Weill Cornell Medicine
Center on Aging
& Behavioral Research

NewYork-Presbyterian

July 21st, 2022

Title: A Non-pharmacological Intervention for Patients with Alzheimer's Disease and Family Caregivers (Care Partners Program)

NCT Number: NCT03333252

WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title:	A non-pharmacological intervention for patients with Alzheimer's disease and family caregivers (Care Partners Program)
Research Project #:	1803019068
Principal Investigator:	Dr. Sara J. Czaja
Arm/Group	*Caregiver*
Subject Name or number:	

INSTITUTION: **Weill Cornell Medical College**

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you showed interest in this study by responding to a flyer and answered questions over the telephone to determine eligibility. You care for a loved one with Alzheimer's or other dementias at least 8 hours a week for the last 6 months and are over the age of 21.

Please take your time to make your decision. If you have questions at any time please feel free to ask. 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. The National Institute on Aging is providing a research grant/funds for this study. Dr. Sara J. Czaja is the primary investigator.

The study is recruiting participants who are considered care recipients, defined as those that receive care or assistance to perform independently higher level of instrumental activities of daily living. We are also recruiting the care recipient's caregivers, defined as someone who provides care or support for a friend or relative.

The study will take place in your home and via videoconference through a laptop provided to you at no cost for the study. Some portions of the study may take place at facilities of NewYork-Presbyterian Hospital/Weill Cornell Medical College (WCMC), where the investigators are members of the medical staff. In rare instances where we are unable to visit your home at the time of your visit, we may request to do this visit by phone or videoconference. NewYork-Presbyterian Hospital/WCMC is neither a sponsor nor an investigator for this study.

WHY IS THE STUDY BEING DONE?

The number of individuals with Alzheimer's Disease (AD) is increasing rapidly. Most people with AD or dementia are cared for at home by a family member or friend. These caregivers provide a great service to their loved ones; however, they often experience emotional and physical health problems such as depression, anxiety, and stress.

The focus of this study is to get information on how the program can:

- Reduce caregiving burden and improve quality of life.
- Lower depression among caregivers.
- Increase quality of life and delay patient placement among care recipients.

This study is computer-based. It will allow us to present the information and resources in different ways. You will be able to access the program from your home.

The goals of the study for the caregiver are to 1) improve overall well-being, 2) help their ability to provide care to their loved ones; and 3) reduce gaps in getting needed services and support.

The goals of the study for the care recipient are to 1) help their cognitive and functional performance; and 2) to lessen psychological distress and improve quality of life.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About 240 caregiver and 240 care recipient subjects will take part in this study worldwide; 160 caregiver and 160 care recipient subjects will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate, all study activities will take place in your home. We are asking that you take part in the study for 12 months. Visits may take place by telephone or videoconference if we are unable to see you in-person at the time your visit is supposed to take place. You and your loved one will be assigned (by chance, like the flip of a coin) to either the Care Partners or Health Promotion groups. You will have an equal chance of being placed in each of the study groups. A study team member will call you and let you know your group. We may call you additional times to check-in on you and your use of the study technology.

The research associate will work with you to schedule all study-related appointments.

Regardless of your assigned group, you and your loved one (as a dyad) will be given a laptop computer. It will be connected to the internet for the duration of the study at no charge to you. You will use it to access study-related materials that are web-based. Only one laptop computer will be provided per dyad. You will use the laptop computer to view study material and complete homework/assignments.

Care Partners Group: If you are in this group, you will have access to skill building sessions, videos from experts, resources, and information and tips on caregiving-related topics.

Health Promotion Group: If you are in this group, you will have access to training sessions on different topics/strategies to help you be a healthier caregiver.

The study includes 12 sessions throughout the first 6 months of the study. Most of the sessions will be individual and a few of them will require you and your loved one to be present at the same time. Each session lasts between 45-60 minutes. The first, second, third, and last session will be in-person at your home. Sessions 4-11 will be in video-conferencing format using your laptop computer. In cases where a session cannot occur in person, it will be held over videoconference.

In addition to the individual sessions, those in the Care Partners Group will attend 5 support group sessions. These sessions are in a video-conferencing format. During these sessions, you will have the chance to meet, interact, and learn from one another. The sessions last about 60 minutes.

For security and privacy reasons, the laptop computer provided by the study is solely for you and your loved one's use. Features not relevant to the study will be disabled. Also, we will be monitoring your frequency of use of the laptop. We will only be measuring use at a more global level, meaning we will count the number of times you use the program and the number of times you use each feature of the program. This information helps us to understand which parts of the program were most useful to you.

During your time participating in the study, you have to notify us if the laptop computer is lost or stolen.

The laptop computer is yours to keep at the end of the study. We will reset it to the original manufacturing state.

In addition to the study related activities above, regardless of what group you are in, the study also includes 3 face-to-face assessments with a study staff member in your home: one in the start of the study, one in 6 months, and one in 12 months. These assessments are not done on your computer and the information gathered is not recorded on your computer, but kept separately in a secure file by the study team. Each assessment will last about 3 hours. Assessments include questions about basic background information, health, caregiver burden, social support, and physical health indicators. We can split these assessments in multiple sessions/visits if necessary. All the study related activities and assessments will be conducted in English or Spanish, whichever is your preference. In cases where these visits cannot be held in-person, they may be held over videoconference or telephone.

We will also be asking the person whom you are caring for some questions. We will get their consent before asking any question. The assessments with your loved one will last about 90 minutes. It includes questions about their memory, orientation, attention, and ability to perform basic daily living tasks, and tasks on a computer. We could ask these questions with or without you being present.

With your written and expressed permission, someone may come to take a picture or record the session. With your permission, the pictures and audio/video recordings may be used only for research, education, and/ or scientific publication purposes. The still photographs, videotapes, and/or sounds recordings are used for quality assurance purposes. The Principal Investigator, Dr. Sara Czaja, also may use the photographs, videotapes, and/or recordings as content for research presentations. Audio/video recordings will be deleted from the secure servers on which they are stored upon completion of the research study

I hereby authorize the NewYork-Presbyterian/WCMC to take still photographs, videotapes, and/or sound recordings of me and use in any manner said photographs, film, video or tape recordings, in whole or in part as follows *(Please read and check box next to appropriate permission statement):*

☐ ***For the purpose of teaching, research, scientific meetings and scientific publications, including professional journals or medical books*;**

☐ ***For research purposes only.***

☐ ***I wish to opt out of any video or tape recordings and request to have telephone sessions instead.***

I agree that the NewYork-Presbyterian/Weill Cornell Medical College, its Trustees, officers, employees, faculty and agents will not be responsible for any claims arising in any way out of the taking and use as described above of such photographs and/or recordings. I understand that I will not have an opportunity to inspect and approve such photographs or recordings prior to their use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 12 months. In rare instances where we are unable to return to your home at the time of your 6-month or 12-month visit, we may request to do this visit by phone or videoconference.

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, 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, if you need additional or different medication, 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?

During the assessment, we will be asking questions that are personal/sensitive, you may feel uncomfortable or embarrassed answering some of these questions. You may skip any questions that you do not wish to answer.

You can stop being in the study at any time. We will give you breaks if you feel tired. You will participate in group interviews with other participants at which we will instruct all participants to only use first names and emphasize the need for confidentiality. You also have the option to opt-out of these group sessions to avoid this risk. You will also be informed of any new findings that may change your mind to continue in this study.

Risks from Invasion of Privacy:
Every effort will be made to protect your privacy. Included in this form is a HIPAA authorization regarding your privacy rights with respect to your participation in this study. No personal health information will be used/disclosed unless you agree to sign this form.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

No benefit can be promised to you from your time in the study. However, the results of the study may help investigators in designing future technology-based programs for caregivers of dementia or Alzheimer's Disease patients.

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 medical 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
- The University of Miami
- 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
- Vidyo
- Posit Science
- Zoom Video Communications

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medical College and NewYork-Presbyterian Hospital by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. Data will be stored on a secure server that can only be accessed by a password protected computer. Any hard copy data will be stored in a locked file cabinet in a locked office. In addition, only personnel who are associated with the study will have access to the study specific records in the database and file cabinet. You are responsible for safeguarding your own device for your protection of your confidential information.

You will be counseled and trained to password protect your laptop, and you will be encouraged to log out of the laptop when not in use. Participants have the right to refuse teleconferencing through Vidyo and can opt for telephone sessions instead. Some participants will be using Posit Science. Posit Science will not have access to any information that identifies you personally. Data collected through Posit Science include how much and how often you use the Posit Science features available to you.

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.

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, WCMC researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medical College (WCMC) and/or NewYork-Presbyterian Hospital (NYPH) researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCMC and/or NYPH researcher's permission to use or share your protected health information 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 WCMC and/or NYPH researchers to use or share your 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 WCMC 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. Your 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 medical records and from any test results, which includes your survey data and interview data.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor the WCMC 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 WCMC and/or NYPH researchers permission to use or share your protected health information, 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: (646) 962-6930 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCMC 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 not have access to see or copy certain parts of your protected health information that contains research information as described in this authorization form, in accordance with Weill Cornell Medical College (WCMC) and/or NewYork-Presbyterian Hospital (NYPH) policies. This is done to prevent knowledge of study results affecting the reliability of the study. The part of your private information that you will not have access to are your recorded sessions but **you will have access** to all other study data that we will collect. Your information will be available should an emergency arise that would require the treating physician to know this information in order to best treat you. Your right to access this information will not be reinstated upon completion of the study because we need to maintain the privacy between you and your loved one. If you wish to appeal this suspension at any time, please write to the Privacy Officer at the address on this form. By signing this form, you are agreeing to this suspension of your rights to access protected health information.

WHAT ARE THE COSTS?

Other than the time that you will take to be in this study, you will have no other cost for your participation.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

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

We are obligated to inform you about WCMC'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 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 $30.00 for each of the assessments: the first, the 6th month, and the 12th month assessment. If you are not eligible to participate, you will receive $10.00. This will be given 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.

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, NewYork-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. Sara Czaja at 212-746-1374 or NYPH at 212-746-5454.

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: Care Partners Program

Principal Investigator: Sara Czaja, Ph.D.

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. Sara Czaja 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