Enhancing & Mobilizing the Potential for Wellness & Emotional Resilience (EMPOWER) of Caregivers of ICU Patients

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WEILL CORNELL MEDICINE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title:	Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience (EMPOWER) of Caregivers of ICU Patients
Research Project #:	1610017622
Principal Investigator:	Holly G. Prigerson, PhD
Group:	Pediatric Caregiver-Randomized Controlled Trial
Subject Name:	

INSTITUTIONS: Weill Cornell Medicine

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because someone you care for has been admitted to the ICU.

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. 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), an organization within the National Institutes of Health. The *National Cancer Institute* is called the Sponsor and Weill Cornell Medical College ("WCM") is being paid by The *National Cancer Institute*, to conduct the study. Dr. Holly G. Prigerson, PhD is the principal investigator. Dr. Wendy Lichtenthal, PhD at Memorial Sloan Kettering Cancer Center is a co-principal investigator.

The study will primarily take place at Weill Cornell Medicine (NYC). Portions of the study will also take place at the facilities of NewYork Presbyterian Hospital, an affiliate of Weill Cornell Medicine, as well as New York-Presbyterian Hospital-Queens, and Memorial Sloan Kettering Cancer Center. NewYork-

Presbyterian Hospital-Weill Cornell Medicine, NewYork Presbyterian Hospital- Queens, and Memorial Sloan Kettering Cancer Center are not sponsors of this study.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to pilot a new, time-limited informal caregiver intervention that is called EMPOWER -- Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience in Surrogate Decision-Makers of ICU Patients. We hope EMPOWER will help informal caregivers with the stresses and strains of caring for a close friend or family member in the ICU.

This research study is being conducted because preliminary data suggest a need for a stress-reducing intervention for caregivers whose loved ones were admitted in the ICU. Being an informal caregiver (e.g., parent or guardian) of a patient admitted to the ICU is an upsetting and stressful situation. Stress is known to make the challenges of caregiving and decisions regarding patient care more difficult. We have developed and wish to pilot test EMPOWER as a way to reduce the stress and promote better mental health of caregivers and enhance ability to make sound medical decisions on the patient's behalf.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects. Approximately 70 patients and 70 caregivers will take part in this study; 10 patients and 10 caregivers will be recruited as training cases for the EMPOWER intervention in an open trial. After these initial cases are enrolled, 60 patients and 60 caregivers will be recruited, with half randomized to EMPOWER and the other half to a usual care condition. Additionally, up to 15 stakeholders will be recruited to review the study material.

WHAT IS INVOLVED IN THE STUDY?

Your participation in this study will involve no more than 4 assessments and either a usual care condition or EMPOWER sessions. A screening assessment will determine if you meet the eligibility criteria. If you do not, then you will be ineligible for enrollment in the study. If you meet eligibility criteria, you will receive up to 4 sequential assessments within 3 months conducted in person, online or by telephone. You will be "randomized" into 1 of 2 study groups receiving either EMPOWER sessions or the usual care condition. Random assignment to study group will be performed using a block-randomization strategy. The EMPOWER arm includes 6 modules (approximately 15 minutes each) 1-on-1 with an interventionist. It will take approximately 1.5 to 2 hours to complete all 6 modules. There will then be 2 booster sessions, approximately 1 hour each. Modules and booster sessions can take place in person or by telephone. With your approval, EMPOWER sessions will be audio- or video-recorded for supervision and training purposes. EMPOWER is based on well-established cognitive-behavioral techniques that aim to promote the expression and understanding of a person's emotional reactions. The EMPOWER interventionist will be compassionate and attempt to teach you tools for remaining present-focused, validate your experience, explore your and the patient's wishes, values and your decision challenges, increase your acceptance and sense of permission to experience challenging emotions, and prepare you for future distressing situations.

If you are randomized to receive the EMPOWER intervention, at the end of all of the sessions, we will ask you to complete an interview to provide feedback on your overall experience with the program, as well as how we can improve the program. This interview will be audio and/or video recorded with your

permission, and we may transcribe or use audio/video clips of some of these recordings for academic, educational, or training purposes and/or for publications and presentations.

Usual Care condition is intended to serve as a control condition which is regular ICU care with referral to resources.

If your child is currently receiving care at New York Presbyterian – Weill Cornell Medical Center, information from the records of the child whom you make medical decisions for (referred to further as "the patient") will be collected as well. This includes, but is not limited to diagnoses, labs, and treatment and procedure orders. If your child is not receiving treatment at New York Presbyterian – Weill Cornell Medical Center, we will ask you to provide basic demographic and medical information about the patient. By taking part in this study, you agree to share this information on behalf of the patient. Sharing this information reflects the full extent of the participation of the patient in this study.

HOW LONG WILL I BE IN THE STUDY?

All the assessments and the intervention will be performed within 3 months, and the overall study of all subjects will last about 2 years.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigators first.

If you choose to not participate in the study or to leave the study, your relations with WCM, NewYork-Presbyterian Hospital, your physicians, or other personnel will not be affected. In addition, you will not lose any of the benefits to which you are entitled.

WITHDRAWAL BY INVESTIGATOR, PHYSICIAN, OR SPONSOR

The investigators 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 reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

There are risks to taking part in any research study. The risks associated with this study are small. There are no risks of physical injury. The interviewer will ask you questions about the patient and yourself. You have the right to not answer a question or stop the interview at any time. You may find yourself becoming emotional, anxious or sad in response to some questions about the patient's illness. If you find the interview upsetting and wish to talk with someone, please contact the study Principal Investigator, Dr. Holly Prigerson, PhD. at (646) 962-2882 or (617) 459-3304 and she will make a referral to a mental health professional should you want one. You have the right to not answer a question or stop the interview at any time.

Risks from Invasion of Privacy:

Given that your personal responses will be used or disclosed to the sponsor, their representatives, and other authorized persons and entities, there is the risk of loss of confidentiality. Every effort will be made to protect your privacy.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research 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 and caregivers admitted to the ICU in the future.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate in this study. Participation, discontinuation of participation, or lack of participation will not affect your employment or relationship with Weill Cornell.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your records, the patient's 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. You or the patient will not be identified personally in any reports or publications resulting from this study. Any transcriptions, audio, or video clips from exit interviews used in publications or presentations, and/or for academic, educational, or training purposes, will be anonymized. Organizations that may request to inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- Weill Cornell Medicine and NewYork-Presbyterian Hospital
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- The National Institutes of Health and/or their representatives

By signing this consent form, you authorize access to this confidential information. You also authorize the release of some other necessary information to Weill Cornell Medicine and New York-Presbyterian Hospital.

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 requiring a unique ID and password to log into the database. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

If the results of the study are published, your identity and the patient's identity will remain confidential.You have the right to not answer a question or stop the interview at any time.

EXCEPTIONS TO CONFIDENTIALITY:

There will be only one exception to the strict participant confidentiality policy described, which pertains to information obtained during the research assessment, which would indicate that you or the patient may pose a significant and acute risk of self-harm or harm to others. Such information will be shared with the Principal Investigators of the study, and may be shared with the attending medical provider of the patient in the ICU, so that timely and appropriate assessment and care can be provided by a licensed/board-certified mental health provider or local providers when geographically necessary.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCM researchers need your permission to use both your protected health information and the patient's protected health information. If you give permission, Weill Cornell Medical College (WCM) and/or NewYork-Presbyterian Hospital (NYPH) researchers may use your information or share (disclose) information about you and/or the patient for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCM and/or NYPH researcher's permission to use or share your protected health information and the protected health information of the patient for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCM and/or NYPH researchers to use or share your and the patient's protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCM and/or NYPH.

Protected Health Information to Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information and the protected health information of the patient. This medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your or the patient's medical records and from any test results, which include but not limited to demographic information, disease diagnoses, medications, vital status, ventilator/oxygen supply settings, pain evaluations, physician/nurse notes, blood test, radiology tests, and etc**.**

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information and or the protected health information of the patient to develop new procedures or commercial products. They could share your protected health information with the study sponsor the WCM Institutional Review Board, inspectors who check the research, government agencies and research study staff.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCM and/or NYPH researchers permission to use or share your protected health information and the protected health information of the patient, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Officer
1300 York Avenue, Box 303
New York, NY 10065

If you have questions about this, call: (212) 746-1179 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCM and/or NYPH researchers to use or share your protected health information for their research will never end.

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 as described in this authorization form in accordance with Weill Cornell Medical College (WCM) and/or NewYork-Presbyterian Hospital (NYPH) policies.

WHAT ARE THE COSTS?

Taking part in this research study will not lead to adding costs to you.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

Compensation for wages, time lost, disability or discomfort is not available. You do not give up any of your legal rights by signing this consent form.

The Policy and Procedure for Weill Cornell Medicine are as follows:

We are obligated to inform you about WCM'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 WCM 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 $25 by Clincard for completing each assessment and $100 in total with the completion of 4 assessments. You can expect to receive the Clincard in person or by mail after the first assessment.

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. Your participation, discontinuation of participation, or lack of participation will not affect your employment or relationship relations with the Weill Cornell Medicine, NewYork-Presbyterian Hospital, your physicians, or other personnel will not be affected. 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 (212) 746-1374 (office) or (617) 459-3304 (cell).

If you have questions about your rights as a research participant, contact the WCM 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: Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience (EMPOWER) of Caregivers of ICU Patients

Principal Investigator: Holly G. 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 (Co-investigator or Research Staff)	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 any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Holly Prigerson and the research staff.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date

If you agree to have the intervention sessions/exit interview video-recorded, please check "YES", If not please check "NO" and the sessions will be audio-recorded.

____ YES ____ NO

Do we have your permission to reach out to you in the future about studies that you may be eligible for?

____ YES ____ NO

Would you like to be provided with a copy of the published results of this study following its completion?

____ YES ____ NO