College of Nursing Faculty Publications   College of Nursing

11-2014

Multidisciplinary Group Clinic Appointments: The Self-Management and Care of Heart Failure (SMAC-HF) Trial

Carol A. Smith
University of Kansas Medical Center

Ubolrat Piamjariyakul
University of Kansas Medical Center

Jo A. Wick
University of Kansas Medical Center

John A. Spertus
Saint Luke's Mid America Heart Institute

Christy Russell
University of Kansas Hospital

See next page for additional authors

Follow this and additional works at: http://openprairie.sdstate.edu/con_pubs

Part of the Nursing Commons

Recommended Citation

Authors

Carol A. Smith, Ubolrat Piamjariyakul, Jo A. Wick, John A. Spertus, Christy Russell, Kathleen M. Dalton, Andrea Elyachar, James L. Vacek, Katherine M. Reeder, Niaman Nazir, and Edward F. Ellerbeck

Multidisciplinary Group Clinic Appointments: The Self-Management and Care of Heart Failure (SMAC-HF) Trial:

Smith et al: Reducing HF Rehospitalizations SMAC-HF

Carol E. Smith, RN, PhD[1], **Ubolrat Piamjariyakul, RN, PhD**[2], **Jo A. Wick, PhD**[3], **John A. Spertus, MD, MPH**[4], **Christy Russell, RN, MSN**[5], **Kathleen M. Dalton, RN, MSN**[5], **Andrea Elyachar, MA**[6], **James L. Vacek, MD, MS**[7], **Katherine M. Reeder, RN, PhD**[8], **Niaman Nazir, MBBS, MPH**[6], and **Edward F. Ellerbeck, MD, MPH**[9]

[1]University of Kansas Medical Center, School of Nursing, Kansas City, KS; University of Kansas Medical Center, Department of Preventive Medicine and Public Health, Kansas City, KS

[2]University of Kansas Medical Center, School of Nursing, Kansas City, KS

[3]University of Kansas Medical Center, Department of Biostatistics, Kansas City, KS

[4]Saint Luke's Mid America Heart Institute, Kansas City, MO

[5]University of Kansas Hospital, Kansas City, KS

[6]University of Kansas Medical Center, Department of Preventive Medicine and Public Health, Kansas City, KS

[7]University of Kansas Hospital, Kansas City, KS; University of Kansas Medical Center, School of Medicine, Kansas City, KS

[8]Goldfarb School of Nursing, Barnes Jewish College, St. Louis, MO

[9]University of Kansas Medical Center, Department of Preventive Medicine and Public Health, Kansas City, KS; University of Kansas Medical Center, School of Medicine, Kansas City, KS

Abstract

Background—This trial tested the effects of multidisciplinary group clinic appointments on the primary outcome of time to first HF rehospitalization or death.

Methods and Results—HF patients (N=198) were randomly assigned to standard care or standard care plus multidisciplinary group clinics. The group intervention consisted of 4 weekly clinic appointments and one booster clinic at month 6, where multidisciplinary professionals engaged patients in HF self-management skills. Data were collected prospectively for 12 months

Correspondence to Ubolrat Piamjariyakul, PhD, RN, School of Nursing, University of Kansas Medical Center, School of Nursing, 3901 Rainbow Blvd., Mail Stop 4043, Kansas City, KS 66160, Phone: 913-588-3392, Fax: 913-588-4531, upiamjariyakul@kumc.edu. Carol E. Smith, PhD, RN, FAAN, School of Nursing & Preventive Medicine and Public Health, University of Kansas Medical Center, School of Nursing, 3901 Rainbow Blvd., Mail Stop 4043, Kansas City, KS 66160, Phone: 913-588-3392, Fax: 913-588-4531, csmith@kumc.edu.

beginning after completion of the first four group clinic appointments (2 months post randomization). The intervention was associated with greater adherence to recommended vasodilators (p=0.04). The primary outcome (first HF-related hospitalization or death) was experienced by 22 (24%) in the intervention group and 30 (28%) in standard care. The total HF-related hospitalizations, including repeat hospitalizations after the first time; were 28 in the intervention group and 45 among those receiving standard care. The effects of treatment on rehospitalization varied significantly over time. From 2-7 months post randomization, there was a significantly longer hospitalization-free time in the intervention group (Cox proportional HR = 0.45 (95% CI = 0.21, 0.98; p=0.04). No significant difference between groups was found from month 8 through 12 (HR = 1.7, 95% CI = 0.7, 4.1).

Conclusions—Multidisciplinary group clinic appointments were associated with greater adherence to selected heart failure medications and longer hospitalization-free survival during the time that the intervention was underway. Larger studies will be needed to confirm the benefits seen in this trial and identify methods to sustain these benefits.

Keywords

heart failure; group clinic; clinical trial; rehospitalization; survival analysis

---

Heart Failure (HF) affects approximately 5 million Americans and is expected to have a 23% increase in prevalence by 2030. [1] HF is the most frequent cause for hospitalization among Medicare beneficiaries. Accordingly, Medicare has adopted new reimbursement policies with penalties to hospitals for higher readmission rates after a HF discharge. [2] This has created a pressing need to develop better strategies for minimizing rehospitalizations. Indeed, current guidelines emphasize the importance of implementing systems to coordinate and deliver effective care.[3] Yet, recent meta-analyses and clinical management reviews have found most HF interventions are resource intensive, difficult to replicate and don't improve the high rate of repeat hospitalizations.[4,5]

One strategy that still holds promise for reducing HF readmissions is to improve patients' abilities to self-manage their disease. This requires that HF patients learn how to use specific HF home-care skills and implement complex daily self-care tasks.[6] Notably, patients are often discharged from the hospital with unresolved HF symptoms and with few HF self-management skills.[7] In fact, many HF patients lack the basic knowledge needed for appropriate dietary management,[8] are unsure of basic weight and fluid self-monitoring practices, and delay seeking treatment for HF symptoms, all of which can result in frequent rehospitalizations.[9]

Group clinic appointments, also known as 'shared medical appointments' have the potential to address these challenges and improve care for HF patients.[10] Group clinic appointments can provide more extensive education than is usually offered in traditional office visits, can provide more face time with healthcare providers and, perhaps most importantly, can give patients the opportunity to identify self-management issues and engage in shared problem solving with multidisciplinary professionals and fellow patients.[11] For patients with diabetes and other chronic illnesses, group clinic appointments have been associated with better treatment adherence.[12] However, the impact of group clinic appointments on HF

clinical outcomes has rarely been studied in controlled trials.[5] Two small pilot studies suggested that HF group appointments could improve HF knowledge, decrease HF rehospitalizations, and promote greater satisfaction with treatment.[13,14]

To examine the impact of an efficient, standardized group clinic program in HF, we developed the Self-Management and Care of Heart Failure (SMAC-HF) program and prospectively tested its impact on HF related rehospitalizations in a randomized controlled trial.

Methods

Between March 2007 and April 2011, we enrolled patients hospitalized for an exacerbation of HF into a randomized controlled clinical trial of multidisciplinary group clinic appointments. After giving written informed consent, patients were randomized to receive either standard care or the SMAC-HF group appointment intervention. Patients were prospectively followed for 12 months after randomization. The study was reviewed and approved by the Institutional Review Board (IRB) of the University of Kansas Medical Center. In addition, the study progress was reviewed and approved annually by an external Data Safety and Monitoring Board comprised of a cardiologist, a statistician, and an IRB representative.

Subjects

Hospitalized HF patients were prospectively identified by reviewing the daily admission records of all patients at a single academic medical center. Eligible patients had to have been hospitalized with NYHA class III or IV HF, but were not required to have a reduced left ventricular ejection fraction (EF). Exclusion criteria were evidence of transient, reversible HF, a planned heart transplant, end-stage renal disease (creatinine > 4 mg/dl), unresected malignancy or other terminal illness, or discharge to a nursing home, rehabilitation unit, or extended care facility. Patients were also excluded if they had a condition that would preclude them from engaging in the group clinic intervention, including blindness, deafness, dementia, cognitive deficiency or could not write and speak in English.

Nurses who were trained on trial enrollment procedures, informed consent and baseline data collection then enrolled patients during or within 2 weeks of their index hospitalization. Of the 774 patients identified with HF and meeting the criteria for enrollment, 198 (26%) were enrolled in the study (Figure 1). The primary reasons for patients not enrolling in the study were either those patients were "not interested" or that study staff failed to reach the patient within 2 weeks of discharge.

Randomization

In order to form groups of patients for the clinic appointments in a timely fashion, blocks of patients were randomized rather than individual patients. Block sizes ranged from 4 to 8 participants. Depending on the rate of subject recruitment, it typically took up to 3 weeks to form a group, randomize the group, and initiate the group visits. The initial group clinic schedule was a series of 4 weekly appointments, thus the intervention clinics typically did not finish until 8 weeks post randomization. Thus, randomization plus 8 weeks (month 2)

was the time pre-specified to begin observation for HF related endpoints. The same observation period was pre-specified for both comparison groups.

After 4 to 8 participants had consented, that whole block of patients was randomly assigned to receive either the intervention or standard care. Randomization was blinded so that no patient or project staff was aware of the allocation until after that block of patients was randomized. We enrolled 32 blocks containing a total of 198 study subjects, of whom 106 (53%) were in blocks that were randomized to standard care and 92 (47%) were in blocks randomized to receive the SMAC-HF intervention.

Standard Care and Intervention Descriptions

Standard care—Patients in both treatment arms received HF care from their existing treatment team both during and after hospitalization. This care typically included education from a discharge nurse that addressed the national HF core measures requirements, a post-discharge phone call from a NP within 3-7 days after discharge, and a follow-up at outpatient MD clinic visit within one month of discharge, with many patients seen sooner depending on their clinical status. Patients' HF related medications were initiated or up-titrated per their provider based on clinical need. There were no differences in the percentage of patients seen by NP under the direction of a cardiologist versus an MD only between subjects in the intervention and control group (χ^2= 1.25, p=.32).

SMAC-HF intervention—The SMAC-HF intervention began with four weekly group visit appointments followed by a 5th 'booster' appointment held 6 months after randomization. The first series of 4 weekly group clinic appointments were completed within 8 weeks after randomization. Transportation vouchers were provided for travel to each group clinic appointment.

The patient-centered SMAC-HF intervention was based on empirically-verified clinical management and pedagogical educational theory.[15] The pedagogy approach used with patients was based on the American College of Physicians' Family Home Care Management Guide [16] and the Chronic Care Model (CCM) which emphasizes engaging patients in self-management partnerships with multiple professionals.[17] Each group clinic visit included multidisciplinary health professionals: a nurse practitioner with extensive clinical experience in HF management, a mental health clinical nurse specialist, a social worker, and a dietician. At the beginning of each group clinic appointment, the patients' weight, vital signs and HF symptoms were assessed, medications were reviewed, and depression screening conducted. Group appointment participants were shown how to complete daily self-monitoring/ checklist diaries with spaces to daily record weight, fluid/sodium intake, physical activity, emotions and moods, and HF symptoms.

Once the assessments were completed at each clinic appointment, the patients and the multidisciplinary health professionals sat at a round table to view and then discuss that clinics short HF DVD. This 5-part DVD series was produced under an NIH grant (SBIR-1R43AG1700701) and illustrated HF patients using the national ACCF/AHA guideline based HF self-management strategies.[18] A different DVD was shown at each group appointment with each DVD focusing on a different self-management topic.[19]

Control group participants who received standard care also received a copy of the HF DVD series. Thus, our short DVDs were used to standardize the educational information across groups, so that the primary difference between the study arms was exposure to group clinics.

At the end of each group clinic discussion, a one-page, HF self-management summary was completed. This form provided patients with a personal report of their trends in weight, blood pressure, heart rate, and depression scores. In addition, on this form, patients wrote questions they wanted to ask and discuss with their health care provider. Also the patient self-management summary indicated whether the patients were receiving a β blocker, an ACE inhibitor or ARB, or an aldosterone receptor antagonist. (For African American patients, the combination of hydralazine and a nitrate was considered equivalent to use of an ACE inhibitor or ARB.) Although each group visit was supervised by a nurse practitioner, this nurse practitioner did not directly alter the clinical treatment plan during the group visit, but rather worked with the patient to adhere to their prescribed regimen, to identify issues to address with their primary providers and for early referral of HF exacerbation symptoms to physicians.

Data Collection and Follow-up

Hospitalizations that occurred post-randomization were identified by querying hospital electronic medical records at the academic medical center. Copies of medical records were also requested for any hospitalizations that data collection uncovered or subjects reported occurring outside of the medical center. The control patients had follow-up data collection on the same time schedule as the intervention group participants. Nurses, blinded to group assignment, conducted telephone follow-up quarterly on all participants to ensure that all rehospitalizations were identified. An experienced physician, blinded to treatment arm assignment, reviewed these medical records using *a priori* determined adjudication rules, and classified each hospitalization as being "HF related" or "not related to HF." Comparable methods were used to identify deaths and adjudicate the cause of death from obituary/death and medical records.

Measurements

The *a priori* primary outcome was time, in days, to cardiovascular-related death or the first heart failure-related hospitalization with the start time lagged to commence 8 weeks post-randomization. Measures collected at baseline included: demographic variables (age and gender); measures of HF severity (including left-ventricular function and length of HF diagnosis); HF functional status as assessed by the Kansas City Cardiomyopathy Questionnaire score (KCCQ); [20] depressive symptoms as assessed by the Center for Epidemiological Studies Depression Scale (CES-D) [21] and patients' current HF related medications. At the end of each group appointment, patients assigned to the intervention arm also rated each multidisciplinary group clinic and each DVD on a 5-point Likert scale ranging from 1 = not helpful to 5 = very helpful.

Statistical Analysis

Means (standard deviations) and frequencies (percentages) of baseline characteristics were calculated for the two treatment arms and compared using chi-square or Student's *t* tests, as

appropriate. Survival analysis methods were used to analyze the primary outcome of time-to-first HF related hospitalization or death, with censoring at 12 months post randomization which included the 8 weeks lag time for intervention completion. Kaplan-Meier survival estimates were calculated by treatment group, and a Cox proportional hazards regression model was used to determine whether treatment was significantly associated with the hazard (i.e., risk) of HF-related death or rehospitalization.

Tests for statistical assumptions were performed prior to performing the planned analyses. Thus, prior to conducting the Cox proportional hazard model, tests were conducted to verify the assumption that hypothesized treatment effects did not vary over time. However, these tests showed violation of the assumption that the hazards were independent of time. Specifically, the hazard functions crossed at month 7 (which is one month past the 6-month booster group appointment), indicating the effect of treatment was changing with time (Figure 2). When such a violation of statistical assumptions occurs, the Cox model does not provide a valid (unbiased) estimate of the treatment effect because these analyses require constant hazard ratios for group comparisons across the entire time period.[22] In this circumstance, a hazard ratio produced by such a model would be indicative of the 'average' effect of treatment over the entire period of interest and would not produce meaningful information about effects that change over time.

Consequently, a time-varying treatment effect was added to the Cox model to first test and then account for the changing effect of treatment over the period of interest. Based on the crossing hazards at 30 days after the final booster visit, an interaction term, z_t, was added to the model, where z_t was set to treatment group assignment if the event occurred prior to 30 days post-intervention booster visit and set to zero otherwise. A test of this treatment-time interaction within the Cox model showed a significant change in the treatment effect 30 days after the post-intervention booster visit ($p = 0.03$), providing empiric evidence of the change in the hazard functions over time. In our primary analysis, we used hospital medical records to track outcomes on all patients, including those that did not complete telephone follow-ups.

Since telephone follow-ups and obituaries were our primary means of identifying hospitalizations and deaths that might have occurred outside of the academic medical center, we performed another analysis in which subjects were censored on the date of last completed follow-up. We also compared recurrent or multiple HF related rehospitalizations between treatment arms using a counting process approach with the proportional means model using a robust sandwich covariance estimator. [23] Changes in medication usage over the course of the trial (baseline to 12 months post randomization) were compared between treatment arms using generalized estimating equations (GEE). All statistical analyses were completed using SAS® version 9.3.

Results

Of the 198 participants who enrolled in the study, 106 (53%) were randomized to the standard care control arm and 92 (47%) into the intervention arm. Of the 198 enrolled, 180 (91%) completed 12-month follow up data; deaths and dropouts were similar across arms

(Figure 1). The randomization process was successful in creating comparable groups (Table 1). The mean age of participants was 62.3 years (SD = 13.2 years); 76 (38%) were female; 87 (44%) were African American; 105 (53%) were Caucasian; and 6 (3%) were other or more than one race. Participants reported having had a diagnosis of HF for an average 6.2 years prior to study enrollment, (SD = 7.6 years; median=3.3 years); the mean Charlson Comorbidity Index score was 6.7 (SD = 2.8); the mean left ventricular ejection fraction (LVEF) was 30% (SD=16.1). There was no significant difference between intervention and control arm patients on LVEF (χ^2 = 0.69, p=.41) with 94% in the control arm and 91% in the intervention arm having an LVEF < 40. In this sample, there were 14 patients EF >/= 40%. There was no difference in percentage of these patients with EF >/= 40% between the intervention and standard care participants (χ^2= 0.69, p = 0.41). Between the intervention and standard care arms, there were no statistically significant differences on these measures at baseline (Table 1).

The intervention patients attended on average 4.6 of the 5 available intervention group clinic appointments. There were a total of 72 group clinic appointments held during the study and each group clinic appointment on average was rated by participants as 4.8 where 5 indicates very helpful. Participants rated the helpfulness of each DVD as 4.5 on a 5-point Likert scale. The intervention group reported watching the DVD series 2.7 times plus the times watched during each group clinic visit. The standard care control participants reported viewing the DVD series 3.6 times on average. There was no significant difference in the viewing time or exposure to the DVD series (χ^2 = 3.27, p=0.71) between groups. No formal evaluation of DVD helpfulness was collected about individual DVDs from the control arm to avoid a potential co-intervention effect.

At baseline, the majority of patients were receiving treatment with recommended vasodilators (ACE inhibitor, ARB or hydralazine/nitrate combination) and β-blockers (Table 2). Use of recommended vasodilators declined more in the standard care group (−15%) than in the intervention group (−5%) at 12 months (p = 0.04). There was a similar, although non-significant higher decline in use of β-blockers in the standard care arm (−9%) than in the intervention arm (−1%) (p = 0.06).

Of the 198 subjects, 48 (24%) patients had one or more HF-related hospitalizations during the observation period. There were 2 deaths in each group. Overall a total of 52 (26%) patients experienced the primary outcome of HF-related hospitalizations or death), 22 (24%) in the intervention group and 30 (28%) receiving standard care. Based on examination of the treatment group hazard functions of time to first event, a time-varying treatment effect was identified. The hazard functions were approximately parallel up until month 7 (30 days after the 6 month booster group appointment) but crossed several times in the period thereafter, indicating the effect of treatment was changing with time (Figure 2). From the onset of the observation period, lagged 8 weeks to complete the intervention, up until month 7 (which is 30 days after the 6 month booster clinic), the time-dependent Cox model identified a significantly longer event-free time associated with the intervention (p = 0.04). The hazard ratio for the *a priori* primary outcome (time to first HF related rehospitalization or death) during this period of follow-up was 0.45 (95% CI = 0.21, 0.98). This model also demonstrated that beyond month 7, there were no significant differences between treatment

groups (HR = 1.7, 95% CI = 0.7, 4.1). To determine the sensitivity of these results to our *a priori* choice of censoring, another Cox model analysis that censored participants following their last completed follow-up was performed and provided similar results (Figure 3). In a secondary analysis, which looked at the total HF-related hospitalizations, including repeat hospitalizations during the observation period; there were 28 total hospitalizations in the intervention group and 45 among those receiving standard care (HR = 0.68, 95% CI = 0.37, 1.24).

Discussion

Nationally, approximately 25% of Medicare patients hospitalized with HF are readmitted within 30 days of discharge [3] and by 12 months approximately 40-60% of patients with HF are rehospitalized and 12 to 31% of patients die.[1] To address this concern, a large number of studies have been undertaken to improve discharge planning for patients with HF and to enhance post-discharge support and follow-up care. [24] Yet, case-management and disease management interventions, including follow-up programs, have not consistently demonstrated beneficial effects, improved outcomes, or reductions in health care costs.[25] The SMAC-HF program was the first controlled trial to examine group clinic appointments on rehospitalizations related to HF and the impact of DVD HF self-management videos alone. In this study, a benefit for the group clinic appointments was seen which lasted until month 7 or 30 days after the last 'booster' group clinic appointment, but this benefit was not maintained afterwards.

Although use of recommended HF medications was high in both arms, it is possible that some of the positive effect seen in this study could be due to the intervention group patients' medication adherence. There was higher adherence to recommended vasodilators in the intervention group compared to the standard care group and a statistically insignificant increase in use of β blockers over time, also favoring the intervention group. The observed decline in use of HF related medications over time may have been due to non-adherence, adverse effects or to cost as numerous patients reported concerns about the costs of all their medications.[26] The social worker did assist each patient who voiced concern with applying for cost saving programs; however these may take months to fill. Notably there we no significant differences on patients reporting stopping medications because of cost between groups across the trial (χ^2= 1.64, p = 0.22).

A variety of factors may have influenced the small observed differences between groups in medication adherence. One of the group clinic appointments was devoted primarily to medication management and adherence. These patients also received written information on optimal HF medication use as part of the individualized patient summaries provided at the end of each weekly group clinic appointment with instructions to share these summaries with their primary providers. They worked with the group clinic multidisciplinary team to list specific issues to monitor and discuss with their doctors, including questions related to their HF medications.

The SMAC-HF intervention was well-received by the participants as evidenced both by the positive evaluations from participants and by high rates of attendance to the group clinic

appointments. Other investigators have also observed positive responses from patients participating in group appointments. The success of group appointments for other disease conditions, however, has been difficult to replicate,[27] possibly due to lack of standardization of the information delivered or lack of a patient centered approach such as that used in SMAC-HF group discussions. Information variation was controlled in the SMAC-HF group clinics by the DVD series. The DVD audiovisual media may be particularly supportive to patients with neurologic or cognitive decline, different learning styles or lower health information literacy levels.[28] Use of the DVD during the group clinic appointment allowed standardization of the overall self-management theme but still allowed patients to discuss their own concerns with the oversight of multidisciplinary professionals input.

While improvements in outcomes were noted up until month 7 or 30 days after the last intervention booster group appointment, these positive outcomes were not sustained. This suggests that there may be a need for continuing the booster interventions after this time or a need to reinforce specific HF self-management skills such as using the pill organizer box for adhering to daily medications or clarifying low-sodium in food labels. However, other programs for HF have also shown decrements in the effectiveness of the tested intervention in the follow-up period. Also, it has been shown that in these NYHA Class III and IV HF patients, the overall poor prognosis may limit the impact of many treatments.

Limitations

One limitation of this study is that the overall HF related rehospitalization or death event rate in this study was much lower than anticipated.[29] In our total sample, 24% of patients had a rehospitalization for HF during 12 months of follow-up. The low rates of rehospitalization or death could also have reduced our ability to detect a persistence of the intervention effect beyond the last booster session. The relatively low event rate seen in this study could be related to the high levels of guideline concordant medications seen at baseline (Table 2); it also may reflect under-appreciated benefits of the DVD educational videos alone. The low rates of readmission also reduced our ability to detect a difference in all rehospitalizations where a 32% reduction in total HF hospitalizations was nevertheless not statistically significant. This reinforces the preliminary nature of the finding from this study. The length of time needed to set up the group clinic appointment enrollment also limited our ability to impact hospital readmissions that might happen early after the index hospitalization. Finally, this was a single-center study with unique features of an academic health center patient population; results might differ in settings where HF care was either more or less regimented. These characteristics limit the generalizability of the observed benefits. A future, multi-center study of a longer duration of patient support would help further clarify the potential benefits of the multidisciplinary group clinic approach.

Conclusion

Our findings suggest that group clinic appointments hold promise for reducing HF rehospitalizations, but these findings from this small, single-site study need to be confirmed in a larger, multi-site study. The group clinic appointments were highly rated by patients and the multidisciplinary professionals involved. Emerging reimbursement policies could

facilitate adoption of group appointments under the existing Current Procedural Terminology (CPT) codes and Medicare rules. The effect of the group clinic appointments, however, appears to be limited to the period of group clinic exposure. To reduce earlier rehospitalizations, future studies could consider initiating parts of the intervention prior to hospital discharge. Future studies of group appointments for HF might also consider additional telephone follow-up reinforcement, home visits, or additional booster sessions to sustain positive impact.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

References

1. Heidenreich PA, Albert NM, Allen LA, Bluemke DA, Butler J, Fonarow GC, Ikonomidis JS, Khavjou O, Konstam MA, Maddox TM, Nichol G, Pham M, Piña IL, Trogdon JG, American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council. Forecasting the impact of heart failure in the United States. Circ Heart Fail. 2013; 6:606–619. [PubMed: 23616602]

2. Dharmarajan K, Hsieh AF, Lin Z, Bueno H, Ross JS, Horwitz LI, Barreto-Filho JA, Kim N, Bernheim SM, Suter LG, Drye EE, Krumholz HM. Diagnoses and timing of 30-day readmissions after hospitalization for heart failure, acute myocardial infarction, or pneumonia. JAMA. 2013; 309:355–63. [PubMed: 23340637]

3. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, Fonarow GC, Geraci SA, Horwich T, Januzzi JL, Johnson MR, Kasper EK, Levy WC, Masoudi FA, McBride PE, McMurray JJ, Mitchell JE, Peterson PN, Riegel B, Sam F, Stevenson LW, Tang WH, Tsai EJ, Wilkoff BL. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013; 62:e147–239. [PubMed: 23747642]

4. Gheorghiade M, Vaduganathan M, Fonarow GC, Bonow RO. Rehospitalization for heart failure: problems and perspectives. J Am Coll Cardiol. 2013; 61:391–403. [PubMed: 23219302]

5. Wakefield BH, Boren SA, Groves PS, Conn VS. Heart Failure Care Management Programs Review of Study Interventions and Meta-Analysis of Outcomes. J of Cardiovasc Nurs. 2013; 28:8–19. [PubMed: 22343208]

6. Riegel B, Moser DK, Anker SD, Appel LJ, Dunbar SB, Grady KL, Gurvitz MZ, Havranek EP, Lee CS, Lindenfeld J, Peterson PN, Pressler SJ, Schocken DD, Whellan DJ. State of the science: Promoting self-care in persons with heart failure: A scientific statement from the American Heart Association. Circulation. 2009; 120:1141–1163. [PubMed: 19720935]

7. Clark AM, Freydberg CN, McAlister FA, Tsuyuki RT, Armstrong PW, Strain LA. Patient and informal caregivers' knowledge of heart failure: Necessary but insufficient for effective self-care. Eur J Heart Fail. 2009; 11:617–621. [PubMed: 19414477]

8. Vaughan Dickson V, Riegel B. Are we teaching what patients need to know? Building skills in heart failure self-care. Heart Lung. 2009; 38:253–261. [PubMed: 19486796]

9. Ambardekar AV, Fonarow GC, Hernandez AF, Pan W, Yancy CW, Krantz MJ. Characteristics and in-hospital outcomes for nonadherent patients with heart failure: Findings from Get With The Guidelines-Heart Failure (GWTG-HF). Am Heart J. 2009; 158:644–652. [PubMed: 19781426]

10. Paul S, Yehle KS, Wood K, Wingate S, Steg B. Implementing shared medical appointments for heart failure patients in a community cardiology practice: a pilot study. Heart & Lung. 2013; 42:456–61. [PubMed: 24075619]

11. Bartley KB, Haney R. Shared medical appointments: improving access, outcomes, and satisfaction for patients with chronic cardiac diseases. J of Cardiovasc Nurs. 2010; 25:13–19. [PubMed: 20134280]

12. Housden L, Wong ST, Dawes M. Effectiveness of group medical visits for improving diabetes care: a systematic review and meta-analysis. CMAJ. 2013; 185:E635–44. [PubMed: 23939218]

13. Yehle KS, Sands LP, Rhynders PA, Newton GD. The effect of shared medical visits on knowledge and self-care in patients with heart failure: A pilot study. Heart Lung. 2009; 38:25–33. [PubMed: 19150528]

14. Lin A, Cavendish J, Boren D, Ofstad T, Seidensticker D. A pilot study: Reports of benefits from a 6-month, multidisciplinary, shared medical appointment approach for heart failure patients. Mil Med. 2008; 173:1210–1213. [PubMed: 19149341]

15. Sochalski J, Jaarsma T, Krumholz HM, Laramee A, McMurray JJ, Naylor MD, Rich MW, Riegel B, Stewart S. What works in chronic care management: the case of heart failure. Health Aff (Millwood). 2009; 28:179–89. [PubMed: 19124869]

16. Houts, PS.; Nezu, AM.; Nezu, CM.; Bucher, JA.; Lipton, A., editors. American College of Physician's Home Care Guide. American College of Physicians; Philadelphia: 1994.

17. Bodenheimer T, Wagner E, Grumbach K. Improving primary care for patients with chronic illness: the chronic are model. JAMA. 2002; 288:1775–1779. [PubMed: 12365965]

18. Smith CE, Koehler J, Moore J, Blanchard E, Ellerbeck E. Testing videotape education for heart failure. Clin Nurs Res. 2005; 14:191–205. [PubMed: 15793275]

19. Blanchard, E. Robert Wood Johnson Foundation: Transitions to Better Care, 100 Top videos on care transitions and readmissions. Robert Wood Johnson Foundation; Washington D.C: 2013. Live Webcast http://www.informedhealthsolutions.com/

20. Green PC, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: A new health status measure for heart failure. J Am Coll Cardiol. 2000; 35:1245–1255. [PubMed: 10758967]

21. Radloff LS. The CES-D Scale: A Self-Report Depression Scale for Research in the General Population. Appl Psychol Meas. 1977; 1:385–401.

22. van Walraven C, Davis D, Forster AJ, Wells GA. Time-dependent bias was common in survival analyses published in leading clinical journals. J Clin Epidemiol. 2004; 57:672–82. [PubMed: 15358395]

23. Lin DY, Wei LJ, Yang I, Ying Z. Semiparametric Regression for the Mean and Rate Functions of Recurrent Events. J R Statist Soc. 2000; 62:711–730.

24. Feltner C, Jones CD, Cené CW, Zheng ZJ, Sueta CA, Coker-Schwimmer EJL, Arvanitis M, Lohr KN, Middleton JC, Jonas DE. Transitional care interventions to prevent readmissions for persons with heart failure. Ann Intern Med. 2014; 160:774–784. [PubMed: 24862840]

25. Bradley EH, Curry L, Horwitz LI, Sipsma H, Wang Y, Walsh MN, Goldmann D, White N, Piña IL, Krumholz HM. Hospital strategies associated with 30-day readmission rates for patients with heart failure. Circ Cardiovasc Qual Outcomes. 2013; 6:444–50. [PubMed: 23861483]

26. Albert NM, Yancy CW, Liang L, Zhao X, Hernandez AF, Peterson ED, Cannon CP, Fonarow GC. Use of aldosterone antagonists in heart failure. JAMA. 2009; 302:1658–65. [PubMed: 19843900]

27. Levine MD, Ross TR, Balderson BH, Phelan EA. Implementing group medical visits for older adults at group health cooperative. J Am Geriatr Soc. 2010; 58:168–72. [PubMed: 20002506]

28. Smeulders ES, van Haastregt JC, Ambergen T, Stoffers HE, Janssen-Boyne JJ, Uszko-Lencer NH, Gorgels AP, Lodewijks-van der Bolt CL, van Eijk JT, Kempen GI. Heart failure patients with a lower educational level and better cognitive status benefit most from a self-management group programme. Patient Educ Couns. 2010; 81:214–21. [PubMed: 20153132]

29. Phillips CO, Wright SM, Kern DE, Singa RM, Shepperd S, Rubin HR. Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a meta-analysis. JAMA. 2004; 291:1358–1367. [PubMed: 15026403]
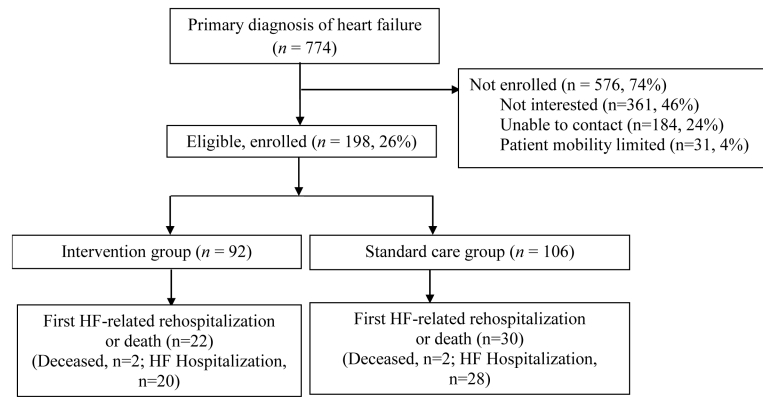
Figure 1.
Flowchart of SMAC-HF enrollment, randomization and follow-up to first HF-related rehospitalization or death.
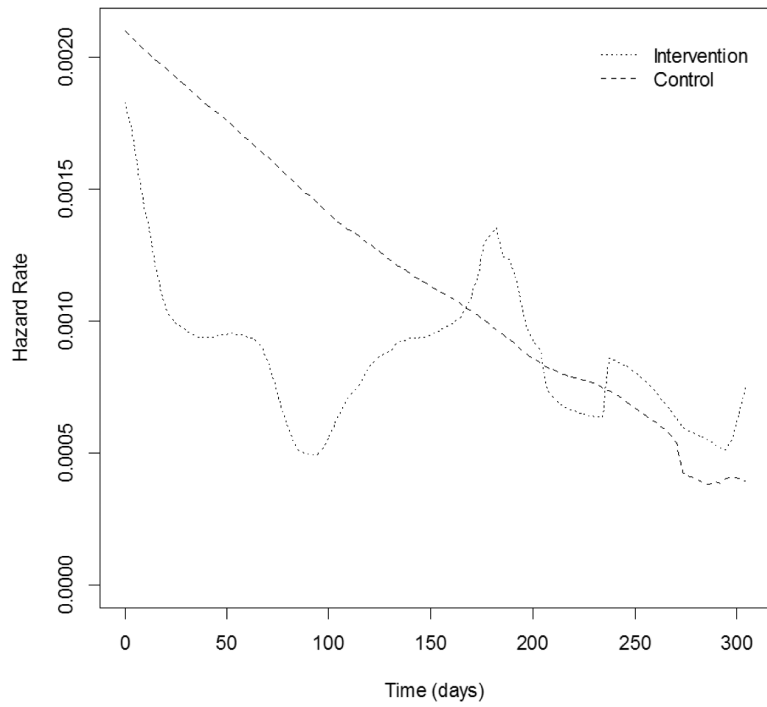
Figure 2.
Kernel-smoothed hazard functions for the event HF rehospitalization or death. Zero was pre-specified as the randomization date plus 8 weeks. The hazard functions represent the probability of HF rehospitalization or death at time t conditional on survival to that point. The group hazards cross at approximately 7 months post-randomization, with the rate of rehospitalization or death in the intervention group lower than that of the control group prior to 7 months.
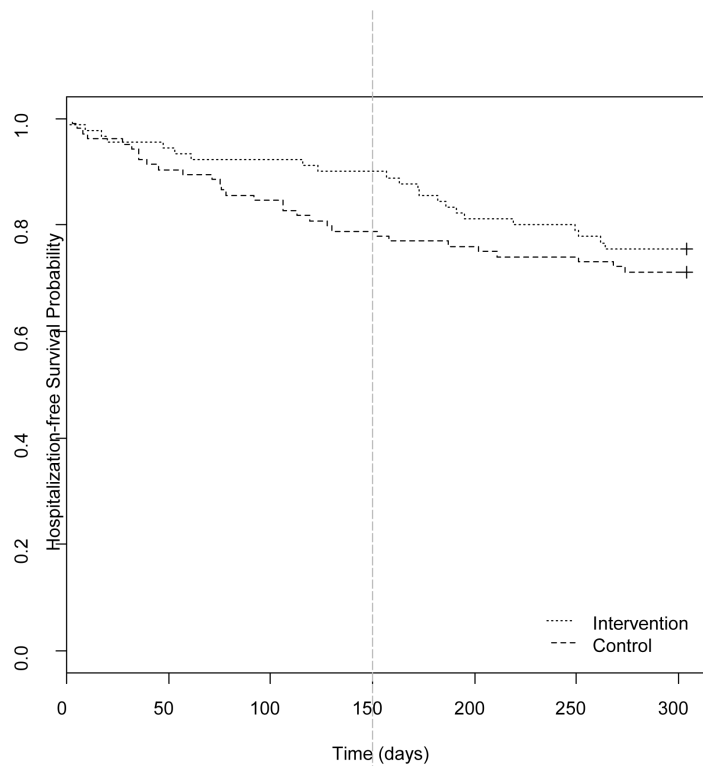
Figure 3.
Kaplan-Meier survival estimates of time to first HF rehospitalization or death. Zero was pre-specified as the randomization date plus 8 weeks. The dashed horizontal line at month 7 (which is 30 days after the final booster group clinic appointment occurs) marks the month at which the difference in treatment group hazard functions cross, thus indicating the effect of treatment compared to standard care is different prior to and after this point. Up to month 7 (all events with t > 30 days post-booster censored), the Cox model identified a significantly longer event-free time associated with the intervention (p = 0.04) for recipients of the intervention. The effect of the intervention did not extend into the later period of follow-up (p = 0.30).

Table1

Patient baseline characteristics means & comparison between groups.

	Overall (n=198)	Intervention (n=92)	Standard Care (n=106)	*p*
Demographics				
Age, mean years (SD)	62.3 (13.2)	62.6 (14.1)	62.1 (12.5)	0.78
Female gender, n (%)	76 (38)	40 (44)	36 (34)	0.17
African American, n (%)	87 (44)	45 (49)	40 (38)	0.12
Hispanic, n (%)	14 (7)	8 (9)	6 (6)	0.39
Employed, n (%)	32 (16)	16 (17)	16 (15)	0.66
Living alone, n (%)	136 (31)	22 (24)	38 (36)	0.06
Comorbidities				
Diabetes, n (%)	95 (48)	44 (48)	51 (48)	0.97
Hypertension, n (%)	178 (90)	82 (89)	96 (91)	0.74
Chronic lung disease, n (%)	81 (41)	40 (44)	41 (39)	0.49
Current smoker, n (%)	53 (27)	30 (25)	23 (28)	0.60
Charlson Comorbidity Index, mean (SD)	6.7 (2.8)	6.9 (3.0)	6.4 (2.7)	0.25
Cardiac function				
Ejection fraction, mean % (SD)	30 (16.1)	30 (15.6)	30 (16.6)	0.79
EF>=40, n (%)	14 (7)	8 (4)	6 (3)	0.41
Duration of HF, mean years (SD)	6.2 (7.6)	6.9 (8.9)	5.5 (6.2)	0.19
Atrial fibrillation, index admission, n (%)	40 (20)	23 (25)	16(15)	0.09
Functional Status				
CES-D Depression score, mean (SD)	8.9 (6.6)	8.9 (6.0)	8.9 (7.0)	0.98

Table 2

Changes in medication treatment use throughout the course of the trial among 184 subjects with a baseline LVEF < 40% ($n = 184$).

	Standard Care			Intervention			
	Baseline	**12 months**	**Change**	**Baseline**	**12 months**	**Change**	***z (p)*** [†]
Medication	***n* (%)**	***n* (%)**		***n* (%)**	***n* (%)**		
Recommended vasodilator	79 (79%)	54 (64%)	−15%	72 (86%)	51 (81%)	−5%	2.1 (0.04)
(ACE/ARB/Hydralazine & Nitrate)							
β Blocker	97 (97%)	74 (88%)	−9%	74 (88%)	55 (87%)	−1%	−1.9 (0.06)
Aldosterone antagonist	37 (37%)	37 (44%)	7%	38 (45%)	30 (48%)	2%	0.7 (0.5)

[†]: Parameter estimates and p-values based on Generalized Estimating Equations