Weill Cornell Medicine

February 4th, 2025

Title: Developing a Communication Intervention for People With Memory Challenges and Their Care Partners

NCT Number: NCT05143255

WEILL CORNELL MEDICINE

Oral Informed Consent for Clinical Investigation

Project Title: Developing a communication intervention for people with memory challenges and their care partners

Research Project #: 21-04023598

Principal Investigator: Sara Czaja, PhD

Arm/Group: Care Partner Group – Phase 2

Subject Name: _____

INSTITUTION: **Weill Cornell Medicine**

KEY INFORMATION ABOUT THIS RESEARCH STUDY	
We are asking you to choose whether to volunteer for a research study used to help people with memory challenges and their primary care partners communicate with each other about medical care. Specifically, we are examining a new resource to help people with memory challenges and their care partners communicate about treatment decisions and care needs as part of a research study. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.	
Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to develop an intervention to help people with memory changes and their primary care partners communicate with each other more effectively. To accomplish this goal, we aim to examine whether this new resource is helpful to people with memory challenges and their care partners, as part of a research study. This research study is being done because interventions that improve communication between people with challenges in memory and their care partners are not currently available. Your participation in this research will last 16-20 weeks.
Benefits: **Key reasons you might choose to volunteer**	The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit other patients with memory challenges and their care

	partners in the future.
Risks: **Key reasons you might choose NOT to volunteer**	There are minimal risks associated with participation in this study. These risks include: possible distress related to answering personal questions related to your memory challenges, health, and treatment planning, and a possible loss of confidentiality. All efforts will be made to protect your medical records and other personal information to the extent allowed by law. You can stop your participation at any time.
Voluntary Participation: **Do you have to take part in the study?**	Taking part in the study is entirely voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you chose not to volunteer.
What if you have questions, suggestions, or concerns?	The person in charge of the study is Dr. Sara Czaja. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is**:** 646-962-7148 or sjc7004@med.cornell.edu. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu.
This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.	

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 who is experiencing memory challenges. 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 Institute on Aging (NIA). The National Institute on Aging (NIA) is providing a research grant for this study. Dr. Sara Czaja is the primary investigator.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to examine the feasibility and acceptability of a new intervention designed to help people experiencing memory challenges and their primary care partners communicate with each other about memory challenges and planning for future care and to examine the impact of the intervention on people with memory challenges and care partner's 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 memory challenges and their care partners are not currently available.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 90 subjects will take part in this study worldwide: 60 subjects will take part in this Phase of the study. All 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 in person or over the telephone or videoconferencing by a member of our team. These surveys will ask about the person you care for and their memory challenges and treatment preferences, your distress, communication with the person you care for, and the impact of caregiving on you. These surveys will take approximately 30 minutes to complete.

You will then be contacted by an interventionist to start the intervention. If you are participating with a person with memory challenges, you and the person you care for will work with the same interventionist. Sessions will be conducted either with the interventionist, you, and the person you care for or the interventionist and you. All sessions you complete with just the interventionist will be kept confidential and not shared with the person you care for. The intervention consists of four sessions over telephone or videoconferencing. Each session lasts 30-45 minutes each. You will be asked to complete exercises between sessions related to the information you discuss with the interventionist. 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, video conferencing, or in person to complete another set of surveys. Three months later, a member of the study team will contact you to complete a final brief survey. These surveys will take approximately 30 minutes to complete and will ask you about the person you care for and their memory challenges and treatment preferences, your distress, communication with the person you care for, the impact of caregiving on you, and your views of the intervention. They will also ask about your treatment preferences. All study surveys will be administered separate from the person you care for.

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 interventionist 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 recorded, you are not eligible to participate in the study.

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

Yes ***No***

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for 16-20 weeks.

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 WCM, NewYork-Presbyterian, 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 person you care for; increased tension with the person you care for; distress related to answering personal questions related to the person you care for and their memory challenges, health, and treatment planning; and a possible loss of confidentiality. All efforts will be made to protect your personal information to the extent allowed by law. You can stop your participation at any time.

For more information about risks of participating in this study, ask the researcher, Dr. Sara Czaja at 646-962-7148 or sjc7004@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 memory challenges and their care partners 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 Medicine and NewYork-Presbyterian
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- National Institute on Aging (NIA)

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 network. 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.

Confidentiality may be suspended in the event of a psychological emergency.

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 Institute on Aging (NIA) will not pay for care necessitated by a research related injury.

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. Further information can be obtained by contacting the Institutional Review Board at (646) 962-8200 or irb@med.cornell.edu.

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 $25 for completing the third set of surveys, for a total of up to $75. 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 Medicine, NewYork-Presbyterian, 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. Sara Czaja at 646- 962-7148 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 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
Email: irb@med.cornell.edu

Consent for Research Study

Project Title: Developing a communication intervention for people with memory challenges and their care partners

Principal Investigator: Sara Czaja, PhD

SUBJECT'S STATEMENT

I 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 voluntarily agree to be audio recorded. 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. Sara Czaja and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Name of subject Date

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 Print Name of Person Date