TITLE: ENgaging in Advance Care Planning Talks Group Visit Intervention for Cognitive Impairment (ENACT-aMCI)

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For Use
25-Sep-2018
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Study Title: ENgaging in Advance Care Planning Talks Group Visit Intervention (ENACT) for individuals with amnestic Mild Cognitive Impairment

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about how to improve advance care planning for patients with memory impairment.

Advance care planning is a process where individuals can think about what's important to them regarding future medical care if they are seriously ill. It can include talking with others, choosing someone to help make medical decisions if you are too sick to make decisions for yourself, and completing medical forms that tell their doctors what kind of medical care you want.

You are being asked to be in this research study because you have AD, DS, or are being evaluated for thinking/memory issues.

You must also have a study partner (a family member or close friend) who knows you well and is willing to accompany you to annual research visits.

Up to 12 people (6 patients and 6 study partners) will participate in focus groups for this study.

What happens if I join this study?

If you join the study, you will be invited to participate in 3 focus groups over one year. Focus groups will last roughly 2 hours

In the focus group, we will be asking you to discuss and provide feedback for advance care planning group visits for individuals with amnestic Mild Cognitive Impairment. We will be audio recording and videotaping the focus groups with your feedback and collecting your feedback on brief questionnaires.

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 any publications.

Contact for future research recruitment: If you agree, we would like to use the data collected in this study to assess if you may be eligible for future clinical research studies.

I am interested in being contacted for participation in future research studies:

YES_____ NO_____

Initials_____

Participant Initials_____

For verbal consent: Study Staff Initials _____

You can always withdraw your consent to be contacted for future studies at a later date. In order to do this, please call Dr. Hillary Lum at (303) 724-1911 and say you no longer wish to be contacted for research studies.

HIPAA Authorization for Optional Additional Study Procedures – *[delete the remainder of this section if there are no optional procedures in this study]*

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

What are the possible discomforts or risks?

1. Discomforts: Some people may feel some 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 focus groups, and stop answering any questions at any time.

2. Confidentiality: In any study there is always a risk of some loss of confidentiality. Focus groups will be held in a conference room or other space with a closed door and information remains private. Your study records will be kept safe in locked cabinets and will be destroyed at the end of the study. Only Dr. Lum will be able to open these cabinets. There is risk for loss of confidentiality inherent in any group setting.

3. Inconvenience: You will be asked to complete brief questionnaires and to participate in group discussions during focus group sessions lasting two hours which may take up to 10 minutes in total. You will be given a $50 check after participating in each of the three focus groups.

Certificate of Confidentiality:
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, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. 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. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how individuals with memory impairment want to receive advance care planning information. This could help doctors take better care of patients when they are very sick. All participants will receive information about advance care planning.

Who is paying for this study?

This research is being paid for by the National Institutes of Health (National Institute on Aging).

Will I be paid for being in the study? Will I have to pay for anything?

You will each be given a $50 check after participating in each of the three focus groups.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Hillary Lum. You may ask any questions you have now. If you have questions later, call Hillary Lum at (303) 724-1911.

You may have questions about your rights as someone in this study. You can call Hillary Lum with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Hillary D Lum, MD, PhD
12631 E 17th Ave, Mail Stop B179
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institutes of Health/National Institute on Aging, who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Video-audio Recordings will be collected and kept secure by study personnel. The files will be transferred to a password protected secure computer network and the originals will be destroyed. All files will be kept for 7 years because they are part of research, and then also destroyed.

You have the right to request access to your personal health information from the Investigator. Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Psychological tests (brief cognitive screening tests may be conducted)
- Other: Advance care planning documentation in Medical Records

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date/Time:_____

Print Name: _____

For use with non-reading subjects:

Witness Signature:_____ Date:_____

Witness Print Name:_____

Study Partner Information and Consent

As the subject's study partner, you have important tasks that need to be carried out in order for the study to be conducted in the best manner possible. These responsibilities include:

1) You must attend all research visits, and then be available for in-person surveys and an interview and/or survey by phone.
2) You are an important source of information about the subject. You will be asked questions either in person, on the phone, and/or through online surveys to find out whether there are any changes in the subject.
3) We will not collect and record information about you, but we will record your answers to questions about the subject.
4) Your participation in the focus groups will be recorded using audio-visual technology and these recordings will be accessible only to study staff.

If for some reason you become unable to carry out your responsibilities or do not wish to be the study partner, please tell the study coordinator immediately. You may be asked, if possible, to select a substitute who can take over your duties.

Agreement to be the study partner for this study

I have read all the preceding information which describes both the subject's participation in the study and my involvement as the subject's study partner. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Study Partner Signature:_____Date:_____

Print Name:_____

Person Obtaining Consent:_____Date/Time:_____

Print Name:_____

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Advance care planning is a process where individuals can think about what's important to them regarding future medical care if they are seriously ill. It can include talking with others, choosing someone to help make medical decisions if you are too sick to make decisions for yourself, and completing medical forms that tell their doctors what kind of medical care you want.

You are being asked to be in this research study because you have memory issues or are being evaluated for memory issues.

You must also have a study partner (a family member or close friend) who knows you well and is willing to participate with you.

Up to 40 people (20 patients and 20 study partners) will participate in this study.

What happens if I join this study?

If you join the study, you will be invited to participate in up to two group visits with up to 10 people held one month apart. Group Visits will last roughly 2 hours. A group visit tries to provide support, education, and discussion about advance care planning.

Three months after joining the study and participating in the focus groups, we will contact you by phone to ask a few brief survey questions about your experience. This should take about 10-20 minutes.

Some participants will be contacted within one week to participate in a brief interview to learn about what worked and what did not work in the group visit. These individuals will be selected randomly for interviews, using a computer program.

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 any publications.

Contact for future research recruitment: If you agree, we would like to use the data collected in this study to assess if you may be eligible for future clinical research studies.

I am interested in being contacted for participation in future research studies:

YES_____ NO_____

Participant Initials_____

For verbal consent: Study Staff Initials _____

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.

HIPAA Authorization for Optional Additional Study Procedures – *[delete the remainder of this section if there are no optional procedures in this study]*

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If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

What are the possible discomforts or risks?

1. Discomforts: Some people may feel some 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.

2. Confidentiality: In any study there is always a risk of some loss of confidentiality. At the group visit, we will remind all participants about the importance of not sharing any information outside of the group. Group visits are held in a conference room or something similar with the door closed and information remains private. Your study records will be kept safe in locked cabinets and will be destroyed at the end of the study. Only Dr. Lum will be able to open these cabinets.

3. Inconvenience: You will be asked to complete brief surveys and/or follow up interviews, which may take up to 10 minutes in total. You will be given a $50 check after participating in the group.

Certificate of Confidentiality:
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, with the exceptions listed below. 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. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse or elder abuse, and required communicable disease reporting, or
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What are the possible benefits of the study?

This study is designed to learn more about how individuals with memory impairment want to receive advance care planning information. This could help doctors take better care of patients when they are very sick and unable to make decisions for themselves. All participants will receive information about advance care planning and will be invited to participate in group visits.

Who is paying for this study?

This research is being paid for by the National Institutes of Health (National Institute on Aging).

Will I be paid for being in the study? Will I have to pay for anything?

You will each be given a $50 check after participating in the group visits.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

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The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

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We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institutes of Health/National Institute on Aging, who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Video-audio Recordings will be collected and kept secure by study personnel. The files will be transferred to a password protected secure computer network and the originals will be destroyed. All files will be kept for 7 years because they are part of research, and then also destroyed.

You have the right to request access to your personal health information from the Investigator. Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory studies, radiology studies, procedure results
- Psychological tests (brief cognitive screening tests may be conducted)
- Advance care planning documentation in Medical Records

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to improve health. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. If I choose to be in this study, I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

For use with non-reading subjects:

Witness Signature:_____ Date:_____

Witness Print Name:_____

Study Partner Information and Consent

As the study participant's study partner, you have important tasks that need to be carried out in order for the study to be conducted in the best manner possible. These responsibilities include:

1) You must attend both research visits and then be available for an in-person survey and an interview and/or survey questions by phone.
2) You are an important source of information about the subject. You will be asked questions either in person or on the phone.
3) We will not collect and record information about you, but we will record your answers to questions about the subject.
4) Your participation in the focus groups will be recorded using audio-visual technology and these recordings will be accessible only to study staff.

If for some reason you become unable to carry out your responsibilities or do not wish to be the study partner, please tell the study coordinator immediately. You may be asked, if possible, to select a substitute who can take over your duties.

Agreement to be the study partner for this study

I have read all the preceding information which describes both the subject's participation in the study and my involvement as the subject's study partner. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Study Partner Signature:_____Date:_____

Print Name:_____

Person Obtaining Consent:_____ Date:_____

Print Name:_____