JAMDA 14 (2013) 710.e5–710.e11

JAMDA

journal homepage: www.jamda.com

Original Study

A Randomized Trial of Heart Failure Disease Management in Skilled Nursing Facilities: Design and Rationale

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Keywords:
Heart failure
disease management
SNF

A B S T R A C T

Background: Heart failure (HF) disease management can improve health outcomes for older community dwelling patients with heart failure. HF disease management has not been studied in skilled nursing facilities, a major site of transitional care for older adults.

Methods and anticipated results: The objective of this trial is to investigate if a HF- disease management program (HF-DMP) in skilled nursing facilities (SNF)s will decrease all-cause rehospitalizations for the first 60 days post-SNF admission. The trial is a randomized cluster trial to be conducted in 12 for-profit SNF in the greater Cleveland area. The study population is inclusive of patients with HF regardless of ejection fraction but excludes those patients on dialysis and with a life expectancy of 6 months or less. The HF-DMP includes 7 elements considered standard of care for patients with HF documentation of left ventricular function, tracking of weight and symptoms, medication titration, discharge instructions, 7-day follow-up appointment post-SNF discharge, and patient education. The HF-DMP is conducted by a research nurse tasked with adhering to each element of the program and regularly audited to maintain fidelity of the program. Additional outcomes include health status, self-care management, and discharge destination.

Conclusions: The SNF-Connect Trial is the first trial of its kind to assess if a HF-DMP will improve outcomes for patients in SNFs. This trial will provide evidence on the effectiveness of HF-DMP to improve outcomes for older frail HF patients undergoing postacute rehabilitation.

Heart failure (HF) challenges our clinical management skills through unpredictable exacerbations, frequent hospital utilization, and complicated treatment regimens. Older adults prove particularly challenging because of additional morbidities, altered medication tolerance, cognitive and physical decline, and often lack of social support. In the setting of system-wide financial penalties for re-hospitalizations from Medicare, evidence-based strategies to reduce rehospitalizations in older adults are needed. Community HF-disease management programs (HF-DMP)s have evidenced success through reduced hospitalizations, mortality, and improved quality of life.[1,2] The effectiveness of HF-DMP in reducing re-admissions from the postacute rehabilitation setting remains unknown. The rehabilitation and transitional setting receives some of the sickest and most medically complicated HF patients.

The purpose of the skilled nursing facility (SNF) Connect Study is to determine whether a HF-DMP can reduce rehospitalizations for older adults. The study focuses on the immediate postacute patient (ie, 30 days posthospital discharge) and the immediate post-SNF discharge (ie, 60 days post-SNF admission). The study period has been chosen to illuminate the effects of the HF-DMP during the vulnerable time period when the patient transitions from 1 care-site to the next.

The SNF provides an ideal setting to initiate a HF-DMP as it already relies on a multidisciplinary team for patient care. McAlister et al have already demonstrated the effectiveness of the team approach for HF disease management.[3] We hypothesized that a SNF HF-DMP will

The authors declare no conflicts of interest.

This project is made possible through grant NIH 5R01HL113387-02.
Clinical Trials Registration: www.clinicaltrials.gov NCT01822912.

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http://dx.doi.org/10.1016/j.jamda.2013.05.023

Table 1
Inclusion and Exclusion Criteria

Inclusion criteria
A HF diagnosis is listed as the hospital discharge primary or secondary diagnosis.
Exclusion criteria
Patients with a life threatening condition which predicts mortality in ≤6 months.
Patients who are admitted to the hospital from a long term care facility.
Patient with cognitive impairment and no POA/caregiver.
End-stage renal disease with dialysis.

HF, heart failure; POA, Power of Attorney.

reduce rehospitalization rates compared with usual care (UC) for the first 30 days posthospital discharge and 60 days after SNF admission.

The Study Partnerships

Partnerships were formed with multiple community-based for-profit SNFs. We chose for-profit entities as they hold 70% of the market share[4] and increase the chances for rapid dissemination of practice change through the corporate structure. The pressure to reduce readmissions and the marked competition between the facilities to demonstrate the ability to manage these complex patients has primed the healthcare climate for our study. In the greater Cleveland area, it has resulted in enthusiastic cooperation from the facilities and their affiliated companies.

Trial Population

We plan to enroll 1404 patients admitted to a SNF following an acute-care hospital discharge with a principal or secondary diagnosis of HF and independent of ejection fraction. Inclusion and exclusion criteria are listed in Table 1. We include cognitively impaired patients to improve the generalizability of our study population. These patients required a caregiver who is the identified key learner to assist in HF management at home.

Sample characteristics focus on relevant geriatric phenomena common in the SNF setting and associated with adverse outcomes but rarely collected for HF trials. These include a frailty measures (15-foot walk plus hand grip strength), comorbidity, cognitive impairment, and delirium. When possible, instruments already used in the SNF are used to assess patients. For example to detect dementia and delirium, the Minimum Data Set (MDS) measures [Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM)] will be used. These measures are collected by the research staff at the time of enrollment since the SNF staff may not complete the MDS until 14 days after admission. Detailed description of the HF patient population in SNF provides future opportunity to further tailor interventions.

Trial Design

Considerations to Reduce Bias

The study employs a blocked, cluster randomization design,[5] with physicians, defined as either high or low admitters, serve as clusters, and SNFs as blocks. This provides the best opportunity for balance between groups. Using the SNF as the block takes advantage of any within-SNF correlation (besides that attributable to a physician) to increase power. Specifically, for each SNF we randomize the patients by physicians/physician group to either a HF-DMP or UC in a 1:1 ratio. This avoids contamination between the intervention and the UC group through the physician practice. A constrained randomization is used to balance the number of physicians assigned to each study arm within each SNF.

Intervention HF-DMP

The intervention was designed to fit with measures collected in the acute care setting to ease the transfer of information. The intervention's simplicity makes it readily replicated and sustained; if proven effective. The intervention is conducted by a HF Nurse Advocate (HFNA) who implements the intervention; the facility staff members do not conduct the intervention.

The HF-DMP applies the important elements of care transitions and specific HF components recommended by the National Priorities Partnership, Hospital to Home initiative and the American Heart Association Get with the Guidelines Program for the transition from hospital to home. Therefore, the SNF HF-DMP builds on the approaches modeled by national organizations across the continuum of care. The American Heart Association/American College of Cardiology HF Guidelines and Clinical Performance Measures were also used to develop our intervention.[6–8] The HF-DMP emphasizes 2 components of SNF HF care, clinical management and patient/caregiver self-efficacy at discharge. Clinical management of HF intends to optimize medical therapy. The fostering of self-efficacy centers on iterative education both conceptually and through coaching of HF self-care techniques for the duration of the SNF stay, at discharge, and at 7-day follow-up. HF disease management programs led by nurses can improve both patient quality of life and cost effectiveness.[9] Figure 1 illustrates the 7 measures of the 2 components of the HF-DMP, the Clinical Care Measures and the Discharge Care Measures.

The HFNA assures that each care measure is performed on each patient. Enrolled patients are followed through to 60 days post-SNF admission. This duration permits us to capture patient activity and learning both during the SNF stay and immediately post-SNF

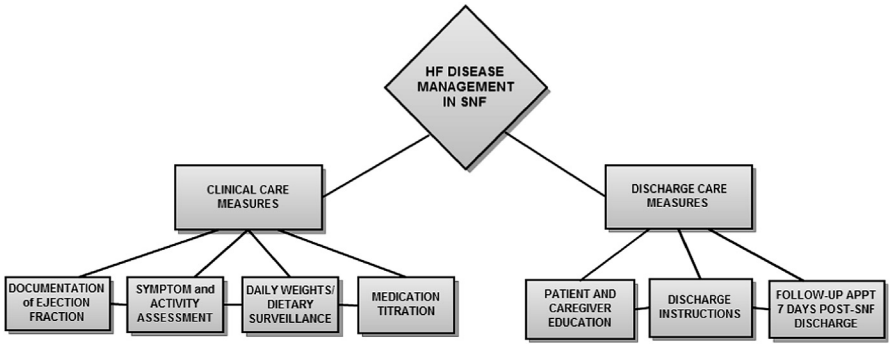

Fig. 1. The HF-DMP in skilled nursing facilities.