Randomized Controlled Effectiveness Trial of Reciprocal Peer Support in Heart Failure

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Background—Although disease management programs for patients hospitalized with heart failure (HF) are effective, they are, however, 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 patients with HF.

Methods and Results—In this randomized controlled trial, Reciprocal Peer Support (RPS) arm patients participated in a HF nurse practitioner–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 3 nurse practitioner–facilitated peer support group sessions. Patients in the nurse care management arm attended a nurse practitioner–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 nurse care management 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, more than half of RPS participants had no or minimal engagement with the RPS program, and the program did not improve outcomes compared with usual HF nurse care management.


Key Words: heart failure ■ nurse case management ■ peer support ■ randomized controlled trial ■ self-management

Developing effective strategies to improve self-management and thereby reduce readmissions of patients with heart failure (HF) is a national health priority.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%.4 Such poor HF self-management contributes to HF hospitalizations and readmissions.5-7

Intensive multifactorial care management programs can improve patient HF self-management and reduce readmissions.8-12 These programs, however, are labor- and resource intensive. Many practices face multiple barriers to deliver such resource-intensive support for patients with HF.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.16-18 There remains a pressing need to identify innovative and cost-effective approaches to improve patients’ HF self-management. In recent randomized controlled trials (RCTs), we and other researchers found improved clinical outcomes with peer support among patients with chronic conditions, such as diabetes mellitus, compared with usual nurse care management (NCM).19,20 As in diabetes mellitus, peer support might allow patients with HF 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.

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Few peer support models for HF have been evaluated, and the 1 peer mentor model evaluated by Riegel et al21 had very low participation rates and did not find clinical benefits. 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. Specific components found effective include face-to-face peer- and clinician-led group visits and training sessions. However, in part due to the debilitating nature of HF, attending frequent face-to-face sessions is often difficult for patients with HF. Novel delivery mechanisms to extend the reach of evidence-based peer support models may be especially important for adults who already have had at least 1 hospitalization for HF exacerbations.

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 nurse practitioner (NP)-led group sessions as recommended by Riegel et al with telephone-based peer support between paired patients with HF facing similar HF self-management challenges. Similar to the model we found effective in improving glycemic control among patients with diabetes, the model was intended to be egalitarian, that is, 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 NCM in an RCT in a community-based clinical setting. We hypothesized that helping and receiving help from other patients with HF 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.

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 previous 12 months for HF exacerbations and receiving care at the Heart Failure Clinic.

Exclusion Criteria

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

Randomization

Individual patients were block randomized within sex 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. After randomization, intervention subjects were placed in pairs according to sex 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–based facilitation led by one of the investigators (K.R.). 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.

NP Care Management

Patients randomized to 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.

RPS Group

Patients randomized to the RPS intervention attended a 3-hour group session 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 (IVR)–facilitated telephone platform that recorded call initiation, frequency, and duration that enabled partners to telephone without exchanging telephone numbers; set time periods in which calls could be blocked; and generate 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 3 optional 1.5-hour group sessions facilitated by an 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 nondirective 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 rehospitalization 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. 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.

Comorbidities 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 6-month HF-quality of life as measured by the Minnesota Living with Heart Failure Questionnaire.
Failure Questionnaire and in HF-specific social support, using a validated Diabetes Social Support Scale adapted to reference HF. The IVR telephone system collected IVR usage 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 and based on data from previous HF trials at the study site. 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, Inc., Cary, NC) was used to create the data sets, with R used for sample size calculations and analyses. 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 sex to account for the stratification used in the randomization schema. The test statistic for the alternative hypothesis of a treatment effect for at least 1 sex group versus the null hypothesis of no effect for men and for women is the sum of the 2 sex-specific squared z-scores; the associated probability value is obtained using a $\chi^2$ 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, Schaubel and Cai), accounting for sex-based stratification and using a test statistic for the alternative hypothesis of a treatment effect for at least 1 sex group versus a null hypothesis of no effect also constructed from 2 sex-specific squared z-scores.

Adjusted analyses of the primary outcomes were also conducted and controlled for postrandomization 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 nonwhite), number of previous hospitalizations, and age, fit separately by sex.

In all analyses, SEs and confidence intervals (CIs) were computed using 5000 nonparametric bootstrap samples in each sex group; the bootstrap was used to properly account for the paired nature of the intervention. In the IPT analyses, the use of the bootstrap reflects sampling variability in the IPT 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. 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. Eighty-two percent (101/124) made <50% of 24 weekly peer calls during the 6-month intervention. Fifty-nine percent (73/124) of RPS participants attended the initial group session, and 28% (35/124) completed the telephone orientation. Sixty-six percent

| Table 1. Participant Baseline Characteristics (n=266)* |
|---------------------------------|------------------|------------------|------------------|------------------|
| Characteristic                  | Intervention (n=135) n (%) or mean (SD) | Control (n=131) n (%) or Mean (SD) | Between-Group Difference | Total (n=266) n (%) or Mean (SD) |
| Age, y                          | 70.4 (11.5)       | 67.9 (12.6)       | 0.15             | 69.1 (12.1%)      |
| Women                           | 70 (51.9%)        | 68 (51.9%)        | 0.99             | 137 (51%)         |
| Race or ethnicity               | 104 (77.0%)       | 93 (71.0%)        | 197 (74.1%)      |
| White                           | 26 (19.3%)        | 32 (24.4%)        | 58 (21.8%)       |
| Black                           | 5 (3.7%)          | 6 (4.6%)          | 11 (4.1%)        |
| Other                           | 104 (77.0%)       | 93 (71.0%)        | 197 (74.1%)      |
| Education                       | 58 (43%)          | 58 (44%)          | 115 (43%)        |
| High School graduate or less    | 45 (34%)          | 50 (38%)          | 95 (36%)         |
| Some college, technical, or vocational | 32 (24%)        | 23 (18%)          | 55 (21%)         |
| 4-year college or more          | 32 (24%)          | 27 (21%)          | 66 (25%)         |
| Annual income                   | 33 (27%)          | 27 (24%)          | 60 (26%)         |
| ≤$19 000                        | 49 (40%)          | 56 (50%)          | 105 (45%)        |
| $20 000 to $39 000              | 41 (33%)          | 29 (26%)          | 70 (30%)         |
| Household size                  | 39 (29%)          | 27 (21%)          | 66 (25%)         |
| Lives alone                     | 96 (71%)          | 104 (79%)         | 200 (75%)        |
| Lives with others               | 32 (24%)          | 21 (16%)          | 53 (20%)         |
| Self-rated general health status| 44 (33%)          | 42 (32%)          | 86 (32%)         |
| Very good or better             | 40 (29%)          | 43 (33%)          | 81 (30%)         |
| Good                            | 21 (16%)          | 25 (19%)          | 46 (17%)         |
| Fair                            | 115 (85.8%)       | 105 (80.8%)       | 220 (83.3%)      |
| Employment status               | 19 (14.1%)        | 20 (15.3%)        | 39 (14.7%)       |
| Retired/not employed            | 58 (43.0%)        | 70 (53.4%)        | 128 (48.1%)      |
| Hospitalization in the past year| 40 (29.6%)        | 27 (20.6%)        | 67 (25.2%)       |
| History of atrial fibrillation  | 18 (13.3%)        | 14 (10.7%)        | 32 (12.0%)       |

*Baseline characteristics are the results from surveys taken before the first group meeting/enrollment. History of comorbidities taken from health system administrative data. Wilcoxon nonparametric test used for continuous measures of age. χ² test used for categorical variables.
(82/124) did not attend >1 group session of the 4 offered. No RPS participants used the IVR system to leave messages or questions for the NPs.

**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 sex. No difference between study arms for either men or women was found with either the IPT-weighted or unweighted analysis. The treatment effect estimate from the IPT-weighted Cox Regression models for men was $-0.17$ (95% CI, $-0.69$ to $0.34$). The treatment effect for women was $0.13$ (95% CI, $-0.33$ to $0.58$). Mean time-to-first event in the RPS group was 348 days (95% CI, 336–359) compared with 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 after randomization. The mean number of hospitalizations for participants in the RPS group surviving at least 1 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). Forty-four percent 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 (6 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 6 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 RPS program found successful in diabetes mellitus 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 2 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 previous HF hospitalizations randomized to RPS had a risk of rehospitalization or death, no different than patients randomized to HF NCM. Moreover, there were no significant differences between arms in HF-quality of life or HF-specific social support at 6 months.

Poor participant engagement in HF interventions has been a persistent challenge. In Chaudhry et al., 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 3 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 previous trial among diabetes
mellitus 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 multisite 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 mellitus, it is important to understand why engagement levels in this intervention were so low, and outcomes on average were no better than HF NCM. One possibility is that in diabetes mellitus, 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 more outside the patients 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.

Table 2. Summary of Number of Patients by Events After 365 Days Follow-up

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Total (NCM+RPS)</th>
<th>NCM (100%)</th>
<th>NPS (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not rehospitalized but dead</td>
<td>105 (39%)</td>
<td>57 (44%)</td>
<td>48 (36%)</td>
</tr>
<tr>
<td>Rehospitalized but not dead</td>
<td>105 (39%)</td>
<td>55 (42%)</td>
<td>50 (37%)</td>
</tr>
<tr>
<td>Not rehospitalized but dead</td>
<td>6 (2%)</td>
<td>3 (2%)</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Rehospitalized and dead</td>
<td>27 (10%)</td>
<td>12 (9%)</td>
<td>15 (11%)</td>
</tr>
<tr>
<td>Withdrew or lost to follow-up</td>
<td>23 (9%)</td>
<td>4 (3%)</td>
<td>19 (14%)</td>
</tr>
</tbody>
</table>

NCM indicates nurse care management arm; and RPS, reciprocal peer support arm.

Table 3. Change Between Baseline and Six-Month Survey Outcomes in Intention-to-Treat Analyses

<table>
<thead>
<tr>
<th></th>
<th>NCM (Mean)</th>
<th>6-mo (Mean)</th>
<th>RPS (Mean)</th>
<th>6-mo (Mean)</th>
<th>Coefficient</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart failure-specific social support</td>
<td>23.2</td>
<td>25.9</td>
<td>22.8</td>
<td>27.2</td>
<td>1.40</td>
<td>1.06</td>
</tr>
<tr>
<td>MLHF physical</td>
<td>21.9</td>
<td>18.9</td>
<td>21.6</td>
<td>17.1</td>
<td>−1.71</td>
<td>1.45</td>
</tr>
<tr>
<td>MLHF emotional</td>
<td>9.3</td>
<td>8.6</td>
<td>9.6</td>
<td>7.8</td>
<td>−0.99</td>
<td>0.89</td>
</tr>
<tr>
<td>MLHF total</td>
<td>45.9</td>
<td>40.6</td>
<td>44.5</td>
<td>36.7</td>
<td>−3.23</td>
<td>3.18</td>
</tr>
</tbody>
</table>

Note: N=199 (Nurse Care Management [NCM] arm=106, Reciprocal Peer Support [RPS] arm=93) for summary statistics and analyses with Minnesota Living with Heart Failure (MLHF) scale scores. N=183 (NCM=101, RPS=82) for heart failure (HF)-specific social support scale, because 16 patients were newly diagnosed with heart failure at baseline and did not provide responses about their prior HF-specific social support. Both scales were scored from 0 to 100. For the Social Support scale, higher scores indicated more social support. For the MLHF, lower scores indicated less disruption of quality of life from HF. Ordinary least squares (OLS) regression was performed to assess differences in 6-month survey outcome between NCM and RPS, adjusting for each scale’s baseline score. 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.
subpopulations of patients with HF that are cost-effective remains an important challenge. Although RPS 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 several limitations. First, it was performed 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 sex. 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, although 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 sex-matched partners with HF supplemented with periodic NP-facilitated group sessions provided no incremental benefit to enhancing access to HF NCM in a community hospital health system. The major explanation seems to be lack of engagement in the intervention, as only a minority of patients with HF 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\textsuperscript{50} when it comes to providing interventions that significantly reduce acute events among patients with HF; rather, more intensive, multimodal interventions may be needed to improve outcomes.

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Disclosures

None.

References

A significant challenge for heart failure (HF) clinicians is to find effective, low-cost ways to support HF patients’ self-management between office visits to reduce future HF hospitalizations and death. Peer support programs have led to improved outcomes among patients with other chronic conditions and may result in similar improvements for patients with HF. We compared nurse care management with a reciprocal peer support program among HF patients who had recently been hospitalized with an HF exacerbation. Only about half of the participants in the peer support group participated in intervention activities, and there were no differences between groups in clinical outcomes. As with other severe chronic conditions, this study suggests that, among patients with HF severe enough to have already been hospitalized for their HF, more intensive multimodal interventions may be needed to significantly improve their self-management and reduce acute events.
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