

Impact of Discharge Teach-Back Education on Heart Failure Patients' Knowledge/Self-Care

Behaviors and 30-Day Readmissions

Study Protocol (Completed Study)

NCT07280208

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## 1. Protocol Summary (Synopsis)

This project evaluated whether a structured discharge education session using the teach-back method improved heart failure self-care behaviors and reduced 30-day heart failure-related readmissions among hospitalized adults with systolic heart failure.

### 1.1 Objectives

- Primary Objective: To evaluate change in heart failure self-care behaviors from pre-intervention to immediate post-intervention using the European Heart Failure Self-care Behavior Scale-9 (EHFScB-9).
- Secondary Objective: To describe the 30-day heart failure-related readmission rate following the discharge teach-back intervention.
- Exploratory Objective: To explore whether the magnitude of EHFScB-9 improvement differed by readmission status (event-limited).

### 1.2 Endpoints

- Primary Endpoint: Mean change in total EHFScB-9 score (post minus pre).
- Secondary Endpoint: Proportion of participants with heart failure-related readmission within 30 days of discharge.
- Process Measures: Participation rate; completion rates for pre- and post-surveys.

### 1.3 Study Design (as implemented)

- Design: Single-site quasi-experimental pre-test/post-test quality improvement project.
- Participants: Hospitalized adults with systolic heart failure (LVEF  $\leq 40\%$ ), NYHA class II–IV, ACC/AHA stage C or D.
- Intervention: Standardized ~30-minute in-person discharge teach-back education session.
- Assessments: EHFScB-9 survey pre-intervention and immediately post-intervention; 30-day readmission review via EHR.

## 2. Background and Rationale

Heart failure is associated with high hospitalization and readmission rates. Inadequate understanding of discharge instructions and suboptimal self-management contribute to preventable rehospitalization. Teach-back is an evidence-based communication method that verifies understanding by asking patients to restate key information in their own words. This project implemented a structured teach-back discharge education workflow to improve self-care behaviors and reduce early readmissions.

## 3. Study Setting

The project was conducted on inpatient units at a single hospital site. Participant procedures occurred during routine discharge preparation; follow-up was completed via EHR review at 30 days.

## 4. Participant Eligibility

### 4.1 Inclusion Criteria

- Age  $\geq 18$  years.
- Diagnosed with systolic heart failure with left ventricular ejection fraction (LVEF)  $\leq 40\%$ .
- NYHA functional class II, III, or IV; ACC/AHA stage C or D.
- Hospitalized at the study site and clinically appropriate for discharge.
- Able to read/understand English at approximately 8th-grade level.
- Had access to a smartphone or tablet capable of scanning a QR code to complete surveys (REDCap).
- Provided electronic informed consent.

### 4.2 Exclusion Criteria

- Cognitive impairment preventing informed consent or teach-back participation.
- Non-English speaking (for this implementation).
- Declined participation.

## 5. Recruitment and Enrollment (Completed)

Potentially eligible participants were identified during hospitalization by the advanced heart failure cardiologist during routine clinical care and referred to the primary investigator for screening. The primary investigator confirmed eligibility, explained the project, emphasized voluntariness, and provided access to electronic consent and surveys via QR code.

## 6. Intervention (Completed)

### 6.1 Teach-Back Discharge Education Session

A standardized, approximately 30-minute discharge education session was delivered in the participant's hospital room by the primary investigator using teach-back. Core topics included daily weights, symptom monitoring (dyspnea, edema, fatigue), response to weight gain, fluid restriction, low-sodium diet, medication adherence, and physical activity. Participants were asked to explain key points back in their own words to confirm understanding and correct misconceptions.

### 6.2 Educational Materials

- American Heart Association: "How Can I Live with Heart Failure?"
- American Heart Association: Heart Failure Symptom Tracker.

## 7. Study Procedures and Schedule (Completed)

### 7.1 Baseline (Pre-Intervention)

- Electronic consent in REDCap via QR code.

- Creation of a participant alias to link surveys without identifying information.
- Baseline EHFSdB-9 survey (self-administered privately).

## 7.2 Intervention

- In-person teach-back discharge education (~30 minutes).
- Review and provision of printed educational materials.

## 7.3 Immediate Post-Intervention

- Post-intervention EHFSdB-9 survey in REDCap via a second QR code (self-administered privately).

## 7.4 30-Day Follow-Up

- Retrospective EHR review at 30 days post-discharge to determine heart failure-related readmission (yes/no), date, and reason.

# 8. Outcomes and Measures

## 8.1 EHFSdB-9

The European Heart Failure Self-care Behavior Scale-9 (EHFSdB-9) is a 9-item questionnaire assessing key self-care behaviors. Items are rated on a 5-point scale; lower scores indicate better self-care. The total score is the sum of items (range 9–45).

## 8.2 30-Day Heart Failure-Related Readmission

Readmission was defined as an unplanned inpatient admission for heart failure-related reasons to the study-site hospital within 30 days of index discharge and was determined through EHR review.

# 9. Enrollment and Sample Size (Actual)

A total of 57 participants were enrolled and completed both the pre- and post-intervention EHFSdB-9 surveys. Enrollment occurred during a 30-day implementation window at the single hospital site.

Key dates (Actual): Study Start Date September 11, 2025 (Actual); Primary Completion Date October 11, 2025 (Actual); Study Completion Date November 10, 2025 (Actual).

# 10. Data Collection, Management, and Confidentiality

- Survey data were collected in REDCap using de-identified aliases.
- A separate secure crosswalk list (medical record numbers only) was maintained solely for 30-day readmission ascertainment and stored in a locked location.
- Electronic files were stored on encrypted/password-protected devices per institutional policies.

- Only minimum necessary information was collected for EHR review.

#### 11. Ethical Considerations

The project was conducted with IRB approval. Participation was voluntary, and electronic informed consent was obtained prior to survey completion.

#### 12. Risks, Burden, and Benefits

- Risks were minimal and primarily related to time burden and potential fatigue during education.
- Potential benefits included improved understanding of discharge instructions and better self-care behaviors.
- Privacy was protected through de-identification and secure data handling.

#### 13. Quality Assurance

- A standardized education script and teach-back prompts were used to support fidelity.
- REDCap validation rules supported data quality.
- Completeness of surveys and follow-up ascertainment were monitored throughout the project.

#### 14. References and Supporting Documents

Copies of the EHFS cB-9 instrument and AHA education handouts were retained in secure project files in accordance with IRB and site policy.

### Key Study Dates (Actual)

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