Heart Failure Medication Study

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1) Protocol Title

Heart Failure Medication Study

2) Objectives*

The objective of this investigation is to pilot test a medication in-hand intervention (Meds to Beds) compared to standard care for patients with heart failure (ICD-50[all numbers]). We expect the intervention to improve adherence and physical health, and reduce hospital re-admissions. We also expect the study to provide evidence for the feasibility and acceptability of the medication-in-hand intervention.

3) Background*

Heart failure is a chronic disease that increases mortality, reduces quality of life, and increases health care system costs. About 6.5 million people in the United States and 26 million worldwide have heart failure. Heart failure patients face many barriers to adherence to their medication regimen, including being prescribed an average of 6.4 medications daily. Promoting continuity of care in regard to prescription medication from the bedside with a medication in-hand intervention (Meds to Beds) may therefore help patients with heart failure improve adherence to medications, and thus improve health.

4) Inclusion and Exclusion Criteria*

Primary inclusion criterion is an admission diagnosis of heart failure ICD-50, including I50.1, I50.2, I50.20, I50.21, I50.22, I50.23, I50.3, I50.30, I50.31, I50.32, I50.33, I50.4, I50.40, I50.41, I50.42, I50.43, I50.8, I50.81, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84, I50.89, I50.9, or any combination thereof.

To be included patients must also be:

1. age 18 or older;
2. in New York Heart Association Heart Failure Class II or Class III, with ejection fraction below 45%;
3. Cognitively intact, without significant psychological impairment affecting medication adherence such as dementia noted in patient record.

Exclusion criteria are:

1. Patients with medical conditions, such as active cancer or pregnancy, expected to alter heart failure medication management;
2. Patients discharged to nursing homes or hospice care, as they may not responsible for their own adherence;
3. Prisoners and those unable to provide a point of contact for follow-up assessment;
4. Patients who do not plan to fill discharge medications at the Jackson Memorial Hospital pharmacy.

5) Procedures Involved*

Participants will be identified and recruited from inpatient units at Jackson Memorial Hospital using the electronic health record. At consent, participants will be asked to sign a HIPAA waiver to allow access to their medical record for 60 days after discharge. 60 participants will be randomly assigned to one of two intervention conditions: 1) Meds to Beds, patients receive medication in-hand at discharge from the hospital, and 2) standard care (patient pickup at the pharmacy) comparison group. Adherence to medication will be measured with 1) self-report Adherence to Refills and Medications Scale (ARMS), and 2) pharmacy refill data. Health will be assessed with the self-report PROMIS 10, a measure developed by researchers for patient-reported evaluation of global health. Information on hospital readmission, other hospital visits, and deaths will be obtained from the electronic health record. Feasibility will be determined by tracking the number of patients who receive medications before discharge in the Meds to Beds intervention and by asking patients at follow-up how they received their discharge medications and about their experiences with healthcare. Acceptability will be assessed with 2 questions created for this study. A self-report questionnaire with 7 items created for this study will assess theoretical mechanisms of change for the Meds to Beds intervention. Self-report measures will be administered in-person before randomization, and/or about 30 days post-discharge by telephone or in-person. Prescription refill and other information from the electronic health record will be monitored for up to 60 days post-baseline in order to collect data about the period 30 days post-discharge. Measures are either available in English and Spanish from the authors, or will be translated using a translation back-translation approach.

6) Data and Specimen Banking*

There will be no specimen banking.

7) Data Management*

Protection of patient privacy and confidentiality will be maintained in highest priority at all times. All files will be kept in a locked office and data stored on a secured drive. All personally identifying patient information will be kept separate from patient data at all times.

8) Risks to Subjects*

This study is expected to be of minimal risk to participants. Special care will be taken to ensure patients do not confuse participation in this study with their treatment plan, and continue to contact their regular providers for any issues or questions regarding their medication or health.

9) Potential Benefits to Subjects*

This study provides no direct benefit to participants.

10) Vulnerable Populations*

This study will not include pregnant women, prisoners, children or cognitively impaired adults.

11) Setting

Some study data will be collected at inpatient units at Jackson Memorial Hospital, with follow-up via telephone or in-person with these participants.

12) Resources Available

Lila de Tantillo, BSN, RN, PhDc is a fourth-year doctoral student in Nursing at the University of Miami School of Nursing and Health Studies. She has spent the past three years researching cardiovascular disease and medication adherence, including a participating in graduate-level nursing clinical at Jackson Memorial Hospital. She is fully bilingual in English and Spanish, and will be responsible for all data collection.

13) Prior Approvals

Approval of Jackson Memorial Hospital will be obtained before commencing this study.

14) Recruitment Methods

A partial HIPAA waiver will be requested to identify patients admitted to Jackson Memorial Hospital with a heart failure diagnosis who may qualify for the investigation. These patients will be approached at bedside by a known person such as a nurse or physician and invited to participate in the study. If interested in participating patients will be screened by researcher with a preliminary questionnaire regarding medical history and contact information. Qualifying patients will be asked to sign a consent form. At the time of inclusion in the study, participants will receive a gift card worth $20 as compensation. In addition, participants will receive $50 as compensation for completing the telephone follow-up portion of the study.

15) Local Number of Subjects

There will be up to 60 participants (30 Meds to Beds, 30 standard care).

16) Confidentiality

Patient confidentiality will be maintained at all times; they will only be contacted by one researcher. Data and responses will be linked using a numerical ID; a linking list with names matched to ID will be stored separately from data by the principal investigator in secure location.

No specimen samples will be taken, used or stored in this investigation.

17) Provisions to Protect the Privacy Interests of Subjects

One researcher will be responsible for the screening, consent process and interviews of participants to limit intrusion of privacy.

18) Consent Process

Potential participants will be approached at Jackson Memorial Hospital after identification in the medical record.

Only patients with qualifying diagnoses identified by physicians as stable for participation in the research study will be approached after an introduction by a "known individual" (such as a nurse or doctor).

The study PI is fluent in English and Spanish, and will recruit English- and Spanish-speaking participants for the study. All informational and consent material will be available in English and Spanish.

There will be no individuals under age 18 included in the study.

19) Process to Document Consent in Writing

Potential participants will be approached and informed of potential eligibility to enroll in the study. If the participants agree, they will be explained the risks and benefits of being involved in the study. They will be asked several screening questions to confirm eligibility. Participants who are eligible and wish to enroll in the study will be provided the consent form and any questions or concerns will be answered and addressed. A copy of the signed and dated consent form will be provided to the participant.