Wake Forest®
School of Medicine

Department of Social Sciences & Health Policy

CONNECTING CAREGIVERS TO SUPPORTIVE SERVICES (CONNECT)

Chandylen Nightingale, PhD, Principal Investigator
Caregiver Verbal Consent Script to Participate in Research

STUDY PURPOSE

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 head and neck 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 head and neck cancer. Your participation in this research will involve three visits over a three-month period. Your participant is voluntary.

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?

After agreeing to participate in the study, you will be asked to complete a baseline survey. The surveys will ask questions about yourself including things like age and marital status, relationship to the person you are providing care for, your emotional reactions to the caregiving experience, your use of supportive care resources, quality of care that the patient received, and your mood.

After you and your loved one complete the baseline surveys, you will be randomized to one of the two study groups described below. Randomization means that you are put into a group by chance (like flipping a coin). You have a one in two (50%) chance of being placed into either group.

Caregivers in the Group A:

Caregivers assigned to Group A will access a study website that is designed to help identify any unmet needs you have and connect you with tailored supportive care resources, based on your specific needs. You will watch a brief education video about the importance of caregiving and supportive care resources, complete a survey which will help us make recommendations about which supportive care resource you should be referred to. For some resources, there is an option for an referral. If you select that you would like an optional referral, your name and telephone number will be shared with our partners at the resource. If you select an optional referral, information regarding whether or not you used the service and date of service use will be collected from the resource. We will contact you by phone to remind you about the available resources and to provide another opportunity for an optional referral.

As part of this research study, your interview at one month after going through the study website 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.

Do you consent to be audio recorded?
_____ Yes, I agree to be audio recorded
_____ No, I do not agree to be audio recorded

**Branching logic added for the following question if the participant agrees to be audio recorded. **

Please choose 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 the Group B:
You will receive a list of hospital, community, and national supportive care resources.

For both groups, you and your loved one will be asked to complete a survey at one month (T1) after the going through the study website and receiving resources (Group A) or receiving the list of resources (Group B) and then again at three months (T2). These surveys will ask questions about your emotional reactions to the caregiving experience, your use of supportive care resources, quality of care that the patient received, 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.

- A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.
- 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?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. 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.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or

program evaluation by The National Institute of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you 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.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to yourself or others.

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 after completing the baseline survey(T0), a $20 gift card one month later after completing the T1 survey and a $20 gift card two months later, at the end of the study after completing the T2 survey. 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.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institute of Health. 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.

WHAT ABOUT MY HEALTH INFORMATION?

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

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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 the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading

centers or analysis
centers; the Institutional Review Board; representatives of Wake Forest Baptist Hospital; 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
Wake Forest School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157

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.

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.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00056635
Meeting Date Approved 12/3/2021
Version Valid Until: 12/2/2022

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.

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 or the Research Subject Advocate.

By continuing, I agree to take part in this study.