MOTIVATional intErviewing to Improve Self-care in Heart Failure Patients (MOTIVATE-HF): Study Protocol of a Three-arm Multicenter Randomized Controlled Trial

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Scientific background

Self-care has been shown to improve HF patient outcomes (e.g., QOL, hospitalizations).[5] HF self-care was defined as "a naturalistic decision-making process that influences actions that maintain physiologic stability (maintenance), facilitate the perception of symptoms (symptom perception), and direct the management of those symptoms (management)", (p. 1).[6] Self-care maintenance, symptom perception, and self-care management are mastered in sequence and prior works have already shown that self-care maintenance predicts self-care management.[7,8] Self-care maintenance, symptom perception and management are influenced by confidence in the ability to perform self-care or task-specific self-efficacy in the self-care process.[6] Prior work Caregiver contributions to HF self-care have been defined as the "provision of time, effort, and support in behalf of another person who needs to perform HF self-care" (p. 246).[9] Although patient self-care and caregiver contributions to self-care are important to improve patients' HF outcomes, both patients and caregivers struggle and self-care has been shown to be suboptimal.[10,11]

Trials designed to improve HF self-care have shown inconsistent results. Some studies have found that educational interventions improve self-care[12] while others have not.[13] A recent systematic review with meta-analysis[14] that included 20 randomized controlled trials (RCTs) with a total of 5624 HF patients showed that interventions designed to improve self-care were effective in reducing mortality and hospitalization; however, the authors concluded that the mechanisms by which self-care could be improved were unclear.

Motivational interviewing (MI) is a counselling technique defined as a "person-centered method of guiding to elicit and strengthen personal motivation for change"[16] (p. 25) with a collaborative and evocative approach that honors patient autonomy to elicit his/her own motivation to change behaviors in the interest of health.

MI was originally developed in psychology but the technique has been adopted by health-care providers. Several RCTs have been conducted showing that MI improves medication

adherence[17], dietary adherence and weight loss in diabetes patients[18], and smoking cessation, depression, and quality of life in people with cardiovascular diseases.[19]

In HF care, few studies have been conducted using MI.[20 21 22 23] Results of these studies yielded inconsistent results. Therefore, the aims of this RCT are: 1) to evaluate the effect of MI in HF patients and caregivers in improving self-care maintenance in HF patients (primary outcome); 2) to evaluate if MI in caregivers improves patient self-care over and above MI performed solely on patients; 3) to evaluate the effect of MI on the following secondary outcomes: a) in HF patients: self-care management, self-care confidence, HF somatic symptom perception, generic and disease-specific quality of life, anxiety and depression, cognition, sleep quality, mutuality with caregiver, hospitalizations, use of emergency services, and mortality; b) in caregivers: caregiver contribution to self-care, quality of life, anxiety and depression, sleep, mutuality with patient, preparedness, and social support.

Methods

Study design

This is a three-arm randomized controlled trial that complies with the Declaration of Helsinki, has been approved by the Institutional Review Board of the University of Rome "Tor Vergata" and has been registered at ClinicalTrials.gov (Identifier: NCT02894502). In this trial patients will be randomized in three arms: 1) MI intervention to only patients, 2) MI intervention to patients and caregivers, 3) standard of care to patients and caregivers.

Intervention

MI will be delivered by registered nurses who have attended a 40-hour course on MI. This intervention will be performed in Arm 1 to only patients and in Arm 2, to both patients and caregivers. The intervention will include a first session (about 60 minutes) where the interventionist will address one or two aspects of self-care that the participants want to address. After this first

intervention, the same interventionist will contact the participant by telephone to bolster the first intervention and provide further support as needed. These telephone contacts will be done three times at two week intervals following the first intervention (for a total of two months). Patients and caregivers that receive the intervention also will be given informational material on HF management that is consistent with international guidelines.

Treatment fidelity

All interventions will be audio recorded in order to assess the quality of MI for treatment fidelity purposes as described in the Motivational Interviewing Treatment Integrity Coding Manual 4.1.[25]

Control group

Patients and caregivers in the control group (Arm 3) will receive the standard care, which in Italy generally includes oral information on the disease and its treatment given to patients and their family members and a medical check-up every 6-12 months depending on patient condition. The control group also will be given the same informational material given to the intervention groups in arms 1 and 2.

Recruitment and eligibility assessment of study participants

HF patients and caregivers will be recruited in several hospital, outpatient, and community settings across Italy. HF patients and caregivers will be assessed for study eligibility based on the following inclusion and exclusion criteria. The inclusion criteria for patients are: 1) a confirmed diagnosis of HF according to international guidelines;[1]; 2) New York Heart Association (NYHA) functional class II- IV; 3) inadequate self-care assessed with a score of 0, 1 or 2 in at least two items of the self-care maintenance or self-care management scales of the Self-Care Heart Failure Index (SCHFI); 3) willingness to participate in the study and to sign the informed consent form. The exclusion criteria for patients are: 1) severe cognitive impairment evaluated with a score 0 – 4 on

the Six-item screener[26]; 2) acute coronary syndrome event during the last three months; 4) living in a residential settings (e.g., nursing home): 5) caregiver not willing to participate in the study.

Inclusion criteria for caregivers are: 1) designated by the patient as the primary informal caregiver, that is, the person inside or outside the family who takes most of care of the HF patient; 2) Exclusion criteria for caregiver are: 1) patient not willing to participate in the study.

Baseline and follow-up assessment

Patients' and caregivers' sociodemographic characteristics will be assessed at baseline. At baseline patients also will be assessed for their HF clinical characteristics (e.g., NYHA functional class), comorbidity with the Charlson Comorbidity Index,[27] and cognition, with the Montreal Cognitive Assessment.[28] Follow-up assessment will be performed at 3, 6, 9 and 12 months after enrolment, patients and caregivers will be tested with a battery of psychometrically sound tools (Table 1) in order to evaluate the primary and secondary outcomes. Baseline and follow-up assessment will be performed by trained nurse research assistants, who are blinded to group and different than those who perform MI.

Randomization and blinding

After enrolment and baseline data collection, each patient-caregiver dyad will be randomized (1:1:1) to one of the three arms. Randomization will be done at the University of Rome Tor Vergata with the use of an informatics software program that will generate randomization lists.

Outcome measures

<u>Primary outcome</u>

The primary outcome of this RCT will be HF self-care maintenance in patients that will be measured with the Self-Care Maintenance Scale of the Self-Care of HF Index version 6.2 (SCHFI).[29] The SCHFI is an instrument used worldwide to measure the self-care dimensions of

maintenance and management. The Self-Care Maintenance Scale captures HF symptom monitoring (e.g., weighting every day) and treatment adherence (e.g., taking medications as prescribed) and was tested for its validity and reliability[29]. The Self-Care Maintenance Scale yields a score from 0 to 100 with higher scores meaning better self-care maintenance. The primary outcome of self-care maintenance of patients will be evaluated 3-months from the enrolment. Also, we will evaluate HF patient self-care maintenance at 6, 9 and 12 months from the enrolment.

Secondary outcomes

Several secondary outcomes will be evaluated with a battery of tools, all with established validity and reliability (Table 1). Specifically, in patients we will use: the Self-Care Management and Self-Care Confidence scales of the SCHFI[29] to measure the responses to symptoms and signs of HF exacerbation and the confidence in managing all self-care processes, respectively; the HF somatic perception scale[30] to measure the burden of symptoms; the SF-12,[31] to measure generic physical and mental QOL; the Kansas City Cardiomyopathy Questionnaire[32] to measures HF specific QOL; the Hospital Anxiety and Depression Scale[33] to measure anxiety and depression; the Montreal Cognitive Assessment[28] to measure cognition; the Pittsburg Sleep Quality Index[34] to measure sleep quality; the Mutuality scale-patient version [35] to evaluate the relationship between the patient and caregiver. In caregivers we will use: the Caregiver Contribution to Self-Care of HF Index (CC-SCHFI)[9], that investigates the extent to which caregivers recommend to patients to perform self-care or perform self-care on behalf of the patients if they are unable to do so; the SF-12; the Hospital Anxiety and Depression Scale;[33] the Pittsburgh Sleep Quality Index;[34] the Mutuality scale-caregiver version to evaluate the relationship with the patient;[36] the Caregiver Preparedness Scale,[37] which measures caregiver preparedness to meet the patient's physical and psychological needs; the Multidimensional Scale of Perceived Social support. [38] At each follow-up, caregivers will be asked about patient hospitalization, use of emergency services and death. All

secondary outcomes will be evaluated baseline and 3, 6, 9 and 12 months after the enrollment (Table 1).

Statistical analysis

Sample size: A total sample of 240 subjects (80 per each group) achieves 90% power to detect a 8% difference in self-care maintenance[39] obtained by patients at 3 months with MI intervention (arms 1 and 2, with a mean self-care maintenance of 63) versus patients in standard care (arm 3 with a mean self-care maintenance of 55) using an F test with a 0.05 significance level (one-way ANOVA). The common standard deviation within a group is assumed to be 18.[20] The sample of 240 subjects will also provide 83% power to detect a 8% difference in patient self-care management and self-care confidence at 3 months in arm 1 and 2 versus 3, assuming a standard deviation of 20.[39] Based on the available literature and in order to account for an estimated 50% attrition rate[20], 480 participants (240 patients and 240 caregivers) will be recruited. As far as the evaluation of MI in caregivers (aim 2), group sample sizes of 80 achieve 80% power to detect a difference of 8 points of caregiver self-care maintenance and with estimated group standard deviations of 18 and with a significance level of 0.05 using a two-sided two-sample t-test. As for patient self-care management and self-care confidence, with an expected group standard deviations of 20, the power for aim 2 is 71%.

Planned statistical analysis: Measures of central tendency and of variability will be used to describe HF patient and caregiver characteristics as well as the outcome measure scores. For the primary end-point a one-way ANOVA will be used comparing arm 1 and 2 with arm 3. A two-sample t-test will be used to compare self-care of participants in arm 1 and 2 to evaluate MI in caregivers. The percentage of patients with a SCHFI score over 70[39] will be compared with the Chi-square test. A longitudinal linear regression model will be used to evaluate the trend of Self-Care in the three arms. Secondary outcomes will be evaluated with ANOVA.

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