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An Economic Evaluation of a Self-Care Intervention in Persons with Heart Failure and Diabetes

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Abstract

Background—Persons with concomitant heart failure (HF) and diabetes mellitus are a growing population whose quality of life is encumbered with worse clinical outcomes as well as high health resource use (HRU) and costs.

Methods and Results—Extensive data on HRU and costs were collected as part of a prospective cost effectiveness analysis of a self-care intervention to improve outcomes in persons with both HF and diabetes. HRU costs were assigned from a Medicare reimbursement perspective. Patients (n=134) randomized to the self-care intervention and those receiving usual care/attention control were followed for 6 months, revealing significant differences in the number of hospitalization days and associated costs between groups. The mean number of inpatient days (d) was 3d with bootstrapped bias corrected (BCa) confidence intervals (CI) of 1.8d – 4.4d) for intervention group and 7.3d (BCa CI 4.1d – 10.9d) in the control group; p= .044. Total direct HRU costs per participant were an estimated $9,065 (BCa CI $6,496 to $11,936) in the intervention and $16,712 (BCa CI 8,200 to $26,621) in the control group, for a mean difference of −$7,647 (BCa CI −$17,588 to $809, p= .21) in favor of the intervention, including intervention costs estimated to be $130.67 per patient.

Conclusions—The self-care intervention demonstrated dominance in lowering costs without sacrificing Quality Adjusted Life Years.

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Keywords

Diabetes; Cost-Effectiveness Analyses; Self-care intervention

Introduction

The most recent statistics reveal that over 5.7 million persons in the United States have heart failure (HF) with an expected growth to over 8 million by 2030.[1] As the most common cause of hospitalization in older adults, [2] HF accounts for 6.5 million hospital days each year as well as over 18 million office visits.[1] High economic and individual patient burden of HF is partially due to the rate of rehospitalizations which are reported as high as 25% within 30 days,[3] 47% by 90 days[4, 5] and 54% within 6 months.[6] A striking 40–60% of these are believed to be preventable by greater provider attention to standards of care and better patient self-care.[7–9] Diabetes mellitus is also increasing due to aging and obesity epidemics, and studies report that approximately 30%–47% of HF patients have concomitant diabetes.[1011, 12] There is an increased risk of mortality among HF patients with diabetes, ranging from 40% to 80% excess risk, and a reported 1.6 fold increase in the relative risk for rehospitalization over those without diabetes.[5, 13–18] The prevalence of both diseases is increasing worldwide as the general population ages with over 1.5 to 2% of individuals over the age of 65 now having both HF and diabetes, and exponential growth expected in the next decades.[1] Therefore, patients with concomitant HF and diabetes represent a growing population whose quality of life is encumbered with worse clinical outcomes as well as high health resource use (HRU) and costs.[19]

The purpose of this study was to conduct a prospective cost-effective analysis of a randomized clinical biobehavioral trial (Quality HF-diabetes) focused on improving comorbid self-care for persons with both HF and diabetes. The self-care intervention improved HF quality of life, physical function and self-reported physical activity.[20] This analysis of HRU and costs was undertaken to provide a comprehensive picture for determining the usefulness of the intervention and implications for translation into practice.

Methods

Design, Setting and Sample

The design and methods of Quality HF-diabetes have been described in detail previously.[20, 21] Participants were recruited during or within 3 months of an inpatient HF hospitalization at one of four participating urban hospitals between 2011 and 2013. All were large tertiary care facilities with HF outpatient clinics. Inclusion and exclusion criteria are presented in Table 1. HF-diabetes patients who were experiencing their first HF hospitalization were also excluded to allow for some experience with self-care before a comorbidity-focused intervention. All study procedures were approved by the Institutional Review Board 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, and body mass index (BMI). These variables, considered antecedent factors influencing self-care, were used to fully describe the sample and to compare treatment groups. Participants were randomized to intervention or control groups. Data were collected at baseline (BL), and at 3 and 6 months after enrollment, such that all visits were completed within 1 year of an acute HF hospitalization.

Intervention Vs. Usual Care Attention Control Group

Self-monitoring is a powerful behavioral tool for self-care and behavior change.[22] A detailed explanation of the intervention is available in the accompanying article that fully describes the primary goals and outcomes of the study.[20] The intervention was based on principles of adult learning, motivation and feedback, goal setting and provided both content and self-management strategies.[23–28] The intervention was initiated in the hospital setting or soon after baseline data collection and study enrollment, and initially included an individualized educational and counseling session. The intervention was structured but also individually tailored based on a well-established baseline HF and diabetes knowledge test, and the individual medication regimen. Family members were encouraged to attend.

The 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". The goals of the integrated intervention were to: 1) provide education and skills to perform integrated self-care related to their HF and diabetes diet, medication taking, and symptom and self-monitoring, 2) enhance physical activity, and 3) increase self-efficacy related to both HF and diabetes self-care, and 4) promote recognition of the interaction between self-management strategies for HF and diabetes and facilitate decision making for treatment and provider contact when symptoms occur. Content was selected from standard teaching recommendations and guidelines for HF and diabetes patients[23, 25, 29, 30] and was reviewed in a prior pilot study by HF and diabetes experts from nursing, medicine, and nutrition.[21]

At 48–72 hours, a home visit by the research nurse was made to review self-monitored glucose and weight information, 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 and the patients' interpretation of the data, and queried about diet and medication-taking behavior. In-depth physical activity (PA) counseling occurred at the 2 week visit when participants routinely returned to the clinic. The research nurse emphasized why PA was helpful to both HF and diabetes, provided 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 utilized problem solving for issues such as 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 short (15 minutes), scripted phone calls occurred at 1, 2 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. Participants in the control group received routine education and standard hospital discharge instructions from their providers and the hospital nursing staff, with all enrolling institutions routinely including family members in the discharge teaching if present. In addition to routine post discharge follow up care, the control group received "attention control" phone calls from the research nurses at the same schedule as the intervention participants (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.

Outcome measures

The central hypotheses of the study was that the intervention group would consume less direct healthcare resources over the 6 months than those in the control group, plus have improved outcomes of health related quality of life (HRQOL) and physical functioning.

Resource Use and Cost Determination—Health Resource Utilization (HRU) was collected prospectively within the clinical trial through patient completed HRU diaries and thorough medical record review for all HRU encounters for the period of enrollment in the trial, or their last research collection point in those patients who died or dropped from the study. The research nurse reviewed the participant's HRU diary at every visit and at least monthly for the 6 months of the study follow-up. All HRU encounters were then evaluated for relation to cardiovascular disease (CVD) and or diabetes to limit contamination of effect from other comorbidities or interventions.

Given that most persons with HF receive their health benefits through Medicare and the reimbursement of such care is directly tied to outcomes including 30 day readmission, costs were assigned from a Medicare perspective using standard Centers for Medicare Services (CMS) reimbursement for the most recent year available. No discounting or inflation was necessary as the study period was only 6 months long. Further, all fixed cost value was used for the same healthcare utilization regardless of when the patient received the services during the 3-year study period. Thus, costs were only higher in the two arms if patients used a different mix of services.

The costs of the intervention included the educational and self-monitoring materials provided to intervention group, calculation of the RN time of 3.25 hours for the initial education/counseling, home visit, and follow up visits and calls for education/counseling. The costs of the control group were based on the minimal materials (brochures) provided to the participants, and RN time of .5 hr to make follow up attention control phone calls. Not included in either total was the nursing time devoted to research data collection nor the intervention development costs including a focus group in the pilot study which would not be part of a program adapted for use in practice. Thus an intervention cost of $130.76 was determined to be the difference between groups and added to the total direct costs (TDCs) costs for the intervention group participants only. To limit bias, following collection of the patient reported HRU by the research nurse, all final assessment of HRU including medical record review and assignment of charges was done by researchers blinded to randomization.

Effectiveness Measures—Quality adjusted life years (QALYs) derived from the EQ-5D with associated utility weights for the US were used as the final health outcome for this

analysis.[31, 32] A recent meta-review validated this method for use in persons with CVD including HF.[33] Participants completed the EQ-5D at baseline, three, and six months with change values presented.

Statistical Analysis

Baseline statistical analysis was conducted using SPSS v. 21.[34] A p-value of 0.05 was used to determine mean differences between group in each of the components of effectiveness and HRU and 95% bootstrapped bias corrected (BCa) confidence intervals (SPSS BOOTSTRAP procedure) were generated for the sensitivity analyses. BCa confidence intervals were computed since they provide the desired coverage in the presence of outliers in the cost component of the cost-effectiveness-ratio (CER).[35] Total observed number of contacts and proportions of each group who experienced readmissions, ED visits and provider contacts, and mean group readmission rates, total LOS and pattern of care use for those readmitted were analyzed.

All data were reviewed for completeness, outliers and deviations from normality. Only minimal data was missing, with no statistical difference in this missing data between groups, requiring no adjustment or substitution. Differences between the 2 groups on demographics and baseline clinical characteristics were tested using t-tests (for normally distributed continuous measures), chi-square tests (for categorical measures), and Mann Whitney non-parametric tests (for non-normally distributed measures). Descriptive statistics and multilevel mixed models (to adjust for the attrition amounts over time) were run for all outcome measures for all subjects and by group at all 3 time points. The covariates of age, gender, BMI, Charlson Comorbidity Index, and NYHA were investigated for TDCs as well as the change scores (from baseline to 6 months) for the EQ-5D calculation of QALYs. None of the covariates were significant for the effect change scores and TDCs and thus were not adjusted for in each model presented.

The nonparametric bootstrap methods using the BCa approach for computing the confidence limits for the incremental cost-effective ratio (ICER) recommended by Mahoney and Chu[36] were followed to create the confidence boxes for the cost-effectiveness plane scatterplots. For each outcome, the improvements from baseline to 6 months were computed as the changes scores subtracting the baseline scores from the 6 month scores such that positive change scores indicated improvement from baseline to 6 months. Using R version 3.1.0 (2014-04-10; © 2014 The R Foundation for Statistical Computing) with package boot (version 1.3–11), bootstrapping was performed to compute the mean difference between the outcome effects for the intervention group and the outcome effect for the control group. During this bootstrapping process the mean differences between the groups were also computed for the total direct costs plus intervention. This bootstrapping approach was repeated 1000 times such that BCa 95% confidence intervals were estimated for these group differences for each outcome effect and for the differences for the associated total direct costs. The joint distribution of group differences in total direct costs and group differences in outcome effects were plotted in a scatterplot with the 95% BCa confidence intervals overlaid the confidence boxes for the cost-effectiveness plane (Figure 1). Further, because cost and HRU data is inherently skewed, the bootstrapping approach greatly minimizes the impact of

both higher cost skewed values as well as extreme values (outliers) by repeatedly random sampling. In our study, only 2 cases, both in the control group, were outliers (defined as persons who accrued costs/HRU greater than 2 standard deviations from the mean). Following Intent-to-treat principles and not removing data without due cause, these outliers were retained in the analysis. However, their impact was small overall as they represented only 3% of the patient pool, which was well below the published norms that suggest adjustment or imputation for amounts greater than 5 or 10% of the sample.[35] Additionally, the bootstrapping random sampling is performed 1000 times which further minimizes the impact of these outliers.

Results

Demographics and baseline clinical characteristics

The consort table detailed by Dunbar et al, 2015, reflects that overall 741 HF-diabetes patients were screened, and 606 were excluded or refused participation with the most common reasons related to serious comorbidities, living too far from enrolling institution, and actual or perceived mobility issues preventing participation in the walking component of the intervention. Between 2010 and 2013, 134 subjects were enrolled with baseline characteristics presented in Table 2. The average age of participants was 57.4 years (SD 10.6). Participants were more likely to be male (65.7%), African American (69.4%), and have more than a high school education (62.7%). Slightly more than half of study participants were married (51.5%). Key clinical characteristics indicated that the average BMI was 37.1, subjects had an average ejection fraction of 33.9, and 57.5% were classified as being NYHA class III or IV. All subjects had HF and diabetes to be included in the study, but 71.6% had additional comorbidities. A majority were diagnosed with diabetes before HF (67.4%), having had diabetes an average of 10.5 years longer than HF. No statistically significant differences in any of the clinical variables between the two groups at baseline were observed.

Of the 134 subjects randomized at baseline (64 control, 70 intervention group), 108 completed the study [54 control (84.4%), 54 intervention group (77.1%)], with no statistical significance between the 2 groups (χ^2 (1) =1.118, p=.290). Of the 26 who did not complete the study, 4 subjects died, 12 withdrew and 10 were lost to follow-up, but there were no differences in percent of completers between groups.

Healthcare Utilization and Costs

The HRU by category count and costs are detailed in Table 3. As can be visualized, there were no differences in the counts of lower cost items of provider office visits, procedure and treatment costs, and emergency department encounters. Total direct HRU costs per participant were an estimated $9,065 (BCa CI $6,496 – $11,936) in the intervention group and $16,712 (BCa CI 8,200– $26,621) in the control group, for a mean difference of −$7,647 (BCa CI −$17,588 to $809, p= .208). The direct cost intervention costs estimated to be $130.67 per patient were included in the TDC for intervention group.

As HRU costs are driven primarily by hospitalizations, a thorough evaluation of hospitalizations is warranted. Nearly half of the study participants (n= 55, 41.0%) experienced at least one and up to 5 rehospitalizations within the 6 months follow-up, for a total of 108 hospitalizations. By calculating days out of the hospital by group, a significant difference by group was observed with the intervention group having a mean of 177 (*SD* 5.7) days vs 173 (*SD* 14.7) in the control group (p= .04). Analysis of the 55 patients requiring hospitalizations as presented in Table 4 revealed a difference in the number hospitalizations experienced by group (intervention group= 1.62 [BCa CI 1.35 – 1.94] vs control= 2.35 [BCa CI 1.84 – 2.84], p= .03), a difference in the length of stay by group (intervention group= 7.21 [BCa CI 4.78 – 9.94] vs control = 17.96 [BCa CI 11.4 – 26.39], p= .02), and a trend for lower hospital cost by group an average of −$19,249 (BCa CI −$45,985 to $1208) savings in hospital costs for the intervention as compared to the control patients, p= .17.

Given the CMS penalties and nonpayment for 30day HF readmissions, a subset of 38 subjects who were enrolled from an acute hospitalization and rehospitalized at least once were evaluated revealing fewer rehospitalizations within the 30 day window in the intervention group (n=3, 16.7%) compared with controls (n=9, 45%). This difference of 28.3% fewer hospitalizations within 30 days in the intervention group is clinically and financially important, achieving a trend towards statistical significance (χ^2 (1) =3.52, p=.06).

Cost Effectiveness Analysis

Final Health Outcome: QALYs—Measured with the EQ-5D at baseline and 6 months, the estimated effect difference is presented in Table 5 where a mean undiscounted QALYs of 0.04 (BCa CI −.0.04 to 0.11) difference was due to the decline in QALYs observed in the control group while the intervention group remained stable from baseline to the final 6 month assessment. While this was not a significant difference, when combined with the cost savings as demonstrated in Figure 2, the dominance of the intervention is obvious. This scatterplot of 1000 bootstrap samples represents the joint distribution of differences in mean direct medical costs (including intervention costs) and these mean QALYS. The dotted lines represent the 95% confidence limits. The figure indicates that most bootstrap estimations were consistent with a decrease in cost while QALYs remained the same or modestly improved, with 79.3% of the samples falling into the lower right quadrant II of the cost effectiveness plane (Figure 2) whereby costs are less and effects improved.

Discussion

In the large tertiary medical centers serving diverse population, this intervention targeted improving self-care of persons with comorbid HF and diabetes, thereby hoping to improve patient reported and clinical outcomes while diminishing costs. The results presented indicate that the intervention group showed a trend toward reducing HRU and thus costs, and modestly improved HRQOL.

Rehospitalizations account for most HRU costs as evidenced by a mean of $28,496 ($44,457) TDC in persons requiring a rehospitalization, compared with $900 ($1181) in persons who did not require rehospitalization. In line with previous research, [3–6] these

rehospitalizations were observed in 43% of our total participants for the 6 month period. This paired with the near significant decrease in 30 day readmissions (in those recruited from the hospital) observed in persons receiving the intervention compared to those in the control group holds great implications for hospitals. Despite CMS penalties for 30 day readmissions of persons with HF, minimal progress has been achieved in reducing 30day HF readmission rates.[37] While a small sample, we were able to document a rate of 17% 30day readmission in persons who received the intervention compared to over double that in the control group. The effect size, omega (ω) was of moderate size (ω = 0.30), which for a sample size of 38 achieves only 47% power – a larger sample of 85 or more would be needed to achieve 80% power or higher.

In comparing groups using bootstrapping sampling, unadjusted direct medical costs in the intervention group were observed to be $7,647 lower than the control group. While the confidence interval contained zero, 93% of the bootstrapped estimates for the group differences were below 0 indicating evidence of cost savings in the intervention group. One of the most visuals means of evaluating cost effectiveness is through analysis of the scatterplot graphs created by plotting the 1000 generated samples of the data on a cost-effectiveness plane presented in Figure 1. It is easiest to interpret this plane by starting in quadrant II where an intervention is found to be more effective and cost less. Typically, when the majority of the samples fall within this quadrant, the intervention is determined to dominate over the usual care or comparator. Similarly, interventions plotted to quadrant IV indicating greater cost and less effectiveness would not be adopted. The 2 quadrants then that require further analysis to validate a cost per amount of effect are quadrants I and quadrant III where you can either have a more effective intervention for more cost, or a less effective intervention for less cost. This amount of trade-off is then quantified with cost effectiveness ratios.

In our study, we demonstrated in Figure 2 that the majority of the bootstrap samples fall within quadrant II, interpreted as dominance of the intervention as opposed to usual care in both cost and effect. Importantly, less than 1% of the scatterplots fell into the top left quadrant IV of the CE plane where the intervention is deemed unacceptable by being both less effective and more costly. In addition, we conducted a one-way sensitivity analysis by increasing total intervention costs by incremental percentage up to 500%. As shown in Figure 3, even if total intervention cost equaled $1307 (500% of observed intervention cost), the intervention group still accrued significantly less costs. In fact, to achieve cost neutrality, the intervention would have to cost $7778 in our sample.

Limitations

A few limitations are important to note. Foremost, HRU costs are inherently positively skewed with a small percent of patients accruing the majority of costs. We attempted to correct for this with bootstrap sampling as recommended by experts in costing techniques,[35, 36] whereby each group was sampled 1000 times, thus greatly minimizing the impact of any outliers. Further, we did note two cost outliers, both in the control groups, representing 3% of the total patients. As this did not approach the 5–10% recommended for

applying imputation methods, we followed our intent to treat procedures and did not alter them for the analysis.

The computation of these costs was from that of a Medicare reimbursement perspective which could have itself limited our findings. While a standardized process and accounting method, it does not take into account the actual costs incurred by the patients or the healthcare facilities which may be substantially greater. We believe this methodology may have limited the significance of our costing results by not accounting for the presumed greater costs in delivering care to control patients who had significantly more rehospitalizations and greater than twice the length of stay for these subsequent hospitalizations. Thus the positive impact of this analysis may be understated.

Finally, the sample is limited by the strict criteria used to enroll participants who could successfully participate in the intervention and exclusion of factors that would confound the outcome measures, thus the generalizability is limited. On the other hand, the diverse sample represents successful recruitment of both women and African Americans, two groups not consistently represented in clinical trials, and this should help increase generalizability. The ability to reproduce the findings in other settings is not known, however the reproducibility of the co-morbidity intervention is possible. A future study with modified intervention approaches appropriate for a larger, more representative HF-diabetes population is suggested. Additionally the study excluded those experiencing their first HF admission, and removal of this restriction may allow for self-care intervention in this group earlier in the illness trajectory.

Implications

The reduction in HRU of the intervention group holds significant implications for hospitals on two fronts. First, across all patients necessitating rehospitalization, subsequent visits in the intervention group accrued significantly shorter lengths of stay than those in the control group. This most likely reflects the reduced acuity of these patients upon readmission, indicating that because of the education received as part of the intervention, they may have recognized symptoms and sought care earlier than their counterparts in the control group. Second, in the subset of patients recruited directly from the hospital for an acute HF exacerbation, persons in the intervention group had near significant less recidivism in the first 30 days than persons in the control group. It is believed with a larger sample, this trend would have demonstrated significance reflecting the timely delivery of this intervention in the home within a few short days of discharge. This intervention provided the patients with valuable information and resources to help better manage their comorbid conditions that often have conflicting strategies.

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Highlights

- A self-care intervention to improve outcomes in patients with both heart failure and diabetes mellitus was associated with net cost savings of $7647 per patient over a 6-month period.
- The reduced cost was driven primarily by a reduction in the number of days hospitalized, which averaged about 4 days/patient.
- The cost of the intervention was low, averaging $131/patient.

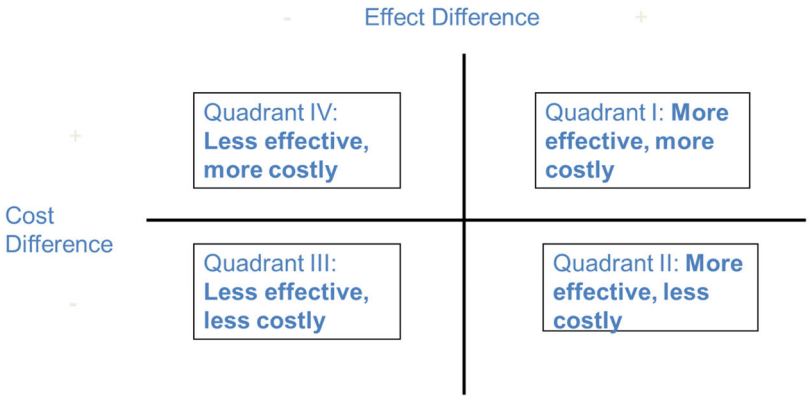

Figure 1.
Cost Effectiveness Plane

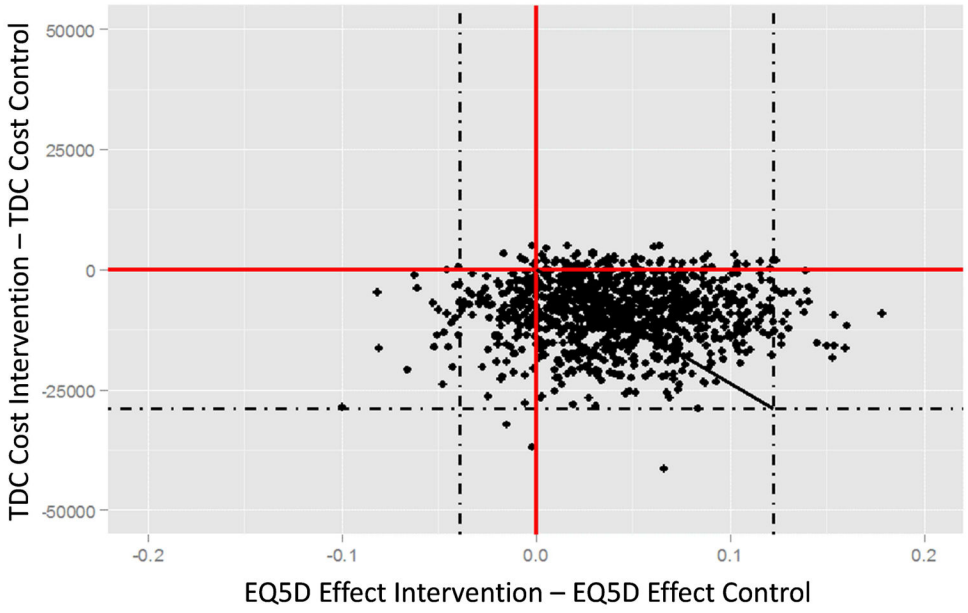

Figure 2.
Scatterplot of Cost Savings Associated with the Intervention per QALY

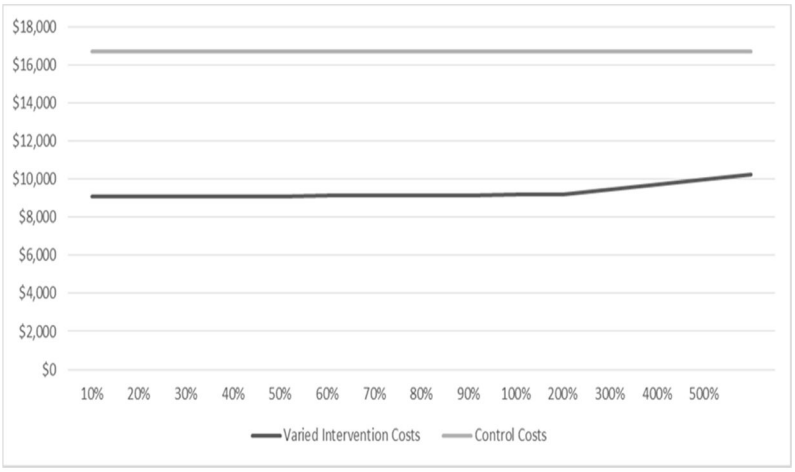

Figure 3.
One-Way Sensitivity Analysis of Intervention Costs

Table 1

Inclusion and Exclusion Criteria

Inclusion	Exclusion
• Age 21–82 years	• Uncorrected hearing or vision problem
• Admitting diagnosis of HF	• Depressive symptoms (>10 on PHQ-9)
• NYHA Class II–IV	• Cognitive impairment (>11 BOMC)
• Concomitant Type II Diabetes	• Undergoing cardiac transplant or VAD evaluation
• Planned discharge to home	• Renal failure
• English fluency	• Lack of telephone access
• Cognitive screen	
• Optimal HF meds	
• Ambulatory	

Abbreviations: NYHA: New York Heart Association Functional Class; PHQ-9: Patient Health Questionnaire-9; BOMC: The Blessed Orientation-Memory-Concentration; VAD: Ventricular Assist Device

Table 2

Demographics and Baseline Clinical Characteristics

	Overall (n=134)	Control Group (n=64)	Intervention Group (n=70)	Group Differences (p-value)
Age years [mean (SD)]	57.4 (10.6)	57.0 (10.8)	57.7 (10.5)	.674
Gender (% male)	88 (65.7%)	41 (64.1%)	47 (67.1%)	.708
Race (% AA)	93 (69.4%)	41 (64.1%)	52 (74.3%)	.200
Married/Partnered	69 (51.5%)	31 (48.4%)	38 (54.3%)	.499
Education (% HS or less)	50 (37.3%)	25 (39.1%)	25 (35.7%)	.689
NYHA				
Class I (%)	1 (0.7%)	0 (0.0%)	1 (1.4%)	.786
Class II (%)	56 (41.8%)	28 (43.8%)	28 (40.0%)	[I/II Vs III/IV]
Class III (%)	67 (50.0%)	31 (48.4%)	36 (51.4%)	
Class IV (%)	10 (7.5%)	5 (7.8%)	5 (7.1%)	
LVEF % [mean (SD)] [n=130]	33.9 (17.6)	35.7 (18.6)	32.3 (16.6)	.278
BMI [mean (SD)] [n=133]	37.1 (9.0)	36.4 (7.8)	37.7 (10.1)	.392
HgA1c [mean (SD)] [n=118]	8.0 (1.7)	8.2 (1.6)	7.9 (1.8)	.218
Charlson Comorbidity Index	4.11 (2.3)	4.20 (2.4)	4.03 (2.4)	.524
Number Comorbidities (% >2)	96 (71.6%)	47 (73.4%)	49 (70.0%)	.659
% diabetes before HF [n=132]	89 (67.4%)	40 (62.5%)	49 (72.1%)	.242
Years with diabetes before HF	N=89	N=40	N=49	
	10.5 (7.8)	11.0 (8.5)	10.0 (7.2)	

Abbreviations: SD: standard deviation; AA: African American; HS: high school completion; LVEF: Left ventricular ejection fraction; BMI: Body mass index; HgA1c: hemoglobin A1c level.

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Table 3

Health Resource Utilization and Cost Data by Group

			ANOVA BCa BCa 95% Confidence Interval for Mean			
		n	**Mean**	**Lower Bound**	**Upper Bound**	**p-value**
Total Hospitalizations count	Control	64	0.95	0.63	1.33	0.21
	Intervention	70	0.67	0.46	0.87	
Difference			−0.28	−0.75	0.16	
Hospital costs (DRG means)	Control	64	$15,477	$7,372	$25,399	0.21
	Intervention	70	$7,809	$4,997	$10,862	
Difference			−$7,669	−$18,343	$931	
Office visit count	Control	64	5.2	4.15	6.43	0.56
	Intervention	70	5.73	4.53	6.99	
Difference			0.53	−1.20	2.20	
Office costs	Control	64	$255	$207	$305	0.54
	Intervention	70	$280	$220	$344	
Difference			$26	−$51	$104	
Procedure and Treatment costs	Control	64	$242	$188	$300	0.35
	Intervention	70	$363	$224	$553	
Difference			$121	−$50	$363	
ED visit count	Control	64	0.55	0.27	0.93	0.37
	Intervention	70	0.36	0.21	0.52	
Difference			−0.19	−0.59	0.13	
ED visit costs	Control	64	$738	$354	$1,166	0.37
	Intervention	70	$482	$311	$665	
Difference			−$256	−$734	$181	
TDC costs (DRG Means)	Control	64	$16,712	$8,344	$27,989	0.21
	Intervention	70	$8,934	$6,305	$11,913	
Difference			−$7,777	−$19,872	$1,269	
TDC + Intervention Group costs	Control	64	$16,712	$8,200	$26,621	0.21
	Intervention	70	$9,065	$6,496	$11,936	
Difference			−$7,647	−$17,588	$809	

			ANOVA BCa BCa 95% Confidence Interval for Mean			
		n	**Mean**	**Lower Bound**	**Upper Bound**	**p-value**
Hospital LOS	Control	64	7.30	4.05	10.94	0.04
	Intervention	70	2.99	1.80	4.42	
Difference			−4.31	−8.49	−0.91	
Days out of Hospital	Control	64	172.7	168.7	176.2	0.04
	Intervention	70	177.0	175.4	178.3	
Difference			4.31	0.53	8.44	

Abbreviations: ANOVA: Analysis of variance analysis; BCa: bootstrapped bias corrected; DRG: Diagnosis related group; TDC: Total direct costs; LOS: Length of stay

Table 4

Hospitalized Patient Data (n=55)

		ANOVA Bca BCa 95% Confidence Interval for Mean				
		n	**Mean**	**Lower Bound**	**Upper Bound**	**p-value**
Hospitalization Count	Control	26	2.35	1.84	2.84	0.03
	Intervention	29	1.62	1.35	1.94	
Difference			−0.73	−1.30	−0.14	
Hospital costs	Control	26	$38,098	$18,558	$64,786	0.17
	Intervention	29	$18,849	$14,511	$23,625	
Difference			−$19,249	−$45,985	$1,208	
Hospital LOS	Control	26	17.96	11.4	26.39	0.02
	Intervention	29	7.21	4.78	9.94	
Difference			−10.75	−19.10	−4.08	

Table 5

Differences in Quality Adjusted Life Years (QALYs) from EQ-5D by Group

Measure	Baseline		3 month		6 month		Changes BL to 6 month	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean
EQ-5D QALY								
Control	64	0.74 (0.2)	57	0.66 (0.2)	53	0.69 (0.2)	53	−0.04
BCa 95% CI							*[−0.11, 0.02]*	
Intervention	68	0.75 (0.2)	55	0.69 (0.2)	53	0.75 (0.2)	51	0.00
BCa 95% CI							*[−0.05, 0.05]*	
Effect Difference							0.04 *[−.04, .11]*	