Wake Forest®
School of Medicine

Department of Social Sciences & Health Policy

CAREGIVER ONCOLOGY NEEDS EVALUATION TOOL (CONNECT): A TECHNOLOGY-BASED INTERVENTION TO CONNECT LUNG CANCER CAREGIVERS WITH SUPPORTIVE RESOURCES

Caregiver Informed Consent Form to Participate in Research
Chandylen Nightingale, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate a technology-based intervention, Caregiver Oncology Needs Evaluation Tool (CONNECT), which may increase lung cancer caregivers' knowledge about available supportive care resources as well as connect them with these resources. You are invited to be in this study because you are providing care for your loved one who is being treated for lung cancer. Your participation in this research will involve three assessments at separate times over approximately three-months and receipt of one of two groups.

Your participation in this study will involve the completion of study surveys at three time points. You will also participate in one of two groups being tested in a brief intervention that may include accessing a website, receiving a list of supportive care resources, and having a brief follow-up phone call to discuss use of resources. All research studies involve some risks. There is also the possibility that you may benefit from participation in this study.
Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is **Dr. Chandylen Nightingale, PhD, MPH**. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is:

Chandylen Nightingale, PhD, MPH
[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study ***because you are providing care for a loved one with lung cancer who is being treated at Wake Forest Baptist Comprehensive Cancer Center.*** Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate a technology-based intervention, Caregiver Oncology Needs Evaluation Tool (CONNECT), which may increase lung cancer caregivers' knowledge about available supportive care resources and help connect them with supportive care resources. We will also determine our ability to recruit and keep patients and caregivers in the study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

40 caregivers and 40 patients from this research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will be randomized to one of the two study groups described below. Randomization means that you are put into a group by chance (it's like flipping a coin). You have a one in two (50%) chance of being placed into either group.

> **Group A-** Caregivers assigned to Group A will access a study website, receive a list of supportive care resources, and receive a brief follow-up phone call two weeks after using the website.
>
> **Group B–** Caregivers assigned to Group B will receive a list of supportive care resources.

Caregivers in Group A:

You will be asked to watch a brief video and complete an e-tool (electronic program) on an i-Pad while you are in the clinic with your loved one. This intervention is designed to help identify any unmet needs that you may have and connect you with tailored supportive care resources, based on your specific needs.

If you take part in this study, you will have the following tests and procedures:

At the beginning of the study (T0):

- You will watch a brief educational video about the importance of caregiving and supportive care resources.
- You will complete a survey which will help us make recommendations about which resources may be helpful for you. For some resources, there is an option for an automatic referral. If you select that you would like an automatic referral, your name and telephone number will be shared with our partners at the resource. If you select an automatic referral, information regarding whether or not you used the service and date of service use will be collected from the resource.
- You will complete other surveys that ask questions about yourself including things like age and marital status, relationship to the person you are providing care for, your confidence in providing care, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood. These surveys can be completed by mail, in-person at the clinic, or by telephone if preferred.

Two weeks after CONNECT:

- We will contact you by phone to remind you about the available resources and to provide another opportunity for an automatic referral.

One month after CONNECT (T1):

- You will complete surveys one month after the intervention that ask questions about your confidence in providing care, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood. These surveys can be completed by mail, in-person at the clinic, or by telephone if preferred.

At the end of the study (T2): The end of study visit will take place 3 months after the intervention.

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood.
- You will complete an interview to discuss what you liked and disliked about the CONNECT e-tool intervention.
- These surveys can be completed by mail, in-person at the clinic, or by telephone if preferred. The interview can be completed in-person at the clinic or by telephone.

As part of this research study, your interview at the end of the study will be audiotaped, and a transcription of the audiotape will be reviewed by the researchers. This is being done to make sure that the conversation you have with the interviewer is captured accurately. You understand that you may request the recording be stopped at any time during the interview. You can also withdraw your consent to use and disclose the audiotape before it is used. You should also understand that you will not be able to inspect, review, or approve the audiotapes before they are used in this study.

Please initial next to one of the following regarding whether or not you consent to be audio recorded.

_____ Yes, I agree to be audio recorded

____ No, I do not agree to be audio recorded

If you agree to be audio recorded, please initial next to one of the following regarding the use and disclosure of the audiotape used in this research study:

_____ I would like the audiotapes of me to be destroyed once their use in this study is finished.

_____ The audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

Caregivers in Group B:

If you take part in this study, you will have the following tests and procedures:

At the beginning of the study (T0):

- You will receive a list of hospital, community, and national supportive care resources.
- You will complete surveys that ask questions about yourself including things like age and marital status, relationship to the person you are providing care for, your confidence in providing care, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood.

One month after intervention (T1):

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood. These surveys can be completed by mail, in-person at the clinic, or by telephone if preferred.

At the end of the study (T2): The end of study visit will take place 3 months after intervention.

- You will complete surveys that ask questions about your confidence in providing care, your emotional reactions to the caregiving experience, your use of supportive care resources, and your mood. These surveys can be completed by mail, in-person at the clinic, or by telephone if preferred.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for approximately 3 months.

You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no consequences to withdrawing from this study.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to this study include:

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about your mood and emotional reactions to the caregiving experience. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope the information learned from this study will benefit other people in the future. If you agree to take part in this study, there may or may not be direct benefit to you. The benefits of participating in this study may be: improved emotional or physical well-being, more knowledge of available supportive care resources and confidence in accessing these resources.

WHAT OTHER CHOICES ARE THERE?
This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?
There are no costs to you for taking part in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Following data collection subject identifying information will be destroyed three years after closure of the study, consistent with data validation and study design, producing an anonymous analytical data set.

Participant information may be provided to Federal and other regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?
You will be paid a $20 gift card after completing each study visit. You will receive a $20 gift card upon completion of surveys at the beginning of the study, a $20 gift card one month after the intervention, and a $20 gift card two months later, at the end of the study. The total amount that you will be compensated for completion of all of the study visits is $60 (in gift cards).

If you withdraw for any reason from the study before completion you will be not be paid for study visits not yet completed.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements and fill out the reporting form labeled as a W9. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?
This study is being sponsored by The Lung Cancer Research Foundation. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Chandylen Nightingale at [redacted] (after hours number [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information gathered from your survey responses.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are members of the study team; the Institutional Review Board; and representatives of Wake Forest University Health Sciences; the research sponsor and representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; individuals who are affiliated with central laboratories, reading centers, or analysis centers participating in the study; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.
Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell **Dr. Chandylen Nightingale, PhD, MPH** that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Chandylen Nightingale, PhD, MPH
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 Web site at any time.

A Wake Forest Baptist Medical Center medical record will be created for all study participants. Information about your participation in the study will be placed in the WFBMC medical record, along with any routine medical test results that were obtained at WFBMC as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because we are unable to make contact with you or you have stopped providing care for your loved one. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Chandylen Nightingale at [redacted] (after hours' number [redacted]).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date:_____ Time:_____ am pm