Contemporary Clinical Trials 71 (2018) 140–145

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

# Group medical visits after heart failure hospitalization: Study protocol for a randomized-controlled trial

Wen-Chih Wu[a,*], Melanie Parent[a], Sandesh Dev[b], Rene Hearns[c], Tracey H. Taveira[a], Lisa Cohen[a], Jeneen Shell-Boyd[c], Jeri Jewett-Tennant[c], Vanessa Marshall[c], Julie Gee[c], Kimberley Schaub[c], Sharon LaForest[c], Sherry Ball[c]

[a] Providence VA Medical Center, 830 Chalkstone Ave, Providence, RI 02908, USA
[b] Carl T. Hayden Medical Research Foundation, 650 E. Indian School Road 151A, Phoenix, AZ 85012-1892, USA
[c] Louis Stokes Cleveland VA Medical Center, 10701 East Boulevard, Cleveland, OH 44106, USA

ARTICLE INFO

*Keywords:*
Group visits
Shared medical appointment
Health status
Quality of life
Self-care

ABSTRACT

A primary goal of this research project is to better understand how shared medical appointments (SMAs) can improve the health status and decrease hospitalization and death for patients recently discharged with heart failure (HF) by providing education, disease state monitoring, medication titration, and social support to patients and their caregivers. We propose a 3-site randomized-controlled efficacy trial with mixed methods to test a SMA intervention, versus usual care. Patients within 12 weeks of a HF hospitalization will be randomized to receive either HF-SMA (intervention arm) with optional co-participation with their caregivers, versus usual care (control arm). The HF-SMA will be provided by a non-physician team composed of a nurse, a nutritionist, a health psychologist, a nurse practitioner and/or a clinical pharmacist and will consist of four sessions of 2-h duration that occur every other week for 8 weeks. Each session will start with an assessment of patient needs followed by theme-based disease self-management education, followed by patient-initiated disease management discussion, and conclude with break-out sessions of individualized disease monitoring and medication case management. The study duration will be 180 days for all patients from the day of randomization. The primary study hypothesis is that, compared with usual care, patients randomized to HF-SMA will experience better cardiac health status at 90 and 180 days follow-up. The secondary hypotheses are that, compared to usual care, patients randomized to HF-SMA will experience better overall health status, a combined endpoint of hospitalization and death, better HF self-care behavior, and lower B-type natriuretic peptide levels.

## 1. Introduction

Nearly half of Americans who develop heart failure (HF) die within 5 years of diagnosis [1] and more than one third of HF patients require frequent hospitalizations [2] or placement in long term care [3]. Fifty percent of HF readmissions are judged to be preventable [4,5]. Patient and health system factors play an important role in these preventable readmissions. Some patient factors include non-adherence to medication or dietary sodium restriction [6–8], failure to seek medical attention [4], and social factors such as lack of social support [4]. Health system factors include inadequate care coordination, inadequate patient and caregiver education and support, and limited access to providers after hospitalization [4,5]. However, traditional one-to-one patient-provider visits are labor intensive and inefficient in addressing these multi-disciplinary needs [9,10]. Shared medical appointments (SMAs) are an innovative approach to address care needs by providing an education and behavioral modification, medication management, and disease state monitoring in a group setting with peers.

SMAs are defined as visits in which several patients with the same chronic condition meet with one or more provider(s) at the same time [11] and typically involve a multidisciplinary team of a behaviorist, prescribing provider, and a medical record documenter [12]. An important distinction is that SMAs are not merely 'didactic classes' because they provide individualized medication management and clinical monitoring of patient health status. An SMA also distinguishes itself from the traditional disease management which is usually provided by one provider to one patient at a time and without medication management [13,14]. As such, SMAs may promote greater care efficiency and improved access to care. Further, an important focus of SMAs is behavioral change facilitated through self-management education, and

* Corresponding author at: Providence VA Medical Center, 830 Chalkstone Ave., Building 35, Providence, RI 02908, USA.
*E-mail address:* Wen-Chih.Wu@va.gov (W.-C. Wu).

https://doi.org/10.1016/j.cct.2018.06.015
Received 23 March 2018; Received in revised form 12 June 2018; Accepted 21 June 2018
Available online 22 June 2018
1551-7144/ 

group peer support [15–17]. Thus, we postulate that the change in self-care behaviors and individualized medication prescribing and clinical monitoring in HF-SMA will lead to improvement of patient's health status, reduction in B-type natriuretic peptide levels and hospitalizations for HF.

Evidence supporting the efficacy of SMA across various disease states is promising. Currently, no studies reported significant differences in health status or clinical endpoints; therefore we postulate a randomized-control trial to study SMAs for HF.

## 2. Methods

This will be an open-label multi-center randomized-controlled parallel design trial of 375 patients of HF-SMA versus usual care.

### 2.1. Study setting

The study will be conducted at three urban sites one from the Northeast, one in the West and another one in the Midwest regions.

### 2.2. Study hypothesis

The primary study hypothesis is that, compared with usual care, patients randomized to HF-SMA will experience better cardiac health status at 90 and 180 days follow-up. The secondary hypotheses are that, compared to usual care, patients randomized to HF-SMA will experience better overall health status, a combined endpoint of hospitalization and death, better HF self-care behavior, and lower B-type natriuretic peptide levels.

### 2.3. Study population

The trial will enroll patients hospitalized for HF within the prior 12 weeks. The trial will not exclude patients who are currently enrolled in HF education classes, support group or HF clinics, as these co-interventions are often present in optimal “usual care”. We will account for co-interventions using stratified randomization. The Inclusion Criteria are:

- 18 years and older
- Within 12 weeks of discharge from a hospitalization with a principal diagnosis of HF
- Able to participate in a group setting
- Able to read and understand questionnaires and health information and able to sign informed consent

The Exclusion Criteria are:

- Unable to attend the group sessions due to either psychiatric instability (acutely suicidal, psychotic) or organic brain injury (e.g. severe dementia, encephalopathy) that precludes self-reporting on health status.
- Discharged to hospice or nursing home facilities for long-term care, or patients with a code status of comfort-measures-only
- Recipients of heart transplant or ventricular assist devices, patients receiving intravenous inotropic infusions, pregnant women, and patients with end-stage liver disease or renal disease on dialysis

### 2.4. Randomization and retention

Patients will be randomly assigned on a 1:1 ratio to HF-SMA or usual care arms using a stratified randomization (urn method by PL. Leduc, 2013, v1.16). Stratification will be based on the study site and: a) current co-intervention enrollment to HF clinic, support group or education versus none, b) $\leq 2$ versus $> 2$ hospitalizations in the last 6 months, and c) left ventricular ejection fraction $< 40\%$ versus $\geq 40\%$.

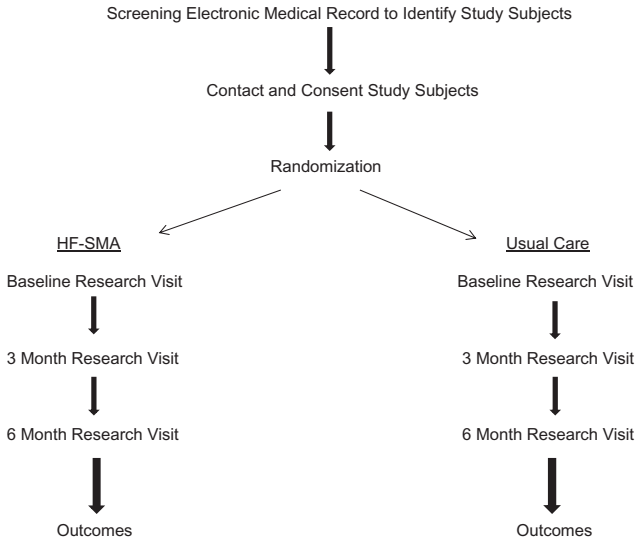


**Fig. 1.** Study flow.

Computerized randomization will be done by the call-in method to the coordinating site (see Fig. 1).

### 2.5. Study intervention arm - HF-SMA

Patients randomized to intervention arm, HF-SMA, will participate in four HF-SMA visits, which are two weeks apart. Patients are continuously enrolled in HF-SMA on a rolling basis (not a fixed cohort). To facilitate scheduling, we have a fixed schedule of the group medical visits on one afternoon a week with a fixed rotation of four themes for the four sessions. Therefore, if a patient misses one session, he or she can continue on the other sessions and make-up the theme he/she missed when it rotates back again.

The HF-SMA team provides interdisciplinary, individualized longitudinal care and can include a dietitian, a health psychologist, a nurse, a nurse practitioner and/or a clinical pharmacist with specialized heart failure training; one of which will lead the group discussions (facilitator). Each group is composed of 4–6 patients and their caregivers (if applicable) are encouraged to attend. At the beginning of each session the facilitator will instruct patients on the importance of maintaining privacy and confidentiality of fellow group members. The facilitators are specifically trained not to offer any protected health information that is not disclosed by the participant. The session will start with an assessment of the patients and their needs followed by pre-assigned disease self-management education, followed by patient-initiated disease discussion, and conclude with break-out sessions of individualized behavioral intervention, medication and disease management by the prescriber (nurse practitioner or clinical pharmacist). Specific components of 2- h HF-SMA visits are explained in Table 1.

Prior to every SMA visit, each site's interdisciplinary team reviews the electronic medical record of each patient for pertinent past medical and psychosocial history, current medications, previous cardiac testing, laboratory data, and other relevant interventions or care (e.g. specialty consultation, inpatient hospitalization, primary care concerns, telehealth data). This information is formatted into a pre-clinic annotated note that assists clinic staff in identifying individual patient needs. During each group visit, current heart failure symptoms are assessed using a standardized tool and educational information is provided focused on weight monitoring, heart failure symptom recognition, medication management, and low sodium diet adherence.

The Group Education (15–30 min) consists of theme-based discussion based on curriculum published by the HF Society of America [18] into 4 sessions: