Health Coaching to Improve Self-Management in Thoracic Transplant Candidates
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Hypothesis: Individualized health coaching including strategies to address poor resilience, coping with uncertainty, frailty, and/or negative affect will be an effective therapeutic strategy at improving self-management while in the pre-transplant state.

Aims, purpose, or objectives: We will conduct a randomized, controlled pilot trial to test whether heart and lung transplant candidates who receive health coaching will experience improvement in self-management abilities compared to transplant candidates who receive standard pre-transplant care. We will also explore the relationship between self-management and pre-transplant risk factors such as uncertainty, resilience, frailty, and affect.

Background: The ability to adhere to complex medical regimens is critical to achieving successful transplant outcomes, as non-adherent patients may experience graft failure or death following transplantation. Since potential recipients exceed organ availability, identification of candidates who will adhere to complex post-transplant regimens is critically important and emphasized by practice guidelines. When selecting candidates for transplant, physicians attempt to subjectively predict post-transplant adherence because tools that reliably predict future adherence are lacking. Despite rigorous screening procedures pre-transplant, non-adherence is common following transplant. As a result, new strategies for predicting future non-adherence are necessary. Self-management ability, defined as "taking responsibility for one's own behavior and well-being" involves the patient's ability to manage their medical condition, their emotions, and their social roles. Self-management ability can be measured objectively, and it may be improved through interventions such as health coaching. Understanding self-management and related factors such as uncertainty, resilience, frailty, and affect may lead to an intervention for optimizing pre-transplant risk factors and adherence post-transplant.

Study Design and Methods

This is a randomized, controlled pilot study to be conducted at Mayo Clinic in Rochester, MN examining the effects of a health coaching intervention on the self-management ability of patients awaiting heart or lung transplant. The relationship between self-management and pre-transplant risk factors such as uncertainty, resilience, frailty, and affect will also be explored. Patients on the active or deferred waiting lists or with a waiting list status of "temporarily inactive" will be approached for recruitment in the Transplant Clinic at a routine clinical follow-up appointment (occurring every 1 to 3 months) or by phone or mail. All participants will complete a written consent form in person via email-PTRAX, phone or by mail. After consenting, patients will schedule a research visit to complete baseline measures including questionnaires, a hand grip strength test, a timed gait speed test over a distance of 15 feet, Short Physical Performance Battery (SPPB) and a 60-second body composition scan. A body composition analyzer (InBody 770) will be used to determine body composition (body mass, fat mass, and fat-free mass) via electrical impedance. Participants will also receive an activity monitor at their baseline visit to be worn for 5-7 days. In addition; participants will be given a pedometer to track their steps throughout the study. If participants are unable to schedule a research visit, they may be mailed the questionnaires or sent via Redcap (electronically) and activity monitor will be sent via the mail, which will be returned in postage-paid envelopes. Participants will be randomized to one of two groups while completing their baseline measures. Participants in one group will continue to receive the standard pre-transplant care for 12 weeks. Participants in the intervention group will receive a health coaching intervention in which they will be assigned a health coach trained in motivational interviewing who will call the patient weekly for 12 sessions for an approximately 30 minute intervention. 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 health coaching calls will be recorded and externally monitored by an independent expert to assure treatment fidelity, and all recordings will remain private. In

addition to the health coaching intervention, participants in the intervention group will also continue to receive standard pre-transplant care. After completion of the intervention, all participants will be asked to complete a follow-up research visit in which they will complete the questionnaires, hand grip strength test, timed gait speed test, SPPB, and bioelectrical impedance test a second time. All participants will also be asked to wear an activity monitor again for 5-7 days. At the end of the intervention, participants will be asked to complete a qualitative/satisfaction survey by phone or by mail. Follow-up testing will be completed within 90 days of completing the study. 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 data, measurements, and abstracted data (age, type of transplant, 6 minute walking distance, race, ethnicity, psychological assessment information, marital status, height, weight, date of listing, primary diagnosis, etc.) 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:
Participants will complete the following testing, SPPB measures, and wear an Actigraph at baseline and after completing the intervention (or in an equivalent time-frame if a control patient).

1. Hand grip strength test: Hand grip strength will be measured using a Jamar Digital Hand Held Dynamometer. Participants will complete the grip strength test 3 times with their dominant hand. The 3 trials will be averaged and adjusted by sex and BMI using a normative table.
2. Gait speed test: The participant's gait speed will be measured using a stopwatch as the participant walks a distance of 15 feet at a self-selected walking speed. The average of 3 trials will be calculated and adjusted for sex and height. To determine the participant's SPPB score, the results of the gait speed test will be prorated for 4 meters (13.1 feet). The best of 3 trials will be used to calculate the participant's SPPB score.
3. Short physical performance battery (SPPB): The SPPB consists of a gait speed test over 4 meters (13.1 feet), timed repeated chair stands, and 3 balance tests.

a. Gait speed test: See #2.
b. Timed repeated chair stands: Participants will be asked if they feel safe to stand from a chair without the use of their arms and without assistance. If the participant feels safe to stand from a chair without the use of their arms and without assistance, they will be asked to complete 5 repeated chair stands. The participant's SPPB score will be determined by the time required to complete 5 repeated chair stands.
c. Balance testing: The participant's balance will be tested in side-by-side, semi-tandem, and tandem stands. In the side-by-side stand, participants will stand with their feet as close together as possible. In the semi-tandem stands, participants will stand with one heel touching the big toe of the opposite foot. In the tandem stands, participants will stand with the heel of one foot in front of the toes of the other foot (as if on a balance beam). Participants will be asked to hold each position for up to 10 seconds.

4. Body composition scan: Participants will stand on the InBody 770 body composition analyzer, which determines body composition by electrical impedance (i.e., sending an electrical signal through the body). Height, weight, BMI, skeletal muscle mass, percent body fat, and segmental lean mass will be recorded. Participants with a pacemaker, an implantable cardioverter-defibrillator (ICD), or an automated ICD (AICD) will not be able to complete this body composition scan. Those patients will have their height and weight collected. BMI will be calculated.
5. Activity monitoring: Participants will receive an Actigraph activity monitor to be worn on the wrist for 5-7 days. The activity monitors are capable of measuring the number of steps taken, the number of calories

burned, the intensity of physical activity, the amount of sedentary time, and other variables. Participants will receive a prepaid addressed envelope to return the activity monitor.
6. Center for Epidemiologic Studies Depression Scale (CES-D): Participants will answer 2 questions from the CES-D about their level of exhaustion.
7. Self-reported weight loss: Patients will be asked whether they intentionally lost 10 or more pounds within the last year. As available, weight changes in kg will also be abstracted from the medical record to trend the weight over the prior year's time.
8. Demographic information: Patients will be asked to self-report their sex, race, ethnicity, marital status, education level, and the relationship of their primary caregiver post-transplant.
9. Questionnaires:
Chronic Respiratory Questionnaire (lung disease only)
Kansas City Cardiomyopathy Questionnaire (heart disease only)
Mishel Uncertainty of Illness Questionnaire
Positive Affect Negative Affect Questionnaire (affect)
Perceived Stress Scale (stress)
PHQ 2 and GAD 2 (mood/affect)
RISC-10 (resilience)
Frailty Deficit Index (frailty)
SMAQ (adherence)
SMAS-30 (self-management)

Resources:
The PI will oversee the study through weekly meetings to ensure proper study protocol adherence and recruitment and data progress. A study coordinator in the Pulmonary Division will conduct day to day activities of the study such as mailing of participant documents, data collection and input, and time points to send out materials. All mailing and data input will occur on Gonda 18 in the research laboratory.

Subject Information

Target accrual: 60 patients
Subject population: Patients on the heart and lung transplant waiting lists
Inclusion Criteria: Aged 18 or older, consenting to research, and listed (active and temporarily inactive) or deferred for lung or heart transplantation at Mayo Clinic in Rochester, MN
Exclusion Criteria: Patients will be excluded if ineligible for transplant, non-English speaking, non-verbal or extremely hard of hearing.

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☐ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☐ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☒ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☒ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☒ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

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

☐ (5a) Only data that exists before the IRB submission date will be collected.

☒ (5b) 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 conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) 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 _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☒ (6) Video audio recording: All health coaching intervention sessions will be audio recorded. All recordings will be kept private, and all recordings will be destroyed at the end of the study.

HIPAA Identifiers and Protected Health Information (PHI)

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name	X	
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	X	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	X	
Social Security number	X	
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images	X	
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes	X	
Phone or fax numbers	X	
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☒ None

Data Analysis

Power analyses and study endpoints are not required for minimal risk research, pilot or feasibility studies.

☒ No statistical information. *If checked, please explain*: This is a pilot study to obtain preliminary data for future NIH grant application.

Power Statement: Not required for a pilot study.

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

Endpoints
Primary: Acceptability and feasibility of health coaching by 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 patient reported outcomes of resilience, quality of life, affect, and self-management ability. We will also look at change in frailty parameters.