A Randomized Controlled Effectiveness Trial of Reciprocal Peer Support in Heart Failure

Heisler et al: Reciprocal Peer Support in Heart Failure

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Abstract

**Background**—Disease management programs for patients hospitalized with heart failure (HF) although effective, are often resource intensive, limiting their uptake. Peer support programs have led to improved outcomes among patients with other chronic conditions and may result in similar improvements for HF patients.

**Methods and Results**—In this randomized controlled trial, Reciprocal Peer Support (RSP) arm patients participated in a HF nurse practitioner (NP)-led goal setting group session, received brief training in peer communication skills, and were paired with another participant in their cohort with whom they were encouraged to talk weekly using a telephone platform. Participants were also encouraged to attend three NP-facilitated peer support group sessions. Patients in the Nurse Care Management (NCM) arm attended a NP-led session to address their HF care questions and receive HF educational materials and information on how to access care management services. The median age of the patients was 69 years, 51% were female, and 26% were racial/ethnic minorities. Only 55% of RPS patients participated in peer calls or group sessions. In intention-to-treat analyses, the RPS and NCM groups did not differ in time to first all-cause rehospitalization or death or in mean numbers of rehospitalizations or deaths. There were no differences in improvements in 6-month measures of HF-specific quality of life or social support.

**Conclusions**—Among patients recently hospitalized for HF, over half of RPS participants had no or minimal engagement with the reciprocal peer support program, and the program did not improve outcomes compared to usual HF-nurse care management.

**Clinical Trial Registration**—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00508508.

**Key Words:** heart failure, peer support, randomized controlled trial, self-management, nurse case management
Developing effective strategies to improve self-management and thereby reduce readmissions of patients with heart failure (HF) is a national health priority.\textsuperscript{1-3} Even when providers prescribe evidence-based medical therapies, patient nonadherence to HF medications ranges from 30 to 60\%, with nonadherence to lifestyle recommendations even higher at 50 to 80\%.\textsuperscript{4} Such poor HF self-management contributes to HF hospitalizations and readmissions.\textsuperscript{5-7}

Intensive multifactorial care management programs can improve patient HF self-management and reduce readmissions.\textsuperscript{8-12} These programs, however, are labor- and resource-intensive. Many practices face multiple barriers to delivering such resource-intensive support for HF patients.\textsuperscript{13-15}

Recent interventions testing different approaches to enhance the reach of HF self-management support, including telemonitoring and group-based self-management training, did not provide clinical benefits beyond usual care.\textsuperscript{16-18} There remains a pressing need to identify innovative and cost-effective approaches to improve patients’ HF self-management. In recent RCTs, we and other researchers found improved clinical outcomes with peer support among patients with chronic conditions such as diabetes compared to usual nurse care management.\textsuperscript{19, 20} As in diabetes, peer support might allow HF patients to share experiences and receive reinforcement for ongoing HF self-management unavailable from time-pressed clinicians to help motivate and support them to initiate and sustain the multiple, challenging tasks required for effective HF self-management.

Few peer support models for HF have been evaluated, and the one peer mentor model evaluated by Reigel et al had very low participation rates and did not find clinical benefits.\textsuperscript{21} Riegel et al. in discussing their trial’s negative results recommended supplementing peer support with periodic nurse-led group sessions. Effective peer support models for other chronic diseases
combine peer support with more structured program of self-management education and assistance.\textsuperscript{22, 23} Specific components found effective include face-to-face peer- and clinician-led group visits\textsuperscript{24-26} and training sessions.\textsuperscript{27-29} However, in part due to the debilitating nature of HF, attending frequent face-to-face sessions is often difficult for HF patients.\textsuperscript{30} Novel delivery mechanisms to extend the reach\textsuperscript{31} of evidence-based peer support models may be especially important for adults who already have had at least one hospitalization for HF exacerbations.\textsuperscript{19}

To build on the potential benefits of face-to-face peer support while addressing access barriers, we designed and piloted an intervention supplementing optional periodic HF NP-led group sessions as recommended by Riegel et al. with telephone-based peer support between paired HF patients facing similar HF self-management challenges.\textsuperscript{32} Similar to the model we found effective in improving glycemic control among diabetes patients,\textsuperscript{19} the model was intended to be egalitarian, i.e., encouraging both peers to receive and provide support, with no designation of a ‘helper’ or ‘helpee’. In the current study, we compared this reciprocal peer support (RPS) program with usual HF NP-led care management (NCM) in an RCT in a community-based clinical setting. We hypothesized that helping and receiving help from other HF patients in group sessions facilitated by NPs and in one-on-one telephone conversations would increase HF-specific social support, improve HF-specific quality of life and reduce hospital readmissions and death.\textsuperscript{33-35}

**Methods**

**Study Design and Oversight**

The study protocol was approved by the institutional review boards of the study site and University of Michigan. An independent data and safety monitoring board provided oversight.
Setting and Identification of Patients

Adult subjects gave informed consent and were enrolled from the inpatient unit and outpatient HF clinic of the study site—a nonprofit, community-based teaching hospital in southeastern Michigan. Enrollment began in May 2007 with follow up concluding in October 2010.

Inclusion criteria

Inpatients receiving intravenous diuretics with a potential diagnosis of diastolic or systolic HF were screened. Confirmation of the diagnosis by the attending physician was required for enrollment. Outpatient study participants were identified from records of patients hospitalized in the prior 12 months for HF exacerbations and receiving care at the Heart Failure Clinic.

Exclusion criteria

Patients were ineligible if they (a) had a serious mental illness or cognitive dysfunction; (b) did not speak English; (c) were unable to use the telephone; (d) were being discharged to a long-term care facility or hospice care; (e) were actively abusing drugs or alcohol; (f) had open heart surgery within the prior 6 weeks; (g) were actively participating in another HF self-management program; (h) were receiving active cancer treatment; or, (i) had a diagnosis of end stage renal disease.

Randomization

Individual patients were block-randomized within gender strata to either intervention or control arms once a month via a web-based application with a random number generator. The sequence was concealed until interventions were assigned. Following randomization, intervention subjects
were placed in pairs according to gender and if possible approximate age and level of risk for readmission (high risk, low risk). After 8 months of enrollment losses because many interested participants did not attend the initial face-to-face session, our IRBs approved a protocol change allowing telephone orientation for those missing the first visit. Data assessors were blinded to group assignment.

**Description of the Intervention**

*Initial Case Manager Training*

As this was an effectiveness study, the HF NPs at the site facilitated the groups as part of their assigned work duties with no additional salary support. The NPs completed an 8-hour initial training and 4-hour booster session in Motivational Interviewing (MI)\(^37-39\)-based group facilitation led by one of the investigators (KR).\(^40\) We encouraged the NPs to use these same behavioral approaches in their interactions with patients in both arms. Participants in both arms received the same HF self-management instructions.

*Nurse Practitioner Care Management (NCM)*

Patients randomized to NP care management (NCM) attended an initial 1.5 hour NP-led HF self-management group in which participants were encouraged to ask questions and discuss their HF self-management challenges. The NPs provided their contact information and encouraged participants to schedule appointments with them. Each participant was also provided with HF self-management educational materials. NCM patients thus received enhanced usual care, because although all hospitalized patients with HF during the study period were encouraged to follow up in the Heart Failure clinic, not all patients used this service.
Reciprocal Peer Support (RPS) Group

Patients randomized to the reciprocal peer support (RPS) intervention attended a 3-hour group facilitated by a HF NP and research associate. In the first session, attendees’ HF self-management challenges and questions were elicited and action planning was introduced. Participants then received brief training in basic peer communication skills and participated in an ice-breaking exercise with their matched peer partner. Those not attending the first session received a telephone orientation and intervention materials via mail. At the end of the session, intervention participants were given a DVD demonstrating peer communication skills and a HF self-management workbook they could use to help guide their peer telephone calls.

Peer partners were encouraged to talk at least weekly using an interactive voice response-facilitated telephone platform that recorded call initiation, frequency, and duration; enabled partners to telephone without exchanging telephone numbers; set time periods in which calls could be blocked; and generated automated reminders every 7 days if no calls were attempted. The system also enabled participants to leave voice messages for research staff or care managers.

Intervention participants were also offered three optional 1.5-hour group sessions facilitated by a NP and research associate at months 1, 3, and 6 during which participants were encouraged to share concerns, questions, strategies, and progress on their action plans. Research associates helped maintain intervention fidelity by encouraging non-directive facilitation of group discussions and completing a checklist of key areas covered and communication skills used in each session.
Outcomes and Measurements

The primary outcomes were time to death or first re-hospitalization regardless of cause (“primary composite all-cause outcome”); death within 365 days of randomization (“primary time-to-event outcome”); and number of hospitalizations for those surviving 365 days (“primary hospitalization outcome”). Hospitalizations occurring at the study site were determined from health system administrative data. The approximately 10% of outside hospitalizations were identified via patient report and verification of outside hospital discharge summaries. Deaths were determined from the health system’s administrative data, the Social Security Death Index and family member reports.

Co-morbidities were determined from hospital administrative data. Baseline surveys were completed at enrollment. Follow-up survey questionnaires were completed at 3, 6 and 12 months. We used validated measures to determine changes between baseline and six-month HF-quality of life as measured by the Minnesota Living with Heart Failure Questionnaire (MLHF) and in HF-specific social support, using a validated Diabetes social support scale adapted to reference HF. The Interactive Voice Response [IVR] telephone system collected IVR utilization information but did not record the content of peer calls. IVR contacts with NPs and study staff and attendance at group sessions were similarly tracked.

Statistical Analyses

Intention to Treat Analyses

We calculated the target sample size to provide 80% power and Type I error of 0.05, assuming a 37% event-free survival at 1 year (or hazard rate of 0.994) for the NCM group, a 35% decrease in the hazard rate for those in RPS group, a within-pair correlation of 0.1, and 20% attrition rate.
A sample size of 288 subjects was obtained using a combination of simulation and formulae provided in Gangnon and Kosorok\textsuperscript{43} and based on data from prior HF trials at the study site.\textsuperscript{44} In the final year of recruitment, we determined that actual attrition was one-half of the anticipated rate. After discussion with the study’s Data Safety and Monitoring Board in May 2009, the target sample size was reduced to 260. No interim analyses of the outcomes were conducted.

SAS version 9.1.3 (SAS Institute, Cary NC) was used to create the datasets, with R utilized for sample size calculations and analyses.\textsuperscript{45} The unadjusted difference in the primary time-to-event outcome was evaluated using a Cox regression model with a single binary covariate representing study arm. Models were fit separately by gender to account for the stratification used in the randomization schema. The test statistic for the alternative hypothesis of a treatment effect for at least one gender group versus the null hypothesis of no effect for males and for females is the sum of the two gender-specific squared z-scores; the associated p-value is obtained using a chi-square distribution with 2 degrees of freedom. The primary rehospitalization outcome, defined as the unadjusted difference in the number of rehospitalizations for those surviving 1 year, was evaluated in a related manner (see, for example, \textsuperscript{46}), accounting for gender-based stratification and using a test statistic for the alternative hypothesis of a treatment effect for at least one gender group versus a null hypothesis of no effect also constructed from two gender-specific squared z-scores.

Adjusted analyses of the primary outcomes were also conducted and controlled for post-randomization residual imbalances in potential prognostic factors using inverse probability-of-treatment (IPT) weighting. The probability of a subject being assigned to his/her actual study arm was computed via logistic regression models as a function of patient source (hospital versus
clinic), race (white versus non-white), number of prior hospitalizations and age, fit separately by gender.

In all analyses, standard errors and confidence intervals were computed using 5000 nonparametric bootstrap samples in each gender group; the bootstrap was used in order to properly account for the paired nature of the intervention. In the IPT analyses, the use of the bootstrap reflects sampling variability in the inverse probability of treatment weights as well as the paired nature of the intervention.

_Treatment of Missing Data._ Six-month survey data were missing for 40 randomized participants in both arms (15%). We therefore conducted a sensitivity analysis that imputed missing data.47 Our results in both analyses were indistinguishable, so we report the results with imputed data. Thirteen participants (5%) withdrew.

**Results**

The CONSORT diagram in Figure 1 shows participant flow. Participants’ baseline characteristics are reported in Table 1. Figure 2 shows the average duration and number of recorded calls each month among the 60% (75/124 individuals) of peer pairs who had at least one conversation. 82% [101/124] made less than 50% of 24 weekly peer calls over the 6-month intervention. 59% (73/124) of RPS participants attended the initial group session, and 28% (35/124) completed the telephone orientation. 66% [82/124] did not attend more than one group session of the four offered. No RPS participants used the IVR system to leave messages or questions for the Nurse Practitioners.
Twelve-month Primary Outcomes

In the NCM group, 11% (15/131) died and 51% (67/131) were rehospitalized. In the RPS group, 13% (18/135) died and 48% (65/135) were rehospitalized. Figure 3 shows the Kaplan Meier curves of time (in days) to either death or first hospitalization in the RPS and NCM groups, stratified by gender. No difference between study arms for either men or women was found with either the inverse probability-of-treatment (IPT)-weighted or unweighted analysis. The treatment effect estimate from the IPT-weighted Cox Regression models for men was -0.17 (95% CI: -0.69-0.34). The treatment effect for women was 0.13 (95% CI: -0.33-0.58). Mean time to first event in the RPS group was 348 days (95% CI: 336-359) compared to 352 days (95% CI: 342-361) in the NCM group. Median time to first event for both groups was 363 days.

Similarly, both IPT-weighted and unweighted analyses of all hospitalization events revealed no differences between treatment groups in the average number of hospitalizations in the 365 days following randomization. The mean number of hospitalizations for participants in the RPS group surviving at least one year was 1.06 (95% CI: 0.74 - 1.38), 0.98 for men and 1.13 for women, and 1.08 (95% CI:0.80 – 1.36) in the NCM group (1.17 for men and 1.00 for women). 44% of NCM patients (n=57) and 36% of RPS patients (n=48) had no hospitalizations and were alive at the end of the 12-month study period (Table 2).

Post-Intervention (Six Month) Survey Measures of HF Quality of Life and Social Support

As Table 3 shows, participants in both arms had improvements in reported HF-specific quality of life and HF-specific social support between baseline and six months. In intention to treat analyses, there were no significant differences in improvements in HF-specific quality of life or in HF-specific social support between arms.
Discussion

This RCT examined whether a reciprocal peer support program found successful in diabetes care could improve HF outcomes, in the face of the relative lack of success of other HF self-management programs that do not rely on intensive health care professional support. We also sought to address the call by two recent Cochrane Reviews for high-quality research on the clinical effectiveness of peer support in chronic disease management. In this community hospital setting, patients with prior HF hospitalizations randomized to reciprocal peer support had a risk of re-hospitalization or death no different than patients randomized to HF NP-care management. Moreover, there were no significant differences between arms in HF-quality of life and HF-specific social support at six months.

Poor participant engagement in HF interventions has been a persistent challenge. In Chaudry et al’s telemonitoring intervention, 14% of patients randomized to receive telemonitoring never used the system, and by the end of the study period, only 55% of the patients were still using the system at least three times a week. We hypothesized that telephone peer support between patients facing similar HF challenges supplemented with optional NP-led group sessions might mitigate barriers to engagement among patients with a high illness burden. In our prior trial among diabetes patients with poor glycemic control, participation rates indeed exceeded 80% among those randomized to the RPS arm. Yet, in the current study, more than two thirds of participants randomized to RPS had minimal phone contacts with their peer partner and did not attend the optional group sessions. Thus, the study can be considered a case of Type III error. Type III error occurs when lack of intervention effects could be attributed to insufficient intervention uptake.
The low rates of engagement and negative results of this RCT indicate that optimal strategies for less-resource intensive, patient-centered HF management remain elusive. In a recent negative multi-site HF trial that provided physicians with information about their patients’ clinical status through automated telemonitoring, investigators hypothesized that additional patient self-management education or peer support might have enhanced the effectiveness of that intervention. Our study suggests that adding a peer support component would not necessarily have improved patients’ engagement or outcomes. Riegel et al. hypothesized that holding small groups with both peers and nurse educators might complement peer support alone to enhance clinical outcomes. Yet, we found similarly low rates of engagement in our group sessions as in the peer telephone calls. Similarly, in the largest HF self-management trial to date, Powell et al found no differences between death or HF hospitalization among patients with mild to moderate HF when group-based self-management skills training was added to educational interventions.

In light of the promising results of peer support programs among patients with other chronic conditions such as diabetes, it is important to understand why engagement levels in this intervention were so low and outcomes on average no better than HF NP care management. One possibility is that in diabetes, self-management goals are often improvements in tangible and easily measured intermediate outcomes such as improving glycemic control that provide clear benchmarks for improvements. In contrast, in HF ‘self-management’ is often promoted as a means to prevent exacerbations leading to hospitalizations, which may seem to patients more outside their control. Another possible explanation is that peer support works optimally when patients are in good enough health to participate meaningfully and perceive that there is a good chance that engagement could improve symptoms and quality of life. As suggested by baseline
physical functioning scores and MLWHF scores, the acuity level of eligible patients was high, and many reported difficulty engaging in activities of daily living. Patients with such poor baseline health simply may not feel able or willing to complete the physical and mental activities required to effectively engage in the social interactions required by peer support. For these patients, it is difficult to find a less resource-intensive but equally effective approach as the kind of multi-disciplinary, intensive programs that have been found in multiple RCTs to lead to improved HF outcomes.

A 2009 review of evidence on approaches to reducing rehospitalization and death among patients with chronic conditions concluded that successful approaches often include a combination of close coordination of care in the post-acute period, early post-discharge follow-up, enhanced patient education and self-management training, and extending the resources and clinical expertise available to patients over time via multidisciplinary team management.49 Finding the optimal approach or combination of approaches for different subpopulations of patients with HF that are cost-effective remains an important challenge. While reciprocal peer support programs may not be effective for patients with HF on average, there may be subgroups of patients for whom RPS is indeed beneficial. One goal of further work, therefore, will be to examine in greater detail which patients with HF may have a greater likelihood of engaging and benefiting from such an intervention.

Our study had a number of limitations. First, it was carried out at one community hospital health system, so generalization to other settings should be done with caution. Second, there is evidence that more similar peers are more likely to have mutually supportive peer relationships. Peer support initiatives may thus be especially effective among participants with common identity bonds, such as shared experiences, cultural and ethnic backgrounds, or religious faith. In
this study, all patients had been hospitalized for HF and we tried to match patients of similar ages and the same gender. However, peer pairs were assigned by the research team and empathy with or commitment to the peer partner may have been low. A program in which patients were allowed to choose peer partners or were matched on more shared characteristics may have promoted higher levels of engagement. Third, while nurse care managers and other providers were blinded to the study’s hypotheses, the nature of the intervention prevented blinding to treatment group.

In conclusion, one-on-one peer-support telephone calls between gender-matched partners with HF supplemented with periodic NP-facilitated group sessions provided no incremental benefit to enhancing access to HF NP care management in a community hospital health system. The major explanation appears to be lack of engagement in the intervention, as only a minority of HF patients randomized to the peer support arm participated in a meaningful way with either the peer telephone calls or group sessions. Identifying methods to engage this population in behavior change and social support interventions, as well as identifying subgroups of HF populations who are candidates for peer support and other behavioral interventions, remains a high priority. As with other severe chronic conditions, this study suggests that there is “no free lunch” when it comes to providing interventions that significantly reduce acute events among patients with HF; rather, more intensive multi-modal interventions may be needed to improve outcomes.
Acknowledgements

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Disclosures

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References


23. Doull M, O’Connor AM, Robinson V, Tugwell P, Wells GA. Peer support


Table 1. Participant Baseline Characteristics (n=266)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention n = 135</th>
<th>Control n = 131</th>
<th>Between-Group Difference</th>
<th>Total n = 266</th>
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<tr>
<td></td>
<td>n(%) or mean(SD)</td>
<td>n(%) or mean(SD)</td>
<td>P-value</td>
<td>n(%) or mean(SD)</td>
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<td><strong>Age in years</strong></td>
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<td>67.9 (12.6)</td>
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<td>69.1 (12.1%)</td>
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<td><strong>Female gender</strong></td>
<td>70 (51.9%)</td>
<td>68 (51.9%)</td>
<td>.99</td>
<td>137 (51%)</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>White</td>
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<td>93 (71.0%)</td>
<td>.53</td>
<td>197 (74.1%)</td>
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<td>Black</td>
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<td>32 (24.4%)</td>
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<td>5 (3.7%)</td>
<td>6 (4.6%)</td>
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<td></td>
<td></td>
<td></td>
</tr>
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<td>HS graduate or less</td>
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<td>58 (44%)</td>
<td>.43</td>
<td>115 (43%)</td>
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<td>Some college, technical, or vocational</td>
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<td>50 (38%)</td>
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<td>95 (36%)</td>
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<td>4 year college or more</td>
<td>32 (24%)</td>
<td>23 (18%)</td>
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<td>55 (21%)</td>
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<td><strong>Annual Income</strong></td>
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<td></td>
<td>.27</td>
<td></td>
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<tr>
<td>≤ $19,000</td>
<td>33 (27%)</td>
<td>27 (24%)</td>
<td></td>
<td>60 (26%)</td>
</tr>
<tr>
<td>$20,000 to $39,000</td>
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<td>56 (50%)</td>
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</tr>
<tr>
<td>$40,000 or more</td>
<td>41 (33%)</td>
<td>29 (26%)</td>
<td></td>
<td>70 (30%)</td>
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<td><strong>Household size</strong></td>
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<td>.12</td>
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<tr>
<td>Lives alone</td>
<td>39 (29%)</td>
<td>27 (21%)</td>
<td></td>
<td>66 (25%)</td>
</tr>
<tr>
<td>Lives with others</td>
<td>96 (71%)</td>
<td>104 (79%)</td>
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<td>200 (75%)</td>
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<td><strong>Self-Rated General Health Status</strong></td>
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<td>Very Good or better</td>
<td>32 (24%)</td>
<td>21 (16%)</td>
<td></td>
<td>53 (20%)</td>
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<tr>
<td>Good</td>
<td>44 (33%)</td>
<td>42 (32%)</td>
<td></td>
<td>86 (32%)</td>
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<tr>
<td>Fair</td>
<td>36 (28%)</td>
<td>43 (33%)</td>
<td></td>
<td>81 (30%)</td>
</tr>
<tr>
<td>Poor</td>
<td>21 (16%)</td>
<td>25 (19%)</td>
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<td>46 (17%)</td>
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<td></td>
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<tr>
<td>Retired/Not employed</td>
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<td>105 (80.8%)</td>
<td></td>
<td>220 (83.3%)</td>
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<td><strong>Hospitalization in the past year</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>none</td>
<td>19 (14.1%)</td>
<td>20 (15.3%)</td>
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<td>58 (43.0%)</td>
<td>70 (53.4%)</td>
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<td>40 (29.6%)</td>
<td>27 (20.6%)</td>
<td></td>
<td>67 (25.2%)</td>
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<tr>
<td>3+</td>
<td>18 (13.3%)</td>
<td>14 (10.7%)</td>
<td></td>
<td>32 (12.0%)</td>
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<td><strong>Health History</strong></td>
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<td>.84</td>
<td></td>
</tr>
<tr>
<td>History of atrial fibrillation</td>
<td>50 (37%)</td>
<td>47 (35.9%)</td>
<td></td>
<td>97 (36.5%)</td>
</tr>
<tr>
<td>History of myocardial infarction</td>
<td>14 (10.4%)</td>
<td>12 (9.2%)</td>
<td>.74</td>
<td>26 (9.8%)</td>
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<td>History of chronic obstructive pulmonary disease</td>
<td>41 (30.4%)</td>
<td>38 (29.0%)</td>
<td>.81</td>
<td>79 (29.7%)</td>
</tr>
<tr>
<td>History of diabetes</td>
<td>57 (42.2%)</td>
<td>55 (42.0%)</td>
<td>.97</td>
<td>112 (42.1%)</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>97 (71.9%)</td>
<td>85 (64.9%)</td>
<td>.22</td>
<td>182 (68.4%)</td>
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<td>History of respiratory failure</td>
<td>16 (11.9%)</td>
<td>11 (8.4%)</td>
<td>.35</td>
<td>27 (10.2%)</td>
</tr>
<tr>
<td>History of valvular heart disease</td>
<td>27 (20%)</td>
<td>26 (19.9%)</td>
<td>.98</td>
<td>53 (19.9%)</td>
</tr>
<tr>
<td>History of valvular surgery</td>
<td>5 (3.7%)</td>
<td>4 (3.1%)</td>
<td>.77</td>
<td>9 (3.4%)</td>
</tr>
<tr>
<td>History of dialysis</td>
<td>2 (1.5%)</td>
<td>3 (2.3%)</td>
<td>.63</td>
<td>5 (1.9%)</td>
</tr>
</tbody>
</table>

*Baseline characteristics are the results from surveys taken prior to the first group meeting/enrollment. History of co-morbidities taken from health system administrative data

** Analysis of primary outcomes uses differential event rates for these populations

*Wilcoxon nonparametric test used for continuous measures of age, Chi-square test used for categorical variables.*
Table 2. Summary of Number of Patients by Events for 365 days follow-up

<table>
<thead>
<tr>
<th>N. of patients</th>
<th>(1) Total (NCM+RPS) N=266 (100%)</th>
<th>(2) NCM N=131 (100%)</th>
<th>(3) RPS N=135 (100%)</th>
<th>(4) RPS-Engaged N=28 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Event free (not re-hospitalized nor dead)</td>
<td>105 (39%)</td>
<td>57 (44%)</td>
<td>48 (36%)</td>
<td>17 (61%)</td>
</tr>
<tr>
<td>2. Re-hospitalized but not dead</td>
<td>105 (39%)</td>
<td>55 (42%)</td>
<td>50 (37%)</td>
<td>11 (39%)</td>
</tr>
<tr>
<td>3. Not re-hospitalized but dead</td>
<td>6 (2%)</td>
<td>3 (2%)</td>
<td>3 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>4. Re-hospitalized and dead</td>
<td>27 (10%)</td>
<td>12 (9%)</td>
<td>15 (11%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>5. Withdrew or lost-to-follow-up</td>
<td>23 (9%)</td>
<td>4 (3%)</td>
<td>19 (14%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>
Table 3. 6 month survey outcomes - Intention to Treat and CACE (Complier-Average Causal Effect)

<table>
<thead>
<tr>
<th></th>
<th>Control (N=106)</th>
<th>Intervention (N=93)</th>
<th>Engaged (N=26)</th>
<th>Model 1 CACE X0,D (N=124/131)</th>
<th>Model 2 CACE IPW (N=124/131)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average Score</td>
<td>Average Score</td>
<td>Average Score</td>
<td>Coef std. error</td>
<td>Coef std. error</td>
</tr>
<tr>
<td>Social Support (Glasgow)</td>
<td>25.9</td>
<td>27.2</td>
<td>30.2</td>
<td>5.87*** 1.48</td>
<td>7.53*** 1.77</td>
</tr>
<tr>
<td>MLHF physical</td>
<td>21.9</td>
<td>21.6</td>
<td>18.4</td>
<td>-2.03 2.38</td>
<td>-5.29 5.22</td>
</tr>
<tr>
<td>MLHF emotional</td>
<td>9.3</td>
<td>9.6</td>
<td>8.5</td>
<td>-0.6 1.48</td>
<td>-1.79 2.62</td>
</tr>
<tr>
<td>MLHF total</td>
<td>45.9</td>
<td>44.5</td>
<td>38.7</td>
<td>-2.92 5.24</td>
<td>-8.18 11.08</td>
</tr>
</tbody>
</table>

X0: measurement at baseline  D: socio-demographic characteristics  IPW: inverse probability weight

Note: Engagement (or complier) criteria include that i) patients participate in two or more classes and ii) made nine or more phone calls. Out of 93 patients who responded to 6 months follow-up survey, 26 were engaged. Out of 26 patients who engaged, 25 were used for analyses because 1 patient had a missing value in the education variable even after imputed dataset. In the Nurse Care Management (NCM) group, 106 patients responded to the 6 months follow-up survey and were used as references. Therefore 131 (=26+106) patients were potentially considered for analyses. Out of 131 patients, 7 patients who were newly diagnosed with heart failure at baseline did not provide responses about their prior heart failure specific social support (Glasgow). As a result, 124 patients were used for analysis with social support (Glasgow) while 131 for other outcomes. OLS was performed for all measurements listed in the table. Gender, education, living arrangement and each of baseline scores (Social support, MLHF physical, MLHF emotional and MLHF total) were used as control variables for analysis model 1 and predictors to obtain inverse probability weight for model 2. There were some missing values in items of composite scores (Social Support and MLHF scores). We used multiple imputations by chained equation (MICE) method to impute missing items.
Figure Legends

Figure 1. CONSORT 2010 Flow Diagram

Figure 2. Mean Frequency and Duration of Calls

Figure 3. Kalpan Meier Curves
Figure 1. CONSORT 2010 Flow Diagram

4566 Patients Identified

3303 Excluded
- 2518 Patients Did Not Meet Inclusion Criteria
- 785 Unable to Contact

1204 Patients Total Eligible

- 111 Consented but Not Randomized
- 626 Patients Declined to Participate

267 Underwent Randomization

Allocation

136 Assigned to Intervention
- 1 Administrative withdrawal

131 Assigned to Control

Six-Month Survey

93 Completed Surveys
- 11 Withdrew
- 24 Did not return 6 month survey
- 10 Died at 6 month
(N=93) Analyzed Survey Outcomes*

106 Completed Surveys
- 2 Withdrew
- 16 Did not return 6 month survey
- 7 Died at 6 month
(N=106) Analyzed Survey Outcomes*

Twelve-Month Primary Outcomes

(N=124) Analyzed Primary Outcomes**

(N=129) Analyzed Primary Outcomes**

*Survey outcomes: Social Support, Depression, QOL, Self Efficacy, and Treatment Satisfaction

**Primary Outcomes: Death and Hospitalization. Data censored after date of last contact for 10 subjects lost to follow-up.
* 75/124 (60%) had at least one call
Figure 3. Kaplan-Meier Curves - Time to Hospitalization or Death (in days)

Survival Probability

Time (in days)

- Control (Male)
- Treated (Male)
- Control (Female)
- Treated (Female)
A Randomized Controlled Effectiveness Trial of Reciprocal Peer Support in Heart Failure
Michele Heisler, Lakshmi Halasyamani, Mark E. Cowen, Matthew D. Davis, Ken Resnicow, Robert L. Strawderman, Hwajung Choi, Rebecca Mase and John D. Piette

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