confidence regarding PA. By teaching self-care strategies for appropriate levels of PA including overcoming barriers,

alternative activities, and problem solving, a significant proportion of the intervention group was able to succeed.

The sample in this study represents successful recruitment of African Americans, and this increased representation of diversity should increase generalizability. Most participants (n=89, 67.4 %) had DM first and had lived with DM for a mean of 10.5 + 7.8 years which highlights the repercussions of altered glucose metabolism on pathology of cardiac muscle and function. The younger age of the women is consistent with the trend for DM to be a particularly important driver of HF and acute hospitalizations for women.[5152]

Because careful attention was given to screening and excluded many participants for conditions that would interfere with the study measures, ability to perform the intervention, or complete the study, the study is limited in generalizability. The opportunity exists to conduct a study with modification of the study measures and physical activity intervention to test the effects and benefits for a broader HF-diabetes population. Additionally the study was limited to patients who had readmissions, not a first admission for HF for the purpose of enrolling those who had some experience with HF self-care. However this restriction was determined not to be essential to the success of the education/counseling session because self-care was poor overall at baseline, and given the potential benefits, future studies should test the intervention effects with patients earlier in the HF-diabetes trajectory.

The study is limited by the generalizability issues noted above, the attrition and by the lack of blinding of the participants. Although attrition was not greater than other behavioral studies in HF, it compounded the analysis resulting in only a portion of the sample having complete data for the analysis of the 6MWT. Lack of blinding may have been less problematic given that the participants did not interact with each other, and the brochures given to the control group discussed independent and not integrated HF and DM self-care. Blinding of subjects in a behavioral clinical trial is difficult, and it is unlikely that the lack of blinding influenced the quality of life or 6MWT results in this study for several reasons: 1) the informed consent indicated that “the purpose of this study was to compare the effect of two ways of teaching patients with heart failure and diabetes about their conditions on quality of life, physical function, reducing hospitalizations, and the cost effectiveness of treatment.” Thus both groups expected to receive differing amounts of information at different times with the research team. 2) The 6MWT assessments were done in the Clinical Research Unit of the CTSA by staff who were trained to follow a standard protocol, and both fidelity and inter-rater reliability for the protocol were high. Although group number may have been known, the ability or motivation to bias data was low. 3) Questionnaires for QOL and PA assessments were completed by the participants at baseline prior to group assignment and at 6 months with return by mail. Reporting bias for physical activity questionnaire is possible, but not likely due to the concordance of the self-report PA with changes in both the objective 6MWT and physical component scale of the MLHFQ. Finally, the intervention was multi-modal and included education, counseling, the tool kit of resources, telephone and face-to-face follow up with a trained Hf nurse. Thus, it is not possible to determine whether the degree to which any single component contributed to the results.

Restricted inclusion criteria may have excluded significant groups who could likely benefit from such an integrated intervention. Particularly, this is a population with multiple conditions (peripheral artery disease, peripheral neuropathy, amputations, low uptake of PA across their lifespan, obesity) that interfere with ability or willingness to agree to a walking program. Future studies should adapt the intervention to these issues to ascertain if the benefit achieved in this study can be extended to a broader set of HF-diabetes patients.

The relationship between DM and HF is bidirectional, with each disease independently increasing the complexity and adverse events for the other. However in practice, comorbidity self-care may not receive adequate attention because of provider specialty versus general knowledge and expertise, or appreciation of the intricacies chronically ill patients face in trying to juggle more than one complex self-care regimen. The projections of substantial increases in the prevalence of type 2 DM over the next several decades due to the aging and obesity epidemics heightens concerns about risk for both the onset and worsening of HF.[53954] This nurse-delivered, patient-centered and patient-informed intervention may provide one model for developing new approaches to education/counseling to improve patient behavior and outcomes. The intervention is clinically feasible in that it was provided by trained registered nurses, and a focused approach to inpatient and outpatient patient education could be translated and tested in practice.

Conclusions

In a randomized clinical trial with participants who had concomitant heart failure and diabetes, those receiving an integrated self-care intervention experienced greater improvements in HF total, physical, and emotional QOL, and general QOL but not DM QOL when compared with a usual care attention control group. Additional intervention effects were observed in improved physical function as measured by the 6MWT and self-reported physical activity. Further analysis of these data examining the effects of the integrated HF and DM self-care interventions on other outcomes such as hospitalization and cost are warranted as are future studies designing and testing efforts to improve comorbidity self-care.

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HIghlights

- An integrated heart failure and diabetes self-care intervention was developed, and a prospective randomized trial was conducted to compare the intervention to usual care with attention control.
- At 3 and 6 months follow-up, the intervention group, but not the control group, had improved heart failure related quality of life.
- In a subgroup of patients who completed 6-minute walk tests at baseline and 6 months, distances increased in the intervention group but declined in the control group.
- The intervention group reported higher physical activity levels than the control group.

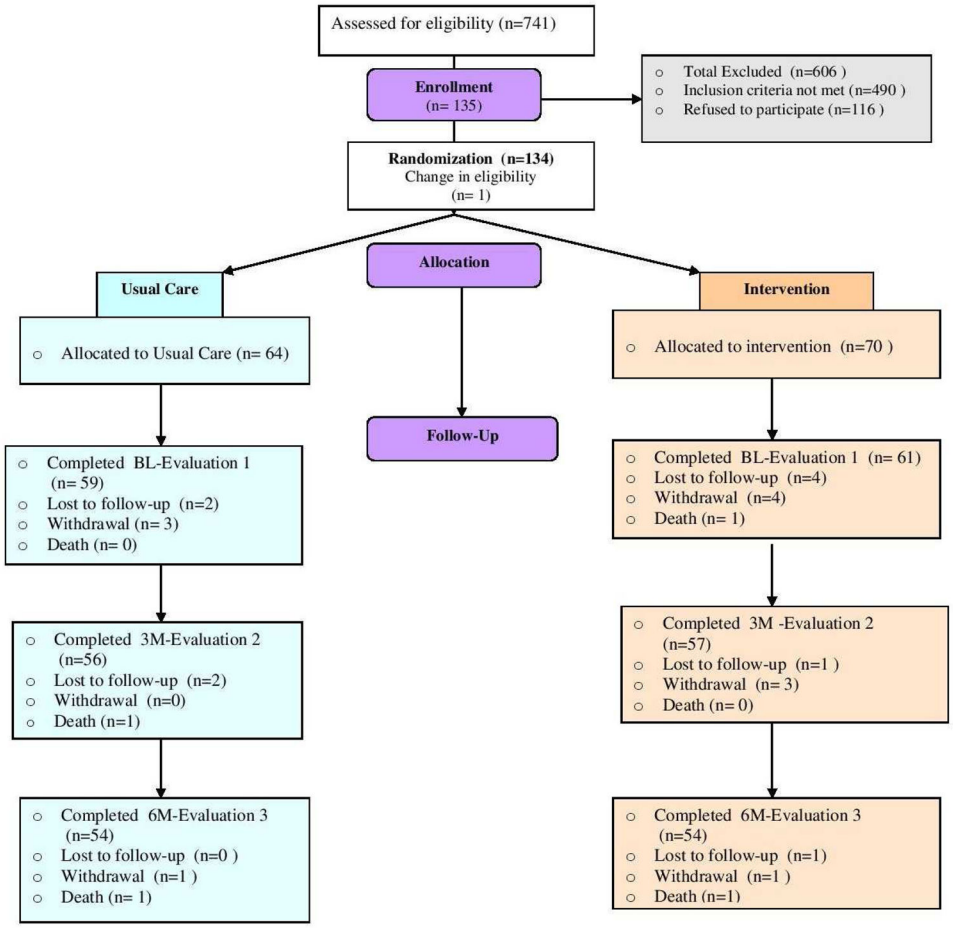
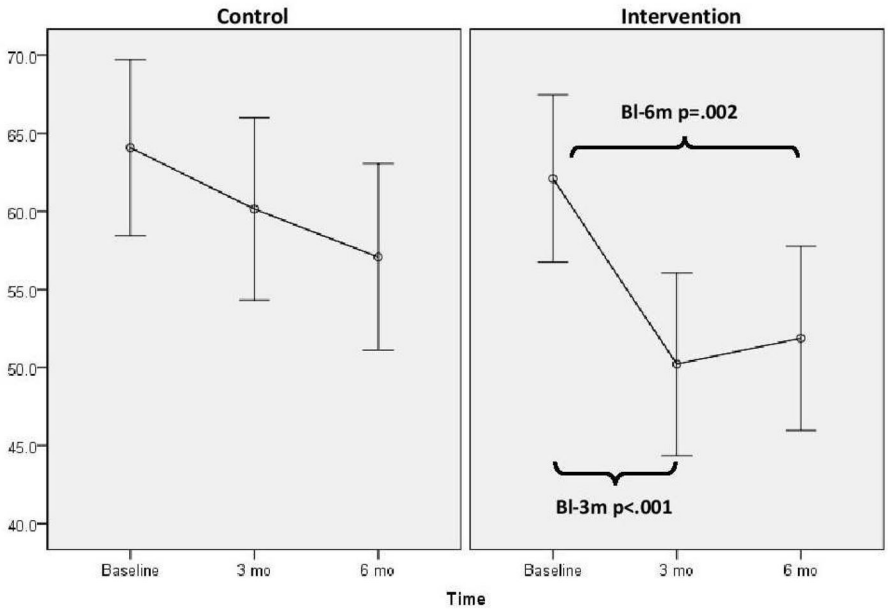
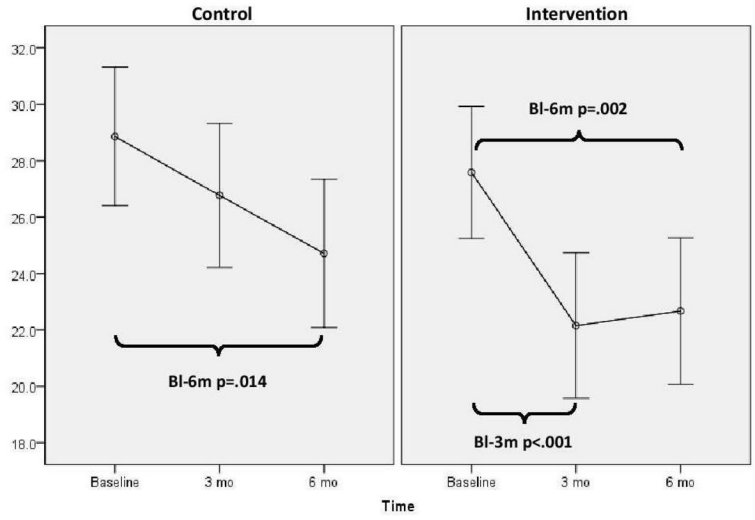


Figure 1.
QUALITY HF-DM Consort Flowchart

a. MLHFQ Total: Adjusted Means and 95% CI (for Age, BMI, CCI)



b. MLHFQ Physical: Adjusted Means and 95% CI (for Age, BMI, CCI)



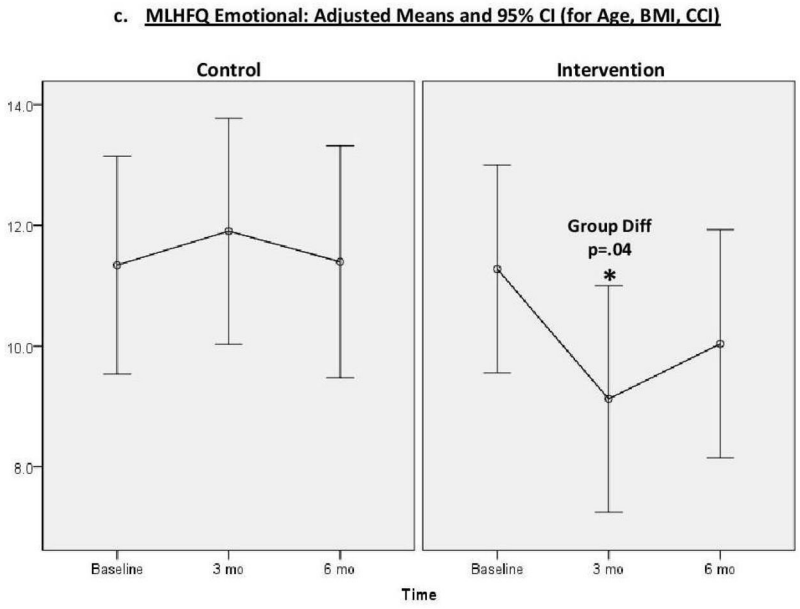


Figure 2.

Minnesota Living with HF Questionnaire (MLHFQ) Scores over time by group. Means and 95% Confidence Intervals for Total, Physical and Emotional scores (adjusted for Age, BMI and CCI).

a. MLHFQ Total: Adjusted Means and 95% CI (for Age, BMI, CCI)

b. MLHFQ Physical: Adjusted Means and 95% CI (for Age, BMI, CCI)

c. MLHFQ Emotional: Adjusted Means and 95% CI (for Age, BMI, CCI)

Table 1

Content and Behavioral Strategies of the Integrated HF-DM self-care Intervention

Content
• Overview of HF and DM; brief description of how HF and DM interact and worsen the other condition
• Expected self-care for HF and DM; Potential conflicts in HF and DM self-care
• Diet: Principles for an integrated low sodium and carbohydrate diet; portion control, label reading for HF and DM, and sample menus; eating out with HF-DM
• Medications: Overview of HF and DM medication goals; individualized HF-DM meds, Potential medication conflicts, over the counter medications, and medication-taking behavior to promote adherence
• Symptom Monitoring: How to assess, interpret and report edema, fatigue, shortness of breath, sleep difficulties, depressive symptoms and mood,
• Self-Monitoring: Blood Glucose and Weight; how to interpret together; relationship to HF-DM symptoms
• Physical Activity: rationale, frequency, duration, safety (physical and effect on glucose levels), walking and alternative activities
• Oral and Foot Care
Educational strategies
• Individual teaching and discussion with illustrated content
• Coordinated written materials
• Health Literacy: 6th grade reading level and multiple illustrations
• Demonstration, return demonstration (e.g. label reading for portion, sodium, carbohydrates, symptom and self-monitoring interpretation)
• Questions and answers
• Repetition of content, recheck of learning (follow up home and clinic visits, phone calls)
Behavioral strategies
• Goal setting and evaluation
• Symptom and Self-monitoring
• Problem-solving
• Seeking support
• Motivational messages

Table 2

Demographic and Clinical Characteristics

	Overall (n=134)	Control (n=64)	Intervention (n=70)	Difference (p-value)
Age years (mean (SD)) [range min, max]	57.4 (10.6) [29, 81]	57.0(10.8) [29, 76]	57.7 (10.5) [31, 81]	.674
Gender (n, % male)	88 (65.7%)	41 64.1%)	47 (67.1%)	.708
Race (n, % AA)	93 (69.4%)	41 64.1%)	52 (74.3%)	.200
Married/Partner (n, %)	69 (51.5%)	31 48.4%)	38 (54.3%)	.499
Lives alone (n, %)	30 (22.4%)	14 (21.9%)	16 (22.9%)	.892
Education (n, % hs or less)	50 (37.3%)	25 39.1%)	25 (35.7%)	.689
NYHA				
Class I (n, %)	1 (0.7%)	0 (0.0%)	1 (1.4%)	.786
Class II (n, %)	56 (41.8%)	28(43.8%)	28 (40.0%)	
Class III (n, %)	67 (50.0%)	31(48.4%)	36 (51.4%)	
Class IV (n, %)	10 (7.5%)	5 (7.8%)	5 (7.1%)	
LVEF % mean (SD)	33.9 (17.6)	35.7 18.6)	32.3 (16.6)	.278
BMI (mean (SD)	37.1 (9.0)	36.4 (7.8)	37.7 (10.1)	.392
Health rating n, (%)				
Poor	32 (24.8%)	20 (33.3%)	12 (17.4%)	.112
Fair	56 (43.4%)	23 (38.3%)	33 (47.8%)	
Good	41 (31.8%)	17 (28.3%)	24 (34.8%)	
HgA1c (mean (SD) [range min, max]	8.0 (1.7) [4.5, 12.6]	8.2 (1.6) [5.0, 12.2]	7.9 (1.8) [4.5, 12.6]	.218
Charlson Comorbidity Index (CCI)	4.11 (2.3)	4.20 (2.4)	4.03 (2.4)	.524
Comorbidities (% >2)	96 (71.6%)	47 (73.4%)	49 (70.0%)	.65[b]
Prior MI (% yes)	43 (32.1%)	25 (39.1%)	18 (25.7%)	.098
PVD (% yes)	9 (6.7%)	5 (7.8%)	4 (5.7%)	.736
Renal Disease (% yes)	38 (28.4%)	17 (26.6%)	21 (30.0%)	.659
% DM before HF	89 (67.4%)	40 (62.5%)	49 (72.1%)	.242
Medications				
Ace or ARB	90 (68.7%)	39 (62.9%)	51 (73.9%)	.175
Beta Blockers	126(94.7%)	62 (96.9%)	64 (92.8%)	.443
Loop Diuretics	122(91.7%)	57 (89.1%)	65 (94.2%)	.282
Aldosterone Inhibitor	44 (33.3%)	23 (35.9%)	21 (30.9%)	.538

SD (Standard Deviation); AA (African American); NYHA (New York Heart Association); LVEF (Left-Ventricular Ejection Fraction); BMI (Body Mass Index); MI (Myocardial Infarction); PVD (Peripheral Vascular Disease); DM (Diabetes); HF (Heart Failure); ARB (Aldosterone Receptor Blocker)

Table 3

Quality of Life: MLWHF, ADDQOL and EQ5D Results

Measure	Baseline	3 months	6 months
	Mean (SD)	**Mean (SD)**	**Mean (SD)**
MLWHF (Cα=0.92)			
Control	64.6 (20.6)	60.8 (23.5)	57.2 (25.9)
Intervention	62.1 (24.3)	50.0 (25.7)	50.9 (25.4)
MLWHF Physical (Cα=0.90)			
Control	28.9 (8.6)	27.0 (10.6)	24.8 (10.9)
Intervention	27.6 (9.8)	22.3 (11.2)	22.6 (11.2)
MLWHF Emotional (Cα=0.89)			
Control	11.5 (7.2)	12.0 (7.4)	11.2 (8.4)
Intervention	11.3 (8.1)	9.0 (7.4)	9.7 (7.7)
ADDQOL (Cα=0.92)			
Control	−2.98 (2.1)	−3.04 (2.1)	−2.95 (2.0)
Intervention	−3.51 (2.2)	−3.16 (2.1)	−3.49 (2.3)
EQ-5D (Cα=0.67)			
Control	0.74 (0.2)	0.66 (0.2)	0.69 (0.2)
Intervention	0.75 (0.2)	0.69 (0.2)	0.75 (0.2)
EQVAS			
Control	56.4 (20.1)	58.7 (16.3)	57.8 (19.9)
Intervention	60.6 (19.5)	63.2 (21.8)	67.5 (17.4)

MLWHF, Minnesota Living with Heart Failure; ADDQOL (Audit of Diabetes-Dependent Quality of Life); SD (standard deviation); Cα (Cronbach's alpha reliability); EQ-5D (EuroQol 5 Dimension) EQVAS (EuroQol Visual Analogue Scale)

Table 4

Physical Functioning (six minute walk test distance in feet)

Continuous (feet)	Baseline (BL)			6 mo			Diff (6mo – BL)		
Group	**n**	**Mean SD)**	**Median**	**n**	**Mean SD)**	**Median**	**n**	**Mean SD)**	**Median**
ALL	66	924.1 (314.9)	949.5	66	983.3 (302.5)	1000.0	66	59.2 (318.5)	4.00
Control	37	865.6 (324.1)	856.0	37	904.8 (314.6)	900.0	37	39.2 (336.7)	3.0
Intervention	29	998.7 (291.3)	995.0	29	1083.6 (258.0)	1100.0	29	84.8 (297.6)**	100.0

Dichotomized (6MWT (% > 984)				
	N	**n (%)**	**N**	**n (%)**
ALL	66	29 (43.9%)	66	36 (54.5%)
Control	37	14 (37.8%)	37	14 (37.8%)
Intervention	29	15 (51.7%)	29	22 (75.9%)
		$\chi^2_{(1)}$=1.273 p=.259		$\chi^2_{(1)}$=9.481 p=.002

** 6MWT adjusted for BMI, RM-ANOVA $F_{1, 63}$=6.86, p=.01

BL (Baseline); BMI, Body Mass Index, 6MWT; Six Minute Walk Test; RM-ANOVA, repeated measures analysis of variance