“Patient-Caregiver Communication Intervention for Prognostic Understanding”

NCT03833817

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Copy of Informed Consent Form

WEILL CORNELL MEDICAL COLLEGE
NEW YORK-PRESBYTERIAN HOSPITAL
BROOKLYN METHODIST HOSPITAL

Informed Consent for Clinical Investigation

Project Title:	A communication-based intervention for advanced cancer patient-caregiver dyads to increase engagement in advance care planning and reduce caregiver burden
Research Project #:	1803019107
Principal Investigator:	Holly Prigerson, PhD
Arm/Group	Caregiver Group – Phase 2
Subject Name	

INSTITUTIONS: **Weill Cornell Medical College- New York-Presbyterian Hospital (WCMC/NYP)**
Brooklyn Methodist Hospital- New York-Presbyterian (BMH/NYP)

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you provide care to a person that has been diagnosed with cancer.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research study is being funded by the National Cancer Institute (NCI). The National Cancer Institute (NCI) is providing a research grant for this study. Dr. Holly Prigerson is the primary investigator. The study will take place over the telephone or at Weill Cornell Medicine/NewYork-Presbyterian Hospital and

Brooklyn Methodist Hospital/New York-Presbyterian.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine the feasibility of a new intervention to help people with cancer and their primary caregivers communicate with each other about cancer and to examine the impact of the intervention on patients' and caregivers' understanding of the cancer, preferences for treatment, communication, and distress as part of a research study.

This research study is being done because interventions that improve communication between people with cancer and their caregivers are not currently available.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 60 subjects will take part in this study worldwide: 30 patients and 30 caregivers; all 60 subjects will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate, we will ask you to complete surveys that will be administered over the telephone by a member of our team. These surveys will ask about the patients' cancer and treatment preferences and your distress, quality of life, and communication with the patient. These surveys will take approximately 40 minutes to complete. You will then be contacted by a social worker on the study team to start the intervention. You and the patient you care for will work with the same social worker. Some sessions will be conducted with the social worker and the person with cancer; some sessions will include only you and the social worker. The patient you care for will also have some sessions separately with the social worker. All sessions completed with just the social worker will be kept confidential and not shared with the patient. The intervention consists of seven sessions over the telephone. Each session lasts 45-60 minutes each. You will be asked to complete exercises between sessions related to the information you discuss with the social worker. These exercises will take 10-20 minutes to complete each week. After you finish the final session of the intervention, a study team member will contact you by telephone to complete another set of surveys. These surveys will take approximately 40 minutes to complete and will ask you about the patients' cancer and treatment preferences and your distress, quality of life, communication with the patient, and views of the intervention. Three months later, a member of the study team will contact by telephone to complete a final brief survey. This survey will ask about your treatment preferences and will take approximately 10 minutes to complete. All study surveys will be administered separate from the patient.

If you agree to participate in this study, your interviews with study team members during which you complete study surveys and your intervention sessions with the social worker will be audio recorded. All recordings will be confidential and will be destroyed after the study is completed. If you do not agree to being audiotaped, you are not eligible to participate in the study.

Do you give us permission to audio record our interviews and intervention sessions with you? (record caregiver response):

Yes No

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for approximately one year.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with WCMC, BMH, NewYork-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

There are risks of participating in any study. There are minimal risks associated with participation in this study. These risks include: worsening distress or worry associated with talking about the patient's cancer; increased tension with the patient; and distress related to answering personal questions related to the patient's cancer, health, and treatment planning. You can stop your participation at any time.

For more information about risks of participating in this study, ask the researcher, Dr. Holly Prigerson at 646-962-2882 or hgp2001@med.cornell.edu.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. We hope the information learned from this study will benefit other patients with cancer and their caregivers in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options: You may choose not to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medial record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medical College and NewYork-Presbyterian Hospital
- Brooklyn Methodist Hospital/New York-Presbyterian Hospital
- The Institutional Review Board (IRB)

- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- National Cancer Institute (NCI)

By signing this consent form, you authorize access to this confidential information.

If information about your participation in this study is stored in a computer, we will take precautions to protect it from unauthorized disclosure, tampering, or damage by password protecting all computers, requiring a unique ID and password to log into the system and study-specific database, and storing all study information on the secure Weill Cornell Medicine and Brooklyn Methodist Hospital networks. Further, all computers used for the purpose of this study are kept in locked offices. Only personnel who are associated with the study will have access to the study specific records in the database.

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.

ACCESS TO RESEARCH RECORDS

During the course of this study, you will have access to your research record and any study information that is part of that record.

WHAT ARE THE COSTS?

You will not have to pay to participate in this study. Your insurance company will not have to pay for any part of this study.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for the Sponsor are as follows:

The National Cancer Institute (NCI) will not pay for care necessitated by a research related injury.

The Policy and Procedure for Weill Cornell Medical College and Brooklyn Methodist Hospital are as follows:

We are obligated to inform you about WCMC and BMH's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC, BMH or NewYork-Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will receive compensation for participating in this study. You will receive a stipend of $25 for completing the first set of surveys in this research study, $25 for completing the second set of surveys, and $10 for completing the third set of surveys. This will be paid to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 48 hours after you complete your study visit. Please also review the ClinCard Frequently Asked Questions provided to you by the study staff.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medical College, Brooklyn Methodist Hospital, New York-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Holly Prigerson at 646-962-2882 during the hours of 9am-5pm, Monday through Friday. If you are calling on a weekend, before 9am, or after 5pm, please call 212-746-5454 or 646-962-2800. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:
Address: 1300 York Avenue
Box 89
New York, New York 10065
Telephone: (646) 962-8200

Consent for Research Study

Project Title: A communication-based intervention for advanced cancer patient-caregiver dyads to increase engagement in advance care planning and reduce caregiver burden

Principal Investigator: Dr. Holly Prigerson, PhD

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Holly Prigerson and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date