

**Community Paramedic Coaching Program for Caregivers and
People with Dementia (CP3D)**

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UNIVERSITY OF WISCONSIN-MADISON

**Subject 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)

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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 have a diagnosis of dementia and are living with your primary caregiver. 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."

If you are consenting to participate in this study as the legally authorized representative (LAR) for the study participant, by signing this form, you are providing consent on behalf of the person you represent.

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. At the start of the study, you will be asked a few short demographic questions, followed by a formal dementia assessment as a benchmark and to help inform the delivery of the intervention sessions given to your primary caregiver. This assessment generally takes about 10 minutes to complete, and will be conducted in person by a member of the research team.

This assessment is purely for research purposes, and will not be used for any type of diagnosis or in your clinical care.

What to expect: Over the course of this year, paramedic coaches will come to your home to deliver caregiver-focused coaching sessions. These sessions will be every week for about a month, and then 1-2 times each month for the rest of the year. The coach will be meeting with your caregiver at your house for 1-2 hours at each of these visits. You are not required to participate in any of these sessions,, but there is the possibility that your caregiver might ask for your input about topics addressed during these sessions at a later time.

Some of the information that your caregiver tells the coach will be communicated back to your 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 shared with our local social service partners so they can provide or connect you/your caregiver to community services that your coach and healthcare team think might help.

We will also collect data from your electronic health record during this year, and for 1 year after you and your caregiver have completed all intervention visits, to monitor your health, progress, and use of healthcare services.

You are free to withdraw from this study at any time. If the caregiver with whom you are participating decides to withdraw, your participation in the study will also end.

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 will continue to have these visits as you normally would. As part of this study, your caregiver 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 healthcare team, who may choose to enter it into your medical record so they can follow up with you or use it during your healthcare appointments.

Will I receive the results of research tests?

All of the tests and survey questions that your caregiver answers 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 tests.

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. Although *caregiver* participants will likely receive some measure of direct benefit from full participation, direct benefits to *patients* with dementia are currently unknown. Therefore 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 your caregiver takes, you (yourself and your caregiver 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 your caregiver, who can then share the payment between the two of you.

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 taking the initial cognitive assessment, 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 causing 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 or neglected. 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 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 caregiver 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 talk to people who are not officially part of the study team, we will not use your name or anything else that could let people know who you are.
5. Health Information you or your caregiver provide could be shared with your health care providers using the secure, HIPAA compliant communication system used by UWHealth. The purpose of 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 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 outside 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 or your caregiver 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 your caregiver. 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 or assessments into your medical record or the record of your caregiver.
- 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 caregiver's coach. They would only add this information to your

medical record if they feel it would be useful for members of your healthcare team to know, or would want to follow up with you/your caregiver about.

H. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

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 (or do not permit a Legally Authorized Representative to sign the form on your behalf), 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.

If you are a Legally Authorized Representative (LAR) for the person being invited to take part in this study, you are deciding whether the person can be in this research study. You do not have to sign this form. If you refuse to sign, however, the person cannot take part in this research study. If you sign the line below, it means that:

- you believe the person wants, or would want, to be in the study;
- OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest
- you give authorization for the person's protected health information to be used and shared as described in this form

Name of Participant (please print): _____

Signature of Participant

Date

AND, if the participant lacks consent capacity:

Signature of Legally Authorized Representative

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