Community **P**aramedic **C**oaching **P**rogram for **C**aregivers and **P**eople with **D**ementia **(CP3D)**

PI: Manish Shah
Co-I: Gwen Costa Jacobsohn
Funding: National Institute on Aging (NIH) Award K24AG054560
NCT number: NCT04239924

UNIVERSITY OF WISCONSIN-MADISON

Caregiver/Support Person CONSENT to Participate in Research and AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of the Study: Community Paramedic Coaching Program for Caregivers and People with Dementia (CP3D)

Principal Investigator: Manish N. Shah, MD, MPH UW School of Medicine and Public Health, Department of Emergency Medicine 608-890-6892, mnshah@medicine.wisc.edu

Mailing Address: 800 University Bay Drive Suite 310, Mail Code 9123 Madison, WI 53705

Study Sponsor: National Institute on Aging (NIH)

INVITATION

You are invited to participate in a research study that will examine if providing paramedic-coaching to adults with dementia and their caregivers will help them better navigate dementia-related issues and improve their social and medical outcomes. Participation is completely voluntary. You are invited to take part because you are the primary support person/caregiver to a person with a diagnosis of dementia. We expect a total of 30 persons with dementia and caregivers to be enrolled in this study.

The purpose of this consent and authorization form is to give you the information you need to decide whether or not to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

A. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this program of research is to study whether a program involving coaching provided by paramedics, in coordination with primary care providers, can reduce the need for acute care services by older adults with dementia and their caregivers. Intervention sessions will be delivered at home and over the phone over the course of a year. This study explores the extent to which this program improves patients’ and caregivers’ abilities to better navigate dementia care, access needed resources, and improve social, emotional, and medical outcomes.

B. WHAT WILL MY PARTICIPATION INVOLVE?

This study will last approximately 1 year. You are free to withdraw from this study at any time. You may also skip any survey questions you do not feel comfortable answering. If the person you are caring for (also enrolled in this study) decides to withdraw, your participation in the study will also end.

Coach Visits: Over the course of this year, paramedic coaches will come to your home to meet with you, providing coaching support and information as part of the REACH caregiver program (Resources Enhancing Alzheimer's Caregiver Health). The first 6 coach visits will take place at your home during the first 8 weeks. You will then have coaching sessions scheduled approximately, once per month for the remainder of the program. You will also schedule phone sessions with your coach between your in-person meetings to review information and check in on how things are going.

These sessions are for you, the caregiver. Your care recipient (person with dementia) is not required to be present or participate in any of these visits. If you find that you prefer another setting other than your home to meet with the coach so that your care recipient is cared-for or occupied during the session, you may coordinate that directly with your coach.

Some of the information you discuss with your coach will be communicated back to your (and/or your care recipient's) primary health care team to give them an update on how you are doing and topics they might want to talk with you about in the future. Some of this information may also be discussed with our local social service partners) so they can provide or connect you to community services that your coach and healthcare team think might help.

Surveys/Interviews: At the start of this study, a member of the research team will meet with you (either in person or by phone) to ask you questions about your experiences with dementia caregiving and the effect it has on different aspects of your life. That survey will take about an hour, and will be scheduled within the next two weeks. You will be asked to complete a similar survey three more times during the year, approximately 13, 25, and 50 weeks from now. During your first coach visit, you will also be asked to answer some (different) survey questions.

Some of the survey questions you will answer in this study ask about symptoms of emotional distress such as depression or anxiety. We are using your answers purely for research purposes, not to diagnose mental health or other issues. The answers you provide will not be given to your health care providers, and will not directly affect your clinical care.

A few times during the study, a member of the research team will contact you to ask you for your thoughts and feelings about how the program is going. We are very interested in getting your opinions on what is going well, and what you think we could do differently to make the program better. These meetings will be audio-recorded to make sure that we accurately capture everything you have to say. We will contact you ahead of time to schedule these feedback interviews.

Use of Health Records: We will also collect data from your electronic health record during this year, and for 1 year after you have completed all coaching visits, in order to monitor your health, progress, and use of healthcare services. This allows us to see how well this program works, both during and after the intervention year.

What will happen to my data after my participation ends?
We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called "banking." The banked data will be kept in a secure location for use by researchers.
This is what will happen with your banked data:

- We will use the data in future research projects about how to improve care for people with dementia and their caregivers. We may also use them for other types of research.
- The data may be shared with our research partners at the University of Wisconsin-Madison and Georgia Southwestern State University.
- The banked data will be labeled with a code instead of your name.
- When we give your data to other investigators for research projects, they will not be able to use the code to figure out which data are yours.
- The research team will maintain a link between your data and your identifiable information kept by the study team.
- You can request to have your data removed from the bank by contacting the research team at any time.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of study assessments/surveys
- Things you tell the researchers and coaches about your health
- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history, details about care you receive, the results of tests and assessments, and details of communications with healthcare providers. We will get this information from UW Health.

How is being in this study different from my regular health care?
Older adults, including people with dementia have regular visits with their primary care providers, as well as additional visits with specialists. If you participate in this study, you and your care recipient (person with dementia) will continue to have these visits as you normally would.

As part of this study, your will be answering some questions about living with a person with dementia as part of their visits with a trained coach. Some information from those visits will be shared with your (or your care recipient's) healthcare team, who may choose to enter it into your medical record so they can follow up with you or use it during healthcare appointments.

Will I receive the results of research tests?
The answers you provide on survey and assessments as part of this study are for research purposes only, and will not be used for any kind of diagnosis, treatment decisions, or provision of services. Because of this, we will not tell you or your health care team the results of these research measures.

C. ARE THERE ANY BENEFITS TO ME?

This program has been tested and demonstrated to improve some health outcomes for caregivers of people with dementia. Caregiver participants will likely receive some measure of direct benefit from full participation. As this study is being done to evaluate the delivery of the intervention in a different context, we cannot guarantee that you will experience any particular benefits, or how much of a benefit you might experience. There are, however, indirect benefits of participation, in that the study findings have the potential to improve care delivery for patients with dementia and their caregivers in the future.

D. WILL I BE PAID FOR MY PARTICIPATION?

For each of the four surveys you take, you (the caregiver and patient combined) will receive $50 in cash, for a total of $200. At the end of the study, you will receive another $50 as a thank you for staying in the study all the way through. This payment will be given directly to you, the caregiver, for you to share between yourself and the patient.

E. ARE THERE ANY COSTS?

There are no costs to you to participate in this study.

F. ARE THERE ANY SIDE EFFECTS OR RISKS TO ME?

The primary risks associated with this study are:

1. Embarrassment or stress from the survey questions or assessments, either from the questions themselves or frustration from answering the questions. *You do not have to answer any questions you do not want to.*
2. Accidental release of confidential information could happen and cause social or psychological harm. However, the risk for this is extremely unlikely due to the security procedures we will use to protect your information.
3. Indications of risk to self or others: If our coaches or research staff see anything to suggest that you or others face risk of harm, they will immediately notify study investigators and your health care team.
4. Home visits will occur as part of this study. You will be allowing study staff/coaches into your home, and there is a risk that they may observe something that raises concerns, including the potential that you are being abused, neglected, or are unable to take care of yourself. We are required by state law to report any observed abuse or neglect to the appropriate authorities, or your primary health care provider resulting in legal or social risks to you or other members of your household. Your primary care provider may contact you as a result of this communication.

5. Referral to your primary care provider or emergency medical services may occur if you request assistance or the coach determines that you need additional care.

G. HOW WILL MY PRIVACY BE PROTECTED AND WHO WILL USE MY HEALTH INFORMATION?

To protect your privacy, all verbal discussions and coaching sessions will occur in private, either in person (in a location of which you approve) or via telephone. The research team will collect and maintain all of your Private Health Information securely. The information collected from you during this study will be used by the researchers at the UW-Madison and its partners on this study, including UW Health, the Sugar River Senior Center (if you and/or you care recipient are eligible to receive services), and Georgia Southwestern State University. Federal or state laws may permit or require us to show information to university or government officials, and sponsors at the National Institute on Aging responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as adult protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to elder abuse or suicidal thoughts).

We will take the following steps to keep your information private and confidential:

1. Electronic data will be maintained in an electronic data management system on a UW Madison School of Medicine and Public Health server and maintained by its IT staff.
2. Paper data will be kept in secure areas to which only the study staff have access.
3. At the end of all study activities, the UW research team will destroy all information that can identify who you are.
4. When we write or tell people about this study we will not use your name or anything else that could let people know who you are.
5. Health Information you provide may be shared with your health care providers using a secure, HIPAA compliant UWHealth system. The purpose of this sharing this information is to guide your health care team in how best to ensure your health and wellbeing. This information may be entered into your medical record by members of your primary care team if it seems relevant to your treatment.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Individuals at UW-Madison and its affiliates who may need to use your health information in the course of this research:

- UW-Madison regulatory and research oversight boards and offices
- Members of the research team
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Others <u>outside</u> of UW-Madison and its affiliates who may receive your health information in the course of this research:

- Collaborating researchers outside UW-Madison, including a study team member from Fitchrona EMS
- National Institutes of Health
- The U.S. Office for Human Research Protections
- The Rosalynn Carter Institute for Caregiving at Georgia Southwestern State University [responsible for training, fidelity, and oversight of the REACH intervention protocol]

People outside the UW-Madison and its affiliates who receive your health information may not be covered by privacy laws and may be able to share your health information with others without your permission. Usually when we share information from research studies with others outside the UW-Madison and its affiliates; it is not shared in a way that can identify an individual.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you or the person with dementia for whom you provide care. At most, the website will include a summary of the results. You can search this website at any time.

Will information from this study go in my medical record?

- Coaches and researchers will not be entering any information, survey question answers, or assessments into your medical record or the record of your care recipient.
- However, your health care team (doctors, nurses, and care coordinators) may choose to enter some of the observations or information communicated to them by your coach. They would only add this information to your medical record, or the record of your care recipient, if they feel it would be useful for members of the healthcare team to know, or would want to follow up with you about.

<u>H. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?</u>

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study. You may completely remove yourself from the study at any time. You also may choose to stop taking part or skip any questions that you do not feel comfortable answering.

If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from the UW Madison and its affiliates will not be affected in any way.

I. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study from that point forward.
- To take back your authorization, you will need to tell the researchers by writing to or calling:

  Manish N. Shah, MD, MPH
  UW Madison School of Medicine and Public Health
  Department of Emergency Medicine
  800 University Bay Drive
  Suite 310, Mail Code 9123
  Madison, WI 53705
  608-890-6892
  mnshah@medicine.wisc.edu

J. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Lead Researcher, Manish N. Shah, MD, MPH, at 608-890-6992. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

AGREEMENT TO PARTICIPATE IN THIS STUDY
AND
PERMISSION TO USE AND/OR SHARE MY HEALTH INFORMATION

I have read this consent and authorization form. It describes the research study procedures, risks, and benefits of being in the study. It also describes what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above.

Name of Participant (please print): _____

_____ _____
Signature of Participant Date

_____ I give my permission to be contacted in the future about other research studies.
Initials

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT.

Signature of person obtaining consent, assent (when necessary), and authorization:

_____ _____
Signature Date