INFORMED CONSENT FORMS

Comparative Effectiveness of Health System-Based Versus Community-Based Dementia Care/A Pragmatic Trial of the Effectiveness and Cost-Effectiveness of Dementia Care: The D-CARE Study

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University of California, Los Angeles

RESEARCH INFORMATION SHEET

A Pragmatic Trial of the Effectiveness and Cost-Effectiveness of Dementia Care:
The D-CARE Study

INTRODUCTION

David B. Reuben MD, from the David Geffen School of Medicine at the University of California, Los Angeles is leading a team conducting a research study. This study is being funded by the Patient-Centered Outcomes Research Institute (PCORI) and the National Institute on Aging (NIA).

You were selected as a possible participant in this study because you are a person living with dementia or a person who cares for someone with dementia. Your participation in this research study is voluntary.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

WHY IS THIS RESEARCH BEING DONE?

This study is being done to find better ways of caring for people with dementia and supporting the family members and friends who take care of them (sometimes called caregivers).

This study will compare three different approaches to supporting people with dementia *and* their caregivers. These three approaches do **not** replace the care that is provided by doctors to the person with dementia. These approaches are **in addition** to the care that is provided by doctors.

You will be one of up to 700 participants at <name of site>. At this location:

- Up to 315 people with dementia and their caregivers (about half) will be assigned to receive additional care provided by a clinician in your health system (this care will include an in-office or telemedicine visit – your usual co-pay may be required)
- Up to 315 people with dementia and their caregivers (about half) will be assigned to receive additional care provided by a care consultant who is based at a community organization, (this care will be by telephone) and

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- Up to 70 people with dementia and their caregivers (the remainder) will continue to receive usual care from your providers, plus receive access to the national Alzheimer's Association 24-hour telephone helpline.

Both the Caregiver and Care Recipient will be assigned to the same group. We will use a computer to assign you by chance (randomly) to 1 of the 3 study groups. It is like flipping a coin. This way we can find out which program works best in a fair way.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

Participation will take a total of about 5 ½ hours of your time, over 1 ½ years (or 18 months).

If you are the Caregiver and volunteer to participate in this study, the research team will ask you to do the following:

- Have a Baseline telephone interview (about 1 ½ hours)
- Have 4 follow-up telephone interviews over 18 months (about 1 hour each call)

If you are the Care Recipient and volunteer to participate in this study, the research team will ask you to:

- Complete a Baseline Interview (about 1 ½ hours)
- One Follow-Up interview in 18 months. (about 1 hour)

This section only applies to people who are the spouses *and* the main caregiver for the person with dementia.

- In addition to the telephone interviews mentioned above, we are requesting permission to review your use of health care services from Medicare and other health insurance providers.
- We will not be reviewing your actual medical records, but only what health services you use from Medicare and other health insurance providers, such as visits to doctors, hospitals and other health care providers.

  The reason that this information is important is that it will allow us to determine if being the main caregiver for your spouse affects your health and the amount of health care services that you use.

ARE THERE ANY RISKS IF I PARTICIPATE?

There are no anticipated risks or discomforts. If any of the questions that we ask during the telephone calls make you uncomfortable, you can skip those questions. You can also choose to stop the phone calls at any time.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You may or may not benefit from being in the study. If you take part in this study, other people with dementia, and their caregivers may be helped.

The results of the research may provide evidence about better ways to provide care for persons with dementia, including supporting caregivers. In turn, the results may help persuade health care systems to adopt these new approaches and lead to Medicare and other insurers paying for this care.

What other choices do I have if I choose not to participate?

This study will not replace the care that is provided by doctor(s) to the person with dementia. Care Recipients will keep their current doctor(s). This study is meant to find better ways of adding to the current care that is being provided by their doctor(s).

At this time, there are no other options offered other than the care currently provided by a doctor. Your alternative is to not to be in the study.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

We will label your information with a code number. The master list that links your name to your code number will be stored securely accessible only to the research team. We won't share your study results with anyone unless you ask us to. Your name won't appear in any reports or presentations about this study.

How information about you will be stored:

We will store all your research records in locked cabinets, and secure computer files and databases – much like how your medical records are currently stored.

People and agencies that will have access to your information:

The research team and authorized UCLA personnel may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.

USE OF DATA FOR FUTURE RESEARCH

Your data, including de-identified data, may be kept for use in future research. The research team will keep your data for 7 years after the study is complete.

WILL I BE PAID FOR MY PARTICIPATION?

If you are the Caregiver, you will receive $20 after you complete the Telephone Baseline Interview and you will receive $20 after you complete the last Telephone Interview (1½ years after you begin the study). This is a total of $40. Each payment will be mailed to you as a check or debit card.

If you are the Care Recipient, you will receive $20 after you complete the Telephone Baseline Interview and you will receive $15 after you complete the last Telephone Interview (1½ years after you begin the study). This is a total of $35. Each payment will be mailed to you as a check or debit card.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have any questions, comments or concerns about the research, you can talk to one of the researchers. Please contact Dr. <name of site PI> at <phone number>.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Please keep this copy for your records.

Caregiver Telephone Verbal Consent to Participate in Dementia Care (D-CARE) Study

Hello, my name is [NAME]. I am calling from D-CARE, the Dementia Care Study, which is taking place at [PRACTICE NAME]. You were recently called by a member of our team to determine whether you were eligible for the D-CARE study and you expressed interest in participating.

Is this a good time to talk?

CONTINUE ->	Yes	☐ 1
END INTERVIEW ->	No	☐ 2
	Refused	☐ 7
	DK	☐ 8

[*If 'No'*] Is there a better time for me to call?

SCHEDULE CALLBACK ->	Yes	☐ 1
END INTERVIEW ->	No	☐ 2
	Refused	☐ 7
	DK	☐ 8

Call back date:_____Call back window (e.g., 9-11 am): _____
[Thank them for their time and hang up]
[Return to Baseline Call Record, log the current contact details and record as "Temporary hold" and enter the call back information]

[*If 'No' / do not call back, Refusal, DK*]
[Thank them for their time and hang up]
[Return to Baseline Call Record, log the current contact details and record final outcome of the Baseline (i.e., Refusal).]

Before we can start, I need to make sure that you are informed about the D-CARE study and provide consent for participation. As we move through this, feel free to ask any questions you may have.

You are being asked to join this research study because you take care of a person with dementia. The person that you care for will also be asked to take part.

About 2150 people with dementia and their caregivers will take part in the D-CARE study at four different locations across the United States. Your participation in the study will be strictly voluntary. This study is being done to find better ways of caring for people with dementia and supporting the family members and friends who take care of them (sometimes called caregivers).

This study will compare three different approaches to supporting people with dementia *and* their caregivers. You will be one of up to 700 participants at <name of site>. At this location approximately:

- Up to 315 people with dementia and their caregivers will be assigned to receive additional care provided by a clinician in your health system (this will include an in-office or telemedicine visit – your usual co-pay may be required)
- Up to 315 people with dementia and their caregivers will be assigned to receive additional care provided by a care consultant who is based at a community organization, (this care will be by telephone) and
- Up to 70 people with dementia and their caregivers will be assigned to receive assistance from the National Alzheimer's Association 24-hour telephone helpline

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These three approaches do **not** replace the care that is currently being provided by doctors to the person with dementia, rather they are **in addition** to that care.

This study will help us find out which of these three approaches is most beneficial.

We will use a computer to assign you randomly to 1 of the 3 study groups. This means we will put you into a group by chance. It is like drawing names from a hat.

You will be asked to complete a Baseline Interview on the telephone and four (4) follow-up telephone interviews over the next 18 months. We are doing the follow-up interviews to determine if the care has resulted in any changes in your loved one's dementia, as well as any changes in how caregiving has affected you. Each of the follow-up phone interviews will take approximately 1 hour. In total, your participation in collecting information for this research study will take about 5 ½ hours over 1 ½ years (or 18 months). We will also obtain information from Medicare and other insurers about medical and health services that **[PwD name]** receives.

Your confidentiality is one of our main concerns. Any information that is obtained from this study that can identify you will remain confidential. It will only be released with your permission or as required by law.

This study does not involve anything that causes pain. Your participation will be through telephone interviews. You may refuse to answer any questions that you do not want to answer and still remain in the study. Whether or not you decide to take part in this study, or if you later decide to stop participating, [Pwd Name] will continue to receive care from his/her regular doctor.

For your time, you will receive $20 after you complete the Baseline telephone interview. You will also receive $20 after you complete the last telephone interview. This is a total of $40. Each payment will be mailed to you as (Site indicate: a check or debit card).

Do you have any questions about the study or what is being asked of you?

Would you like to take part in the study?

Yes ☐1

IF NO, END INTERVIEW -> No ☐2

[If No, END] Thank you for your time and answering my questions. Have a nice day.
[Return to Baseline Call Record, log the current contact details and record final outcome of the Baseline Interview (Caregiver refused consent)]

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Do I have your consent to enroll you in the D-CARE Study?

Yes ☐1

IF NO, END INTERVIEW -> No ☐2

[If No, END] Thank you for your time and answering my questions. Have a nice day.

[Return to Baseline Call Record, log the current contact details and record final outcome of the Baseline Interview (Caregiver refused consent).]

[If Yes] (This section only applies to <u>spouses</u> aged 65 and older who are the main caregiver for the person with dementia)

In addition to the telephone interviews mentioned above, we are requesting permission to review your use of health services from Medicare and other health insurance providers for the duration of the study. You do not need to participate in this part of the study to participate in the main study.

We will not review your actual medical records, but only what health services you use from Medicare and other health insurance providers, such as doctors, hospitals and other health care providers.

You will not have to do anything for us to collect your information on your use of health services from Medicare. If you give us permission, we will receive this information directly from Medicare. This information will cover a period of about 3 ½ years, starting 1 year before today and ending 2 ½ years after.

The reason that this information is important is that it will allow us to determine if being the main caregiver for your spouse affects your health and the amount of health care services that you use.

Would you like to participate in this part of the study?

Yes ☐1

No ☐2

Name of Participant (Caregiver): _____

Name of person obtaining Consent:

_____ _____

Print Name Date:

The person obtaining consent verifies that the form was read aloud in its entirety (check box to confirm).

☐

Would you like to be contacted for future research studies?

Yes ☐1

No ☐2

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Thank you, before proceeding with the remainder of your interview we would like to speak with **[PwD name]**. This will involve a few questions about [his/her] memory and quality of life.

[Instructions: If you have a speaker phone, it might be helpful to put the speaker on.]

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Care Recipient Telephone Verbal Consent to Participate in Dementia Care (D-CARE) Study

If MOCA score is ≥17, continue with consenting process with Care Recipient
If MOCA score is <17, obtain verbal consent from Caregiver or LAR (if different than caregiver)

Before we proceed, I need to make sure that you are informed about the D-Care study and provide consent for participation. As we move through this, feel free to ask any questions you may have.

You are being asked to join this research study because you have a diagnosis of dementia. The person that provides most of the care for you will also be asked to take part. To be included in the study, both of you must agree to participate. During this study, if you become incapable of making the decision to continue to participate, your caregiver will decide for you.

About 2150 people with dementia and their caregivers will take part in the D-CARE study at four different locations across the United States. Your participation in the study will be strictly voluntary. This study is being done to find better ways of caring for people with dementia and supporting the family members and friends who take care of them (sometimes called caregivers).

This study will compare three different approaches to supporting people with dementia *and* their caregivers. These three approaches do **not** replace the care that is provided by your doctor(s). These approaches are **in addition** to the care that is provided by your doctors.

This study will help us find out which of these three approaches is most beneficial.

You will be one of up to 700 participants at <name of site>. At this location approximately:

- Up to 315 people with dementia and their caregivers will be assigned to receive additional care provided by a clinician in your health system (this will include an in-office or telemedicine visit – your usual co-pay may be required)
- Up to 315 people with dementia and their caregivers will be assigned to receive additional care provided by a care consultant who is based at a community organization, (this care will be by telephone) and
- Up to 70 people with dementia and their caregivers will be assigned to receive assistance from the National Alzheimer's Association 24-hour telephone helpline

You and your caregiver will be assigned to the same group. We will use a computer to assign you randomly to 1 of the 3 study groups. This means we will put you into a group by chance. It is like drawing names from a hat.

You will be asked to complete a Baseline Interview over the phone today and one follow-up telephone interview in about 18 months from now. We are also asking you to allow us to review your use of services from Medicare and other insurers.

Your confidentiality is one of our main concerns. Any information that is obtained from this study that can identify you will remain confidential. It will only be released with your permission or as required by law.

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This study does not involve anything that causes pain. Your participation will be through telephone interviews. You may refuse to answer any questions that you do not want to answer and still remain in the study. Whether or not you decide to take part in this study, or if you later decide to stop participating, you will continue to receive care from your regular doctor.

For your time, you will receive $20 after you complete the Baseline telephone interview today. You will also receive $15 after you complete the last telephone interview. This is a total of $35. Each payment will be mailed to you as a (Site indicate: check or debit card).

Do you have any questions about the study or what is being asked of you?

Would you like to take part in the study?

Yes ☐1

IF NO, END INTERVIEW -> No ☐2

[If No, END] Thank you for your time and answering my questions. Have a nice day.
[Return to Baseline Call Record, log the current contact details and record final outcome of the Baseline Interview (Refusal).]

Do I have your consent to enroll you in the D-CARE Study?

Yes ☐1

IF NO, END INTERVIEW -> No ☐2

[If No, END] Thank you for your time and answering my questions. Have a nice day.

[Return to Baseline Call Record, log the current contact details and record final outcome of the Baseline Interview (Refusal).]

Name of Participant (Care Recipient): _____

Name of Caregiver or Legally Authorized Representative:

_____

Name of person obtaining Consent:

_____
Print Name

Date: _____

Verbal Consent Care Recipient D Care Study 08.28.20

The person obtaining consent verifies that the form was read aloud in its entirety (check box to confirm).

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If MOCA 17 or greater:
[AFTER CONSENT OBTAINED, COMPLETE THE Patient Baseline Interview and QOL INSTRUMENT WITH THE CARE RECIPIENT. THEN TRANSITION INTERVIEW BACK TO THE CAREGIVER]

If MOCA <17:
[AFTER CONSENT OBTAINED, COMPLETE QOL INSTRUMENT WITH THE CARE RECIPIENT. THEN TRANSITION INTERVIEW BACK TO THE CAREGIVER]

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