Developing and Testing a Spanish-Language Intervention to Reduce Cancer-Related Sleep Disturbance

NCT04101526

ICF Version 2 Dated 9/16/2020

Participant's Name _____

Participant's Study ID _____

MCC #: 20086

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

AIM 3

Study Title:	**"Developing and Testing a Spanish-Language Intervention to Reduce Cancer-Related Sleep Disturbance"**
Sponsor:	**H. Lee Moffitt Cancer Center & Research Institute**
Principal Investigator: (Study Doctor)	**Brian D. Gonzalez, PhD & Jennifer Morales, PhD**
Telephone: (24 hour number)	**(787) 840-2575, ext. 2569**
Address:	**Ponce Health Sciences University PO Box 7004 Ponce, PR 00732-7004**

PURPOSE AND PROCEDURES

You are being asked to take part in a research study. The purpose of this research study is to test a potential new behavioral treatment for sleep disturbance. You have been asked to participate in this study because you are a cancer survivor experiencing sleep disturbance.

You will be randomly assigned by chance (like the flip of a coin) to receive either a behavioral study treatment for sleep disturbance or wait 6 weeks and then receive the behavioral study treatment. You will have a 50% (1 in 2) chance of receiving the behavioral study treatment and a 50% (1 in 2) chance of waiting 6 weeks and then receiving the behavioral study treatment. This is an open-label study. This means that you, the Investigator, study staff and the Sponsor will know the study group you are assigned to.

If you are randomized to the behavioral study treatment group your participation will last about 6 weeks. You will be asked to complete a survey about your sleep and other quality of life factors, attend the 6 weekly group sessions via videoconference, and complete another survey after completing the group sessions.

If you are randomized to wait and then receive the behavioral study treatment group your participation will last about 12 weeks. You will be asked to complete a survey about your sleep and other quality of life factors, wait 6 weeks, complete another survey, attend the 6 weekly group sessions via videoconference, and then complete a third survey after completing the group sessions.

If you participate in this study, you will be expected complete 2-3 surveys, attend weekly group sessions via videoconference, and complete assignments given at the weekly sessions. All group sessions will be recorded.

Up to 30 participants will participate in this part of the study.

RISKS AND BENEFITS

We do not know if you will receive any benefit from your participation. The most common and most serious risks that may be related to taking part in this research include discomfort with some questions in the surveys, group sessions, or homework assigned in the group sessions. You do not need to answer any questions that you are not comfortable with. There is also a low risk of loss of confidentiality. However, even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

You will be emailed a PDF copy of this signed and dated consent form. There is a risk of storing or viewing the consent document on a personal electronic device (PED), especially if that PED is shared with other users, is lost, hacked or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

By signing and dating this informed consent and research authorization form, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

VOLUNTARY PARTICIPATION

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start.

You do not have to be in this study to receive treatment for sleep disturbance. Your options may include behavioral treatment or medication for sleep disturbance. Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

REASONS FOR REMOVAL FROM STUDY

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There is no cost to participate in this study. The study-related procedures will be provided at no charge to you or your insurance company.

STIPEND/REIMBURSEMENT

You will receive up to a total of $100 in gift cards if you are randomized to the behavioral treatment group and you complete the study. You will receive a $25 gift card after completing the first study survey and a $75 gift card after completing the survey after the behavioral study treatment.

You will receive up to a total of $150 in gift cards if you are randomized to wait and then receive the behavioral study treatment and you complete the study. You will receive a $25 gift card after completing the first study survey, a $75 gift card after completing the survey after the 6-week wait, and a $50 gift card after completing the survey after the 6-week behavioral treatment.

If you have any questions regarding your compensation for participation, please contact the study staff.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

CONFIDENTIALITY

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing and dating this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Identifiers might be removed from your identifiable private information collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center and Ponce Health Sciences University, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: H. Lee Moffitt Cancer Center & Research Institute.
- Any federal, state, or local governmental agency that regulates the study (such as the Florida Department of Health (FDH), the U.S. Department of Health & Human Services (DHHS), or Office for Human Research Protections (OHRP).

- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By signing and dating below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You do not need to sign this form, but if you do not, you cannot participate in this study.

You will receive a signed and dated copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail: Study Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724

Participant's Name _____

Participant's Study ID _____

MCC #: 20086

- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00034140.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:

1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

STATEMENT OF CONSENT AND AUTHORIZATION

I freely give my consent to take part in this study. I understand that by signing this consent (typing my name below), I am agreeing to take part in a research study and authorize the use and disclosure of my personal health information.

In signing below, I acknowledge that I have read and understand the words and language in this Informed Consent & Research Authorization. By typing my name in the signature field, I am acknowledging that the entry constitutes and represents my legal signature. Further, I certify that the electronic signature below is given on behalf of myself as the person taking part in the study and not any other person. I understand that a copy of the electronically signed informed consent form is available to me.

_____	_____	_____
Signature of Participant	Date	Time