Wake Forest School of Medicine

Department of Social Sciences & Health Policy

# PREPARE TO CARE, A SUPPORTED SELF-MANAGEMENT INTERVENTION FOR HEAD AND NECK CANCER CAREGIVERS

Informed Consent Form to Participate in Research

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## 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 head and neck cancer who is being treated with radiation therapy. 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 determine our ability to recruit caregivers of patients with head and neck cancer being treated with radiotherapy to a study that includes a kit, *Prepare to Care*, which may increase knowledge about head and neck cancer and enhance stress-management skills. We will also determine how many caregivers continued to use the kit during the study period, what caregivers liked and disliked about the kit, and make modifications to improve the *Prepare to Care* kit. In this study we also want to look at our ability to recruit a waitlist control group of caregivers, that is, caregivers of patients with head and neck cancer being treated with radiotherapy that receive the *Prepare to Care* Kit after the study has ended. Control groups are used in research to see if the intervention being studied really does have an effect.

## 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?

During your first study visit you and the patient that you are caring for will be asked to sign a consent form. A study Team member will review your eligibility and will ask about steroid based medications and/or endocrine disorders. If you cannot remember details about your medications or medical history, study staff may check in your medical records if accessible to confirm eligibility for the saliva portion of the study. If you do have an endocrine disorder or are taking a steroid based medication you may still be eligible to participate, but study staff would

not ask you to collect saliva samples. 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.

**Intervention Group -** caregivers assigned to the intervention group will be provided with the *Prepare to Care* kit, which includes educational materials to promote emotional well-being and coping strategies.

**Waitlist Control Group –** caregivers assigned to the waitlist control group will receive the *Prepare to Care* kit after the study has ended. During your loved one's treatment, there will be no differences with what you normally do, but you will be asked to complete the study assessments.

The *Prepare to Care* kit includes

1) 10-minute introduction video on a DVD,
2) binder including eight workbook modules offered in hard copy, and 3) CD with audio instructions to help you relax.

***Caregivers in the Intervention Group:***

You will be asked to watch the introductory DVD and complete at least one module from the workbook each week. Each module is designed to take approximately 30-45 minutes. All study materials will also be accessible on a study website and you will have access to study i-Pads for use when accompanying your loved one to the radiation clinic for use at the radiation clinic. You can choose which format (workbook, study website, i-Pad) you use to access the *Prepare to Care* kit, and you may use all formats if you like.

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

At the beginning of the study (T1):

- You will meet with study staff to review *Prepare to Care* materials.
- You will sign up for either a weekly email or text reminder to use the *Prepare to Care* kit, depending on your preference.
- You will complete a survey which will help us make recommendations about which module of the kit might be most useful for you in the coming week.
- 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 and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- This initial meeting will take approximately 30-45 minutes, but can also be completed by phone if necessary.

- Your saliva may be collected to measure a stress hormone throughout the study (we will give you materials and instructions for how to do it at home)

*Throughout the study*:

- Each week you will complete at least one module of the *Prepare to Care* kit, which is estimated to take approximately 30-45 minutes each.
- Each week, you will meet with study staff on one occasion, to complete a survey to help us make recommendations about which module of the kit might be most useful for you in the coming week; however, you can choose any module you prefer.

- Study staff will also discuss potential barriers that prevented or limited using the *Prepare to Care* kit the previous week, and help strategize on how you might be able to overcome your barriers, as well as help you finish incomplete activities, should you desire.
- These weekly meetings will take approximately 10-30 minutes, and can also be completed by phone if necessary.

When your loved one completes radiation therapy (T2):

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- You may continue to collect your saliva to measure a stress hormone.

At the end of the study (T3): The end of study visit will take place 6 weeks after your loved one's radiation therapy is completed

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- You may continue to collect your saliva to measure a stress hormone.
- You will complete an interview to discuss what you liked and disliked about the *Prepare to Care* kit if you were in the intervention group.

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 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 Waitlist ControlGroup:***

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

At the beginning of the study (T1):

- 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 and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- Your saliva may be collected to measure a stress hormone throughout the study (we will give you materials and instructions for how to do it at home)

When your loved one completes radiation therapy (T2):

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- You may continue to collect your saliva to measure a stress hormone.

At the end of the study (T3): The end of study visit will take place 6 weeks after your loved one's radiation therapy is completed.

- You will complete surveys that ask questions about your confidence in providing care and engaging in relaxation, your emotional reactions to the caregiving experience, and your mood.
- You may continue to collect your saliva to measure a stress hormone.
- You will be offered the *Prepare to Care* kit at the end of the study.

## HOW LONG WILL I BE IN THE STUDY?

You will be in the study for approximately 12-13 weeks. This includes the duration of your loved ones radiation treatment, typically lasting up to 6-7 weeks, and one follow up study visit which will take place 6 weeks after your loved one has competed radiation treatment.

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?

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.

## 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 increased knowledge about head and neck cancer and improved ability to manage your stress associated with the caregiving experience.

## 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.

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 Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document including all research data.

Audio files will be transcribed, de-identified, and stored securely. Access will be limited to designated study personnel and computer data will be password protected. 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. You may request that your recording be stopped at any time during the interview.

## 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 at the beginning of the study (T1), a $20 gift card when your loved one completes radiation therapy (T2) and a $20 gift card at the end of the study (T3). 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. 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 National Cancer Institute and the Comprehensive Cancer Center of Wake Forest Baptist Medical Center. 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 intervention (*Prepare to Care* kit) 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.

## What About My Health Information?

In this research study, any new information we collect from you or from your medical record 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, and saliva collection results.

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 members of the study team; the Institutional Review Board; and representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital.

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 three 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.

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

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.

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.

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