STUDY PROTOCOL

Feasibility and Acceptability of a Values-Affirmation Intervention Targeting Medication Adherence in Older Adults with Heart Failure

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VALUES-AFFIRMATION INTERVENTION TARGETING MEDICATION ADHERENCE IN OLDER ADULTS WITH HEART FAILURE

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1 STUDY DESIGN

This research will examine the initial feasibility and acceptability of a values-affirmation, education, and skills-training intervention targeting HF medication adherence using the NIH Stage Model for Behavioral Intervention Development (Onken et al., 2014). Older adults with HF will be invited to engage in a values-affirming exercise and review tailored medication education and skills-training with a study interventionist. Participants will use a pillbox with electronic monitoring capabilities with a personalized value label as a reminder of their core values throughout the study.

Design: This study is a Stage 1B (NIA Stage Model) trial and will use a single-arm design. No randomization or participant blinding will occur.

Setting: Study assessments and intervention delivery will occur either at the participant's home or The Miriam Hospital's Center for Behavioral and Preventive Medicine (CBPM). The location will be determined by participant preference. Data management and analysis will be housed at CBPM.

Study Duration: Study duration is estimated to be 9-12 months from the time of enrollment of the first subject to completion of data cleaning and analysis. Each individual participant will complete the protocol within 4 weeks from the time of the baseline visit until the end-of-treatment assessment.

Sample: 12 older men and women with HF, ages 55 and older, who are within the first monthof a CR program in Providence, Rhode Island will be recruited. We aim to recruit a sample that is 50% women and 15% individuals who identify as a member of a racial or ethnic minority identity.

2 PRIMARY OBJECTIVE

This study reflects one of a series of studies designed to develop and test a values affirmation medication adherence intervention for older adults with heart failure (HF). The primary objectives are to assess intervention feasibility and acceptability through a small open, single-arm trial. Primary endpoints are feasibility of recruitment procedures, feasibility of intervention procedures, and acceptability. We hypothesize that the intervention will be 1) feasible, and 2) acceptable.

Note. Administration of assessment measures are for feasibility evaluation only.

3 SELECTION AND ENROLLMENT OF PARTICIPANTS

3.1 Inclusion Criteria

Older adults with a diagnosis of HF upon admission and other CR participants within the first month of enrollment with a HF diagnosis regardless of CR referral reason will be eligible for inclusion. Only HF patients who are indicated as being at risk of medication-non adherence will be eligible (i.e., as indicated by a referral to the CR pharmacy consultation service OR based on medication adherence screening measures OR if they are prescribed ten or more medications).

Additional inclusion criteria will include: (1) adults ≥ the age of 55 at the time of CR initiation and (2) English-speaking.

3.2 Exclusion Criteria

(1) current participation in a medication-monitoring clinical or research protocol, (2) severe cognitive impairment on cognitive screening measures or diagnosis of Alzheimer's or dementia, (3) current suicidality, (4) acute psychosis, (5) chart documentation of NYHA-class IV HF, (6) terminal illness with an expected lifespan of less than six months, or (7) patient report that someone other than the patient is primarily responsible for the patient's medication management and medication-taking.

3.3 Study Enrollment Procedures

Recruitment

Participants will be recruited from the Cardiac Rehabilitation Center at the Miriam Hospital (Providence, RI) and Lifespan Cardiovascular Institute, Lifespan Ambulatory Care Center (East Greenwich, RI). Patients deemed to meet initial inclusion criteria (i.e., HF diagnosis, aged ≥55 years, no chart documentation of severe cognitive impairment or dementia, English-speaking) based on chart review will either be approached in the clinic or will be mailed a letter invitation to participate and contacted via phone one week later. Individuals who are approached in clinic will be asked to complete a "Consent to Contact" form. If patients do not respond to two telephone calls, they will not be telephoned again.

Screening

Patients will be asked to complete eligibility screening via telephone. Questions will be asked to check whether they meet the additional characteristics to be enrolled in the study (e.g., not participating in another medication monitoring protocol). They will also be asked to complete two questionnaires during the phone call: 1) Blessed Orientation Memory Concentration test (BOMC) to screen for significant cognitive impairment, and 2) risk for medication non-adherence as indicated referral to the pharmacist consultation service at cardiac rehab or endorsement of at least 1 non-adherence item on the Voils Extent of Adherence instrument (e.g. "no" on Question 1 or "yes" on Questions 2 or 3) or by being prescribed ten or more medications. Participants who score 10 or greater on the BOMC will not be eligible.

4 ASSESSMENT PROCEDURES

4.1 Baseline Assessments

- Demographics (self-reported)
- Charlson comorbidity index (completed via medical chart review).
- The Medication Management Instrument for Deficiencies in the Elderly
- Timeline follow-back medication adherence interview
- Medication Adherence Scale
- The Rapid Estimate of Adult Literacy in Medicine—Short Form
- Information--Motivation--Behavioral Skills Adherence Questionnaire (adapted for use in HF) – administered for intervention tailoring purposes only (not scored)
- Memory Impairment Screen-Delayed.

Electronically Monitored Medication Adherence- Participants will also be asked to use a Tricella pillbox to monitor medications for 4 weeks. Participants will be asked to review their medication regimen with study staff. Prior to use, a study team member will demonstrate appropriate use of the pill boxes and will invite participates to practice opening and closing the containers. Study staffwill work with the participant to load each bin of the pill box bottle and provide detailed instructions for use. If participants take medications at two or three time points per day (e.g., morning and evening, or morning, noon, and evening), then the participant will be provided with a pillbox for account for each time period up to three.

Written instructions will be provided to all participants, including study staff contact information. Participants will be encouraged to contact staff in the event of any questions or concerns.

4.2 Follow-up call

One week following the baseline assessment and initiation of monitoring, study staff will call the participant to ask if there are any questions regarding use of the devices. Any emergent questions will be answered.

4.3 End of Treatment Assessment

- The Medication Management Instrument for Deficiencies in the Elderly will assess individual patient knowledge of their specific medication instructions.
- Timeline follow-back medication adherence interview
- Medication Adherence Scale
- Monitored Medication Adherence- pillbox collected for data transfer
- Study and Treatment Acceptability. Participants will be asked to take part in a brief (20-30 minutes) qualitative exit interview to gather participant reactions to the intervention and study procedures. These interviews will be completed by phone on the same day (immediately following or shortly thereafter) as the end-of-treatment visit. If needed due to participant availability, these interviews may be conducted within 1 week of the end-of-treatment visit. Exit interviews will be audio recorded to facilitate transcription and note taking. Audio recordings will be stored on a secure server on the Lifespan network and will be deleted at the end of the study.

5 INTERVENTION DELIVERY

Participants will complete a brief intervention in person immediately following the baseline assessment (about 60 minutes) and continued use of the study pillbox with the values affirmation prompt for the following 4 weeks. The session will include:

1. Participation in a values-affirmation exercise (i.e., Values card sort activity).
2. Working with the interventionist to devise a way to tangibly connect that value with medication-taking (i.e., placing a label with a word or picture of the value on a pill box or display next to the pill box).
3. Provision and review of a patient education workbook with recommendations for skills training activities to improve regimen management.

6 COMPENSATION

Participants will be compensated a total of $70 in this research study. Specifically, they will receive $30 in cash at the end of the first study visit, $20 in cash at the end of the second study visit, and a $20 gift card by mail after completing an exit interview via telephone.

7 PRIMARY ENDPOINTS

1) Recruitment feasibility will be determined through examination of the percentage of eligible patients who enroll in the study.
2) Intervention feasibility will be calculated as the percentage of individuals who were enrolled and completed both the baseline assessment, intervention, monitoring period, and end-of-treatment assessment. Attrition will be assessed through examination of rates of dropout and reasons for non-completion. Feasibility of intervention procedures will be defined as achieving a retention rate of 80%.
3) Patient acceptance of the intervention will be determined by analysis of qualitative exit interview.

8 REFERENCES

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