**Health Coaching to Improve Self-Management in Thoracic Transplant Candidates**
**NCT03150095**
**May 25, 2021**

**PI: Cassie C. Kennedy MD, Mayo Clinic Rochester, MN**

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **May 25, 2021**
**Not to be used after:** **May 24, 2022**

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Health Coaching to Improve Self-Management in Thoracic Transplant Candidates

**IRB#:** 17-003921

**Principal Investigator:** Dr. Cassie Kennedy and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep.

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## CONTACT INFORMATION

| You can contact … | At … | If you have questions about … |
|---|---|---|
| **Principal Investigator:**<br>Dr. Cassie Kennedy<br><br>**Study Team Contact:**<br>Study Coordinator | **Phone:**<br>(507) 266-3958<br><br>**Phone:**<br>(800) 753-1606<br><br>**Institution Name and Address:**<br>200 First Street SW<br>Rochester, MN 55905 | ▪ Study tests and procedures<br>▪ Research-related injuries or emergencies<br>▪ Any research-related concerns or complaints<br>▪ Withdrawing from the research study<br>▪ Materials you receive<br>▪ Research-related appointments |
| **Mayo Clinic Institutional Review Board (IRB)** | **Phone:**<br>(507) 266-4000<br><br>**Toll-Free:**<br>(866) 273-4681 | ▪ Rights of a research participant |
| **Research Subject Advocate**<br>**(The RSA is independent of the Study Team)** | **Phone:**<br>(507) 266-9372<br><br>**Toll-Free:**<br>(866) 273-4681<br><br>**E-mail:**<br>researchsubjectadvocate@mayo.edu | ▪ Rights of a research participant<br>▪ Any research-related concerns or complaints<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information |
| **Patient Account Services** | **Toll-Free:**<br>(844) 217-9591 | ▪ Billing or insurance related to this research study |

**Other Information:**
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

## 1. Why are you being asked to take part in this research study?

You are being asked to participate in this study because you are on the heart or lung transplant waiting list at Mayo Clinic in Rochester, MN.

The plan is to have about 60 people take part in this study at Mayo Clinic.

## 2. Why is this research study being done?

The purpose of this study is to determine if pre-transplant health coaching is an effective method of improving self-management ability among patients on the heart and lung transplant waiting lists. Self-management ability is associated with resilience, coping skills, and mood, among other factors.

## 3. Information you should know

**Who is Funding the Study?**

The National Institutes of Health (NIH) is funding this study through a grant awarded to the Principal Investigator.

**Information Regarding Conflict of Interest:**

No study team member has a conflict of interest in this study.

## 4. How long will you be in this research study?

You will be in this study for approximately 4 months.

## 5. What will happen to you while you are in this research study?

If you agree to participate in this study, you will complete questionnaires and a set of physiologic measures both at baseline and 12-16 weeks after enrollment. The measures are described below. When the baseline measures are completed, you will be randomly assigned to one of two groups. You will have an equal chance of being assigned to either group.

**Group A** will receive the usual pre-transplant care, and you will complete 12 health coaching calls over a period of 12 weeks with a coach trained in motivational interviewing. These calls should last approximately 15-30 minutes per week. All calls will be audio recorded to accurately capture statements and to allow for review of the health coaching program.

**Group B** will continue the usual pre-transplant care program, which will include regular appointments with nurses, dietitians, pharmacists, and others who provide care to patients before transplant.

All study participants will complete the following measures both at baseline and 12-24 weeks after enrollment.

**Questionnaires**: You will be asked to complete several questionnaires, which should take about 30 minutes. We can send the questionnaire electronically by providing your email address or we will provide a pre-paid envelope for you to return the completed questionnaires

**Activity Monitor**: You will be asked to wear an Actigraph activity monitor on your wrist for 5-7 days to measure your daily activity. We will provide a pre-paid envelope for you to return the activity monitor.

**Grip Strength**: You will be asked to complete a grip strength test by using a handheld device called a dynamometer. You will squeeze the device as hard as you can for 3 seconds, and the test will be repeated 3 times.

**Short Physical Performance Battery (SPPB):** This includes a 4-meter gait speed test that will be completed two times, a timed repeated chair stand, and three balance tests.

**Gait Speed**: You will be asked to walk a distance of 15 feet at a comfortable walking pace. The test will be repeated 3 times.

**Body Composition**: You will be asked to complete a body composition scan. A body composition analyzer (InBody 770) will use electrical impedance (i.e., an electrical signal will be sent through your body) to determine your height, weight, BMI, and body composition. This test will take approximately 60 seconds and will be similar to standing on a scale.

## 6. What are the possible risks or discomforts from being in this research study?

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

**Questionnaires**: Some questions in the questionnaires may make you feel uncomfortable. You may choose not to answer any question that makes you feel uncomfortable.

**Activity Monitor**: Wearing the activity monitor may rarely cause skin irritation or redness. If you experience any skin irritation or redness, remove the activity monitor and inform the study team.

The risks of this research study are minimal. We do not believe you will experience any risks beyond what you could expect in your daily life or in a routine clinical visit.

## 7. Are there reasons you might leave this research study early?

You may decide to end your participation in this study at any time. If you decide to stop, you should inform the Principal Investigator. You will be advised whether any additional tests may need to be done for your safety.

In addition, the research team or Mayo Clinic may stop you from taking part in this study at any time if:

- it is in your best interest,
- if you don't follow the study procedures, or
- if the study is stopped.

If you leave the research study early, or if you are withdrawn from the study, no new information about you will be collected. However, information already collected about you in the study may still be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

## 8. What if you are injured from your participation in this research study?

**Where to get help:**

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

**Who will pay for the treatment of research related injuries:**

Care for research-related injuries will be billed in the ordinary manner to you or your insurance. You will be responsible for all treatment costs not covered by your insurance including deductibles, co-payments, and coinsurance.

## 9. What are the possible benefits from being in this research study?

This study may not benefit your health directly. However, health coaching may improve your ability to manage your health. The results of this study may also benefit future patients awaiting heart or lung transplant.

## 10. What alternative do you have if you choose not to participate in this research study?

Participation in this study is voluntary. If you choose not to participate in this study, you will continue to receive the standard care for pre-transplant patients, which includes regular visits with nurses, physicians, pharmacists, dietitians, and others who provide care for patients in the pre-transplant period.

## 11. What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for tests and procedures done only for this research study. These tests and procedures are:

- Questionnaires
- Grip Strength and Gait Speed Tests
- Body Composition Test
- Activity Monitoring
- Health Coaching
- Pedometer

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care including co-payments and deductibles.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

## 12. Will you be paid for taking part in this research study?

You will receive $50 for completing this study. Participants will receive a 2-hour parking pass after completing their baseline measures. Participants can keep the pedometer at the conclusion of the study if they wish.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

## 13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

All study subjects will be assigned unique study identifiers that will appear on data collection instruments, audio files, documents, and files used in the statistical analysis and manuscript preparation. Personal information needed for tracking and informed consent will be stored separately from other data with only limited team members having access to that data.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

### Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

### Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

### Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

### With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

## Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

## Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

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Name and Clinic Number

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Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

## ENROLLMENT AND PERMISSION SIGNATURES

**Your signature documents your permission to take part in this research.**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

**Person Obtaining Consent**

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature