Informed Consent Form

Title: Improving Lung Transplant Outcomes with Coping Skills and Physical Activity

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Improving Lung Transplant Outcomes with Coping Skills and Physical Activity – INSPIRE-III
IRB Protocol: Pro00100300

CONCISE SUMMARY

The purpose of this research study is to determine the effectiveness of a coping skills training and exercise intervention among patients that have had lung transplants. Your medical records will be reviewed to see if you qualify to participate. Participants will complete questionnaires, perform a 6-minute walk test, as well as measures of clinical outcomes, physical activity, sleep, quality of life, and coping and self-efficacy. Once the baseline assessments are complete, participants will be randomized to 1 of 2 groups, either Coping Skills Training with Exercise (CSTEX) or to Standard of Care plus Education (SoC-ED). Both groups will complete weekly telephone calls for 12 weeks, each call will last approximately 30 minutes. All participants will return at the end of the 12-week intervention to complete study assessments and then return again for a 1 year follow-up visit. Additional follow-up includes review of your medical records for up to 4 years, which will be completed by study staff and no more in person visits will be required.
The greatest risks of this study include the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have recently undergone lung transplantation. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of ***James Blumenthal, Ph.D. and Scott Palmer, MD's*** and their research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, ***Dr. James Blumenthal*** will conduct the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the effectiveness of a home-based Coping Skills Training plus Exercise intervention among patients who recently underwent lung transplantation.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 400 people are expected to enroll in this study from Duke University Health System Because not all participants who sign this consent form will qualify, we expect to randomize a total of 180 post-lung transplant patients.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form.

Your medical history and current medication usage will be reviewed to make sure that you are eligible.

You will be randomly assigned (like the flip of a coin) to receive either C**oping Skills Training with Exercise (CSTEX) or Standard of Care Plus Education *(SoC-ED)***. You have a 1 in 2 chance of receiving either group. You will still continue with your routine and usual medical care regardless of which group you receive.

If you are in the CSTEX group, you will receive one telephone call each week from a member of the research team for 12 weeks in a row. Each of these calls will last about 30 minutes. During these calls, you will receive training to help you better learn coping skills for stress reduction, improve health behaviors, and maintain (or increase) your levels of physical activity and exercise.

If you are in the SoC-ED group, you will also receive one telephone call each week from a member of the research team for 12 weeks in a row. Each of these calls will last about 30 minutes as well. During these calls, you will receive support and education about lung transplantation.

These phone sessions may be audio-recorded so research supervisors can ensure that the study intervention is going according to the study plan. The audio recordings will only be available to authorized study personnel as necessary to review the content of the sessions.

You will receive a Fitbit activity wristband to self-monitor your activity levels throughout the study intervention. You will be asked to wear the Fitbit daily during the 12-week intervention, from the time you get up in the morning until bedtime. You will be asked to download the Fitbit App to your own smartphone to allow you to monitor your daily activity as well as transfer your daily activity counts to study staff. Your demographic information such as height, weight, age, and gender will be entered into the Fitbit App in order to create an individualized profile, but only your study ID will be used to identify you within this program during your study participation. The Fitbit will be yours to keep.

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All study participants will take part in baselines assessments at the beginning of the study and then repeat these same assessments after the 12-week intervention. You will also be asked to return for a 1-year follow-up visit and researchers will be collecting information from your medical records, for up to 4 years.

These assessments which occur at baseline, 12-weeks and 1 year include the following:

You will be asked to fill out questionnaires online about your mood, attitudes, emotions, sleep patterns, and how you tend to cope with problems.

You will be asked to complete a 6 minute walk test during which the total distance you can walk in 6 minutes is measured. You may rest during the test if necessary.

You will be asked to complete an assessment which measures your health and stamina. You will be asked questions about your weight, ability to complete certain activities, and how tired you may become. You will also be asked to complete another brief walking test, in which your speed to walk 15 feet will be measured and your grip strength will be measured using a handheld device you will squeeze.

You will also be asked to wear a special watch (ActiGraph GT9X Link) that will monitor your physical activity at home for 7 days before the intervention, at the conclusion of the intervention, as well as part of your 1-year follow-up. This watch is to be worn at all times during the week, including during sleep. Your basic demographic information including height, weight, age, and gender will be entered into the ActiGraph program by study staff in order to personalize the watch to you, only your study ID will be used to identify you within this program. This activity watch will be returned to study staff after each 7 day period and you may be provided with a prepaid package to mail the watch and any accompanying paperwork to us at the end of the week.

We will also ask your permission to take your photograph. You may decline having your photograph taken and still continue to participate in the other parts of the study. The photograph will help research staff remember you and will only be stored in a Duke maintained secure server with access limited to study personnel on a password protected computer. If you provide your permission for your photograph to be taken, it will only be kept on file for the duration of the study and erased when the study ends.

_____ Yes, I agree to have my photograph taken

_____ No, I do not agree to have my photograph taken

No blood will be drawn as part of the study, but researchers will look at blood results that are in your medical records. No pulmonary function tests will be performed as part of the study, but researchers will examine the tests that are in your medical records.

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HOW LONG WILL I BE IN THIS STUDY?

The study intervention will last 12 weeks and then you will be asked to for a 1-year follow-up visit. Your medical records will continue to be reviewed by the study team for up to 4 years, but you are not required to complete anything or return during the 4 year medical review period.

It is important to remember that study participation is voluntary and you may choose not to be in the study. If you do not sign this consent form, you will continue to receive care, but not as part of the study. If you agree to be in the study and later change your mind, you can withdraw at any time without penalty or loss of benefits. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Results of this research will be communicated with you and your pulmonologist, if determined clinically relevant by the study team.

WHAT ARE THE RISKS OF THE STUDY?

There are minimal risks associated with this study, primarily the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable; you may refuse to answer any of the questions.

If you are randomized to the exercise group, the exercise that is recommended is not more physically demanding or riskier than what is typically recommended for people who have had lung transplants.

There may be additional risks or discomforts that are not yet known.

For Females: If you are currently pregnant or planning to become pregnant you will be excluded from the study. If you become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to you. You may learn coping skills that improve your quality of life and potentially reduce your pulmonary-related hospitalizations. You may also gain a better understanding of your condition and how to manage your health post-transplant. We hope that in the future the information learned from this study will benefit other people with your condition.

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WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the National Institutes of Health and the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The audio-recordings will be stored on an encrypted (password protected) computer and secure Duke server. The audio-recordings will be available only to authorized study personnel and deleted at the earliest possible time or by the end of the study.

Certificate of Confidentiality:

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not

connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?

All study related-costs associated with your being in this study will be paid by the sponsor, the National Institutes of Health. There will be no additional costs to you as a result of being in this study. However, you or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study.

WHAT ABOUT COMPENSATION?

You will be reimbursed up to $300 for your expenses related to your participation (parking, gas, and time). Payments will be prorated and include the following: $25 for screening, $75 for completion of baseline assessments, $100 for completion of the 12-week intervention, and $100 for the 1-year follow-up visit.

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WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. James Blumenthal at 919-684-3828 during regular business hours and at 919-624-8040 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Blumenthal in writing and let him know that you are withdrawing from the study. His mailing address is DUMC 3119 Durham, NC 27710. You will be asked to return the 7-day activity monitor, if it is in your possession at the time of withdrawal.

You may also be asked to complete the tests that would ordinarily occur when a person completes the study.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

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A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. James Blumenthal at 919-684-3828 during regular business hours and at 919-624-8040 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time