STUDY PROTOCOL

Values-Affirmation + Education 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 heart failure (HF) medication adherence using the NIH Stage Model for Behavioral Intervention Development (Onken et al., 2014).

Design: This study is a Stage 1B trial and will use a randomized controlled trial design. Participants will be randomized 1:1 basis to the Values-affirmation Intervention condition (n = 25) or Usual Care (n = 25).

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 21-24 months from the time of enrollment of the first subject to completion of data collection. Individual participants will complete the protocol within 8-10 weeks from the time of the baseline visit until the end-of-treatment assessment. Study completion is defined as completion of the baseline and end-of-treatment assessments, intervention content, and medication monitoring period.

Sample: 50 older adults with HF, ages 50 and older, who are enrolled in a CR program in Providence, Rhode Island will be recruited. We aim to recruit a sample that is 51% women and 30% individuals who identify as a NIH-defined racial or ethnic minority.

2 PRIMARY OBJECTIVE

The primary objectives of this study are to assess randomized controlled trial feasibility and acceptability through a randomized controlled pilot trial. Primary endpoints are feasibility of study procedures (e.g., monthly recruitment rates, percent of enrolled participants who complete the study), and acceptability (e.g., self-reported patient acceptability questionnaire). We hypothesize that the study and intervention will be 1) feasible, and 2) acceptable.

3 SELECTION AND ENROLLMENT OF PARTICIPANTS

3.1 Inclusion Criteria

Older adults with a diagnosis of HF upon admission and other CR participants with a HF diagnosis regardless of CR referral reason will be eligible for inclusion (e.g., an individual referred for CR following a myocardial infarction who also has a HF diagnosis will be invited to participate).

Additional inclusion criteria will include: (1) adults ≥ the age of 50 at the time of study 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, or

(6) 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 ≥50 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. They will also be asked to complete the Blessed Orientation Memory Concentration test (BOMC) to screen for significant cognitive impairment. Participants who score 10 or greater on the BOMC will not be eligible.

4 ASSESSMENT PROCEDURES

4.1.1 Baseline Assessments (Visit 1)

- Demographics (self-reported) and medical comorbidity (supplemented via medical chart review).
- 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. Participants will be prompted to recall missed or late medications for each day in backwards order during the preceding 7 days.
- Pill Count of 1 medication: We will conduct a pill count of ONE medication per patient using the criteria adopted by Wu et al.
- Medication Adherence Scale.
- LifeWindows Information--Motivation--Behavioral Skills ART Adherence Questionnaire was adapted for use in HF to assess HF medication knowledge, related motivation, and behavioral skills in line with the sIMB-CIM model.
- The Rapid Estimate of Adult Literacy in Medicine—Short Form will assess health literacy.
- Valued Living Questionnaire
- Free, cued, and delayed recall will be measured using the Memory Impairment Screen-Delayed.
- Patient Health Questionnaire 9
- Positive and Negative Affect Scale-Short Form
- Perceived Stress Scale-Short Form
- ENRICHD Social Support questionnaire
- Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy

for Managing Chronic Conditions- Managing Medications and Treatment- Short Form 4a
- the Minnesota Living with Heart Failure Questionnaire (MLHFQ)
- EuroQual-5 Dimension (EQ-5D)

- Monitored Medication Adherence

Participants will also be asked to use a MEMS cap pill bottle to monitor medications for approximately 8 weeks (from the baseline assessment through the end-of-treatment assessment). We will monitor ONE medication per patient using the criteria adopted by Wu et al. Briefly, if the patient takes any HF medication *twice* a day, this medication will be MEMS-monitored. If all HF medications have the same daily prescription schedule, the β-blocker will be monitored. If the patient does not receive a β-blocker, the ACE inhibitor or the angiotensin receptor blocker will be used instead. If none of these drugs is prescribed, the aldosterone antagonist or statin, or digoxin or diuretic will be monitored. Participants will receive a MEMS bottle at the baseline visit and will be instructed to open it only when they actually take their medication; they will also be trained to keep track of unscheduled lid openings (i.e. refills, accidental openings) in a diary; these events will be removed prior to analysis. After the baseline visit, participants will enter a 30-day run-in for the assessment of baseline adherence. Participants will start using the cap on the day following the baseline visit (=time 0), and the intervention will start 30 days later; this 30-day period will be considered our baseline.

MEMs Caps are designed to be easily opened and closed, and to be very similar in design to pill bottles commonly used commercially. Participants will be asked to review their medication regimen with PI/SRA. Participants will be asked to fill the bottle with their prescribed heart medication selected for monitoring Prior to use, a study team member will demonstrate appropriate use of the pill bottle and will invite participates to practice opening and closing the containers.

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. 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.

4.1.2 Intervention Session + Pill Count Check OR Pill Count Check only (Visit 2)

- Following completion of the Baseline monitoring period, study staff will contact the participant and inform the participant of their randomization assignment via telephone, and schedule Visit 2. Visit 2 will be conducted either at the participant's home or the study office, as determined by participant preference. Individuals assigned to the Intervention condition will also complete the intervention at this session (see details in Section 6). For participants in both conditions, we will again conduct a pill count of ONE medication per patient using the criteria adopted by Wu et al. described above.

4.1.3 Final Evaluation (Visit 3)

- 7-day Timeline follow-back procedure to assess self-reported medication adherence.
- Medication Adherence Scale

- Pill Count of 1 medication
- Valued Living Questionnaire
- Patient Health Questionnaire 9
- Positive and Negative Affect Scale- Short Form
- Perceived Stress Scale- Short Form.
- ENRICHD Social Support questionnaire
- Patient-Reported Outcomes Measurement Information System: Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy for Managing Chronic Conditions- Managing Medications and Treatment- Short Form 4a
- Minnesota Living with Heart Failure Questionnaire (MLHFQ)
- EuroQual-5 Dimension (EQ-5D)
- Study and Treatment Acceptability. Participants will complete a self-report measure which gathers feedback about the study.

4.2 Interventions, Administration, and Duration

Following completion of the baseline adherence monitoring period, participants will be randomly assigned to one of two conditions. Participants will be scheduled for Visit 2 at the end of the baseline adherence monitoring period. Participants will be randomized and notified of group assignment upon arrival to Visit 2.

Group A (Usual Care): Participants assigned to Group A will receive the standard care that they would receive as part of cardiac rehabilitation.

Group B (Values affirmation intervention condition): Participants assigned to Group B will receive standard care in addition to the Values affirmation intervention condition. Participants will complete a one intervention session with the study interventionist (about 60 minutes). 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 bottle or display next to the pill bottle). Values labels will be based on images presented on the values card sort cards or personalized pictures taken with a Lifespan-issued tablet and printed on site with a portable photo printer. Once the picture is printed it will be deleted from the tablet.
3. Provision and review of a patient education workbook that recommendations for skills training activities to improve regimen management.

5 COMPENSATION

Participants will be compensated a total of $90 in this research study. Specifically, they will receive $30 in cash following Visit 1 and $60 in cash following Visit 3. Participants who prefer to attend study visits at the Coro Building will also be given a parking voucher.

6 PRIMARY ENDPOINTS

Primary Endpoints:

1) Recruitment feasibility will be determined through examination of the percentage of eligible patients who enroll in the study.
2) Study feasibility will be calculated as the percentage of individuals who were enrolled and completed both the baseline assessment, intervention (when applicable), monitoring period, and end-of-treatment assessment. Feasibility of procedures will be defined as achieving a retention rate of 80%.
3) Patient acceptance of the intervention will be determined by mean satisfaction ratings rated on self-report measures with Likert-type questions and assessed through open-ended responding. Adequate acceptability will be defined as ≥ 80% endorsement of being at least somewhat satisfied with participation.

7 REFERENCES

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