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Wake Forest®
School of Medicine

Department/Section of Social Sciences & Health Policy

CULTURAL AND LINGUISTIC ADAPTATION OF A TELEPHONE-BASED INTERVENTION TO TREAT DEPRESSION AND ANXIETY IN HISPANIC CANCER SURVIVORS

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to see if we can help Hispanic cancer survivors who are experiencing anxiety (feeling nervous, worried) and/or depressive symptoms (feeling down, tired, sad). You are invited to be in this study because you are a Hispanic cancer survivor and you might have anxiety and/or depressive symptoms.

The study intervention consists of cognitive-behavioral therapy (CBT). This treatment teaches people different ways to handle anxiety and/or depressive symptoms, such as by relaxing the body, changing thoughts, and solving problems. Your participation in this study will involve the following:

- You will receive a workbook focused on teaching these strategies. You will read one chapter a week and practice the exercise at the end of the chapter.

- You will receive a call from a therapist (counselor) once a week for 12 weeks. These calls will last about 45 minutes. The purpose of these calls is to review the workbook chapter and the exercises and see how you are doing.

- You will also receive a call from a study team member once a week for 12 weeks after your call with the therapist. These calls will last about 5-10 minutes. The purpose of these calls is to hear how the work with your therapist and the material and exercises in the workbook worked for you.

- You will complete a telephone interview before starting the study, halfway through the study, and upon completion of the study. These telephone interviews will last approximately 15 minutes.

- Upon completion of the study, you will complete an additional telephone interview. This interview may last up to 1 hour. The purpose of this interview is to get your feedback on the workbook and the calls from the therapist. We will use your feedback to improve the ways that we can help other Hispanic cancer survivors dealing with anxiety and/or depression.

All research studies involve some risks. A risk to this study is that some people may find discussing their problems with others to be uncomfortable, embarrassing and/or stressful. 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. Instead of being in this study, you could seek treatment from someone in your community. 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 people in charge of this study are Suzanne C. Danhauer, PhD and Gretchen Brenes, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, their contact information is [redacted] or [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] or the Research Subject Advocate at Wake Forest 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 a Hispanic cancer survivor with a history of distress (i.e., anxiety and/or depressive symptoms). Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your 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 is to assess patients' ability to complete a telephone-based program to treat depression and anxiety in Hispanic cancer survivors.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Up to twelve Hispanic cancer survivors will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

The entire study is conducted by telephone. First, interested participants will complete a telephone interview to determine if they qualify for the study. If you qualify for the study, you will be registered and we will set up a time for you to speak your assigned study therapist (counselor). You will speak to your therapist once a week for 12 weeks to discuss the cognitive behavioral therapy (CBT) study workbook and provide feedback. CBT is a type of treatment that teaches people different ways to handle anxiety and/or depressive symptoms, such as by relaxing the body, changing thoughts, and solving problems. Participants will receive a workbook focused on teaching these strategies. Over the next 12 weeks, a therapist will call to review the information in the workbook, and participants will be asked to practice these strategies between telephone calls and provide feedback. A study team member will give you a brief call each week for your feedback and experience with the therapist and workbook during that week. Participants will complete telephone interviews during week 7 and week 13 in addition to the one at the

beginning of the study.

Additionally, after the completion of the 12-week program, we conduct a one-time, 1-on-1 telephone interview to provide your overall feedback on the CBT workbook and your experience with the therapist so that we can make changes to the workbook based on your experience and needs.

As part of this research study, your interviews and calls with the therapist will be audiotaped. These recordings will ensure we have accurately summarized your experience. You may request the recording be stopped at any time during the course of the research study. 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 audiotapes 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.

How Long Will I Be in the Study?

You will be in the study for about 4 months. The timing of total study involvement may vary due to the time required to receive study materials and schedule with the therapist, but anticipate no more than a 4-month consecutive time period. 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.

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 cognitive behavioral therapy are that some individuals may find discussing their problems with others to be uncomfortable, embarrassing, and/or stressful. Every effort will be made, however, to address each participant's concerns or problems in the most supportive, empathic, and therapeutic manner.

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.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict.

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.

As part of this study, you will be asked questions about emotional distress (anxiety, depressive symptoms). 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. Additionally, situations may occur during the course of your participation when study staff may be concerned for your well-being. These situations include: you indicate concerns or plans about harming yourself or you are very confused and are not acting like yourself. If these situations occur at any time during the study, we will contact the emergency contacts that you provide.

ARE THERE BENEFITS IN 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 decreases in emotional distress (e.g., anxiety and/or depression). Additionally, the findings from this study may help us to provide needed support for Hispanic cancer survivors who experience anxiety and/or depression.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you could seek treatment from a community provider.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including sessions with the therapist and all interviews related directly to the study, will be paid for by the 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 your safety or the safety of others. There is always some risk that even de-identified information might be re-identified.

WILL YOU BE PAID FOR PARTICIPATING?

Participants will be paid $100 at the end of the study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Cancer Prevention and Control Program of the Wake Forest Baptist Comprehensive Cancer 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 product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: your name, address, telephone number, date of birth, your health history, surveys, how you respond to study activities or procedures, audio recordings, and information from study phone calls.

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 University Health Sciences and North Carolina 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.

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.

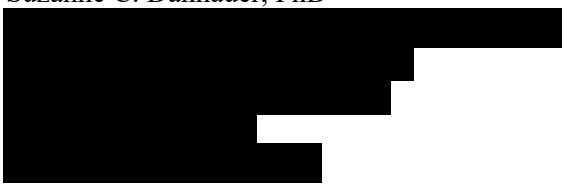
Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time, any research information not already in your medical record will either be destroyed or it will be de-identified. 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.

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,

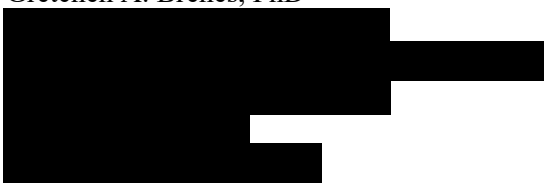
and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

You can tell Drs. Suzanne Danhauer or Gretchen Brenes 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:

Suzanne C. Danhauer, PhD



Gretchen A. Brenes, PhD



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.

What Are My Rights As a Research 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. Information that identifies you may be removed from the data 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 investigators, Suzanne C. Danhauer, PhD at [redacted] or Gretchen Brenes, PhD at 336-[redacted] during normal business hours and for an after-hours emergency (5pm-8:30am M-F or anytime Sat or Sun), call [redacted] and ask for the psychiatrist on call.

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