

Prehab Study

**A pilot study of a home-based
intervention to treat frailty in lung
transplant candidates**

**Informed Consent Form
Date of document: 10/13/16**

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: A pilot study of a home-based intervention to treat frailty in lung transplant candidates.

This is a medical research study, a type of research study. Your study doctor, Jonathan Singer, MD MS from the University of California San Francisco, will explain this study to you.

Medical research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have advanced lung disease and are being evaluated for lung transplantation.

Why is this study being done?

The purpose of this study is to determine the feasibility of implementing a home-based exercise and nutrition program with patients awaiting lung transplantation.

How many people will take part in this study?

About 35 people will take part in this study.

What will happen if I take part in this research study?

You will complete an in-person research clinic visit at the UCSF Clinical Research Center prior to lung transplantation. This visit will take approximately 4 - 8 hours to complete. You will follow an individualized home exercise and nutrition program that will take approximately 2 - 7 hours a week to complete over the course of 8 weeks. You will also complete a follow-up assessment that will take approximately 20 minutes.

Before you begin the main part of the study ...

You will need to have the following “screening” to find out if you can be in the main part of the study.

- Your medical chart will be reviewed by the study doctor.

During the main part of the study ...

If the screening shows that you can be in the study, and you choose to take part, then you will have the following tests and procedures done before lung transplantation.

1. A research clinic visit that will determine your exercise capacity and overall nutritional status:
 - a. A test of overall leg function called the Short Physical Performance Battery. This test takes approximately 3 minutes to complete and consists of three parts:
 - i. Walking speed: We will time how long it takes for you to walk 15 feet.
 - i. Balance: We will ask you to stand with your feet in 3 different positions for 10 seconds each.
 - ii. Muscle strength: We will time how long it takes you to stand up from a sitting position in a chair five times.
2. A test to determine how far you can walk in 6 minutes (Six Minute Walk Test). This is the same test you completed as part of your lung transplant evaluation and you will NOT be asked to do this test if you completed one in the previous 14 days.
 - a. Instruction in performing and learning how to adjust supplemental oxygen levels during exercise and activity.
3. A meeting with a clinical dietitian to review your dietary habits.
4. Measurement of your height and weight

Based on the results of your research clinic visit, you will be given a three-month tailored prescription for exercise from Christine Garvey, NP, who develops treatment plans and exercise prescriptions at the UCSF Pulmonary Rehabilitation Program. Your program will target no less than 30 minutes of combined aerobic and strength training exercises three times a week. Your prescription will include:

- Aerobic exercise: walking or exercise bike or treadmill based on what equipment you have available at home.
- Strength training (we will provide latex-free elastic bands for you to perform necessary exercises):
 - Arms: exercises with elastic bands; push-ups against a wall.
 - Legs: repeated chair stands, extension exercises with elastic bands
- Strategies for improving balance

You will be taught these exercises by a study coordinator. You will also be asked to model the exercises you are taught before you go home.

You will also be given an eight-week individualized nutrition plan by our clinical research dietitian.

You will also receive education and instruction for various self-management skills such as control of dyspnea, fatigue, motivation, and support.

You will be given a tablet computer that will come pre-loaded with an application called Aidcube, which is a program to help you exercise at home. This program was designed for

patients with lung and heart diseases with the input of physicians, physical therapists, respiratory therapists, and nutritionists who specialize in patients with lung and heart disease. You will use Aidcube to track and manage your exercise at home. Through this program, you can see your own progress and send messages to the study team.

You will also be given a Fitbit Zip activity tracker. The Fitbit is a wearable physical activity tracker that must be worn on the body, preferably on the waistband or a bra strap.

The study coordinator will also be contacting you weekly through the Aidcube application and phone for support, feedback, and motivation.

All study procedures will be done at the UCSF Clinical Research Center Exercise and Body Composition Laboratory on which is located in the UCSF Ambulatory Care Center at 400 Parnassus Avenue, San Francisco, CA 94143.

How long will I be in the study?

8 weeks. The duration of the study is, in part, determined by how long you wait for your lung transplantation if you are ultimately placed on the waiting list.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He will tell you how to stop your participation safely.

What side effects or risks can I expect from being in the study?

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and study side effects related to the study procedures include:

Likely risks include:

- Performing home exercise prescription may cause muscle fatigue and soreness. You are also at risk of injury since this part of the intervention will be performed at home and not within a secured exercise lab. Although the risk of fall is very low, injuries may be serious and include bruising, strains, and/or fracture of arms, legs or hips. There is also a risk of hitting your head. As a result, you are encouraged to pay careful attention to recommended fall precautions in this exercise program.

Risks that are less likely may include:

- Short Physical Performance Battery and Six Minute Walk Distance testing may cause muscle fatigue or tiredness during and immediately after the test. You may also desaturate if inadequate supplemental oxygen is used during the testing.
- Performing home exercise prescription puts you at risk of desaturation and hypoxia.
- Weight, waist, hip, and arm measurement may cause embarrassment.
- Examination of your dietary habits may make you feel uncomfortable.
- Adherence to dietary plan may cause some discomfort as it may require you to change long-established dietary habits.
- Reactions to foods recommended as part of your dietary plan.
- Other minimal social risks include being asked questions you may find uncomfortable, loss of privacy or confidentiality, and the inconvenience of the time needed to participate in the study. We have tried to minimize these small risks by keeping all of your information in locked file cabinets.
- Risk of breach of confidentiality since we are collecting medical information.

Risks that are rare, but serious include:

- Performing your exercise prescription may lead to injury or severe desaturation or hypoxia which may require that you go to the emergency room. We have tried to minimize these risks by setting your exercise prescription to begin at no greater than 60% of your determined maximum exercise capacity. Injuries may include bruising, strains, and/or fracture of arms, legs or hips. There is also a risk of hitting your head. As a result, you are encouraged to pay careful attention to recommended fall precautions as well as instructions on oxygen titration with exercise in this exercise program.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in this study?

Yes. Your participation may improve control of dyspnea, muscle functioning, nutritional status, and overall body condition with potential long-term effects. You will also receive a free individualized specialized education regarding your lung disease and will be taught how to manage your breathing problems. You will be given a free consultation which will be used to create your tailored home exercise and nutrition plan designed to optimize your overall condition. We will provide you with a portable pulse oximeter and exercise bands if you do not already own them. You will also have free access to a home exercise program for patients with lung diseases.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting standard treatment for your condition without being in a study.
- Taking part in this study or not taking part in the study will not have any influence on whether you are placed on the waiting list for lung transplant or whether you ultimately receive a transplant.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- University of California San Francisco

What are the costs of taking part in the study?

You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

In return for your time and effort, we will pay you \$30 to reimburse you for the cost of parking for the one-day in-person assessment.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Jonathan Singer, MD MS, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at (415) 476-6030.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at (415) 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Jonathan Singer MD MS, at (415) 476-6030.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at (415) 476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent

WITNESS

The witness is signing to document that an oral presentation in a language the subject can understand took place. The witness can be the interpreter or another adult (other than the person obtaining consent) who witnessed the involvement of an interpreter. Preferably, this adult would not be a family member of the participant, unless the person is a health professional or otherwise knowledgeable about research.

Date

Witness (Print Name)

Witness Signature

