Building a Bridge (between clinical and community care): Post-diagnosis support for persons with dementia and their families

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Principal Investigator: Sato Ashida

Sponsor: University of Iowa College of Public Health

Funded by: National Institute on Aging (NIA)

Manual of Operations and Procedures (MOP)

July 2019

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1.0 Introduction

The overall goal of this study is to minimize negative consequences of Alzheimer's disease and related disorders (ADRD) diagnosis by enhancing the support systems of affected families through the provision of the Options Counseling-Health Education (OC-HE) intervention.

The primary objective is to evaluate the impact of OC-HE intervention on caregivers (caregiver burden) and patients (use of emergency care). The secondary objective is to evaluate the impact of the program through the proposed mechanisms of influence, enhanced social network composition (e.g., network size) and functioning (e.g., social support). In addition, we will assess intervention feasibility and acceptability to better understand intervention impacts and to inform future implementation from the perspectives of the participants, OC-HE interventionist, clinical care staff, and administrator at the Area Agency on Aging.

2.0 Brief Overview of the Study Protocol

The study protocol, presented as an appendix, provides a scientific rationale of the proposed investigation. A brief overview of the study protocol is presented here.

This is a Stage 1 intervention study based on the NIH Stage Model for Behavioral Intervention Development. We aim to enroll 106 family members of individuals newly diagnosed with dementia (PWD); 53 in each of the two group. Participants will be Iowa residents who provide support to a PWD who received diagnosis within the past 6 months. We will recruit adults ages 18 years and older, both males and females, who are not limited cognitively or physically to consent to study participation, to participate in interviews, and to receive intervention.

All participants will be recruited through the University of Iowa Hospitals and Clinics. Three clinics have agreed to facilitate the recruitment: Geriatric Assessment Clinic, Memory Disorder Clinic, and Adult Psychiatry Clinic. Clinical staff members will identify potential participants and either obtain permission for research staff to contact them or provide study and contact information of the research staff for them to contact us. We will not recruit participants outside of the United States. After consenting and completing the baseline interview, participants will be randomly assigned to either OC-HE intervention group or usual care control group.

The intervention consists of two parts, Options Counseling (OC) and Health Education (HE). The OC part includes family assessment, counseling and provision of emotional support, access assistance, and development of independent-living plans (care plans) using the Iowa's Heritage Area Agency on Aging database. The Options Counselor is trained to use motivational interviewing techniques to develop family care plans, provide emotional support, and connect families to available services and programs in the community. The HE part includes post-diagnosis family education using the 7-module health education toolkit developed specifically for this study based on the literature and expert reviews. OC-HE will conduct initial assessment to determine educational needs within 2 weeks of participant's randomization into the intervention group and develop initial care plan; and will conduct 5 monthly follow-up calls to adjust the care plan and provide educational components appropriate at each point. This intervention aims to create direct links between the medical clinics, home and community-based services (HCBS), and family.

Participants assigned to the usual care control group will participate in baseline, as well as 3- and 6-months

follow-up surveys. Those in usual care group will receive a general informational brochure from the Alzheimer's Association, and will be given an option of receiving a call from their local Options Counselor after completing the 6-month survey.

Study duration is about 18 months. We aim to start participant enrollment in August, 2019, complete recruitment by September, 2020, and complete data collection by March 2021. Each participant will be enrolled in this study for about 6 months from enrollment to final interview.

3.0 Study Staff Responsibilities

Project Investigator: Sato Ashida, PhD is an Associate Professor in the Department of Community and Behavioral Health in the College of Public Health. Dr. Ashida is one of 11 faculty in the University of Iowa's Aging Mind and Brain Initiative, a multi-disciplinary program whose vision is to create a world-class collaborative research and implementation entity to enhance the lives of our aging population. She is also a member of the University of Iowa's Center on Aging and Iowa Geriatric Education Center. Dr. Ashida has extensive experience conducting public health and aging research using social network methodology, and has demonstrated the roles of social networks on psychological well-being and health-related behaviors. She has been working closely with local aging network service providers, senior centers, churches, and other community-based organizations in Eastern Iowa through her research projects involving and concerning older residents. She will oversee all aspects of the research including the designing, implementing, conducting on-going quality control, performing administrative tasks as needed, analyzing and interpreting data, and preparing manuscripts and presentations. Dr. Ashida devotes 2.4 person months (20%) of her time to this project. Her duties will include:

- Developing all study materials including the MOP and study forms
- Reporting and monitoring of Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Complying with study intervention administration
- Protecting participants' rights
- Submitting documents to regulatory bodies (i.e., IRB)
- Developing and implementing:
    - Data management procedures including the data flow and procedures for data entry, error identification and correction
    - Quality control procedures
    - Reports - enrollment, participant status (e.g., withdrawals), adverse events, independent safety monitoring body reports

Co-Investigator Kristi Williams, PhD is the E. Jean Hill Professor in Nursing and a nurse gerontologist whose ongoing NIH-funded program of research test interventions designed to improve communication between nursing home staff and residents, promote self-care of assisted living residents using cognitive training, and support family members caring for persons with dementia at home using innovative telehealth technology to provide professional feedback. Dr. Williams is a fellow of the American Academy of Nursing and the Gerontological Society of America. Her research linking elderspeack communication to behavior of persons with dementia was highlighted by the Alzheimer's Association and reported in the national media including Good Morning America, the CBS Evening News, and the New York Times. Dr. Williams

works with Dr. Ashida on developing and implementing caregiver interventions, facilitate data collection and quality control, and collaborate to prepare manuscripts, presentations, and future grant applications. Dr. Williams will devote .24 person months (2%) of her time to this project. Her duties will include:

- Participating in research team meetings as needed
- Ensure reporting and monitoring of Adverse Events (AEs) and Serious Adverse Events (SAEs)
- Protecting participants' rights
- Developing and implementing:
    - Data management procedures including the data flow and procedures for data entry, error identification and correction
    - Quality control procedures
    - Reports - enrollment, participant status (e.g., withdrawals), adverse events, independent safety monitoring body reports

Statistician: Hyunkeun Cho, PhD is an Assistant Professor of Biostatistics at the University of Iowa College of Public Health with research interests in analysis of longitudinal data, missing data, and high-dimensional data. He is a member of the Clinical Trials Statistical and Data Management Center (CTSDMC). Dr. Cho provides statistical support and oversight for CTSDMC, including supervision and mentoring of staff biostatisticians. He has collaborated with researchers from a myriad of scientific disciplines through my role as a statistical consultant. Dr. Cho devotes 1.2 (10%) of his time in year 2 to this project. His duties will include

- Creating statistical analysis plan
- Support quality control procedures
- Leading statistical analysis for project

Clinical Team Consultant: Gretchen Schmuch, MSW is a Social Work Specialist in the Department of Family Medicine, Geriatric Medicine at the Carver College of Medicine. She will serve as a primary supervisor for the interventionist, OC-HE, and assisted Dr. Ashida and Williams in the development of the health education toolkit, training of the OC-HE. In year 2, she will facilitate the recruitment of the study participants, act as a link to the Departments of Social Work and Pharmacy at the University of Iowa Hospitals and Clinics, and provide clinical advice on guiding families receiving diagnosis with dementia. Ms. Schmuch will devote 1.2 person months (10%) of her time to this project. Her duties will include

- Serving as a point of contact between the clinical and research teams
- Assisting with the recruitment of participants by identifying patients through the electronic medical record system
- Participating in research team meetings as requested

Interventionist: Maria Donohoe is an Options Counselor (OC) designated through Iowa Code as an employee of the aging and disability resource centers. Ms. Donohoe trained through a formal program by Boston University and additional training by the Area Agencies on Aging (AAAs) and the Iowa Department on Aging. Training includes person-centered care planning, counseling, and motivational interviewing. OCs are certified through the Alliance for Information and Assistance for the highest quality standards in providing service information. As the Options Counselor – Health Educator (OC-HE), Ms. Donohoe will

participate in OC staff meetings, workshops, and in-service trainings to maintain current information and for supervision through the Heritage Area Agency on Aging and Iowa Department on Aging. Training on providing health education (HE) in clinical settings will be provided by the University of Iowa Hospitals and Clinics (UIHC). Mentoring and supervision will be provided by Gretchen Schmuch, an experienced Social Worker in the Geriatric Medicine Clinic, and Drs. Ashida and Williams. Ms. Donohoe will also participate in staff meetings, workshops, and geriatrics care meetings at the UIHC clinics. She will devote 6 person months (50%) of her time to this project. Her duties will include

- Attending weekly research team meetings
- Preparing intervention materials
- Complying with study intervention administration protocols
- Maintaining communication with participants and clinical staff
- Submitting the intervention section of reports

Research Manager: Lena Thompson, MPH is a doctorate student at the University of Iowa College of Public Health Department of Community and Behavioral Health. Ms. Thompson has served as a project coordinator on projects and centers at the University of Iowa College of Public Health since 2014. She will devote 6 person months (50%) of her time to this project. Her duties will include:

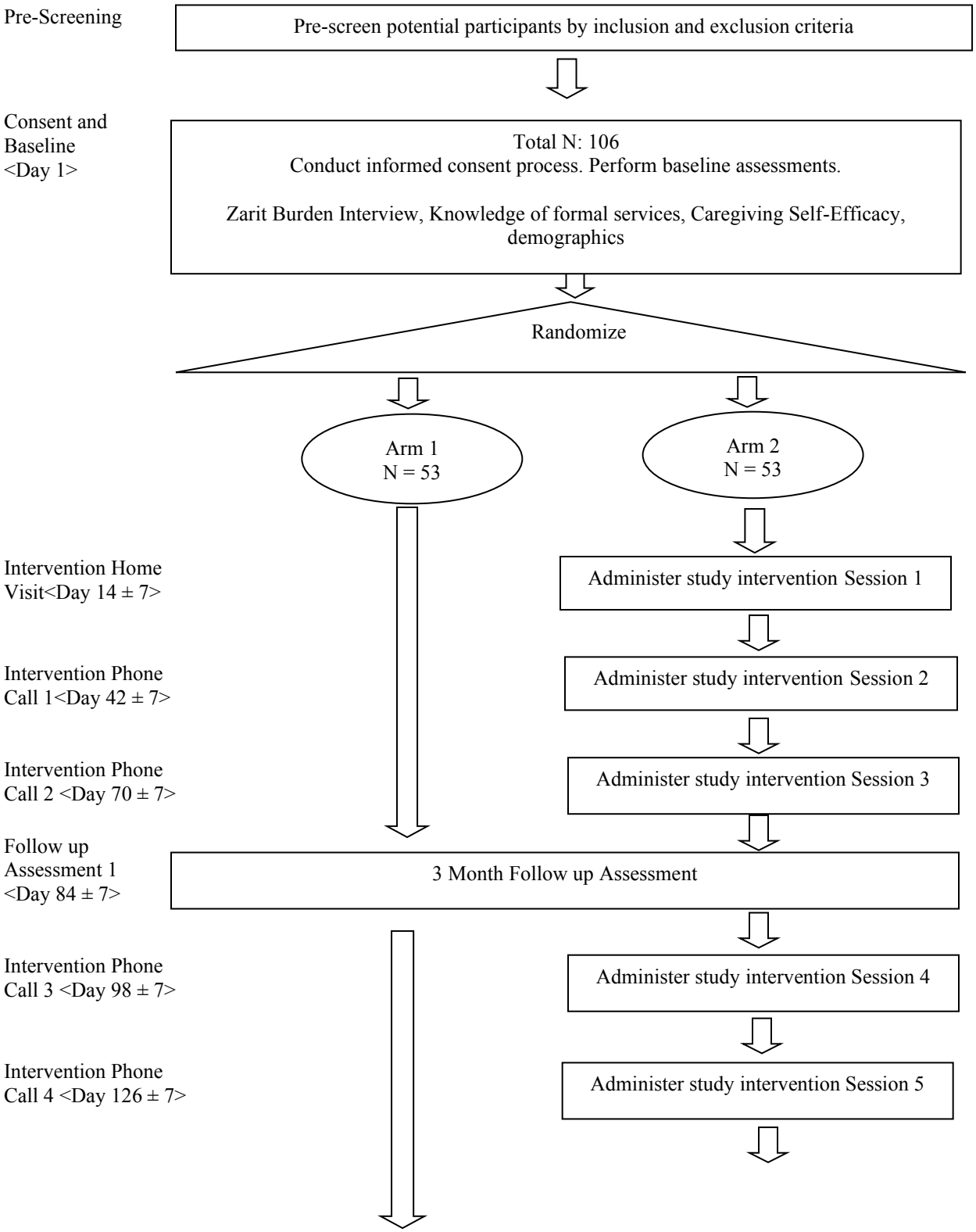
- Developing all study materials including the MOP and study forms
- Obtaining informed consent from each participant
- Recruiting, screening, and enrolling of participants
- Randomizing participants
- Collecting study data and following participants through study completion
- Protecting participants' rights
- Submitting documents to regulatory bodies (i.e., IRB)
- Developing and implementing:
    - Data management procedures including the data flow and procedures for data entry, error identification and correction
    - Quality control procedures
    - Reports - enrollment, participant status (e.g., withdrawals), adverse events, independent safety monitoring body reports

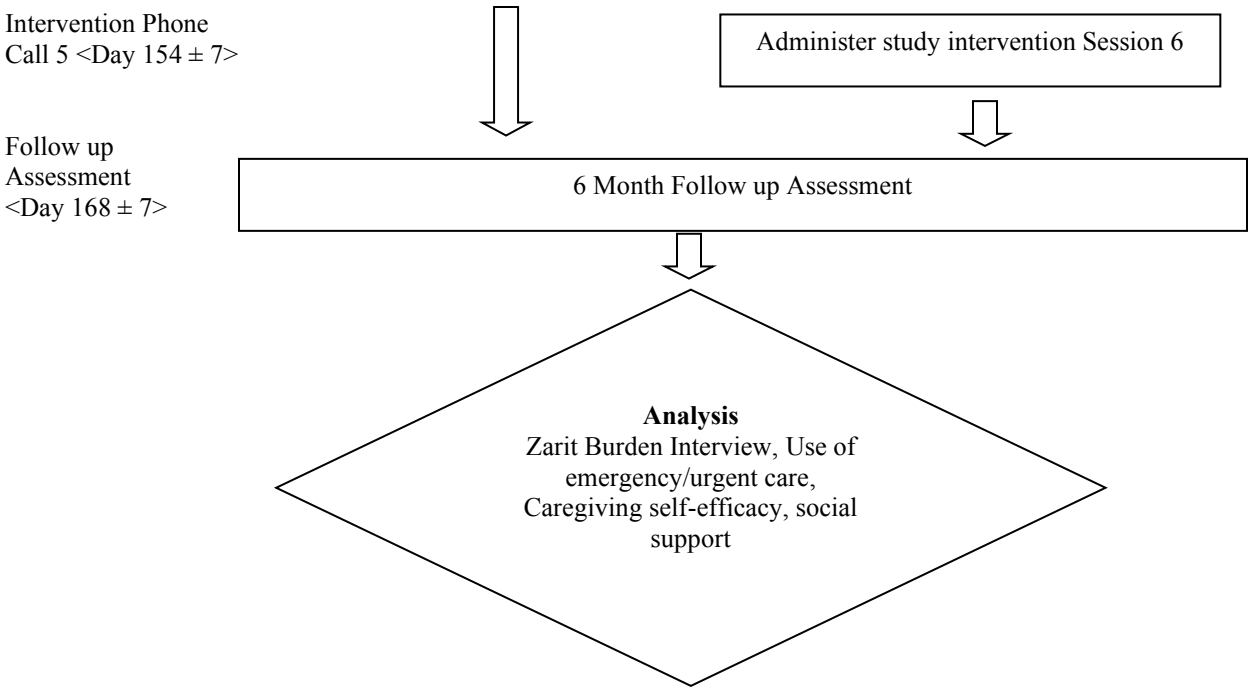
Student Interviewer: Haley Schneider is an undergraduate student at the University of Iowa College of Public Health. She has worked on research projects with aging populations since 2017. Ms. Schneider will devote .4 person months (3.4%) of her time to this project. Her duties will include:

- Obtaining informed consent from each participant
- Collecting study data and following participants through study completion
- Protecting participants' rights

4.0 Study Flow Diagram

Figure 1: Study Flow Diagram





5.0 Recruitment and Retention

Sample

Between June 2015 and May 2016, the 3 UIHC clinics served about 17,500 people with dementia and 657 were newly diagnosed. Power calculations were performed under the assumption of reaching about 12% of newly diagnosed individuals, 106 people; assuming a 25% attrition rate, this will lead to 80 people (40 per group). This will give us about 84% power to detect a 4-point decrease in Caregiving Burden at each 3-month period. Assuming some people may not meet the inclusion criteria, we anticipate screening around 138 potential participants including women and minorities to reach target enrollment size.

Participants

Family participants/caregivers will be family members or friends (e.g., biological and non-biological relatives, friends) who likely will coordinate care and support for the individual who received dementia diagnosis at one of the three participating clinics: Memory Disorder Clinic (Neurology), Geriatric Medicine Clinic (Family Medicine), and Adult Psychiatry (Psychiatry) at the University of Iowa Hospitals and Clinics (UIHC). Potential family participants/caregivers will be referred by the clinical care team members by reviewing EMR in EPIC and identifying patients who have been diagnosed with Alzheimer's or other dementia within the past 6 months. All participants will be asked to participate in a baseline survey and follow-up surveys at three and six months regarding their sociodemographic characteristics, Home and Community-Based Services (HCBS) use and knowledge, caregiving self-efficacy, caregiving preparedness, social support and networks, and their physical and psychological well-being. After completing the baseline, participants will be randomized into either the Options Counselor-Health Educator (OC-HE) intervention group or the standard care (control) group. Participants in the OC-HE intervention group will receive intervention after completing the baseline survey. All consents and interviews will be conducted by the trained research staff from the University of Iowa. Prior to enrolling

participants for the randomized trial, three to five individuals who have family members with dementia diagnosis will be asked to help with pilot testing program materials by providing feedback on the program contents and implementation procedures.

In addition to family participants, **staff participants** (i.e., clinical care team members, interventionist, and administrators of the Heritage Area Agency on Aging) will be asked to complete program logs and exit interviews at the end of the project to provide feedback on the intervention materials and comment on the feasibility and recommendations to improve the program. We expect one person from each clinic/ organization to participate in this part of the study with an estimated number of 5 staff participants.

Consistent with the current OC protocol, PWD may choose to participate in any part of the intervention with the family member. Although assessments will be based on participating individuals' reports, we will incorporate patients' perspectives through the Health Education module that guides families to effectively discuss and include perspectives of the patient and all family members when developing and adjusting care plans.

Recruitment

All participants will be recruited through the University of Iowa Hospitals and Clinics: Geriatric Assessment Clinic, Memory Disorder Clinic, and Adult Psychiatry Clinic. We will not recruit participants outside of the United States.

Clinical teams led by project collaborators (Drs. Butler, Shim, and Duffy) will review electronic medical records (EMRs) and use their existing knowledge of the patient to determine which days a diagnosis may be made. For those patients who have been diagnosed within the past 6 months from the beginning of the study, who are eligible for the study, the research team will be notified by clinical teams when those patients and their caregivers will be at the clinic for a visit. On the identified days, a member of the research team will be present at the clinic. In this case, the clinical team members will notify the research team about cancellations and last minute appointments. If a research team member cannot to be present due to logistical difficulties, the clinical staff will give study flyer to the potential participants. If the potential participant indicates interest, a potential participant packet that includes the flyer, a consent letter, and study information sheet will be handed out. If the potential participant gives permission for research staff to contact them, the potential participant will be asked to fill out a contact form indicating their name and phone number or e-mail address that will be sent to the research staff from the clinical team staff. If the potential participant does not wish to provide contact information, they will be asked to call the research office indicated on the flyer.

There is no signed consent document for this study. There is a consent letter that interviewers will read through with the participant before the baseline interview begins. Since the study has rolling enrollment, caregivers will have up until the last 6 months of the study to participate (to allow participants enough time to receive the entire intervention). Eligibility will be confirmed by the research assistant before reading through the consent letter with the participant.

Anticipate Accrual Rate

- 25% of planned enrollment (26 participants) recruited by 09/30/2019

- 50% of planned enrollment (53 participants) recruited by 01/31/2020
- 75% of planned enrollment (80 participants) recruited by 04/30/2020
- 100% of planned enrollment (106 participants) recruited by 08/15/2020

Participant Retention

Research staff and the OC-HE will make up to 3 phone calls, at least three days apart, leaving a message if possible to schedule each encounter. On the 3rd phone call, the research staff or OC-HE will let the participant know that they are welcome to contact the research team if they would like to stay enrolled in the study. The participant will have up to 1 month to call back after the 3rd phone call before they are dropped from the study. To facilitate retention, participants will receive $20 incentives after completing each survey (baseline, 3-, and 6-month follow-up), and the OC-HE will ask participants about how they are feeling about the program and what can be done to support their continued participation in the intervention at each follow-up encounters.

Participant Incentives

At the end of the baseline interview, participants will fill out the reimbursement form, which collects the participant's name, address, and citizenship status. At the end of the baseline, 3 month, and 6 month interviews, the research assistant will send the information to University of Iowa Shared Services, who will process a $20 check to be sent to the address provided by the participant. The total compensation for the entire study is $60 per participant. If the participant completes at least 51% of the interview questions, they will receive the $20 compensation for that interview. To minimize coercion or undue influence, the level of incentive has been capped at $20 per interview. All participants will be informed during the consent procedure that their participation in this study is completely voluntary, they can stop at any time, deciding not to participate will not impact the services they may receive at UIHC.

Correcting Retention Problems

If the study team encounters retention problems, the PI and Co-PI will meet with the DSMB, clinical staff, interventionist, and research team members to address retention issues. The National Institute on Aging provides recruitment and retention tips in its Recruitment and Retention Tips document, which will be re-visited at that time.

5.1 Screening and Eligibility Criteria

Assuming some people may not meet the inclusion criteria, we anticipate screening around 138 potential participants including women and minorities to reach target enrollment size.

Participants will be screened verbally, with the research assistant asking whether the participant meets the inclusion criteria (*see Eligibility Screening Tool in Appendix B)*. Participants must meet *all* of the inclusion criteria in order to be eligible to participate in the study. Once the individual has been determined to be eligible, research assistant will schedule a time with the individual to consent to the study. After the individual has received the consent letter and the research assistant has read through the document with the individual, and the individual agrees to participate, the he/she will be considered enrolled. The participant will not be randomized until after completing the baseline survey. For every eligible potential participant, the research assistant will collect information about their age, gender, race, physical disability status

(whether the person needs assistance completing study-related tasks such as consenting and participating in interviews), whether the potential participant agreed to participate, and the reason for declining using the recruitment log. This will provide information on the extent to which our program is reaching caregivers of diverse backgrounds and to inform ways to increase reach to under-represented groups. Being included in the recruitment log does not indicate that the individual is necessarily enrolled in the study. Women and minority groups are encouraged to participate in this study. Because of the demographic characteristic of the patient population at the UIHC, primarily white, we will attempt to reach out to minority participants as much as we can to increase diversity. The control group will have the same inclusion/exclusion criteria.

One of the eligibility criteria, diagnosis of dementia, will be determined based on the clinical diagnosis made by physicians in our collaborating clinics. Once potential participants are identified by the clinical staff, research staff will conduct other assessments related to screening to determine eligibility using the above-described eligibility screening tool, before enrolling the participant. Screening and enrollment procedures will be conducted by one or two research staff to minimize variability. If more than one staff will engage in these procedures, two staff members will discuss procedures and criteria in detail to minimize variability in these procedures.

Individuals who exhibit high levels of anxiety based on the GAD-7 scale[1] (score of 10 or higher) in baseline will be advised to seek clinical care. These individuals will have an option to discontinue in this study.

5.2 Screening/Recruitment Log

An example of the recruitment log is provided in Appendix C of this document. The recruitment log will contain the participants' age, gender, race, physical disability status (collected by whether the person needs assistance with evacuation), rurality, whether the potential participant agreed to participate, and the reason for declining. This will give information on whether our program is reaching older adults form diverse backgrounds and to inform ways to increase reach to under-represented groups.

5.3 Eligibility Criteria

Inclusion Criteria

Family Participants/Caregivers

1. Over the age of 18
2. Self-reported family member/caregiver of someone who has been diagnosed with Alzheimer's/dementia within the past 6 months
3. Lives in the state of Iowa or the PWD lives in Iowa
4. No cognitive limitations that prevent them from consenting or participating in interviews (Evaluation to Sign an Informed Consent Document for Research, a form provided by the University of Iowa Institutional Review Board shown in Appendix E)
5. Access to necessary resources for participating in monthly phone calls

Staff participants

1. During the time of the study, worked as staff at the UIHC Neurology, Memory Disorder, or Psychiatry clinic and took a part in this study; or Served in an administrative role at the Heritage Area Agency on Aging during this project period or delivered intervention for this study
2. Over the age of 18

Exclusion criteria:

1. Those residing at care settings at the time of the recruitment
2. Families/caregivers of those diagnosed as predementia or mild cognitive impairment
3. Individuals with cognitive impairments and physical limitations that limit ability to make informed decisions or participate in interviews.

Individuals who exhibit high levels of anxiety based on the GAD-7 scale[13] (score of 10 or higher) in baseline will be advised to seek clinical care. These individuals will have the option to discontinue in this study.

6.0 Informed Consent

Documents Provided Prior to Consent

- Flyer (*Appendix D)*
- Study Information Sheet *(Appendix E)*
- Consent Letter *(Appendix F)*

Consent Procedures and Documentation

About the study: To collect the information about the reach of our program, the research and clinical team will collect information about all potential participants' age, gender, race, physical disability status (collected by whether the person needs assistance with evacuation), rurality, whether the potential participant agreed to participate, and the reason for declining. The PWD who receives the Alzheimer's or related dementia diagnosis is not the participant in the study, but the PWD is welcome to be in the room while the study is discussed. The research team member will explain that the study consists of a baseline interview, randomization into intervention group or standard care group, completing the intervention (if randomized into the intervention group), and a 3 month, and 6 month interview. Those in the standard care group will complete the baseline, 3 month, and 6 month interview on the same schedule as the intervention group, and will have an option of receiving a call from an options counselor after the 6 month interview has been completed. This call from an options counselor is not the intervention being tested, but standard care participants will be connected to an options counselor who will do their own options counseling after the research is complete if the participants desire. The purpose of this protocol is to make sure that anyone who agrees to participate in this study has access to support regardless of their study group status.

While the potential participant wait as the PWD engages in various components of the clinical visit with various clinical care team members, research staff will explain the study, screen for eligibility, and invite one eligible family member who likely will coordinate care for the PWD to participate. If the potential participants agrees to participate in the study, he/she will be consented in the patient's examination room or in other private rooms (e.g., consultation room) using an informed consent letter. If the potential participant would like to think about whether he/she want to participate, the research team member will give the consent letter and ask for permission to share the potential participant's phone number with the research staff who would call them within a week if he/she does not call the research office first. Once the potential participant and research assistant have established contact, they will arrange a time to meet in person in a private location, or via telephone where the research assistant will read through the consent letter with the potential participant and consent them if they agree to participate.

To minimize the possibility of coercion, all participants will be informed during the consent procedure that their participation in this study is completely voluntary, they can stop at any time, deciding not to participate will not impact the services they receive at the UIHC.

Research Manager Lena Thompson and Student Interviewer Haley Schneider will discuss the nature of the study with potential participants. While consent letters do not need to be signed, Ms. Thompson or Ms. Schneider will explain the elements of consent to each potential participant before they complete the baseline interview. The participant will keep a copy of the consent letter and will be offered a new copy of the letter at the 3 month and 6 month follow up interviews.

6.1 HIPAA Authorization

Because we have access to health data through the electronic medical record and because we are collecting some data through the electronic medical record (MoCA and use of medical services), all research team members have completed HIPAA training through the University of Iowa Hospitals and Clinics Human Resources.

7.0 Study Intervention

Intervention Description

The intervention consists of two parts, Options Counseling (OC) and Health Education (HE). The OC part includes family assessment, counseling and provision of emotional support, access assistance, and development of independent-living plans (care plans) using the Iowa's Heritage Area Agency on Aging database. The HE part includes post-diagnosis family education. Options Counselor (OC) is trained to implemented these tasks through using motivational interviewing techniques. We developed seven modules of the HE toolkit based on an extensive literature review on unmet needs of families receiving diagnosis of dementia, experiences of Options Counselors, and expert reviews by experienced staff members at the local Alzheimer's Association.

Through the OC-HE intervention, we aim to minimize caregiver burden through enhancing the social support network system of the participants by providing direct access to community-based programs as well as to the Options Counselor who provides emotional support and instructions on how to form strong support networks. Lower burden and better support are associated with better patient outcomes, thus, we will also evaluate whether PWDs whose caregivers receive OC-HE intervention would use emergency or urgent medical services to a lesser extent.

Each intervention encounter will occur in a setting of the participant's choosing. Typically, the initial visit is in the home of the participant (caregiver) and involves just the participant and the Options Counselor. However, the participant is able to invite whomever they choose to come to the meeting, including the PWD. The participant may choose to have the meeting at different location if the person they are caring for lives with them and they do not want to introduce the information in this manner. Although it is preferable to have this initial visit in person, the meeting can be done via phone call or virtually through a web-conferencing if participant desires so. Normally, each home visit, or face to face meeting, lasts around 1.5 hours, however, because of the addition of the Health Education component in this particular study, we

anticipate our initial visits to take about 2 hours. After the home visit, the Options Counselor will call the participants each month for the next five months to implement follow up phone intervention sessions that will last between 30 to 60 minutes. As a rough guideline, we anticipate one to two modules to be delivered during the initial visit and one module to be delivered at each of the five follow-up phone encounters. We will provide all modules to the participants at the end of the intervention as a resource. At the end of the 6-month study intervention period, participants will have every Educational Module offered in this intervention. At the end of the study the participants will also have access to the local Area Agency on Aging to continue receiving resources, counseling and options. Through this intervention participants will not have intentional interaction with other caregivers or families that are also participating in this study.

Participants in the control group will complete baseline and 3-month and 6-month follow-up interviews. They will receive a standard information brochure from the Alzheimer's Association as part of the usual care provided at the partnering clinics. After completing the 6-month follow-up interview, these participants will have an option of receiving a phone call from an Options Counselor at their local Area Agency on Aging or receiving a contact information of their local OC if they wish to initiate the call.

8.0 Randomization

We will use a randomization scheme with a 1:1 ratio based on computer generated random numbers to assign the family to one of the two study arms. We plan to have 53 in the standard care (control) group and 53 in the intervention (experimental) group. Randomization will occur after baseline assessment. The Project Investigator and Co-Project Investigator will be responsible for handling any randomization errors.

Research Manager Lena Thompson will be responsible for maintaining the master randomization list, assigning randomization codes, notifying appropriate study staff. Ms. Thompson will contact the OC-HE with the name and contact information of participants who have been assigned into the intervention arm.

We plan to maintain the assigned and blinded randomization code in an automated, computerized log that is separate from the study data

9.0 Blinding and Unblinding (Masking and Unmasking)

The student interviewer/data entry assistant will be blinded on who is chosen by random for the intervention group and will not know whose information belongs to whom.

10.0 Safety Reporting

Definition of Adverse Events

This protocol uses the definition of adverse event (AE) from the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). *See Adverse Event Form Appendix G*

Serious Adverse Events

This protocol uses the definition of serious adverse events (SAE) as defined in the OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: Any adverse event that (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization or prolongation of existing hospitalization; (4) results in a persistent or significant disability/incapacity; (5) results in a congenital anomaly/birth defects; or (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition. *See Serious Adverse Event Form Appendix H*

Responsibilities of NIA, IRB, DSMB, and Investigators

AEs will be reported to the University of Iowa IRB and NIA using an Adverse Event Form quarterly or as determined by the NIA. The members of the Data Safety Monitoring Board (DSMB) will receive this report prior to the scheduled board meetings.

Reporting Process

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during interviews and intervention encounters. The PI will meet with the research team bi-weekly to conduct ongoing data and safety monitoring, and will meet bi-annually with the Data Safety Monitoring Board (DSMB) consisting of three external board members, Drs. Connell, McClure, and Mahoney. The PI will be informed of serious adverse events (SAEs) as soon as they occur and will notify the UI IRB and NIA within 24 hours of notification.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate reportable event or case report form (CRF) as provided by the University of Iowa Institutional Review Board in an online form. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship to the study. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. After each interview, the GAD-7 anxiety score will be calculated within two weeks of administration to identify participants experiencing elevated levels of symptoms. In addition, during each intervention encounter, the interventionist will ask the participant "Have you noticed anything different since you started the study?" Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent. *See Appendices I for OC-HE documentation and J for AEs/SAEs Listing.*

The PI or Project Manager will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the staff will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

The DSMB will hold a minimum of two web-based conference calls per year (about two hours per call) to discuss protocols, progress of the intervention and research activities, and data and participant safety. The PI will prepare a Safety Report to be circulated prior to the scheduled call for DSMB members to review. The reports will contain information (i.e., AE, SAE, unanticipated problems) and analyses of study procedures, progress, and data and safety issues. Any reports to the DSMB preparing data broken down by group are only to be prepared by the statistician. The board members will review the study protocol and information presented in the report and will provide recommendations on recruitment, retention, quality control, and safety procedures while ensuring the confidentiality of the study participants and results. Through these activities, we will ensure that all protocols are conducted in compliance with the AE and SAE guidelines and reports are sent to appropriate individuals including the University of Iowa IRB and the Program Officer at the NIH.

Events of Special Interest

The interventionist, Options Counselor (OC), is trained in "Person Centered Care" through the Iowa Association of Community Providers, thus, is a mandatory reporter of any abuse to dependent adults. If the OC encounters situations that may need to be reported, the protocol established by the Heritage Area Agency on Aging will be used.

If a participant discloses potential abuse to other research staff, research staff will provide information on the Heritage Area Agency's Elder Rights Program and a direct line phone number for them to reach a trained counselor, 319-398-5559.

Description of terms used in reporting

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.
- **Potentially Related** – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of study procedures). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

11.0 Study Compliance

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the PI to use continuous vigilance to identify and report deviations within 14 working days of identification of the protocol deviation, or within 14 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, and reported to the NIA Program Official. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The PI will be responsible for knowing and adhering to the reviewing IRB requirements. Only protocol deviations that impact participant safety will be reported within 24 hours of occurrence if possible, or as soon as they are discovered. All other deviations will be reported routinely to the DSMB and IRB. A form for documenting protocol deviations is included in Appendix K.

Protocol deviations/violations may include, but are not limited to, the following:

- Randomization of an ineligible participant
- Failure to obtain Informed Consent
- Failure to keep IRB approval up to date

A log for recording protocol deviations is included in Appendix K.

12.0 Data Collection and Study Forms

This section of the MOP describes the study's data collection and data management procedures. Copies

are included as appendices.

12.1 Participant Folder/Binder

While most of the study data will be monitored electronically, each participant will have a folder, stored in a locked file cabinet in Research Manager Lena Thompson's office. The folder will include:

- Questionnaires completed by the participant (if applicable, most will be online) *Appendix L Baseline Interview*
- Case Report Forms (CRFs)/Reportable Event Form *Appendix M*
- Participant information form (if provided by the clinical team or for providing incentives) *Appendix N*
- Screening form *Appendix B*

The OC-HE will also keep a separate folder locked in a file cabinet in her office at the College of Public Health for each participant in the intervention group. This folder will include

- OC Assessment Tool *Appendix O*
- Care Plan *Appendix P*
- Completed HIPAA form *Appendix Q*
- Participant information form (if provided by the research team)

12.2 Study Forms

Form Name	When Given	When Collected	Appendix	Maintenance
Eligibility Screening	Read to potential participant by RA	Before potential participant receiving any materials	B	Kept in Participant Folder locked in Lena Thompson's office
Study Flyer	In Research Packet after participant screens eligible	N/A	D	N/A
Study Summary	In Research Packet after participant screens eligible	N/A	E	N/A
Consent Letter	In Research Packet after participant screens eligible. Read through with Interviewer before baseline and re-visited before 3 and 6 month follow up	N/A	F	N/A
Participant Contact Form	Given by clinicians when a potential participant appears to be eligible	At PWD appointment by clinicians, given to research manager	U	Kept in Participant Folder locked in Lena Thompson's office

	(Research Manager will do eligibility screening)			
Reimbursement Form	Directly after baseline, 3 month follow-up, 6 month follow-up	Directly after baseline, 3 month follow-up, 6 month follow-up	N	Kept in Participant Folder locked in Lena Thompson's office

12.3 General Instructions for Completing Forms

In order to consistently collect data information, interviewers will complete a training with Dr. Ashida and or Lena Thompson. Research Manager, Lena Thompson, will check forms once a month to assure that forms are filled out correctly.

12.4 Data Flow

Data will be entered into the online database (currently in Excel, considering moving to Access). With Excel, each person will need to alert the next team member when it is time for that person to act. For example, the Research Manager will need to e-mail the interviewer to set up an interview after the potential participant has agreed to conduct the baseline study. If that person is in the intervention group, the Research Manager will need to alert the OC-HE through an e-mail to establish a contact. This process will be monitored weekly through meetings with the PI, Research Manager, Interviewer, and OC-HE present.

12.5 Administrative Forms

Form	Appendix	Description
Participant Identification Code List	R	Used to document the participant's study identification number, name, and other identifying information. Stored separately from research records since it is the link between a study ID and participant's name.
Recruitment Log	C	Used to list participants screened; includes those who fail screening and those who are enrolled. Collects date, age, gender, race, care needs, relationship to PWD, Rural (Y/N), Agreed to participate, Reason for not enrolling, study ID
Phone Call Log	S	Used to log all phone call conversations/follow-ups
Study Personnel	T	Used to list contact information for all study personnel and their specific responsibilities
Heritage AAA Log		Used by the OC, who is an employee at Heritage Area Agency on Aging to log options counseling sessions
Research Log		Extensive Database with points of contact to track participants through the research process
Intervention Log		Database at University of Iowa where the OC-HE tracks options counseling sessions
EPIC		University of Iowa Electronic Medical Record where Care Plans will be uploaded or typed into the "notes"

		section
Participant Contact Form (from Clinic to Research Staff)	U	Used by clinicians to collect contact information about the potential participants so that the Research Manager can contact the interested potential participant
Participant Reimbursement Form	N	Used by the Interviewer to collect information about the participant so that the participant can be paid their $20 incentive for each interview
Interview Script	V	Used by the interviewer to introduce the study, ask about adverse events, conduct the interview, and end the interview
Adverse Event Form	G	Used by the PI to report Adverse Events
Serious Adverse Event Form	H	Used by the PI to report Serious Adverse Events

12.6 Retention of Study Documentation

Study documents will be retained for a minimum of 5 years after the study has ended. After 5 years, paper copies and digital records of the study data will be destroyed.

13.0 Data Management

See Data Management Plan

13.1 External Data

N/A

13.2 Quality Control Procedures

The PI and Co-PI will be responsible for quality assurance, performing internal quality management of study conduct, data collection, documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- While there is no signed consent document, the Research Manager will train interviewers on explaining the informed consent letter. Most interviews are not recorded until after the participant has given informed consent, so the Research Manager will not be able to listen to recordings. The Research Manager will attend 10% of the interviews with the student interviewer to assure that the interviewer is reading through the letter with accuracy and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section** Error! Reference source not found.**, Data Handling and Record Keeping**) and will ultimately be e ntered into the study database. To ensure accuracy, site staff will compare a representative sample of source data against the database, targeting key data points in that review. Interviewers will enter data directly into Qualtrics. Each session will be recorded and 20% of the interviews (21 interviews) will be re-entered and compared to check the accuracy of data entry.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section** Error! Reference source not found.**, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

13.2.1 Standard Operating Procedures

N/A

13.2.2 Data and Form Checks

The PI and the Project Manager will implement data quality control procedures through weekly team meetings to identify potential data anomalies such as:

- Missing data or forms
- Out-of-range or erroneous data
- Inconsistent and illogical dates over time
- Data inconsistency across forms and visits
- Not completing all fields of a "completed form" or no reason for missing data is provided

14.0 Concomitant Medications

N/A

15.0 Data and Safety Monitoring Activities

Given the nature of this study, single-site minimal risk trial, the Dr. Ashida (PI) will be responsible for ensuring participants' safety on a daily basis. The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analysis.

The PI will meet with the research team weekly to conduct ongoing data and safety monitoring, and will meet bi-annually with the Data Safety Monitoring Board (DSMB) consisting of three external board members, Drs. Connell, McClure, and Mahoney. The PI will be informed of serious adverse events (SAEs) as soon as they occur and will notify the UI IRB and NIA within 24 hours of notification.

The DSMB will hold a minimum of two web-based conference calls per year (about two hours per call) to discuss protocols, progress of the intervention and research activities, and data and participant safety. The PI will prepare a Safety Report to be circulated prior to the scheduled call for DSMB members to review. The reports will contain information and analyses of study procedures, progress, and data and safety issues. The board members will review the study protocol and information presented in the report and will provide recommendations on recruitment, retention, quality control, and safety procedures while ensuring the confidentiality of the study participants and results. Through these activities, we will ensure that all

protocols are conducted in compliance with the AE and SAE guidelines and reports are sent to appropriate individuals including the University of Iowa IRB and the Program Officer at the NIH.

The content of the data and safety monitoring report will include: a brief summary of study organization, purpose and procedures, overall study status, participant enrollment and retention, reasons for non-participation, aggregated descriptive information of the participants, changes to study protocol, quality of collected data, status of data management, incidence of ADs/SAEs/unexpected problems and actions taken, and updated study timeline. The design of this study does not involve masking.

15.1 Study Completion and Close-Out Procedures

Close-out activities include:

- Verification that study procedures have been completed, data have been collected, and study intervention and supplies are returned to the responsible party or prepared for destruction.
- Assurance that all data queries have been completed.
- Assurance that correspondence and study files are accessible for external audits.
- Assurance that the study records are maintained and any relevant study information reported to the NIA.
- Assurance that the investigator will notify the IRB of the study's completion and store a copy of the notification.
- Preparation of a report summarizing the study's conduct.
- Participant notification of the study completion.

15.1.1 Participant Notification

Participants will receive a letter indicating that their participation in this study has ended. The letter will thank participants for their participation, let them know how they will be informed of the study results, and let them know who to contact the PI or Project Manager if they would like further information.

15.1.2 Confidentiality Procedures

Procedures

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the DSMB, and the NIA. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. Personally-identifiable information from the study will not be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

Privacy of the participants will be protected by only collecting personal information that is necessary for the purpose of the research. Data will be used only for research purposes. Names and personal information will be used only for logistic purposes such as scheduling interviews and mailing incentives after the completion of their surveys. The consent process will take place in a private location.

The DSMB, other authorized representatives of the NIA, or representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator, including

but not limited to, medical records (office, clinic, or hospital) and other data collected in this study. The study site will permit access to such records.

Study participant research data, for purposes of statistical analysis and scientific reporting, will be transmitted to and stored in the secure online database. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived in the University of Iowa secure database.

Electronic records (computer files, electronic databases, etc.)
All research-related computer and audio files with identifying information will be kept on secure computer servers at the College of Public Health data center facility in a password protected folder accessed only by the study staff. The collegiate data center facility includes climate controlled redundant air cooling and humidity sensors, gigabit network bandwidth, enhanced electrical power, power conditioning, backup power via generator, and restricted access controls including two factor authentication with entry and exit logging. Server backups are run daily (business days) and preserved in a temperature stable and fireproof media safe. Monthly server backups are transported offsite for disaster recovery. The research staff responsible for entering, coding, cleaning, and verifying the transcripts and survey data will be trained in human subjects and confidentiality. Landmark Associates Incorporated (UI vendor ID 662416) is a UI approved vendor with a privacy and confidentiality agreement. Digital audiorecords and transcripts will be transferred via this company's secure file transfer program. Collegiate IT policies, plans, and procedures include Contingency and Disaster Recovery Plan, Incident Handling, Risk Assessment Management and Analysis, Facility Security Plan, Systematic Change Control Procedures, Data Destruction and Sanitization Guidelines, Server Monitoring and Audit Procedures, and Enterprise Password Policy.

- Name - Timothy Shie
- Title - IT Director
- University Job Classification - Faculty/Staff

Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.)
The confidentiality of the participants and responses to interview questions will be protected throughout the study and after its completion. Each participant will be given an identification number for data management purposes and to ensure the confidentiality of his/her responses to interview and surveys. Any hard copy documents that may be produced during the study period will be stored securely in a locked cabinet in private offices of the study personnel. Only participant IDs without names will be indicated on hard copy surveys. Participants' names will not be used during transcription, data entry, and analysis, and will not appear in any report, paper, or presentation to ensure their privacy and confidentiality. Interviewers will be trained to not leave any study-related documents unattended between the time of interview and when materials are securely stored in the locked cabinets. Codes that can link participants to IDs will be stored in a secured locked cabinet separate from the identifying information in private offices, and will be accessible only by the trained study personnel including PI, project manager, research assistants, and interventionist. Audio files, transcripts, participant tracking, and interview responses will be kept in separate

databases using data encryption on the network of the College of Public Health with appropriate Access Control Lists restricting the files to those working directly on the project.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/sharing.htm). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see https://humansubjects.nih.gov/coc/index). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

16.0 MOP Maintenance

Each page of the MOP is numbered, dated, and contains a version number to facilitate any changes and/or additions. The MOP may serve as a history of the project, documenting the time and nature of any changes in procedures and policies.

See MOP Modification Log Template in Appendix W.

References

1. Spitzer RL, Kroenke K, Williams JB, Lowe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine.* 2006;166(10):1092-1097.
2. Bunn F, Goodman C, Sworn K, et al. Psychosocial factors that shape patient and carer experiences of dementia diagnosis and treatment: a systematic review of qualitative studies. *PLoS Med.* 2012;9(10):e1001331.
3. Bruce DG, Paterson A. Barriers to community support for the dementia carer: a qualitative study. *Int J Geriatr Psychiatry.* 2000;15(5):451-457.

APPENDIX A - ACRONYM GLOSSARY

***Adverse Event (AE)* –** Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

***Case Report Form (CRF)/Reportable Event Form* –** A printed, optical, or electronic (eCRF) document designed to capture all protocol-required information for a study. Reportable Event Form is an online form filled out on the University of Iowa Institutional Review Board (Hawk IRB) site.

***Code of Federal Regulations (CFR)* -** is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.

***Data and Safety Monitoring Board (DSMB)* –**A group of individuals independent of the study investigators that is appointed by the NIA to monitor participant safety, data quality and to assess clinical trial progress.

***Good Clinical Practice (GCP)* –** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

***Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule* –** The first comprehensive Federal protection for the privacy of personal health information. The Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI).

***Heritage Area Agency on Aging (HAAA)* -** Heritage Area Agency on Aging (HAAA) is designated by the Iowa Commission on Aging to provide services and supports to older Iowans, adults with disabilities, and family caregivers in its seven-county region. Dr. Ashida and Mr. Sample, Executive Director, have a well-established and active collaborative relationship through multiple research endeavors, including the pilot study that served as a basis for this proposed study.

***Institutional Review Board (IRB)/Independent Ethics Committee (IEC)* –** An independent body constituted of medical, scientific, and nonscientific members whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, protocols and amendments, and of the methods and material to be used to obtaining and documenting informed consent of the trial participant.

***Manual of Procedures (MOP)* –** A "cook book" that translates the protocol into a set of operational procedures to guide study conduct. A MOP is developed to facilitate consistency in protocol implementation and data collection across study participants and clinical sites.

***Options Counselor (OC)* - .** Under Iowa Administrative Code [IAC231.64] HAAA is required to provide options counseling services. OCs meet with family and individuals to develop a person-centered plan to support independent living in their home and community as long as possible based on their current resources and available services. OCs provide transition support from medical to home environment,

ensuring essential supports at home and in the community by providing information to address current and anticipated needs of the family.

Options Counselor/Health Educator Intervention (OC-HE) - This intervention will consist of two components, Options Counseling (OC) and Health Education (HE). Family will receive standard OC services that include family assessment, counseling and provision of emotional support, access assistance, and development of independent-living plans (family action plans) using the Iowa's LifeLong Links database. In the HE component, family will receive post-diagnosis education. Interventions will be ongoing and flexible to meet the needs of the individual family.[2,3] OC-HE will conduct initial assessment to determine educational needs (2 weeks later), and will conduct 5 monthly follow-up calls to adjust the care plans and provide educational components appropriate at each point. This will create direct links between the medical clinics, HCBS, and family

Principal Investigator (PI) - The individual with primary responsibility for achieving the technical success of the project, while also complying with the financial and administrative policies and regulations associated with the award. Although Principal Investigators may have administrative staff to assist them with the management of project funds, the ultimate responsibility for the management of the sponsored research award rests with the Principal Investigator.

Quality Control (QC) – The internal operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of trial related activities have been fulfilled (e.g., data and form checks, monitoring by study staff, routine reports, correction actions, etc.)

Safety *Officer (SO)* - The Safety Officer is an independent individual, usually a clinician, who performs data and safety monitoring activities in low-risk, single site clinical studies. The Safety Officer advises NIA Program Director regarding participant safety, scientific integrity and ethical conduct of a study.

Serious Adverse Event (SAE) – Any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

Standard Operating Procedure (SOPs) – Detailed written instructions to achieve uniformity of the performance of a specific function across studies and patients at an individual site.

APPENDIX B – ELIGIBILITY SCREENING

Participants must meet all of the inclusion and none of the exclusion criteria in order to be eligible to participate in the study.

Each box must be checked "yes" for a participant to be eligible for the study:

Yes	No	
☐	☐	Are you 18 years of age or older as of today?
☐	☐	Are you a family member/caregiver of someone who has been diagnosed with Alzheimer's/dementia within the past 24 months?
☐	☐	Do you have any cognitive limitations that may prevent you from giving informed consent?
☐	☐	Do you have access to a phone line where you can receive monthly phone calls?

"No" must be checked for the question below for a participant to be eligible for the study:

☐	☐	Does the PWD currently reside at a facility/institution of care?

APPENDIX C – RECRUITMENT LOG

	Date	Age	Gender	Race	Care Needs	Relationship to PWD	Rural?	Agreed to participate?	Reason for not enrolling (if provided)	Study ID (if agreed)
1			F / M		A lot / Some / A little		Y / N	Y / N		
2			F / M		A lot / Some / A little		Y / N	Y / N		
3			F / M		A lot / Some / A little		Y / N	Y / N		
4			F / M		A lot / Some / A little		Y / N	Y / N		
5			F / M		A lot / Some / A little		Y / N	Y / N		
6			F / M		A lot / Some / A little		Y / N	Y / N		
7			F / M		A lot / Some / A little		Y / N	Y / N		
8			F / M		A lot / Some / A little		Y / N	Y / N		
9			F / M		A lot / Some / A little		Y / N	Y / N		
10			F / M		A lot / Some / A little		Y / N	Y / N		
11			F / M		A lot / Some / A little		Y / N	Y / N		
12			F / M		A lot / Some / A little		Y / N	Y / N		
13			F / M		A lot / Some / A little		Y / N	Y / N		

APPENDIX D BUILDING A BRIDGE FLYER

APPENDIX E – STUDY INFORMATION SHEET
Building a Bridge: a study to understanding caregiving in Iowa

Study information

What is the project about and why am I being asked to participate?

You have been asked to participate in this study to help us gain better understanding of caregiving in Iowa and evaluate the importance of connecting families affected by Alzheimer's or dementia with community resources.

What will I be asked to do if I choose to participate?

We ask that you meet with a research assistant to complete an initial interview. Once that is complete you will be placed in either Options Counseling or Usual Care group. If in Options Counseling group, you will meet with the counselor in person to learn about resources for your particular situation, and receive monthly phone calls for the remaining months of the study. The research assistant will also be in contact with you to complete surveys three months and six month later. If you are in Usual Care group, you will complete the initial and three- and six-month surveys; then will have an option of meeting with the Options Counselor.

Is there any risk to participation?

There is minimal risk associated with participation in interviews. You may feel uncomfortable answering some questions, but you are free to skip any question in surveys.

Is there any cost or benefit to me to participate?

There is no cost for participating in this study. Each person who participates in the study will receive a $20.00 check after each survey, with a total of up to $60.00 for three surveys.

Will information be kept confidential?

Yes. Confidentiality will be kept within the limits allowed by law. We will not ask for your social security number without HIPAA consent. The researchers and project staff including the Options Counselor are trained to respect your privacy. Authorized project staff will process information you provide in the interviews then keep the materials in a locked cabinet at the University of Iowa. Project reports will not use your name or include anything you said that could identify you. The results of the study will be reported in such a way that no individual will be identified.

Is participation voluntary?

Yes. You are not required to participate in this study. You can sign the consent form and still decide not to participate. You can ask questions or stop your participation at any time. Your decision whether or not to participate in this study will not impact the care you receive at the University of Iowa.

What if I have questions about my participation (now or during the project)?

Please call the Study Investigator, Dr. Sato Ashida at (319) 384-1477 or Research Manager, Lena Thompson at 319-384-1491 and they will answer any questions or concerns regarding this project. If you have any questions about your rights as a participant, you may call the Human Subjects Office at 319-335-6564 or e-mail irb@uiowa.edu

APPENDIX F – BUILDING A BRIDGE CONSENT LETTER

We invite you to participate in a research study. The purpose of the study is to learn about caring for individuals with newly-diagnosed dementia and to evaluate the impact of a new Options Counselor-Health Education (OC-HE) intervention that connects medical and community-settings to support caretakers of newly-diagnosed ADRD patients.

We are inviting you to be in this study because you are an adult who provides care to someone who has been diagnosed with Alzheimer's Disease or Related Dementias (ADRD) within the past 24 months. We have identified the person you care for as newly-diagnosed with dementia and are reaching out to you as someone who provides care for this person. Approximately 106 people will take part in this study at the University of Iowa.

If you agree to participate, your involvement in this study will last 6 months. We would like you to complete a baseline, 3 month, and 6 month interview with our research assistant. The baseline interview lasts between 40-50 minutes and the 3 month and 6 month surveys last between 30 and 40 minutes. To assure accuracy in our data collection, we may ask for your permission to record the interviews and interventions. You can let us know if you would prefer that we do not record the interviews or interventions at any time. Only the research team has access to these recordings and they will be destroyed after the study is complete. You are free to skip any questions you would not like to answer during the interview and can end your participation at any time.

In addition to completing the interviews, you will be randomized to receive the education being analyzed or not if you are in the standard care group. Randomization means whichever study group you are placed in will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of placement in either study group.

If you are randomized into the intervention group, our Options Counselor Health Educator will contact you to schedule one in-home visit within two weeks of your completion of the baseline interview. After that visit, you will complete five monthly phone calls over the next six months with the Options Counselor Health Educator. 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 standard care group, you will receive a call from a local options counselor after you have completed the 6 month interview. The purpose of connecting you to the options counselor after the research is complete is to offer you support, not to deliver the intervention to you. You may elect not to participate in options counseling.

We will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. We will be using an ID code number to identify your data in our database. The link to between your code number and name will be destroyed once the study is over. Once the study is over, it will not be possible for future research use of this data to be performed. If we write a report about this study we will do so in such a way that you cannot be identified.

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. 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 the affected individual.

You will not benefit personally from this study. However, we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study. You will be paid for being in this research study. You may also need to provide your address if a check will be mailed to you. You will receive $20 for each interview where you complete at least half of the interview, for a total of $60. The $20 checks will be mailed to you.

A description of this study will be available on http://www.ClinicalTrials.gov This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time. This study's ClinicalTrials.gov Identifier is NCT03932812.

Taking part in this research study is completely voluntary. 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.

If you have any questions about the research study itself, please contact Lena Thompson (lena-thompson@uiowa.edu or 319-384-1491). If you experience a research-related injury, you may also contact Lena Thompson. If you have questions about the rights of research subjects, 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. 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.

Thank you very much for your consideration.
Sincerely,
Sato Ashida, PhD
Project Investigator

APPENDIX G – ADVERSE EVENT FORM

Adverse Event Form

STUDY NAME	
Site Number: _____	
Pt_ID: _____	

Has the participant had any Adverse Events during this study? ☐ Yes ☐ No *(If yes, please list all Adverse Events below)*

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely related 2 = Possibly related 3 = Not related	1 = None 2 = Discontinued permanently 3 = Discontinued temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = Resolved, No Sequel 2 = AE still present- no treatment 3 = AE still present-being treated 4 = Residual effects present-not treated 5 = Residual effects present- treated 6 = Death 7 = Unknown	1 = Yes 2 = No	1 = Yes 2 = No (If yes, complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Relationship to Study Treatment	Action Taken	Outcome of AE	Expected?	Serious Adverse Event?	Initials
1.									
2.									
3.									

Adverse Event Form Version 1.0

APPENDIX H – SERIOUS ADVERSE EVENT FORM

National Center for Complementary and Integrative Health

Serious Adverse Event (SAE)
Report Form

STUDY NAME

Protocol Number:_____

Site Name:_____

Pt ID:_____

Date Participant Reported:

__ __ / __ __ __ / __ __ __ __
d d m m m y y y y

1. SAE onset date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y

2. SAE stop date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y

3. Location of SAE:_____

4. Was this an unexpected adverse event? ☐ Yes ☐ No

5. Brief description of participants with no personal identifiers:
   Sex: ☐ F ☐ M Age: _____
   Diagnosis for study participation:_____
   _____

6. Brief description of the nature of the SAE (attach description if more space is needed):
   _____
   _____

7. Category of the SAE:
   - ☐ Date of death ___/_____/_____ (dd/mmm/yyyy)
   - ☐ Life threatening
   - ☐ Hospitalization – initial or prolonged
   - ☐ Disability/incapacity
   - ☐ Congenital anomaly/birth defect
   - ☐ Required intervention to prevent permanent impairment
   - ☐ Other:_____

8. Intervention type:

☐ Medication or nutritional supplement (specify):_____

☐ Device (specify):_____

☐ Surgery (specify):_____

☐ Behavioral/lifestyle (specify):_____

APPENDIX J – ADVERSE EVENTS/SERIOUS ADVERSE EVENTS LISTING

Data as of:_____

Date of report:_____

Participant ID	Onset Date	Stop Date	Expected (Y/N)	Relationship to Intervention* (Y/N)	Outcome**	Description of SAE

* *Definite, Possible, Not Related*

** *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present – no treatment
Residual effect(s) present- being treated
Subject died

APPENDIX K – BUILDING A BRIDGE PROTOCOL DEVIATIONS LOG

Building a Bridge Protocol Deviations

Deviation Date	Description	Action Taken	AE or SAE form filled out	Reporting Plan

Deviation Date	Description	Action Taken	AE or SAE form filled out	Reporting Plan

Deviation Date	Description	Action Taken	AE or SAE form filled out	Reporting Plan

APPENDIX M – UNIVERSITY OF IOWA HAWK IRB REPORTABLE EVENT QUESTIONS (FROM ONLINE FORM)

1. What type of event are you reporting?
   - A serious adverse drug event (either expected or unexpected) occurring in a subject enrolled by a UI investigator/research team member.
   - A serious adverse device effect (either anticipated or unanticipated) occurring in any subject enrolled either by the UI investigator/research team member or enrolled by a non-UI investigator at another site.
   - Receipt of new information that may impact the willingness of subjects to participate or continue participation in the research study.
   - An unanticipated problem involving risks to subjects or others which occurs in a subject enrolled by a UI investigator/research team member or that would impact subjects or conduct of the study at UI.
   - Noncompliance with federal regulations or the requirements or determinations of the IRB.

2.Reportable Event Form ID/Short Description:
   - Date of occurrence:
   - Describe the unanticipated problem:

V. Unanticipated Problem
3. Did this unanticipated problem occur in a subject enrolled by a UI investigator/research team member?

Yes No

V. Unanticipated Problem
4. Did this unanticipated problem affect others associated with the subject or others associated with the research at UI (e.g. research team, family members of research subjects)?

Yes No

V. Unanticipated Problem
5.How many subjects have signed a UI consent to enroll in this study?

6.Is this study permanently closed to enrollment at UI?

Yes No

7. In the judgement of the UI Principal Investigator, how likely is it that this unanticipated problem was related to the study drug or procedures associated with this protocol?
   - Definitely Related
   - Probably Related / Likely
   - Possibly Related / Maybe
   - Probably Not Related / Unlikely
   - Definitely Not Related

If you have any attachments that you want to include with your Reportable Event Form (such as supporting documentation), include them here.

APPENDIX N – PARTICIPANT INCENTIVE FORM

Name: _____

Do you have U.S. Citizenship: Yes No

Mailing Address:

_____

Amount paid or value of the item given as compensation: $20.00

If you Circled 'No' for 'Do you have U.S. Citizenship' please also provide the following:

Immigration (visa) status:

_____

Tax residency country (may not be the same as citizenship country)

Permanent foreign address:

_____

U.S. address: _____

APPENDIX Q – OPTIONS COUNSELING HIPAA DOCUMENT

Acknowledgement of Receipt of the Notice of Privacy Practices

I understand, that under the Health Insurance Portability & Accountability Act of 1996 (HIPAA), I have certain rights to privacy regarding my protected health information (PHI). The Notice of Privacy Practices has been made available to me, which explains those rights.

_____ _____

(Client's Signature) *(Date)*

Print Client's Name: _____

_____ _____

(Legal Representative Signature if applicable) *(Date)*

Print Name: _____

Relationship of representative to client: _____

Updated 9/23/2013

APPENDIX R – PARTICIPANT ID LIST

Participant ID List

Participant Name	Study ID

APPENDIX S – PHONE CALL LOG

Phone Call Log

Participant Name	Contacted By	Date Contacted	Contacted About	Notes

APPENDIX T – STUDY PERSONNEL

Administrators

Name	Role	Email	Phone	Address
Elena Fazio	NIA Program Director, Project Officer	elena.fazio@nih.gov		National Institute on Aging/National Institutes of Health Gateway Building, suite 3S600 7201 Wisconsin Avenue Bethesda MD 20892
Lesa McQueen	Senior Grants Management Specialist	Lesa_McQueen@nih.gov	301-496-1472	Grants & Contracts Management Branch National Institute on Aging 7201 Wisconsin Avenue, Ste. 2N212 Bethesda, MD 20892-9205
Lynn Hudacheck	CRA l Associate Director, Division of Sponsored Programs, M. authorized institutional representative, acting on behalf of John Keller, Interim Vice President for Research	Lynn-hudachek@uiowa.edu	319.335.2123	The University of Iowa **l** 2 Gilmore Hall **l** Iowa City, IA 52242
Rob Svetly	Administrative Services Manager	robert-svetly@uiowa.edu	(319) 384-1473	145 N Riverside Dr. N434 CPHB, University of Iowa 52242

Research Team

Name	Role	Email	Phone	Address
Sato Ashida	Project Investigator	Sato-ashida@uiowa.edu	(319) 384-1477	145 N Riverside Dr. N434 CPHB, University of Iowa 52242
Kristi Williams	Co-Investigator	Kwilliams1@kumc.edu		
Hyunkeun (Ryan) Cho	Statistician	Hyunkeun-cho@uiowa.edu	(319) 384-1581	145 N Riverside Dr. N312 CPHB, University of Iowa 52242
Lena Thompson	Research Manager	Lena-thompson@uiowa.edu	(319) 384-1491	145 N Riverside Dr. N471 CPHB, University of Iowa 52242
Haley Schneider	Research Assistant	Haley-schneider@uiowa.edu	(319)	145 N Riverside Dr. N471 CPHB, University of Iowa 52242

Clinical Team

Name	Role	Email	Phone	Address
Nicholas Butler	Geriatric Assessment Clinic	Nicholas-r-butler@uiowa.edu	319-384-7000 319-467-2000	Iowa River Landing East 920 E. 2nd Ave, Coralville, IA 52241
Georgina Aldridge	Neurology Clinic	Georgina-aldridge@uiowa.edu		200 Hawking Dr. Iowa City, IA 52242
Gretchen Schmuch	Family Medicine Social Worker	Gretchen-schmuch@uiowa.edu	319-384-7222	Iowa River Landing East 920 E. 2nd Ave, Coralville, IA 52241
Kristen Caraher	Psychiatry	Kristen-caraher@uiowa.edu		200 Hawking Dr. Iowa City, IA 52242

DSMB

Name	Role	Email	Phone	Address
Cathleen Connell	Chair	cathleen@umich.edu		
Leslie McClure	Member	Leslie.a.mcclure@drexel.edu		
Ellen Mahoney	Member	Ellen.mahoney@bc.edu		

APPENDIX U – POTENTIAL PARTICIPANT CONTACT INFORMATION FORM

Name: _____

Do you give permission for Manager Lena Thompson to contact you about the Building a Bridge Research Study? Ms. Thompson will make up to 3 attempts to contact you: Yes No

Phone Number:

_____

E-mail Address:

_____

Preferred Method of Contact: Phone E-mail

APPENDIX V – INTERVIEW SCRIPTS (WITH ADVERSE EVENT SAFETY CHECK)

Interviewer Script 1: Baseline Scheduling and Basic Information

Interviewer first contact with Caregiver by phone:

Hi this is _____at the University of Iowa College of Public Health. I am calling because you expressed interest in receiving more information about the Building a Bridge project when you were at the _____ clinic.

If Caregiver wants more information:

The purpose of this study is to understand the impact of dementia diagnoses on individuals and those providing support. We have developed a program to help people providing support to someone with dementia and are testing to see how it helps those involved. If you enroll in this study, there is a 50% chance that you will participate in the program and a 50% chance that you will receive the usual care provided by the clinic. All participants, whether they receive the program or not, will complete three surveys either in person or over the phone with me. The surveys take between 30 and 50 minutes to complete. If you would like to participate, we can schedule the first one today. The other two will happen in 3 months and in 6 months. I also want to let you know that even if you receive the usual care during this study, you will have the opportunity to receive the program we created after you complete the 6 months survey. Participants need to be 18 years or older, living in Iowa, and must be caring for someone who has been diagnosed with Alzheimer's or dementia within the past 6 months.

Are you interested in participating in this study?

If yes

Great! The first step is to do a survey, which I will call the baseline survey. It takes about 40-50 minutes to complete. Would you like to schedule a time for me to either come to you or call you to do the survey?

Make sure to note the time, location, best phone number to reach participant, ask about internet (if doing online), ask if participant wants a reminder call, and let them know that it might be helpful to have their packet.

If no

Ok, no problem. For our record, may I ask why you decided not to participate?

Research Assistant Script 2: Baseline Survey

Interviewer calls to do baseline

Hi this is _____at the University of Iowa College of Public Health. I am calling/here to do the baseline survey for the Building a Bridge project with _____.

Before we get started, I just wanted to go through a few things about study

Read through consent letter

Thank you for participating in our study. We would like to ask you some questions about your experiences supporting individuals diagnosed with dementia, how you are feeling in general, about clinical or community-based services that are available, as well as some background information about you and the person who received dementia diagnosis who we refer to as "the individual" in this survey. I'm going to start with questions about your background.

Conduct Baseline Interview

After Baseline:

Thank you for taking the time to speak with me today and answer these questions. I will be sending you $20.00 in the mail and providing a follow up call to make sure you received the money.

If participant decided not to participate:

That's ok. For our records may I ask you why you decided not to participate?

Research Assistant Script 3: 3 Month Follow-up Survey

Interviewer calls to do 3 month follow-up

Hi this is _____at the University of Iowa College of Public Health. I am calling/here to do to do the 3 month follow-up survey for the Building a Bridge project with _____.

Before we get started, I just wanted to check and see how you are doing. Have you noticed anything different since you started the study? *If any adverse events, create an AE form and fill out.*

Thank you for participating in our study. We would like to ask you some questions about your experiences supporting individuals diagnosed with dementia, how you are feeling in general, about clinical or community-based services that are available, as well as some background information about you and the person who received dementia diagnosis who we refer to as "the individual" in this survey. I'm going to start with questions about your background.

Conduct 3 month follow-up survey

After Interview:

Thank you for taking the time to speak with me today and answer these questions. I will be sending you $20.00 in the mail and providing a follow up call to make sure you received the money.

If participant decided not to participate:

That's ok. For our records may I ask you why you decided not to participate?

Research Assistant Script 4: 6 Month Follow-up Survey

Interviewer calls to do 6 month follow-up

Hi this is _____at the University of Iowa College of Public Health. I am calling/here to do to do the 6 month follow-up survey for the Building a Bridge project with _____.

Before we get started, I just wanted to check and see how you are doing. Have you noticed anything different since you started the study? *If any adverse events, create an AE form and fill out.*

Thank you for participating in our study. We would like to ask you some questions about your experiences supporting individuals diagnosed with dementia, how you are feeling in general, about clinical or community-based services that are available, as well as some background information about you and the person who received dementia diagnosis who we refer to as "the individual" in this survey. I'm going to start with questions about your background.

Conduct 6 month follow-up survey

After Interview:

Thank you for taking the time to speak with me today and answer these questions. I will be sending you $20.00 in the mail and providing a follow up call to make sure you received the money.

Thank you for participating in this study. Your participation is now complete. You can contact me at _____ if you have any further questions. You will receive your $20 reimbursement and a letter that will let you know how you can find the results of this study and who to contact with further questions.

If participant decided not to participate:

That's ok. For our records may I ask you why you decided not to participate?

APPENDIX W

Evaluation to Sign an Informed Consent Document for Research
[DeRenzo EG, et al. J Health Care Law Polic 1998;1:66-87]

Subject Identifier: _____ Date of Evaluation: _____

Directions

Make a subjective judgment regarding item 1. Ask the subject questions 2-5 and record responses. The evaluator may use different wording in asking the questions in order to assist the subject's understanding.

1. Is the subject alert and able to communicate with the examiner? Yes ____ No ____

2. Ask the subject to name at least two potential risks of participating in the study.

_____

_____

3. Ask the subject to name at least two things that he/she will be expected to do during the study.

_____

_____

4. Ask the subject to explain what he/she would do if he/she no longer wanted to participate in the study.

_____

_____

5. Ask the subject to explain what he/she would do if he/she experienced distress or discomfort during the study.

_____

_____

Evaluator's Signature

It is my opinion that the subject is alert, able to communicate, and gave acceptable answers to the questions above.

_____

Evaluator's Signature Date

APPENDIX X – MOP MODIFICATION LOG

Section #	Version #	Page #	Text Location	Modification Summary