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Study Protocol Title: Coaching end-of-life palliative care for advanced heart failure patients and their family caregivers in rural Appalachia: a randomized controlled trial

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Principal Investigator: Ubolrat Piamjariyakul, Associate Dean for Research and Scholarship, West Virginia University School of Nursing

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Introduction

Background and Rationale

Heart failure (HF) affects more than 8 million Americans and is increasing at a rate of 46%, with an increase in costs of up to $70 billion annually [1]. Severe symptoms of HF persist despite medical, surgical, or HF device therapy [2]. HF is a debilitating and life-limiting disease that requires extensive home family caregiving assistance and difficult decisions regarding treatment options for patients who are experiencing progressive decline [3, 4]. Studies verify family caregivers contributions to HF home care. Worsening HF has numerous negative impacts on family caregiver health outcomes, resulting in caregiving burden [3, 5]. In turn, the caregiving burden can have a negative impact on caregiver's physical and mental health status [5]. Family caregivers managing patient HF reported unmet needs, [6] lack of communication with health care professionals, [7] and little if any preparedness for home end-of-life and palliative care (EOLPC) [8].

Patients and their families are unprepared for the challenges of this deteriorating condition and for home caregiving burdens. Most have fears of suffering a painful death [9, 10]. Our nurse-led family home EOLPC intervention (FamPALcare) addresses these challenges [11]. Palliative care includes supportive and comfort care to relieve patient suffering and pain/discomfort [12]. HF palliative care also includes treatments specific for the distressing, commonly repeating physical and psychological symptoms of HF (e.g., breathlessness, fatigue, edema, and depression/anxiety). HF palliative care includes discussions for determining the HF care options according to the families' end-of-life (EOL) care preferences [13].

Further, patients with HF who live in rural areas have higher mortality rates than those who live in urban areas [14]. Specifically, in West Virginia (WV), where HF death rates are the highest in the country, residents have limited access to healthcare and experience social service inequities [15, 16]. The rural mountainous terrain and distance from HF specialists and local healthcare services increase the family caregivers' need for more useful home care information [17]. Home palliative care interventions can assist families in managing advancing HF symptoms and end-of-life (EOL) care needs at home [18].

Considering the burden of families managing HF, the increasing prevalence of palliative care needs [19], and the lack of palliative care providers [20], home HF palliative care is understudied with little guidance or information to support caregivers [21, 22]. Thus, family caregivers need preparation for complex home care and palliative care specific to HF with considerations for families in rural settings with limited services [23]. Effective palliative care should incorporate patient cultural values and preferences about their disease state and medical treatment [24]. Preparing caregivers for providing HF home care can reduce patient and caregiver anxiety and help them discuss their end-of-life preferences [25].

Purposes

The purpose of this study is to test whether a home palliative care intervention (FamPALcare) would improve family caregiver and patient HF-related health status and their depression/anxiety scores at 3- and 6-month endpoints. Another purpose is to verify the feasibility, fidelity, helpfulness and costs of FamPALcare remote telephone intervention delivery.

Objectives

The following specific aims, directional hypotheses, and research questions are:

Primary Aim: To test whether the FamPALcare nursing care intervention could reduce the burden of family caregivers by preventing caregiver depression/anxiety and improve patient HF-related health status and depression/anxiety. The hypotheses and research questions are as follows:

Aim 1.1 Compared to those in the control group at 3 and 6 months, the caregivers who receive FamPALcare will have significant improvements in home caregiving burden and depression/anxiety scores.

Aim 1.2 Compared to those in the control group at 3 and 6 months, patients in the FamPALcare group will experience greater improvement in HF-related health and depression/anxiety scores.

Secondary Aim: To assess the feasibility and fidelity of the FamPALcare intervention.

Aim 2.1. What are the participant recruitment, enrollment, and retention outcomes?

Aim 2.2. How helpful the FamPALcare as rated by participants on the anonymous 11-item Helpfulness Questionnaire?

Aim 2.3. What is the FamPALcare implementation cost using traditional tabulated cost-minimization analysis?

Study Design

Overall Design

This study uses a randomized controlled trial (RCT) design to test the FamPALcare intervention. The RCT design is consistent with the National Template for Intervention Description and Replication (TIDieR) checklist and guide [30].

Study Population

Adult (≥18 years) end-stage HF patients (NYHA III and IV and Stages C and D) and their family caregivers who are involved in daily home care will be recruited.

Inclusion and Exclusion Criteria

Inclusion criteria are dyads of family caregivers and patients with advanced systolic and diastolic HF [2, 10]. The cardiology consultants specify inclusion of patients with both systolic and diastolic dysfunction as both require similar HF home care management regimens and have similar advanced EOL symptoms, which FamPALcare can address. All participants must be alert and oriented, provide written consent, and be able to read and write in English. Family caregivers are those designated by the HF patient as non-paid primary persons who assist with HF home care, thus not requiring the dyad to be spouses. Exclusion criteria are patients who have received or are on a waiting list for a heart transplant and those with a terminal illness or dementia, such as Alzheimer's disease. Also excluded are caregivers with a disability that precludes their use of FamPALcare intervention materials such as those suffering with dementia or Alzheimer's disease.

Randomization and Blinding

This RCT uses random assignment to group with stratification of the patient sex (male vs female) to equalize distribution. SPSS version 29 is used to generate random numbers within each group. Each family dyad is randomly assigned to either the control or intervention group in a 1:1 fashion [11]. The researchers are blinded to the group assignments until informed consent is obtained. The Institutional Review Board of the University Health Sciences Center (WVU IRB 1709754988) approved the study protocol.

Study Procedure

Both patients and caregivers will provide consent and will be randomly assigned to a study group as a dyad. Permission to review patients' hospitalization medical records will be obtained per IRB, as in the previous studies. Recruitment is from sites affiliated with WVU Hospital (WVUH) including local health centers or clinics, churches, physician offices, and community centers throughout Appalachia. Personnel

who already have clinic responsibilities and access to patient records, consistent with HIPAA requirements, will perform subject eligibility screening and the initial recruitment contact.

Study Intervention

Standard care group

In this study, all patients and their family caregivers continue the standard health care prescribed by their healthcare providers. Patient standard HF care includes routine educational materials given to them at the outpatient clinics or upon hospital discharge planning.

Family home palliative care (FamPALcare) intervention group

Participants in the intervention group receive standard care and the FamPALcare intervention. FamPALcare aims to provide family caregivers with practical skills for managing patient symptoms and deterioration of their HF status, addressing palliative care needs and home caregiving burden. The FamPALcare clinician nurse will coach patients and their family caregivers on HF palliative symptom management and guide advanced directives discussions.

Intervention participants (Group 1) will receive five coaching sessions with telephone follow-up to reinforce intervention home care. The nurse interventionists will engage each FamPALcare dyad in weekly FamPALcare coaching sessions scheduled at times and locations (home, church, or private room in outpatient clinic) convenient to the patient/family. Each coaching session lasts about 60-120 minutes. **Sessions include: Week 1:** developing rapport, identifying HF home care needs, assessing caregiver involvement in home care, and motivating multiple family caregivers to coordinate home care and be involved in their home HF EOLPC plan. **Week 2:** supporting home care skills to manage advanced HF and worsening HF symptoms and discussing the families' EOL beliefs. **Week 3:** discussing sensitive HF EOLPC options and preparing advance directives. **Week 4:** coaching on managing caregiver burden and seeking professional help/community support. **Week 5:** reinforcing skills specific to advanced HF home care and practicing early symptom reporting to clinicians. The nurse will coach the patient and family in making decisions about EOLPC options based on their preferences and on having the advance directives forms signed and taken to their next doctor appointment. Telephone contact will be conducted at 1-month post-intervention to allow sufficient time for family members to discuss their EOLPC decisions and generate questions.

The FamPALcare intervention manual includes pictures of an advanced scientific-based HF disease progression trajectory graph. The graph is used to explain the typical expected HF decline and how to handle common bothersome HF symptoms (e.g., breathlessness, anxiety/depression, edema, fatigue). In addition, examples of advanced directives forms, Physician Orders for Scope of Treatment (POST) (e.g., do not resuscitate) forms, and local emergency contacts are provided [36]. The FamPALcare clinician will recommend that forms be taken to the patient's next healthcare provider's appointment to sign and document in their medical records. Participants keep the FamPALcare manual with these informative and illustrated guidelines as well as contact lists for any available resources. The FamPALcare clinician follows the HF educational manual, which includes coaching strategies for discussing the sensitive topic of end-of-life care [37] and includes specific information regarding standard palliative and end-of-life care options. The FamPALcare clinician uses an open-ended coaching conversation approach to facilitate patient wishes and preferences regarding end-of-life care.

Compliance Monitoring

The FamPALcare manual provides families with step-by-step guides and visual illustrations for managing HF declines. These FamPALcare materials are designed to support home caregivers and patients with low literacy levels and to overcome barriers to providing adequate HF home care [19]. To ensure that participants fully comprehend the information discussed during each FamPALcare session, the clinician will utilize the effective "teach-back" technique [27]. By asking participants to describe what they had been taught, the nurse ensures that the information has been conveyed accurately and understood completely.

The nurse also identifies any topics that require further reinforcement for future retraining in the follow-

up telephone calls. Furthermore, after three months, a follow-up phone call is made to provide additional support and encourage the continued practice of FamPALcare. A second trained clinician who observes the FamPALcare clinician at randomly selected FamPALcare sessions will confirm the fidelity of the intervention. This clinician documents the accuracy and consistency of the FamPALcare intervention implementation according to the manual [38]. Our research quality assurance measures include quarterly communication and intervention retraining and protocols for data collection monitoring [29].

Safety and Adverse Events

Safety Assessments

Adverse event is any unfavorable and unintended sign, symptom or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure. The Safety Monitoring Committee (SMC) will include two experts who are independent of the study protocol. The SMC members are (1) a palliative care nurse and (2) a Biostatistician who has extensive experience in randomized clinical trial (RCT) studies. The SMC will review each potential adverse event (AE) upon its occurrence (real-time) and bi-annually thereafter. The PI and Co-I will conduct bi-annual meetings with SMC to review the AEs tabulation of all AEs accumulating across the study to identify any possible repeating patterns. Also, the SMC members review any records of adverse events (AEs) and anecdotal notes related to our IRB approved procedures for Depression Prevention and Referrals on a monthly basis. The SMC will provide direction to address any ethical issues that may arise related to palliative care or end-of-life discussions, study safety, and research risks.

Adverse Event Reporting

The SMC will ensure that the PI provides timely reports to IRB and NINR if unanticipated problems or unexpected serious AEs related to the study protocol arise. The interim data analysis will be reported to SMC at the bi-annual meetings. If warranted, the SMC may provide advice and feedback on data analysis to the study statistician. The SMC will make recommendations as appropriate as to whether the trial should continue as originally designed, be changed, suspended or terminated, based on the observed beneficial or adverse effects of any of the treatments under study. These recommendations and actions taken will be reported to the IRB and NINR.

All research staff will notify the PI within 24 hours if any potential study safety risks arise. The PI notifies the IRB within 24 hours and notifies NINR within 7 days of the investigator becoming aware of the event. The biostatistician reviews data quality management procedures and all statistical analyses. The Co-I and team members work with the PI to carefully interpret and disseminate the study results.

Statistical Considerations

Sample Size Calculation

In this R15, sample size is based on reductions in breathlessness; a significant reduction of 1 SD, was found in the PI's previous interventions on end-stage HF breathlessness. A sample size of 30 (15 per group) is able to detect a reduction of 1.3 SDs with a Type 1 error rate of 0.05 and a power of 0.80 [31-33] To account for an expected 20% attrition (due to HF deaths), three additional families will be recruited to each group. Thus, there will be 18 patient-caregiver dyads per each group (total N=72; 36 patients and 36 caregivers).

Statistical Analysis Plan

Descriptive statistics (frequencies, means, standard deviations) will summarize the caregiver and patient characteristics and program implementation costs. A generalized linear model (GLM) will test for significant differences between the control and intervention groups in terms of health outcome scores measured at baseline and at 3 and 6 months, controlling for covariate effects. The GLM is the extended version of the general linear model applicable to variables that are not normally distributed and is commonly used in small sample studies [39]. The GLM also provides a post hoc analysis that yields results similar to those of t tests. A strength of GLM is that it also provides repeated data collection time factors in post hoc analyses. A one-tailed group comparisons will be used to test our *a priori* directional hypotheses using the

Bonferroni adjustment. [40]. Thus, this post hoc paired comparison between groups can reveal significant differences between outcomes at baseline vs. 3 months and at baseline vs. 6 months. The intent-to-treat statistical approach will be used, as all patients are included in the analysis with imputation means replacement [41]. Data analyses will be conducted using SPSS (version 29).

This study will use a traditional cost accounting method to calculate the cost of implementing FamPALcare. All expenses related to delivering the program will be tabulated. The cost of the clinician delivering the intervention will be calculated from an average of a nurse's hourly salary. The costs of educational materials given to participants in the manual will be tallied and summarized.

Data Management

Data Collection Methods

Data will be collected from all patients and caregivers at baseline, 3 months, and 6 months. The analyses file of this project will include repeated questionnaire variables across 3 time points, including caregiver and patients' sociodemographic health data.

To preclude diffusion of treatment across groups, the research nurses working with the intervention group will be different from nurses with the control group. Data collectors are blinded to group. Secure data collection and storage is maintained. A home HF EOLPC checklist is used to assess at 3, 6, and 12 months the home care skills learned by the caregiver and to identify areas that may need reinforcement.

Data Handling and Record Keeping

Data will be stored separately in a locked file at the WVUSON research office. Only selected research staff will have access to the subjects' PHI. Information protection procedures specific to data management and communications are also in place. All subjects and staff are informed that subjects' PHI will not be discussed or placed on the Internet so that incidental disclosure does not occur. Electronic data will be kept in the firewall, password-protected server at the Health Science Center with daily backup. Any staff member who may leave during the project period will have all data access terminated immediately.

Ethical Considerations

Informed Consent Process

The PI and Co-I will train our recruiters per enrollment and recruitment protocols. Recruitment forms with enrollment scripts and consent forms have been successfully used with HF families in the previous studies. Our research team will review all recruitment, consent, and data forms for the study proposal and submit to the IRB prior to any enrollment. Trained research team members who have completed the NIH-approved Human Subjects Protection certification (CITI) will obtain informed consents. Upon screening for eligibility criteria, with the potential participants' permission, a research nurse will contact the individual and use a script to discuss consent for the study. If the individuals agree to participate in the study, they must verbally indicate that they understand the purpose of the study and their rights as participants. Consent will be documented as a signed form, will be kept in a locked file at the study office, and a copy provided to all participants. All subjects will be encouraged to contact the Human Subjects Committee with any concerns about the informed consent document.

Confidentiality

Several procedures are established for protecting against the risk of breaking confidentiality. First is the decoupling of all subjects' Protected Health Information (PHI) from all study materials. Data will be de-identified and subjects will be assigned a unique, unidentifiable code number. A list that links the assigned code number to the subjects' PHI, as well as the informed consents, will be stored separately in a locked file at WVUSON research office. Only selected research staff will have access to the subjects' PHI. Information-protection procedures specific to data management, communications, and the electronic environment are also in place. All subjects and staff are informed that subjects' PHI are not to be discussed or placed on the internet so that incidental disclosure does not occur.

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