Project Title: **BUILDING A BRIDGE (between clinical and community care): Post-diagnosis support for persons with dementia and their family**

NCT 201804835

Principal Investigator: Sato Ashida

Date of Document: update approved on 8/26/2020

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INFORMED CONSENT DOCUMENT

Project Title: **BUILDING A BRIDGE (between clinical and community care): Post-diagnosis support for persons with dementia and their family (NCT 201804835)**

Principal Investigator: Sato Ashida

Research Team Contact: Lena Thompson, 319-384-1491, lena-thompson@uiowa.edu

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are an adult caretaker of someone who has been diagnosed with Alzheimer's Disease or Related Dementias (ADRD) within the past 6 months.

The purpose of this research study is to evaluate the impact of a new Options Counselor-Health Education (OC-HE) intervention that brides the medical and community-settings to support caretakers of newly-diagnosed ADRD patients.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 106 people will take part in this study conducted by investigators at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 6 months. All participants will complete a 20-30 minute baseline, 3 month, and 6 month interview with a member of the research team. If you are randomized into the immediate intervention group, our Options Counselor will make one in home visit within two weeks of your completion of the baseline interview and five monthly phone calls over the next six months. The in person visit will range from 1-2 hours in length and can be completed over the phone if preferred. The monthly phone calls will range from approximately 30 minutes to 1 hour in length. If you are randomized into the delayed intervention group, you will receive the intervention from the Options Counselor after you have completed the 6 month interview.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to sign this consent document, the research assistant will set up a time to complete a baseline interview, either in-person or via telephone. The baseline interview will take 20-30 minutes to complete. Once the baseline survey has been completed, you will be randomized into either the immediate or delayed intervention group. If you are put into the immediate intervention group, our Options Counselor will be given your contact information and will make an in-home or telephone (if preferred) visit within two weeks of your completion of the baseline interview. If you are randomized into the delayed intervention group, the Options Counselor will make this visit after you have completed the 6 month interview. During the initial visit/call, the Options Counselor will assess family needs to develop family actions plans using LifeLong Links to identify local services and to connect you to providers. The Options Counselor will also provide dementia education on the topics that you and your family desire to discuss. The five monthly follow up intervention calls will be used to adjust action plans and implement additional educational modules you select. You will also complete 3 month and 6 month follow-up interviews, either in person or via telephone. The follow up interviews ask similar questions to the baseline interview. Each interview will take between 20 and 30 minutes to complete. If you wish to continue to receive Options Counseling services after the six months of the intervention are complete, you will receive a call from a local options counselor in your area who will continue the services. All participants will receive $20 incentive after each of the three interviews.

If we detect that you may have depression or anxiety through the interviewsyou do, our research assistant will contact you to let you know and will encourage you to consult with your family physician or a counselor. Our surveys only include screening tools that do not allow us to determine diagnosis.

Audio Recording

One aspect of this study involves making audio recordings of you during the baseline and follow-up interviews. These audio recordings will be collected to ensure that all of your answers are collected accurately. The audio files will be stored on the University of Iowa secured server in a folder only accessible to members of the research team. Audio recordings will be destroyed immediately after your data has been entered into our database. If you refuse to be audio recorded, you are still eligible to be enrolled in this study.

[ ] Yes [ ] No I give you permission to make **audio recordings** of me during this study.

WHAT ARE THE RISKS OF THIS STUDY?

While there is minimal physical risk associated with participation in surveys and interviews, potential psychological risk may exist for participants who are under a great amount of stress after their loved one has received a diagnosis of Alzheimer's or related dementia. The intervention being tested aims to ameliorate such stress. Some participants may have difficulty reporting about their support systems if the support they receive from family and friends are not perceived as adequate or realize that they may

not have adequate support systems to care for their loved one. We do not anticipate financial, social or legal risks among the participants in this project.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will personally benefit from being in this study. However, we hope that, in the future, other people might benefit from this study. If the intervention is found to be efficacious, it could reduce the proportion of unpaid caregivers who report unmet need for caregiver support services.

Instead of being in this study, you could seek a local options counselor on your own.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. So that we can mail you a check, you will need to provide your address. You will be paid $20 per interview you complete that is estimated to take between 20-30 minutes. Since you will complete a baseline, 3 month, and 6 month interview, you will be eligible to receive $60 for participation in this study. If you complete at least 51 percent of the interview questions, you will be eligible to receive the $20.

WHO IS FUNDING THIS STUDY?

The Department of Health and Human Services, National Institute of Health is funding this research study. This means that the University of Iowa is receiving payments from the Department of Health and Human Services, National Institute of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the Department of Health and Human Services, National Institute of Health for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

To help protect your confidentiality, we will assign a unique identification number to your data instead of using your name. The code will be linked to your identity and will be kept separate from your responses. Access to the code and study notes will be restricted to researchers on this project. All research materials, audio tapes, and data will be kept locked in cabinets in the research office and electronic information will be kept on a secured server in a folder only accessible to the research team.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.
The University of Iowa Hospitals and Clinics generally requires that we document your participation in

research occurring in a University of Iowa Health Care facility. This documentation will be in a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

*****THIS SECTION MAY NOT BE MODIFIED IN ANY WAY. RELATED DETAILS ABOUT HOW STUDY DATA ARE BEING CODED, STORED, AND SHARED SHOULD BE ADDED TO THE CONFIDENTIALITY SECTION.***]**

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and our data management board.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Sato Ashida (sato-ashida@uiowa.edu, 145 N Riverside Dr. N411, Iowa City, IA 52242). However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

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Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Lena Thompson (lena-thompson@uiowa.edu, 319-384-1491.
If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

Do not sign this form if today's date is on or after $STAMP_EXP_DT.

_____ _____
(Signature of Subject) (Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)