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Study Title: Self-System Therapy for Older Adults with Advanced Lung Cancer (SST-LC)

NCT#: NCT04057196

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in A Research Study
Self-System Therapy for Older Adults with Advanced Lung Cancer (SST-LC)

You are being asked to take part in this research study because you have been diagnosed lung cancer. 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.

CONCISE SUMMARY

The purpose of this study is to see whether a support program for people over 65 years of age with lung cancer will improve how people approach their goals, daily tasks, and challenges, and also cope with poor mood. There are a total of three parts to create and offer the support program. You will be told at the time of this consent, which of the three parts, you are being asked to participate in. You will be compensated for your time. First, we will ask up to 12 individuals over 65 years old who have lung cancer to be a part of a focus group(s) or individual focus group interviews and discuss their experiences and concerns. If you participate in this part, you may also be approached to be a part of an advisory group to offer feedback on the support program. Second, we will test out the support program with 5 individuals. If you are participate in this part, you will have twelve 30-minute video-conference sessions which will be scheduled at your convenience. We will loan you a tablet computer (iPad) to use for video-conferencing and train you in its use. You will complete four assessments – one before starting the sessions, one after the twelfth session, and one after 1 month. Each assessment will include surveys. Third and last, we will revise the program from the feedback obtained in part three and then pilot the support program with 25 individuals. If you are participate in this part, you will have twelve 30-minute video-conference sessions which will be scheduled at your convenience. We will loan you a tablet computer (iPad) to use for video-conferencing and train you in its use. You will complete four assessments – one before starting the sessions, one after the twelfth session, and one after 1 month. For most people, it will take 4 to 5 months to complete this study.

The greatest risk of being in this study is that some of the topics covered in the sessions or in the surveys will make you feel some increased distress.

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

Dr. Katherine Ramos will conduct the study and it is funded by the Duke University's Roybal Center.

The sponsor of this study, the National Institute of Health, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Ramos' salary.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, you will continue to receive medical care through your current providers. You should be in contact with your regular health care providers throughout the study and afterwards as needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn more about how older adults can better cope with their experience of having lung cancer and thereby feel more confident in engaging in activities that improve their physical functioning.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 50 older adults will take part in this study at Duke University.

WHAT IS INVOLVED IN THE STUDY?

If you decide to be involved in this study, you will be asked to sign and date this consent form. This study will ask your involvement in one of four groups. At the time of this consent, based on when you join this study, you will be informed of which group you are being assigned. Thus, you will not be able to choose for yourself of which group you want to participate in.

1) **Focus Groups (12 participants total; in-person visit)-** Participants will be invited to join in on focus groups (that on average will consist of up to 4-8 people per group) or individual interviews. If you decide to be involved in the focus group portion of this study, you will be asked to sign and date this consent form. Focus group members will be asked to discuss their experiences and concerns with late stage lung cancer and its impact. Information gathered from these focus groups will be used to refine the Self-System Therapy program to improve depression and confidence in older adults to be more participatory in physical activities.

2) **Advisory Board (3-4 participants; phone participation)-** Interested participants who participated in one of two focus groups (as described above) will be invited to join the Project Advisory Board group for our designed Self-System Therapy program. If you decide to be involved in the advisory board group portion of this study, you will be asked to sign and date this consent form. Your role in taking part in the group is to meet (by phone) with Dr. Ramos and her project team every four months (3 times in total for the year) to receive an updated report on our progress and to solicit ongoing feedback and advice that you may like to offer about logistical or other issues that arise during testing of and delivery of the intervention program.

3) **Protocol Testing Group (5 participants; video conference)-** If you decide to be involved in the protocol testing portion of this study, you will be asked to sign and date this consent form. You will then receive a working protocol draft of the Self-System Therapy program and in addition be asked

to provide feedback about the program to help improve it, and we will then revise the program with your suggestions.

- You will complete an initial study visit at Duke University Medical Center that will include completing questionnaires using an electronic device (e.g., small tablet computer called an iPad or a laptop).
- Complete brief questionnaires on-line using a tablet computer (or on paper if you prefer).
- Following this, you will participate in a Self-System Therapy program delivered to you using video conferencing (Skype) on an iPad. You will be loaned an iPad to take home with you. A member of the study team will instruct you on how to use and care for the iPad while you have it with you. You will also be provided with written instructions and be given a number that you can call to get assistance with your iPad.
- Because this is a working protocol, you will be asked to complete up to 12 study intervention sessions using video conferencing (Skype) on the iPad. Each session will include a brief overview of the session content and a 45-minute session (or less since we are doing user testing) with the study therapist. The sessions will focus on teaching ways to cope with low mood and worry in order to enhance your ability and confidence to engage in physical activities (e.g., spending time with family and friends).
- In the event that using an iPad is not a flexible format for you, we will accommodate you for in-person sessions or phone sessions (or a combination).
- All participants will complete one post-treatment assessment at least one week following their final study intervention session but not more than two weeks following their final study intervention session.
- Your sessions will be audio recorded and will be reviewed by the study team to assist with the development of the program. Transcriptions will be transcribed by a study staff member.
- All audio recordings will be stored on a secure Duke server and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.
- We will ask for your feedback about the program and gather your opinions to revise the protocol.
- You will be asked to return the iPad after completing the study procedures. This will be the last thing you will be asked to do for this study.

4) **Pilot Trial (25 participants; video conference) -** If you decide to be involved in program/intervention portion of this study, you will be asked to sign and date this consent form. You will then complete an initial study visit at Duke University Medical Center that will include completing questionnaires using an electronic device (e.g., small tablet computer called an iPad or a laptop).
   - Complete questionnaires on-line using a tablet computer (or on paper if you prefer).
   - Following this, you will participate in a Self-System Therapy program delivered to you using video conferencing (Skype) on an iPad. You will be loaned an iPad to take home with you. A

member of the study team will instruct you on how to use and care for the iPad while you have it with you. You will also be provided with written instructions and be given a number that you can call to get assistance with your iPad.

- You will complete 12 study intervention sessions using video conferencing (Skype) on the iPad. Each session will include a brief overview of the session content and a 45-minute session with the study therapist. The sessions will focus on teaching ways to cope with low mood and worry in order to enhance your ability and confidence to engage in physical activities (e.g., spending time with family and friends).
- Your sessions will be audio recorded and will be reviewed by the study team to assist with the development of the program. Transcriptions will be transcribed by a study staff member. All audio recordings will be stored on a secure Duke server and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.
- In the event that using an iPad is not a flexible format for you, we will accommodate you for in-person sessions or phone sessions (or a combination).
- All participants will complete a post-treatment assessment at least one week following their final study intervention session but not more than two weeks following their final study intervention session.
- Participants will also complete one additional assessment at least one-month following their final study intervention session.
- You will be asked to return the iPad after completing the study procedures. This will be the last thing you will be asked to do for this study.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

HOW LONG WILL I BE IN THIS STUDY?

If you participate in the focus group, you will be in the study for one day (no longer that 60-90 minutes). As an advisory board member, you will participate in a total of 3 calls; each call taking place every four months for the duration of one year. Otherwise, as a participant to the user testing protocol or in the pilot trial of the intervention program, you will be in this study for about 12 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?

There are no physical risks associated with this study. There is, however, 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, and you may take a break at any time during the study.

You should not use the iPad for personal use (e.g., internet searching, texting, emailing, storing personal contacts, and downloading mobile apps) during the study. If you do so, this could add your personal information onto the tablet and potentially result in it being disclosed or sent to unauthorized persons. The iPad will be preset to certain security settings. Please do not alter these during the course of the study. When you return the iPad at the end of the study, it will be cleaned to remove any of your personal information. If the iPad is lost or stolen during the course of the study, please contact the study team immediately.

There is some risk of loss of confidentiality due to the use of video conferencing to conduct the study intervention sessions. You will use Skype (www.skype.com) video conferencing program to complete your study sessions.

You may stop your participation in this study at any time.

ARE THERE BENFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may not be direct medical benefit to you. However, you may find that your participation in the study intervention improves your pain and/or other symptoms. We also hope the information learned from this study will benefit other patients with lung cancer.

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.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to **Roybal Center** and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of **the Roybal Center,** 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.

As part of this study, Dr. Ramos and her study team will ask you to complete questionnaires and assessments. Results of the assessments will not be included in your medical record as these are solely for this research study and not part of your regular care.
The study results will be retained in your research record for at least six years after the study is completed. At that time the research information not already in your medical record will be destroyed, or the information identifying you will be removed from the 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.

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 speaking to your attending physician and reporting to authorities, under circumstances to prevent serious harm to yourself or others, or if there is a risk of elder abuse. Under circumstances of threat for self-harm or threat of harm to others, timely and appropriate arrangements for psychiatric assessment and care can be made.

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

WHAT ARE THE COSTS?
There will be no costs to you as a result of being in this study

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WHAT ABOUT COMPENSATION?

Compensation based on the group you consent for is the following:

Focus Groups (12 participants)	$75 total
Advisory Board (3-4 participants)	$50 total
Protocol Testing (5 participants)	$75 total
Pilot Trial (25 participants)	$150 total

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. All data that have already been collected for study purposes will be sent to the study sponsor.

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. Ramos in writing and let her know that you are withdrawing from the study. Her mailing address is Dr. Katherine Ramos, PhD, 2200 Main Street, Ste. 340, Durham, NC 27705.

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

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 Katherine Ramos, PhD, at 919-416-3434.

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 Katherine Ramos, Ph.D., at 919-416-3434 during regular business hours and at 919-970-9864 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.

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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

(Optional):

_____	_____	_____
Signature of Principal Investigator	Date	Time

If applicable, add the following:

_____	_____	_____
Signature of Legal Representative	Date	Time
_____		
Relationship to Subject		