Does a Pre-transplant Health Coaching Intervention for Informal Caregivers of Adult Heart or Lung Transplant Candidates Improve Caregiver-Reported Outcomes?

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IRB Minimal Risk Protocol Template

Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at http://intranet.mayo.edu/charlie/irb/

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points , save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Cassie Kennedy, MD

Study Title: Wellness Coaching for Caregivers of Thoracic Transplant Candidates

Protocol version number and date: Version 2 – February 20, 2020

Research Question and Aims

Hypotheses: Caregivers will have traits and behaviors pre-transplant that will predict caregiver readiness, quality of life, and transplant recipient outcomes. Specifically, thoracic pre-transplant caregivers report stress, symptoms of anxiety or depression, and perceive high caregiver burden. These factors may be amenable to pre-transplant intervention to improve overall patient and caregiver outcomes.

Aims, purpose, or objectives: We will conduct a pilot trial to test whether caregivers of heart and lung transplant candidates who receive wellness coaching will experience improvement in caregiver-related distress. We will also explore the relationship between caregiving and factors such as uncertainty, resilience, stress level, and affect.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc.*): Heart and lung transplant recipients experience a range of psychosocial and medical issues for the duration of the transplant experience, including the initiation of the transplant evaluation, pre-transplant waiting period, perioperative recovery, and long-term adjustment post-transplant. Throughout the process, family caregivers play a major role in maintaining their loved ones' physical and mental health but also undergo exposure to the stressors of

transplantation. Current evidence describes high stress, caregiver burden, and increased mood disorders in the pre-transplant caregiver journey. Currently, limited resources and interventions have been trialed in thoracic transplant caregivers to improve this distress.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol*.

This is a pilot study examining the effects of a health coaching intervention on the stress and burden of caregivers of patients awaiting heart or lung transplant.

Identifying Caregivers for Participation

Potentially eligible caregivers for Mayo Clinic waitlisted adult heart, heart-lung, or lung transplant candidates (including names, address, and phone numbers of caregivers) will be acquired through the electronic medical record of the Mayo Clinic adult heart and lung transplant waitlisted patients. For waitlisted heart and lung transplant candidates without a caregiver specified in the medical record (including patients deferred, active, or with a waiting list status of "temporarily inactive"), they will be sent via mail, PTRAX or Redcap an IRB-approved contact letter including information about this study as well as a caregiver nomination form and a HIPAA form. Patients will have the opportunity to nominate up to 3 caregivers for participation in this study, or they may decline to nominate any caregivers. Non-responders will be contacted by phone to ask for caregiver nominations.

In addition, self-referral or word-of-mouth caregiver referrals would be considered if they otherwise met eligibility criteria. Due to current practices of multi-site listing in the Mayo Clinic Transplant Enterprise, caregivers for patients on the heart and lung transplant lists at Mayo Florida or Mayo Arizona may also be considered for inclusion. Additionally, caregivers for heart or lung transplant patients at the Mayo Clinic who subsequently transfer their listing to a different (non-Mayo) transplant center would continue to be eligible for the study unless they withdrew consent. Likewise, caregivers for heart or lung transplant candidates who receive their organ transplant during the course of the health coaching intervention would remain eligible to complete the study unless they withdrew consent.

Approaching Caregivers for Participation

Nominated caregivers or caregivers identified through the electronic medical record may be contacted by phone, mail, or in person to determine interest in this study. Caregivers not interested will have a mechanism to send a refusal. Non-responders will be sent a second interest letter. If the study team does not receive any correspondence from the caregiver, recruitment calls will be attempted 3 times. If the study team is unable to reach the caregiver for a call after 3 attempts, the participant will be declared a non-responder. Caregivers may be contacted while the patient is deferred or active on the transplant waitlist. If a waitlisted patient is transplanted, then the caregiver's eligibility for recruitment will end once the transplanted patient is discharged

from the hospital. In such cases, a caregiver's enrollment, baseline questionnaires, and randomization need to be complete prior to a patient's post-transplant discharge in order for the caregiver to proceed with the study.

Caregivers who agree to participate in this study will be randomized to either receive a wellness coaching intervention in which they will be assigned a wellness coach trained in motivational interviewing who will call the patient weekly for 12 sessions for an approximately 30-minute intervention or usual care (routine caregiver transplant education). Randomization will be stratified to type of transplant the patient they are caring for is waiting to receive (e.g. heart or lung). Participants who miss a call will be allowed a make-up call with the goal of finishing 12 calls over a 16-week period. The wellness coaching calls will be recorded and externally monitored by an independent expert to assure treatment fidelity, and all recordings will remain private. After completion of the intervention, all participants will be asked to complete the questionnaires a second time in addition to a qualitative/satisfaction survey by phone mail or by Redcap. Demographic data will be collected at the time of the initial questionnaires and verified with the follow-up questionnaires. If a participant leaves large sections or multiple pages of the questionnaires unanswered, they will be sent an IRB-approved letter asking that they complete the unanswered questions or indicate that the questions were purposely left unanswered. Psychometric surveys will be stored in a locked cabinet. Data will be entered into a secure password-protected REDCap database. Questionnaire and qualitative data will be kept in a password-protected REDCap database on our secure network. Audio files from health coaching sessions will also be stored in a password-protected folder on our secure network.

Study Measures:

1. Demographic information: Participations will be asked to self-report their sex, race, ethnicity, marital status, education level, type of transplant the patient they are caring for is waiting to receive, waiting time duration, and the relationship to transplant recipient to whom they are a caregiver.
2. Questionnaires:
   PROMIS Global Health – Mental 2a
   PROMIS Global Health – Physical 2a
   PROMIS Satisfaction with Social Roles and Activities – Short Form 4a
   PROMIS Social Isolation – Short Form 4a
   Chew (2004) Health Literacy Screening Questions
   RISC – 10
   PANAS
   Zarit Burden Interview
   Perceived Stress Scale
   Patient Health Questionnaire-2 (PHQ-2)
   Generalized Anxiety Disorder -2 (GAD-2)

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 60 patients and 60 caregivers

Subject population (children, adults, groups): Caregivers of adult patients on the heart and lung transplant waiting lists

Inclusion Criteria: Aged 18 or older who are the primary caregivers of patients listed (active, deferred, or temporarily inactive) for lung, heart/lung, or heart transplantation at Mayo Clinic in Rochester and Jacksonville, FL

Exclusion Criteria: Individuals younger than 18 will be excluded. Those who are non-English speaking, non-verbal, or extremely hard of hearing will also be excluded.

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☐X The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to ask subjects to complete a questionnaire.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement: Not required for a pilot study.

Data Analysis Plan: Descriptive statistics and change in secondary endpoints.

Endpoints
Primary: Acceptability and feasibility of wellness coaching for caregivers of thoracic transplant candidates. This will be obtained by looking at completion rate of intervention and qualitative surveys after the intervention is completed.
Secondary: Preliminary efficacy data for power calculation for larger R01 application and multisite study. We will look at change in reported outcomes of stress, caregiver burden, resilience, quality of life, affect, and mastery.