Study Title: Dialectical Behavioral Therapy Skills Training for Metastatic Lung Cancer Patients

NCT Number: NCT04973436

Informed Consent Form, Document Version Date: 7/31/2023

Duke University Health System

Consent to Participate in a Research Study
ADULT
Dialectical Behavioral Therapy Skills Training for Metastatic Lung Cancer Patients

CONCISE SUMMARY

The purpose of this study is to test a coping skills training program for patients with lung cancer, "LiveWell". The skills are designed to help you live as well as possible, with cancer. We are hoping to reduce distress and other common emotional and physical symptoms, such as fatigue, pain, and breathlessness. The study is being conducted in 2 parts. You are being asked to participate in **Part 2.** You will be compensated for your time.

We will test the coping skills training program with 30 individuals. If you participate in this study, you will:

- Complete eight, one-on-one, intervention sessions with a study clinician (45-60 minutes). We will loan you a tablet computer (iPad) to use for video-conferencing, if necessary, and train you in its use.
- Learn skills from dialectical behavioral therapy, a type of evidence-based psychotherapy, that have been specifically adapted to help you cope better with distress and other physical (e.g., fatigue, pain, breathlessness) and emotional symptoms.
- Complete three assessments (20-30 minutes) that ask about cancer symptoms and your feedback on the coping skills program.
- Have the opportunity to participate in an interview following the skills training program to discuss your feedback and experience.

For most people, participation in this study will last approximately 12 weeks.

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

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 advanced 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.

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

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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 Kelly Hyland, PhD salary.

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 help patients living with advanced lung cancer to learn skills to cope better with difficult emotions and symptoms.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 30 people with advanced lung cancer will take part in Part 2 of this study at Duke University.

WHAT IS INVOLVED IN THE STUDY?

Part 2: Testing of the Skills Training Program, "LiveWell" (30 participants; in-person or video-conference).
Participants who are asked to test the intervention/program will be asked to sign and date this consent form. You will then complete an initial assessment, either in person at Duke University Medical Center or virtually, that will include completing questionnaires on paper or using an electronic device (e.g., a computer or tablet).

- Complete questionnaires on paper or online.
- Following this, you will participate in a program delivered to you in person or using video conferencing (Zoom) on a computer or smart device. You may be loaned a tablet to take home with you. A member of the study team will instruct you on how to use and care for the tablet 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 tablet.
- You will complete eight coping skills training sessions in person or using video conferencing (Zoom) on the tablet or a personal electronic device (computer, tablet, smart phone). You will meet one-on-one with a study therapist. The program will teach you skills from dialectical behavioral therapy, an evidence-based type of psychotherapy, that have been specifically adapted to help you to better cope with distress and other physical and emotional symptoms that are common in people with advanced lung cancer. Each session will follow a standard structure, including a brief mindfulness activity, homework and content review, and introduction of new material. Sessions will be approximately 45-60 minutes.
- All participants will complete a post-treatment assessment following their final study intervention session.

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- Participants will also complete one additional assessment at least one month following their final study intervention session.
- You will be given the option to participate in an interview to share your experience in the program and provide feedback.
- If applicable, will be asked to return the tablet after completing the study procedures. This will be the last thing you will be asked to do for this study.

HOW LONG WILL I BE IN THIS STUDY?
If you participate in the trial of the skills training 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. There is some risk of loss of confidentiality due to the use of video conferencing to conduct study procedures, if applicable. You will use Zoom for Health video conferencing to complete study procedures conducted via telehealth.

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 may stop your participation in this study at any time.

ARE THERE BENEFITS 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 improves your ability to manage your emotions and/or other symptoms. We hope that in the future the information learned from this study will benefit other people with advanced 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 the National Institutes of Health 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 National Institutes of Health, the Duke University Health System Institutional Review Board, and others

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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, Tamara Somers, PhD 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 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. 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.

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.

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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?

There will be no costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?

You may be compensated up to $150 for completing all parts of the study. You will be compensated $40 for each assessment completed (3 assessments total), and $30 for participation in the exit interview.

Baseline Assessment	$40
Post-Treatment Assessment	$40
1 Month Post-Treatment Assessment	$40
Exit Interview	$30
Potential Compensation	= $150 total

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 Tamara Somers, PhD at 919-416-3408.

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. Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee and will not affect your grades if you are a Duke student. If you do decide to withdraw, we ask that you contact Tamara Somers, PhD in writing and let her know that you are withdrawing from the

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study. Her mailing address is Tamara Somers, PhD, Duke North Pavilion, 7th Floor, 2400 Pratt St., Durham, NC 27705.

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

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 Tamara Somers, PhD at 919-416-3408.

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