Study Title: Effectiveness of Engaging in Advance Care Planning Talks **(ENACT)** Group Visits Intervention in Primary Care for Older Adults with and without Alzheimer's Disease
Principal Investigator: Hillary D Lum, MD, PhD
COMIRB No: 20-1978
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What this study is about:

This study plans to learn more about how to improve advance care planning for patients through their primary care clinic.

You are being asked to be in this study ONLY because you or your loved one receive primary care here. You were NOT chosen to be in the study because of any medical problems that you or your loved one might have. Also, you were NOT chosen because your doctor or the doctors leading this study think that you need to fill out these forms.

What is this study asking you to do?

If you join this study, and you are a Patient:

1. We will ask you about your advance care planning experiences and perspectives on your health. These surveys are estimated to take no more than 20-30 minutes. We will ask brief questions to assess your memory. Study staff will let you know what your score is on the memory screen and will let you know what is considered a normal score. The results of the memory screen are not a diagnosis.

2. After the surveys, you will be randomly selected to receive advance care planning information in one of two ways:
    a) Advance care planning information by mail
    b) Advance care planning information by mail and two group medical visits, about one month apart, held at your primary care clinic. You will be with approximately 8-10 other patients who are also part of the study. Each group visit takes about 2 hours. A group visit provides support, education, and discussion about advance care planning. Group visits will be video-audio recorded. This allows us to study how the group visits intervention works. Recordings will not be distributed or used for any other purpose except research.

If you are selected to receive advance care planning in the group medical visit setting, a clinic visit copayment will be charged. These visits are part of your medical care. Your normal insurance copayments will apply.

3. Six months after joining the study, we will contact you by phone to ask a few brief survey questions about your experience. This should take about 20-30 minutes.

4. Also at six months, some individuals will be invited to participate in a voluntary phone or video interview to ask about what worked and what did not work in the group visit. These interviews may be 20-30 minutes.

5. Study staff will collect data from your medical record to use as part of the study. Information that could identify you (e.g., name, address, date of birth) will not be included in publications.

After the study is over (6 months) and you received advance care planning information by mail, you can choose to participate in the advance care planning group medical visits as part of your medical care.

If you join this study, and you are a <u>Support Person or Caregiver of a Patient</u>:

1. We will ask you to complete brief surveys about your relationship to the patient and demographic questions. These surveys are estimated to take no more than 5 minutes.

2. You will be invited to participate in the study with the patient, who will be randomly selected to receive advance care planning information in one of two ways:
    a) Advance care planning information by mail
    b) Advance care planning information by mail and two group medical visits at the patient's primary care clinic. You will participate as a support person/observer. This group is not part of your clinical care. Group visits will be video-audio recorded.

3. Six months after joining the study, some individuals will be invited to participate in a voluntary phone or video interview to ask about what worked and what did not work in the group visit. These interviews are anticipated to take about 20-30 minutes.

What are the possible risks/side effects:

1. *Psychological Discomforts*: Some people may feel discomfort thinking or talking about advance care planning or end-of-life issues. If you feel uncomfortable, you can stop looking at the advance care planning materials, stop participating in the group visits, and stop answering any questions at any time. Some patients may experience discomfort related to the memory screening.
2. *Loss of Confidentiality*: In any study there is a risk of loss of privacy. Every effort will be made to protect your privacy and confidentiality. If you are part of the group visit, we will remind all participants about the importance of maintaining each other's privacy. Your study records will be kept safe in secured electronic servers and will be destroyed at the end of the study.
3. There may be risks the researchers have not thought of.

This study is voluntary. You have a choice about being in this study. You do not have to be in this study if you do not want to be. You may choose to stop actively participating in the study at any point and we will not contact you further. We will continue to collect data from your medical record to use as part of the study unless you notify Dr. Hillary Lum in writing at:

Hillary Lum, MD, PhD
12631 East 17th Ave
Mail Stop B-179
Aurora, CO 80045
Hillary.Lum@cuanschutz.edu

If you are a patient, you will be offered a $25 gift card for completing the first part of the study and another $25 gift card for completing the 6-month survey.
If you are a care partner and asked to participate in an interview, you will be offered a $25 gift card.

If you or someone else discloses information about an incident (such as elder abuse) that we are legally required to report it, we will do so.

This study is not designed to benefit you directly.
This research is being paid for by National Institute on Aging

Privacy and Confidentiality

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The Colorado Multiple Institutional Review Board (a committee that reviews and approves research studies)
- The National Institutes of Health, the study sponsor

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, any identifiable information, or document from the research. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings. These protections apply only to your research records.

If you have questions, you can call Dr. Hillary Lum at (303) 724-1911. You can call to ask questions at any time. You may have questions about your rights as someone in this study. If you have questions, you can call COMIRB (the responsible Institutional Review Board) at (303) 724-1055.

Contact for future research recruitment: We would like to use the data collected in this study to assess if you are eligible for future clinical research studies. If you agree to allow this, you will be added to a research recruitment database. If you do not agree, you will not be added to the

research recruitment database and will not be contacted about other research opportunities.

Even if you agree, you can always withdraw your permission or consent to be contacted for future studies at a future time. To do this, please call Dr. Hillary Lum at (303) 724-1911 and say you no longer wish to be contacted for research studies.