Official Title: LiveWell: An Adapted Dialectical Behavioral Therapy Skills Training Protocol for Patients Living With Metastatic Lung Cancer

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Duke University Health System

Consent to Participate in a Research Study
ADULT
LiveWell: An Adapted Dialectical Behavioral Therapy Skills Training Protocol for Patients Living with Metastatic Lung Cancer

KEY INFORMATION SUMMARY

The purpose of this study is to user 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 interested in seeing whether skills can help you to balance your emotions and to better manage distress (e.g., anxiety, sadness) and symptoms (e.g., fatigue, pain, breathlessness) that can be common when living with lung cancer. This study will be conducted at the Duke Cancer Institute (DCI) and Duke Raleigh Hospital. You will be compensated for your time. Participation in this research study is voluntary.

We will user test the LiveWell program with approximately 10 individuals. User testing means that you will participate in the program and give feedback along the way to help make it better. User testers will complete a baseline assessment including self-report questionnaires either online or paper/pencil. Next, you will participate in the LiveWell program, including 8 one-on-one sessions with a study clinician (45-60 minutes each). The LiveWell program teaches skills from dialectical behavioral therapy, a type of evidence-based psychotherapy, that have been specifically adapted for people living with lung cancer. We will loan you a tablet computer (iPad) to use for videoconferencing, if necessary, and train you in its use. Following each meeting, you will complete brief ratings of the session material and quality. After finishing the program, you will complete a post-treatment assessment and participate in an exit interview to discuss your feedback and experience. For most people, participation in this study will last approximately 8 weeks. The greatest risk of this study includes the possibility of loss of confidentiality.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about 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 and will be reviewed with you by the study team.

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

Tamara Somers, PhD will conduct the study. The study is funded by a grant from the National Institutes of Health. Portions of Dr. Somers' 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, 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 conduct user testing of the LiveWell coping skills training intervention. User testing means that patients will participate in the program and give feedback along the way to help make it better.

Approximately 10 people will take part in user testing.

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.
- You will then complete a pre-treatment assessment online or paper/pencil. The questions will ask about your health and well-being, emotions, symptoms (e.g., pain, fatigue, stress), and coping strategies. We expect these questions to take about 20-30 minutes to complete.
- You will participate in the LiveWell program, including 8 weekly, one-on-one skills training sessions with a study clinician. Each session lasts 45-60 minutes and is completed from a location convenient for you (e.g., home). 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 balance your emotions and to better manage distress (e.g., anxiety, sadness) and symptoms (e.g., fatigue, pain, breathlessness) that can be common when living with lung cancer. Each session will follow a standard structure, including a brief mindfulness activity, home practice and content review, and introduction to new material.

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- Sessions are completed via videoconferencing (Zoom) on a personal electronic device (computer, tablet, smart phone). You may also have the option to complete sessions in-person at the cancer center. Sessions will be audio recorded and reviewed by Dr. Somers and her research staff to help refine the LiveWell program.
- If you do not have a device or do not wish to use your own, you will be loaned a tablet to take home. A study team member will instruct you on how to use and care for the tablet. You will also be provided with written instructions and given a number that you can call for assistance with the tablet.
- Following each session, you will complete brief online ratings of the session material and quality.
- Immediately following the final intervention session, you will complete a post-treatment assessment.
- You will participate in an exit interview to share your experience in the program and provide feedback.
- If applicable, will be asked to return the tablet after completing 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, you will be in the study for about 8 weeks. You can stop participating at any time without penalty.

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 videoconferencing to conduct study procedures, if applicable. You will use Zoom for Health videoconferencing 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.

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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 find that your participation in the study improves your ability to balance your emotions and/or manage distress and 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 any study-related tests or procedures may be shared with 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 as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record.

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.

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.

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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 confidential. If you decide to share your 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.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on www.ClinicalTrials.gov. 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.

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Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
You will receive up to $110 for completing all parts of the study. You will be paid $40 for each assessment completed (2 assessments total) and $30 for completing the exit interview. You will only be paid for the activities you complete.

Baseline Assessment	$40
Post-Treatment Assessment	$40
Exit Interview	$30
Potential Compensation	= $110 total

In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research 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 Tamara Somers, PhD at [REDACTED] during regular business hours.

What if I want to withdraw from the study?
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.

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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 Tamara Somers, PhD in writing and let them know that you are withdrawing from the study. Their email address is [REDACTED].

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

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

Whom should 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 [REDACTED] during regular business hours.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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