SELF-MANAGEMENT APP FOR PATIENTS WITH LEFT VENTRICULAR ASSIST DEVICES

STUDY PROTOCOL & STATISTICAL ANALYSIS

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Purpose

This study aimed to obtain preliminary efficacy data of using a mobile phone application (VAD Care App)[1] as a self-management tool in patients with left-ventricular assist devices (LVAD). The specific aim was to evaluate the effects of the app on the patient's (1) self-efficacy and (2) adherence to the LVAD care regimen; (3) complications; (4) overall health status, and (5) quality of life.

Study Design

Pilot randomized control trial. Measurements completed at baseline (T0) and months 1 (1), 3 (T2), and 6 (T3) post-hospital discharge.

Sample and Setting

This study recruited a total of 68 patients with newly implanted, non-pulsatile flow durable LVADs and from four VAD Centers in the Midwest and Northeast regions in the United States. The study was implemented in inpatient and outpatient settings of the hospitals.

Study Procedure

Recruitment and screening. A trained clinical research coordinator (CRC) conducted all recruitment and screening of study participants. Recruitment and obtaining informed consent occurred in each hospital's inpatient setting. A screening checklist based on the study inclusion and exclusion criteria (table insert) was used. Since cognitive impairment is common in heart failure, we used the 11-item Mini-Mental State Exam (MMSE) as a screening tool. The MMSE is a valid, reliable, and widely used cognitive screening tool across care settings and conditions worldwide. A score of less than 24 in the MMSE denotes cognitive impairment.[2,3] Participation in this study also required a dedicated caregiver, a customary practice in the participating VAD centers.

	Patients
Inclusion	• First-time LVAD implant
	• 21 to 80 years of age
	• 6th grade education or higher
	• Can read and understand English
	• Planned hospital discharge within a week of enrollment
	• Completed LVAD care training
Exclusion	• Blindness
	• Inability to or refuse to use a smartphone
	• Cannot hear alarms, and/or
	• Cognitively impaired documented in the medical record of an MMSE score <24

Randomization. Upon confirming eligibility to participate, patients were randomized in the study using a sample randomization procedure. Randomization, prepared by a statistician, using a computer-generated 1:1 allocation of patients to either a control group or an intervention group. A coding scheme (ID#, site, study group), matching with the master list of patient names, as study participant identification was developed. Personally, identifiable data and group

assignments kept separately from other study data. Each site kept the study data in a locked cabinet *and* a password protected and encrypted desktop computer.

- **Control group:** Patients received packets containing study instructions and self-administered questionnaires. They also received the *usual care* throughout the study (6 months). Usual care is defined by the routine outpatient care customary to each VAD center. Many VAD Centers in the US share a similar approach to managing LVADs in outpatient clinics with routine follow-up care and as needed educational support (LVAD care) for patients/caregivers provided by specialized VAD nurses (RNs/NPs). Patients in the control group used the usual LVAD self-management process consisting of the utilization of LVAD system operation manuals and videos and logs for daily care, self-monitoring, and reporting to any of the outpatient VAD RNs/NPs. It is also a common practice for VAD Centers to require patients and/or caregivers to bring their LVAD care logs during routine clinic visits.

- **Intervention group:** Intervention patients performed LVAD self-management (assisted by caregivers as needed) as directed by the VAD Care App[1] and supported by VAD RNs/NPs throughout the process. The app provided the patient with directions in completing the tasks and procedures required for daily LVAD care and management. It also provided an efficient channel of communication between RNs/NPs, patients and/or caregivers for interventions related to abnormal results (e.g., low LVAD flow), making recommendations to correct a deficit in knowledge and skills of LVAD self-management and to address other LVAD care-related issues rapidly. Additionally, the app notified the RNs/NPs with text messages when a patient did not complete self-management for two consecutive days. In addition to receiving the *usual care,* patients in the intervention group had:

    a. Completed a study protocol training a day before discharge. First, the CRC downloaded the VAD Care App[1] into an iOS or an Android-compatible smartphone owned by the participant or provided by the study team. Second, the CRC trained the patient and caregiver in the use of the app. Third, the CRC asked the patient and caregiver to demonstrate the use of the app at least twice to ensure proficiency in using the app.
    b. Received an intervention package consisting of study instructions, self-administered questionnaires, and smartphones with the app ready for use at home.
    c. Used the app daily for a total of 6 months post-implantation hospital discharge. As prompted by the app, the patient and/or caregiver will implement the LVAD care regimen.
    d. Completed an "*LVAD knowledge and skill review and evaluation*" at week 1, and months 1 and 5 to facilitate LVAD care self-efficacy and adherence. This review and evaluation were conducted by the VAD RNs/NPs during clinic visits or delivered via a video chat.

Data Collection. Data were collected at baseline (1-2 days before hospital discharge) and 1, 3, and 6 months after implantation hospitalization discharge. Approaches for data collection included reviews of a patient's healthcare/medical record, completion of self-administered questionnaires, and face-to-face interviews. The following data collection tools were used:

- **Demographic and Clinical Profiles.** Common demographic data such as age, sex, race, education, and health history collected from informants (patients and/or caregivers). Clinical profiles included LVAD indication (implant strategy), model, and other pertinent clinical data, including comorbidities and risk stratification in advanced heart failure (INTERMACS Classifications).[3] The Charlson Comorbidity Index (CCI), which evaluated 17 different comorbidities assigned to various weights (scores), were also employed. The CCI is a valid and reliable measurement instrument that is widely used for evaluating comorbidity indexes in cardiovascular, cardiac surgery, and LVAD patients.[4,5]

- **LVAD Care Self-Efficacy** was measured with a 20-item LVAD Patient Self-Efficacy Scale, used to assess a patient's confidence in managing the challenges presented by the daily LVAD care regimen. The instrument employs a 6-point rating scale ranging from 0 (*not confident at all*) to 5 (*extremely confident*), with standardized sum scores ranging from 0 to 100. High sum scores indicate higher confidence in one's ability to manage the complexity of the regimen. The validity and reliability of the instrument were already established by factorial and convergent validity with a Cronbach's alpha coefficient of 0.92.[6-9]

- **Adherence** to the LVAD care regimen was measured with the 9-item LVAD Patient Home Management Adherence Scale, used to assess the degree of the patient's consistency in completing the daily LVAD care. The instrument employs a 6-point rating scale, ranging from 0 (*never*) to 5 (*all the time*), with standardized sum scores ranging from 0 to 100. High sum scores indicate high adherence to the regimen. The validity and reliability of the instrument were also established by factorial and convergent validity with a Cronbach's alpha coefficient of 0.95.[6-9]

- **Complications and Hospital Readmission.** Two separate forms were created for capturing characteristics and frequency of LVAD-related complications and unplanned hospitalization through a monthly review of the patient's medical record(s) and interviews of patients and/or caregivers. These forms consisted of a checklist and tables format, a commonly used approach for collecting complications and healthcare utilization/hospital readmission episodes in heart failure.[10]

- **Quality of Life** was measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ). This 23-item instrument used to assess several health-related QOL domains, including physical function, symptoms, social function, among others. The instrument employs a 6-point Likert response scale with sum

scores ranging from 0 to 100. High sum scores indicate better quality of life. The validity, reliability, and sensitivity of the KCCQ have been well established in patients with heart failure and LVADs worldwide.[11-13]

Data Analysis*.* All data management and statistical analyses performed with REDCap and SAS.[14,15]Study data were checked for quality and completeness. Data were also checked to ensure that assumptions were met before performing statistical analyses. Descriptive statistics and graphical displays used to summarize the data by the study group. Continuous variables summarized with medians and IQR or means and standard deviations, depending on the distribution. Categorical variables were summarized using percentages and frequencies. Differences in the study group's outcome variables were compared for each period (T0, T1, T2, and T3) with Mann Whitney U tests and chi-square tests set at 0.05 level of significance. Confidence intervals (95%) provided with the summary statistics as well as model estimates and effect size estimates for the next stage of this pilot.

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