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A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighbor

NCT: NCT03665909; IRB Study ID: 1401S47541; Protocol date 9/26/22; Protocol approval 10/7/22

ANCILLARY REVIEWS

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PROTOCOL COVER PAGE

Protocol Title	**A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighbor**
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REVISION HISTORY

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#38	N/A	Staff update only	No
#39	9/26/22	Updated plan to share study results with participants; staff update	No
#40	N/A	Re-upload to IRB system of 9.26.22 protocol associated with mod 39	No

Table of Contents

ABBREVIATIONS/DEFINITIONS

ADRD: Alzheimer's disease or a related dementia

AD: Alzheimer's disease

TLHA: The Lutheran Home Association

ADLs: Activities of daily living

AHRQ: Agency for Healthcare Research & Quality

SPM: Stress Process Model

RCT: Randomized controlled trial

PI: Principal Investigator

NIH: National Institutes of Health

AA: Alzheimer's Association

SLUMS: St. Louis University Mental Status

MBA: Minnesota Board on Aging

CAB: Community Advisory Board

PWML: Person with Memory Loss

LAR: Legally authorized representative

DNT: Director of Nursing and Technology

RC: Research Coordinator

ICER: Incremental cost-effectiveness ratio

ISM: Independent study monitor

DSM: Data & Safety Monitoring

1.0 Objectives

Purpose: Sensor-based technologies that operate remotely and are non-invasive could assist family caregivers monitor the daily function of persons with Alzheimer's disease or a related dementia (ADRD). The eNeighbor technology platform includes a combination of remote sensors that are located in key areas of a person with ADRD's home (e.g., bed, medicine cabinet or refrigerator doors, toilet, living rooms). Such sensors can immediately communicate any function that is outside of an expected threshold for the person with ADRD to both a family caregiver and a care professional (e.g., nurse care manager). The goal of the remote health monitoring technology such as eNeighbor is to prevent negative health transitions such as falls or wandering events, and thus provides a more proactive intervention model than many clinical protocols that are currently delivered to family caregivers of persons with ADRD. The Lutheran Home Association, a non-profit long-term care provider located in Belle Plaine, Minnesota, has deployed eNeighbor in residential and home settings the past 5 years.

The objective of this 5-year demonstration project is to build on the work of The Lutheran Home Association and conduct an embedded experimental mixed methods evaluation to determine the efficacy of the eNeighbor technology in improving outcomes among persons with ADRD living in the community and their family caregivers.

In collaboration with a 15-member Community Advisory Board that includes community care providers, healthcare organizations, and ADRD caregivers themselves, the proposed 5-year project will build on the current efforts of TLHA to evaluate eNeighbor remote monitoring technology for persons with ADRD living in the community and their family caregivers. We anticipate that the successful completion of the project aims will position the eNeighbor as an innovative, stakeholder-centric service that offers robust support for family caregivers of persons with ADRD in the community.

The Specific Aims are as follows:

1) To determine the efficacy of remote sensor technology over an 18-month period for 100 persons with ADRD and their caregivers randomly assigned to an eNeighbor treatment condition when compared to 100 usual care controls. We hypothesize:

Hx. 1) Significant ($p < .05$) improvements in caregiver self-efficacy and sense of competence in managing a relative's ADRD;

Hx. 2) Significant reductions in caregiver distress (e.g., subjective stress, or feelings of emotional fatigue and role entrapment; depressive symptoms);

Hx. 3) Significant delay of or reductions in health transitions (falls, wandering) and service utilization (hospitalizations, nursing home admission) for persons with ADRD; and

Hx. 4) Greater cost-effectiveness associated with a person with ADRD's health service use.

2) To "embed" evaluation components: a) during the randomized controlled evaluation through the administration of open-ended survey items to all ADRD caregivers in the eNeighbor treatment condition every 6 months to examine the utility of the remote health monitoring technology; and b) at the conclusion of the 18-month evaluation by purposively sampling 15

ADRD caregivers who reported positive acceptance on the embedded qualitative and quantitative 6-, 12-, and 18-month system reviews and 15 ADRD caregivers who reported low acceptance on the embedded qualitative and quantitative 6-, 12-, and 18-month system reviews to participate in semi-structured interviews. The interviews will help the research team determine why the health monitoring intervention was or was not efficacious; and

3) To engage stakeholders on a quarterly basis throughout the 5-year project with the goal of enhancing the utility (via community-based participatory approaches)[67] and stakeholder-relevance of eNeighbor implementation and evaluation for family caregivers of persons with ADRD.

2.0 Background

2.1 Significance of Research Question/Purpose:

Alzheimer's disease or a related dementia (ADRD) is extremely challenging to manage and treat due to complexities in detection, interacting symptoms, and length of progression.[1] Because persons with dementia rely heavily on informal (i.e., unpaid) sources of care, the prevalence of Alzheimer's disease (AD) has a staggering effect on families. In 2013, 80% of the 5.2 million persons with AD in the United States (U.S.) were cared for by a family member and 15.4 million individuals provided unpaid care to a person with ADRD.[1] There is no one consistent definition of *caregiving*, but in its most global sense caregiving refers to attending to an individual's health needs. More specific definitions emphasize that caregiving includes provision of assistance with one or more activities of daily living (such as bathing, dressing, transferring).[2,3] In the dementia context, caregiving can extend to the management of symptoms such as memory loss, behavioral disruptions, and similar concerns. The typical AD caregiver in the U.S. is female, 48 years of age (suggesting multiple role responsibilities in addition to family care) and assists a relative who is 78 years old.[4] A well-established literature demonstrates the adverse effects of ADRD care on family members including impaired physical health and immune system response,[5-7] financial strain,[4] degradation in social well-being, and increased prevalence of depression, anxiety, or other negative mental health symptoms.[8,9] With the accumulation of evidence demonstrating the physical, financial, social, and psychological risks of dementia family care, a series of clinical interventions have been developed and evaluated. Meta-analyses and systematic reviews suggest moderate overall benefits of these interventions for ADRD caregivers and their care recipients.[1,5,10-12]

Although family members of persons with dementia are willing to utilize technology to improve their respective caregiving situations, few studies have determined whether various technologies can help families alleviate negative outcomes for caregivers of persons with ADRD.[13-20] Among the potential benefits of technological interventions is the ability to assist family caregivers of persons with ADRD regardless of geographical distance, which is in contrast to standard ADRD caregiver interventions where treatment is often delivered face-to-face to family caregivers in

need. Technology-based interventions also have the potential to overcome another barrier to ADRD caregiver interventions: that of time and scheduling.[21] Family members can often utilize and benefit from various types of technology-based interventions at any time, thus making these approaches asynchronous. Technology interventions evaluated include telephone-based approaches (conference calls among family members of persons with ADRD, automated telephone messages and support, respite calls for persons with ADRD) and computer or internet-based strategies (e.g., DVD-based delivery of education and support, online discussion boards, electronic reminders, computer-based encyclopedias and information resources, online decision-making support).[22] While technology interventions for ADRD caregivers have shown some promise, small samples, inconsistent measurement, and lack of high quality randomized controlled evaluations suggest the need for further research.[15,23-36]

The proposed demonstration project will advance scientific knowledge, technical capability, and clinical practice as they pertain to ADRD caregiver interventions. Although research on family caregiving has served as a platform for multidisciplinary research,[37,38] a critical gap in this literature is the lack of randomized controlled studies that evaluate advanced, low-cost, high potential technologies to alleviate the stressors and other negative outcomes associated with everyday ADRD care. The proposed project will be one of very few clinical trials that evaluate the efficacy of home-based sensor technologies on actual user outcomes (e.g., family caregivers, older adults) in a real world environment using an experimental design.[19,22] Specifically, Healthsense, Inc. has developed a suite of remote monitoring tools called the eNeighbor, and the Lutheran Home Association (TLHA: a non-profit, long-term care provider) has been implementing eNeighbor in residential care settings and home environments in Minnesota and Wisconsin as part of its routine services offered over the past 5 years. The overarching objective of eNeighbor is to lower the cost of care, increase independence of disabled older persons, and enhance quality of life for chronically disabled older persons and their family caregivers by allowing older persons to remain in their homes safely for as long as possible.

2.2 Preliminary Data:

A number of case studies and survey research efforts establish the feasibility of the eNeighbor remote sensor technology in various residential and community-based long-term care settings and its potential to prevent falls, medical emergencies, and similar negative health events.[65] An oft-repeated sentiment of users and family caregivers is that the technology represents a "godsend"[66] with no adverse events reported. The feasibility of eNeighbor has been further established with dementia caregivers in home settings through peer-reviewed pilot research by the study consultant, Jennifer Kinney, PhD (who has expertise in studying health technology for ADRD caregivers as PI; R21 AG029224).[14-16] Using a controlled design, Kinney and colleagues[14] enrolled 28 individuals who were caring for a co-resident family member with dementia (13 spouses, 15 adult children). When compared to baseline, intervention group caregivers ranked meaningful activity and enjoyment as significantly more important than usual care controls at follow-up. Qualitative interviews were used to supplement and elaborate upon the quantitative findings; specifically, several caregivers reported adaptation to the constant presence of the

eNeighbor technology in the weeks immediately following installation. As one caregiver stated, "For the first few weeks I thought about it every time I opened something. I thought about it being recorded, but now I haven't been thinking about it anymore." The importance of control also became more salient as caregivers came to trust the eNeighbor technology: "You had asked if we wanted a monitor on the front door and I said never, but then the other day he actually tried to get out the door. It happened to be locked and he couldn't figure it out. I've never noticed that before. Now we want the monitor." Cumulatively, these preliminary studies suggest the potential and the feasibility of eNeighbor for ADRD caregivers.

2.3 Existing Literature:

The eNeighbor directly aligns with components of quality chronic disease care as proposed by healthcare experts and the Agency for Healthcare Research & Quality (AHRQ).[39-42] The eNeighbor and its integrated, remote sensor technology platform aims to prevent negative health transitions (i.e., falls, wandering) by allowing for a method of continuous monitoring and ongoing communication between the ADRD caregiver and a nurse care manager. The eNeighbor also allows for the appropriate management of chronic disease by episode instead of by health care professional encounter (e.g., regular visits to a primary care provider, emergency room visits), again resulting in a more proactive intervention approach. The remote monitoring platform of eNeighbor also allows chronic care to occur across locations as opposed to solely in formal medical settings. For these reasons, the eNeighbor intervention differentiates itself from many existing ADRD caregiver interventions which are often premised on crisis management (e.g., components of a psychosocial or clinical intervention are enacted only after a problem occurs, such as a wandering event or behavioral disruption).

This innovative dimension also becomes apparent when compared to other assistive devices, which do not provide person-centered, dynamic, time-sensitive information on older persons' functional behaviors. Specifically, eNeighbor uses complex algorithms that allow for the identification of routine function of the older adult and whether behaviors occur within or outside expected thresholds to trigger further health intervention. Current assistive devices such as bed alarms provide some degree of monitoring assistance, but are more oriented around crisis management rather than prevention (and existing evidence is not clear on the efficacy of these approaches). Similarly, while assistive supports such as hand rails may offer the least expensive solution, they are not able to provide real-time, monitoring data that is personalized to older persons at-risk. The potential of health monitoring technology such as eNeighbor is also increased due to the increasingly lowered costs associated with sensors and sensor maintenance. As the costs of these technologies decrease along with the concurrent increase in availability of cellular and broadband connectivity in U.S. households (see below), it is anticipated that health monitoring technology use will become more prevalent in caregiving households.

Health care experts have emphasized the need to better utilize technology to enhance care management, track patient outcomes, and effectively administer treatments.[43] While much is made of the promise of electronic health records or other technological advances, it remains

fairly unknown whether they (or other technological aids)[24-33] are actually effective for populations such as ADRD caregivers.[44-47] A comprehensive review identified evidence demonstrating efficacy of health information technology in various chronic disease conditions to facilitate person-centered care as well as barriers to feasibility and utility, but no high quality studies existed demonstrating the efficacy of such technology for dementia family caregivers.[48] The proposed R18 demonstration will attempt to address this gap by examining the efficacy of health monitoring technology for persons with ADRD and their family caregivers to establish it as an evidence-based, innovative protocol.

A key component to this project is the integration of stakeholders' voices throughout the evaluation process. An active Community Advisory Board will serve in a collaborative capacity; it will engage with the PI on various research-related procedures, identify additional key open-ended questions to guide the process and outcome evaluation, explore barriers and facilitators to how health monitoring technology is delivered and utilized by persons with ADRD and their family caregivers, and assist in refining the evaluation design and dissemination to guide ongoing development along with the research team. Such engagement will be critical to ensuring that the benefits of health monitoring technology for persons with ADRD and their caregivers has high relevance for stakeholders.

The development and evaluation of the eNeighbor is grounded in a well-established conceptual model that has been used to successfully evaluate the efficacy of interventions for ADRD family caregivers.[49-51] The Stress Process Model (SPM) has been used extensively to study the manifestation of negative outcomes in dementia caregiving.[52-55] The SPM is based on the mechanism of "proliferation," where the emotional stress of care provision to a person with dementia (primary stress) spreads to other life domains which are then posited to negatively influence global caregiving outcomes such as caregiver mental health or the person with ADRD's institutionalization. Psychosocial resources or formal service use may help stem stress proliferation and protect ADRD caregivers from negative outcomes.[53]

The conceptual framework for the proposed project integrates constructs from the SPM. **Context of care** variables are conceptualized as key covariates; context of care considers key sociodemographic and background characteristics that may influence outcomes for persons with ADRD or their family caregivers. Similarly, **resource** variables such as perceptions of socioemotional support and community-based service use are considered as covariates in the eNeighbor conceptual model that could potentially alleviate negative outcomes. A final set of covariates considered in our conceptual model include **primary objective stressors**, or indices of dementia severity that may require greater day-to-day care provision on the part of family members. The proposed conceptual model positions eNeighbor as a key resource; the remote sensor technology of eNeighbor for dementia caregivers is hypothesized to independently and directly: **improve caregiver self-efficacy and competence, reduce caregiver distress** (subjective stress and depressive symptoms), **delay or reduce negative health transitions for the person with ADRD** (falls, wandering), and **delay or reduce the person with ADRD's service utilization** (residential care placement, hospitalization). The SPM is aligned with conceptualizations of

intervention effectiveness in the health information technology literature, suggesting that utilizing the SPM is appropriate when evaluating the efficacy of eNeighbor.[56]

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: Caregiver self-efficacy and competence

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): Caregiver distress (subjective stress and depressive symptoms), negative health transitions for person with ADRD (falls, wandering), service utilization of person with ADRD (residential care placement, hospitalization).

4.0 Study Intervention(s)/Interaction(s)

4.1 Description: The home-based sensor technology of eNeighbor relies on multiple, non-invasive and safe remote monitors that can alert family caregivers and/or health professionals to potentially negative situations that lead to adverse outcomes (e.g., wandering, falls, incomplete activity of daily living tasks). The eNeighbor core system includes four unobtrusive motion sensors that are placed in a living room, bedroom, bathroom, and an entryway that can detect motion in a room to verify daily activity (and do not include a microphone or camera). These motion sensors operate jointly and exchange information to help identify significant changes in movement or function and can be used to detect urgent needs for help among persons with ADRD such as a fall. Three contact sensors can detect whether a door or cabinet is opened or closed (often placed on a front door, refrigerator, or medicine cabinet); these sensors can measure whether the person with ADRD is accessing important areas of the home and can help to determine if basic care plans are followed or activities of daily living (ADLs) are performed as expected. A toilet sensor is also mounted inside a tank that can monitor flushes. A bed occupancy sensor is placed between the mattress and box spring that can monitor time in and out of bed for the person with ADRD, as such occupancy routines can help to detect potential early stage symptoms of a number of health conditions (e.g., night time rest is frequently interrupted due to pain).

Alerts are sent to the family caregiver as well as a nurse care manager that monitors the real-time information generated by the eNeighbor sensors. An example monitoring event could occur as follows: a motion sensor detects the person with ADRD has entered a bathroom. Once the person with ADRD enters the bathroom, the motion and toilet sensors' timers are set at 10 minutes to determine whether any motion occurs in the bathroom or the toilet is wet or dry. If the motion or toilet sensors in the bathroom do not detect any activity within 10 minutes (or another household sensor detects activity in some other area of the home), an action alert is sent to notify the caregiver and nurse care manager that an expected ADL-using the bathroom-did not take place. eNeighbor sensors operate according to self-adapting thresholds (e.g., time expected to complete a given ADL) that can be set by the family caregiver or the nurse care manager upon installation of the system; if the person with ADRD is outside the normal timing threshold, the eNeighbor sensors will then alert the family caregiver and nurse care manager.

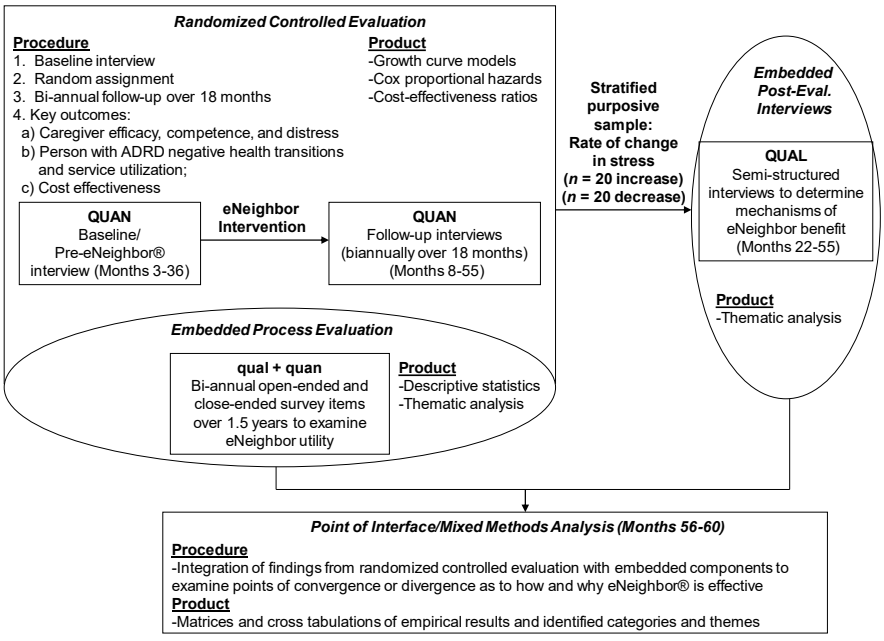
The technology platform of eNeighbor relies on wireless infrastructure that allows for remote monitoring via alerts that are communicated to the family caregiver's or nurse care manager's personal computers or handheld devices. eNeighbor also includes a private care coordination and socialization tool for the family caregiver of the person with ADRD through the MyHealthsense web portal. MyHealthsense provides scheduled reports to the family caregiver and the nurse care manager that summarizes eNeighbor sensor activity and links this information to the person with ADRD's electronic health record. In this manner, primary care providers can review the person with ADRD's daily function.

5.0 Procedures Involved

5.1 Study Design:

Mixed methods is generally defined as the collection and analysis of both quantitative and qualitative data that links these two forms of data concurrently, sequentially, or embedded one into another.[57,58] Among the various rationales for conducting mixed methods research are: a) to better understand a research problem by converging numeric trends from quantitative data and specific details from qualitative data; and b) to obtain statistical, quantitative data from a sample of a population and use them to identify individuals who may expand on the empirical results through qualitative findings.[59] Few evaluations of ADRD caregiver interventions have combined qualitative and quantitative data to obtain a greater understanding of why certain protocols are beneficial or not. For these reasons, an embedded experimental mixed methods design will be utilized for the proposed demonstration. An embedded experimental mixed methods design combines the collection and analysis of qualitative data within a traditional randomized controlled trial (RCT) design; the collection of the embedded qualitative data may occur prior to, during, or after the RCT.[57, p. 90] The embedded experimental design will assist the research team examine the process of eNeighbor's implementation during the conduct of the RCT and determine why and how the eNeighbor worked or did not for ADRD caregivers following the completion of the RCT (see Figure 1).[57,60-63]

Figure 1. Embedded experimental mixed methods design.



5.2 Study Procedures:

Recruitment. The Principal Investigator (PI) or research coordinators (RCs) will initiate email, telephone, or mail contact with ADRD caregivers on the University of Minnesota Caregiver Registry (IRB# 1007S85812) or others recruited by the PI (see above) who potentially meet the project inclusion criteria. In addition, the PI or RCs will ask professional caregivers on the Registry to identify potential ADRD caregivers for recruitment purposes (this will also occur via the various other recruitment and outreach activities noted above). During initial enrollment contacts, the PI or RCs will describe the eNeighbor monitoring system, explain study procedures, and invite potential ADRD caregivers to participate. Caregivers will be offered the opportunity to ask any questions about the study procedures. The Telephone and Email script will be utilized (see Appendix for form location). For an example, audio clip of the PI discussing the project with a hypothetical participants, see the Appendix as well.

These recruitment efforts will be facilitated by the Minnesota Board on Aging (MBA), the Minnesota-North Dakota Alzheimer's Association regional office, and other organizations. The MBA will help us promote this study through Area Agencies on Aging, many of which serve ethnic and racially diverse older adults as well rural ADRD caregivers. Specifically, the Information Sheet will be distributed to the MBA and associated Area Agencies on Aging in Minnesota, the Minnesota-North Dakota Alzheimer's Association, or other organizations to distribute to family members or family members of clients that these organizations serve (see Appendix for form location). The Information Sheet is also used as the basis for any other advertising efforts or by other organizations who wish to reach out to their clients and families regarding this opportunity. Finally, a Letter to Families can be sent to organizations if they wish to distribute to their clients or family members of clients (see Appendix for form location).

Additional recruitment efforts may occur, on an as-needed basis, via the PI's or RC's community outreach efforts. The PI, via the annual Caring for a Person with Memory Loss conference (see https://www.sph.umn.edu/events-calendar/caring-for-person-with-memory-loss-conference/) and a number of other community presentations, will have the opportunity to recruit potential participants. Following an overview of the study procedures, the PI or RC will provide interested participants with a Documentation of Permission form to complete, which will provide the PI and research team members to contact the potential participant to determine eligibility and proceed with enrollment (see Appendix for form). If independent living settings or similar residential providers are willing to collaborate with the research team to identify potential participants, we ask them to: a) distribute via email or print the study flyer, information sheet, letter to families, and/or other recruitment information to announce the study and its availability; b) approach residents or family members to discuss the study, and if there is interest, obtain permission for Dr. Gaugler or his team to follow-up and contact them to initiate the recruitment and enrollment procedure; and c) setting liaisons will simply forward potentially interested family members' contact information to Dr. Gaugler to do so.

Eligibility screening. If caregivers agree to participate, the PI or RC will initiate a brief screening procedure. The following inclusion criteria will be applied for persons with ADRD: 1) English

speaking; 2) physician diagnosis or recognition of ADRD (e.g., Alzheimer's disease, Lewy Body disease, fronto-temporal dementia, or stroke/vascular dementia; mild cognitive impairment); 3) not currently receiving care or case management services; and 4) 55 years of age and over. Caregivers of persons with ADRD must: 1) speak English; 2) be 21 years of age and over; 3) self-identify as someone who provides help to the person with ADRD because of their cognitive impairments; 4) self-identify as the person most responsible for providing hands-on care to the person with ADRD or sharing that role with someone else (i.e., the "primary" family caregiver, which can include highly involved kin or non-kin of persons with ADRD; those who share care responsibilities are also eligible); 5) plan to, or ideally wish to, remain in the area for at least 18 months in order to reduce possible loss to follow-up; and 6) indicate a willingness and need to use eNeighbor. To determine eligibility, the E-Neighbor Screening Form will be administered either in-person over the telephone by the PI or RC to determine and identify eligible persons with ADRD and their family caregivers (see Appendix for form location).

Enrollment/Consent and Assent
Within two weeks following the completion of eligibility screening, consent/assent procedures and baseline interviews will be scheduled within 2 weeks for eligible caregivers. Signed informed consent from the eligible family caregiver will take place. Signed informed consent will be offered in-person, via mail, or if deemed most convenient to the family caregiver, via an online consent form.

If a legally authorized representative (LAR) for the person with ADRD is identified other than the family caregiver, we will also obtain signed consent from this individual. For the purposes of efficiency, we will offer an online consent form to review and approve. All online consent and HIPAA forms will be administered via the secure University of Minnesota Google Docs application.

In addition to administering informed consent forms to family caregivers and LARs, we will additionally provide HIPAA forms (either in-person or via mail and online formats) for the family caregiver and LAR to review and sign. To complete this procedure, the Family Caregiver Consent Form, the LAR Consent Form, and the HIPAA form will be utilized (see Appendix).

Following the securing of consent of primary caregivers and LARs, Verbal Assent of persons with ADRD will take place (see Appendix). While ideally this may take place simultaneously with the consent procedures above, there may be a delay in time (hopefully no more than several days) between when consent is secured from family caregivers and LARs and assent of the person with ADRD.

Baseline

As soon as possible following the completion of consent, HIPAA, and verbal assent, the baseline survey/interview will take place. The survey/interview will ask the family caregiver to complete a survey that will ask questions about the family caregiver, the person with ADRD, and the person with ADRD's and family caregiver's memory loss' emotional, psychological, physical health, the

caregiver's confidence about their care situation. The survey/interview we will also ask the family caregiver about various health events that the person with ADRD may have experienced. The baseline survey can occur in-person, in the family caregiver's home, Mayo Building at the University of Minnesota, or another location of the family caregiver's choosing. A mail survey, telephone interview, or online survey will also be arranged if that is easier for the family caregiver. If the caregiver elects to complete the online version of the survey, the survey link will be emailed to the caregiver; see the Appendix for email script. To complete this procedure, the Baseline eNeighbor Survey will be utilized (see Appendix for form location).

Treatment/Intervention Period

Following the completion of baseline interviews, ADRD caregivers will be randomly assigned to an eNeighbor treatment condition that receives the multi-sensor, remote monitoring system or an attention control group. Randomization (participant is assigned to either the treatment or control condition) will be completed via an a priori list generated from http://randomizer.org by the PI. The PI will inform the ADRD caregiver of their randomization status within 2-3 days following completion of the baseline interviews.

The PI or research coordinators will call caregivers in the control group 48 hours following assignment to the usual care control group to address any questions they may have and to thank them for being part of the study and volunteering their time if no response from the participant in the usual care group is received following randomization). Group allocation (either attention control or treatment condition) will be based solely on their a priori randomization assignment number. The PI or research coordinators will then inform the ADRD caregiver of her/his group assignment within 2 days of baseline survey completion.

Following ADRD caregivers' enrollment into the proposed project and within 2 weeks of randomization to the eNeighbor treatment condition, the Director of Nursing and Technology (DNT) will schedule a visit at the home of the person with ADRD and the enrolled family caregiver. The DNT will oversee all system maintenance (battery changes, troubleshoot in instances where there is a loss of system contact), establish arrangements for other care services that are needed for the person with ADRD in instances of eNeighbor alerts or other health-related transitions, and develop and monitor a care plan with the family caregiver to ensure that it is effectively followed.

An initial Needs Assessment takes place to determine the best use and deployment of the eNeighbor remote sensor technology in the person with ADRD's home (see Appendix for form location). The assessment begins with an identification of risk factors that suggest the need for remote health monitoring (e.g., the person with ADRD lives alone and has little supervision; the caregiver needs support; the person with ADRD has a history of falls or the caregiver has concerns with falls) as well as the use of other monitoring systems such as Safe Return™ or a similar device. The DNT will then discuss the results of the needs assessment with the ADRD caregiver and review how the remote monitoring system works, that the eNeighbor does not include cameras or microphones, is secure, and is private, and that the system learns the normal

activities of the person with ADRD and alerts both the family caregiver and the DNT if something appears unusual (e.g., absence of expected ADL behaviors). Following this operational overview, the DNT will summarize the secure and password-protected MyHealthsense website, which is used by the family caregiver or other trusted family members and friends to coordinate and share information regarding appointments or the well-being of the person with ADRD. The remote monitoring system will then be installed in the person with ADRD's home and the expected performance thresholds and daily routines will be programmed. The DNT will monitor sensor performance throughout the duration of the project, and if these sensors are damaged or become inoperable, she will replace these sensors as needed free of charge.

A particularly important aspect of eNeighbor is its configuration in homes with varying broadband internet service. If broadband services are available at the person with ADRD's home, connection of the sensors involves the simple addition of a wireless router which connects with the existing broadband modem in the person with ADRD's home (and is included in the remote sensor package that will be supported by the proposed project). If broadband is not available, the current project will support connectivity for the person with ADRD's home via purchase of this service as a "bundle" through an existing telephone or cable TV plan. In the instance the family caregiver does not wish to utilize broadband service options for the purposes of eNeighbor, the proposed project will support a low data rate cellular service plan that supports only eNeighbor functions. The quality of data collection is identical across cellular or broadband modalities. The DNT will then share paper versions of the alert system reports generated by the MyHealthsense website.

To address environmental diversity, the DNT will collect information on the approximate square footage of the house; number of bedrooms and bathrooms; distances between primary bathroom (e.g., the one used to shower/bathe in), living room area (e.g., where television or the majority of similar leisure activity takes place), and entryway; and number of levels in the home.

The Needs Assessment form and utilization data collected by the DNT based on the Healthsense/eNeighbor remote health sensor system will be securely transferred to Dr. Gaugler and RC via a secure University of Minnesota Box file transfer procedure. Any hard copy Needs Assessment forms or similar utilization data will be maintained in a locked file cabinet at The Lutheran Home Association. As one of the analyses proposed will focus on the individualization/customization of the eNeighbor system for each family as well as variable utilization data based on the alerts issued by the remote monitoring system and follow-up contacts by the DNT, these utilization data will be collected throughout the 18-month evaluation period for each caregiver and person with ADRD.

5.3 Follow-Up:

Follow-up will continue until Month 55, resulting in a 53-month data collection period. Eligible ADRD caregivers will be interviewed/surveyed at baseline and every 6 months thereafter for up to 18 months. Six-month follow-up interviews/surveys will be completed by the PI or research

coordinators for all participants in the treatment and control conditions. The selected measures (see Appendix) have strong psychometric properties, sensitivity to change, and clinical relevance in the evaluation of remote health monitoring technology as established in the stress process and related conceptual models. Caregivers will complete the proposed measures at each time point (context of care items will be collected at baseline only). Baseline and follow-up interviews will take place at a location and in a format that is convenient to ADRD caregivers (at the University of Minnesota Delaware Clinical Research Unit, the ADRD caregivers' home or through online, telephone or mail formats if desired). Each follow-up interview is expected to take approximately 45 minutes to complete. Information from the follow-up surveys will also be utilized to complete the E-Neighbor Disposition Form (see Appendix for form location) at each follow-up interval. As the information on the Disposition form is available from the follow-up surveys, the PI or RCs can extract and complete the Disposition form following the completion each 6-, 12-, and 18-month survey.

A call will be placed to every participant at the time when the survey is sent out. For participants who are a part of the control group, this call will serve as a time to check-in, and also make these participants feel connected to the research study. A monthly check-in call will be placed to those in the eNeighbor treatment group, as a means to confirm that the eNeighbor sensor system is functioning properly. Furthermore, we will administer a verbal assent procedure prior to or following each 6-month interview/survey (i.e., at baseline, 6 months, and 12 months) for those in the eNeighbor treatment group. The rationale for this approach is that since persons with dementia in the control group do not engage in any way with the research procedures or researchers themselves following baseline (i.e., family caregivers complete all surveys), assent is likely not needed in such circumstances as participants in the control group are essentially participating in a family caregiving study. As persons with memory loss in the treatment condition are experiencing the installation and operation of the eNeighbor remote monitoring system in their homes, ongoing verbal assent is necessary for these individuals for the duration of the study follow-up period (i.e., at baseline, 6 months, and 12 months; by completion of the 18-month follow-up surveys/interviews the study procedures are complete and no further assent is needed). Specifically, verbal assent of persons with Alzheimer's disease or a related dementia (ADRD) (oral only) will take place for those in the eNeighbor treatment condition and over the telephone (unless the family caregiver has requested an in-person interview). Family caregivers may also (and are encouraged to) join the telephone call via a conference connection, another land line, or speaker phone to help facilitate the assent process and effectively communicate with the person with memory loss if needed. If a dissenting behavior or agitation is exhibited by the person with memory loss, a conversation with the caregiver alone should take place, to determine if this behavior related to the eNeighbor system is common. If it is common, then the verbal dissent should be noted and the DNT should be contacted immediately to schedule removal of the sensor technology. This will also occur after any adverse/negative reaction to the eNeighbor remote monitoring system. Also, the PI and RCs will defer to caregiver preference in instances where the caregiver indicates that, due to severity of memory loss issues (e.g., the care recipient does not remember that the sensors are even in the home), the care recipient can no longer provide verbal assent. In these circumstances, the RCs or PI will ask the caregiver if the

care recipient is still agreeable to continue their participation in the study for another 6 months and have not indicated any issue or problem with the sensors; if the caregiver agrees, the RCs or PI will sign a follow-up assent form that indicates the caregiver providers assent on behalf of the care recipient.

Several steps will enhance retention in the proposed study. The research coordinator or PI will complete confirmation calls or emails 1-4 days prior to a scheduled interview or survey, will contact ADRD caregivers within 24 hours of a missed interview to reschedule, and will update participants' contact information as needed throughout the project. For those in the eNeighbor treatment condition, the DNT will contact the caregiver 3-4 days following the installation of sensors to ensure the system is operating appropriately and to troubleshoot any issues. In addition, the DNT will follow-up with treatment participants on a monthly basis to further monitor the overall operation of the eNeighbor sensor system, address issues/concerns of the caregiver, and troubleshoot any issues related to the remote health monitoring system.

We will take several steps to address attrition bias. If a person with ADRD has moved into a residential long-term care facility or has died, caregiver follow-up interviews will include queries determining when these events occurred. Regular follow-up will continue in order to collect as much information on outcome variables that are appropriate (i.e., intention to treat principle) (see Appendix for form location). At the conclusion of the project, Thank You cards will be mailed to all participants to ensure rapport.

Treatment fidelity. Monthly system reviews will take place through system reports generated by the Director of Nursing and Technology. The MyHealthsense portal can also track how often the ADRD caregiver or others utilize the care coordination resources of MyHealthsense. The PI or research coordinator will also determine the degree to which participants apply the eNeighbor monitoring tool to their everyday care situations. An online or mail survey of close-ended, Likert-scale items to determine eNeighbor's acceptability by ADRD caregivers as well as multiple open-ended questions will be administered to all ADRD caregivers in the eNeighbor treatment condition at the 6-, 12-, and 18-month interview intervals (see Appendix for form location). The open-ended responses will provide qualitative data as to the reasons why family caregivers felt the health monitoring technology of eNeighbor was or was not easy to utilize (e.g., "Why or how was the health monitoring technology easy or difficult to use?;" see Appendix for full listing of items). The identification of these barriers or facilitators will be considered when examining ADRD caregivers' perceptions of eNeighbor's design, delivery, and ease of use.

Final Study Visit/Survey.

The final study visit will operate similar to the other follow-up interviews/surveys. Following completion of the final 18-month assessment, participants in the treatment group will be informed of the conclusion of the study and the need to remove the health monitoring sensors. However, available eNeighbor sensor packages purchased for this demonstration project will also be offered to the control group on a first-come, first-serve basis at the conclusion of the randomized control trial evaluation phase as stated in the consent form. If the eNeighbor system

is found to have an overall negative effect (specifically, the eNeighbor system results in greater emotional stress or depressive symptoms on the part of the caregiver) then the eNeighbor system will not be offered on a first-come, first-serve basis for those in the control group. The latter is now included to provide additional clarification in the consent form. For those not selected but who desire the health monitoring technology, the project team will work with Healthsense to determine if discounts are available and applicable.

Post-evaluation semi-structured interviews. Thirty semi-structured interviews with ADRD caregivers in the e-Neighbor treatment condition will take place. These interviews will take place a month after completion of the final 18-month follow-up interview for selected participants. The PI and Dr. Garcia (the Co-I) will identify 15 ADRD caregivers who indicated positive acceptance on the embedded qualitative and quantitative 6-, 12-, and 18-month system reviews and 15 ADRD caregivers who reported low acceptance on the embedded qualitative and quantitative 6-, 12-, and 18-month system reviews.

A stratified purposive sampling approach will also be applied; the PI and Dr. Garcia will purposively identify ADRD caregivers of varying kin relationship (spouse vs. adult child), dementia severity (middle versus late stage dementia symptomatology), caregiver gender, and racial or ethnic background to participate in the post-RCT semi-structured interviews.

The open-ended responses of the semi-structured interviews will provide in-depth information on the reasons why dementia caregivers felt the eNeighbor remote sensor technology did or did not reduce ADRD caregivers' distress, help to manage persons' with ADRD daily function, or prevent negative health transitions and service use for persons with ADRD (see Appendix for form location of the interview guide). The PI and research coordinators will schedule and conduct the semi-structured interviews and will digitally record each interview. Audio recordings will be transcribed by a professional transcriptionist into a Microsoft Word® file which will then be uploaded to nVivo for subsequent analysis.

6.0 Data Banking

6.1 Storage and Access: The datasets generated and/or analyzed will be made publically available upon completion of primary or secondary outcome analyses. When ready, the datasets generated and analyzed will be made available on the National Archive of Computerized Data on Aging (NACDA) and the University of Minnesota Data Repository for U of M (DRUM).

6.2 Data: Only de-identified data will be included in the datasets that are made publically available to NACDA and DRUM.

7.0 Sharing of Results with Participants

7.1 Sharing of Results with Participants: We will create a summary page and brief videos highlighting study results/findings for participants.

8.0 Study Duration

8.1 ADRD caregivers will participate in the study for 18-months; the total project duration is 5 years (3/31/2014-3/30/2019). A project timeline is below:

	Months 1-3	Months 4-12	Months 13-55	Months 55-60
Data management processes, team training	●	○	○	○
Project and Community Advisory Board meetings	●	●	●	●
Recruitment of ADRD caregivers (*n* = 200)	○	●	●	○
Home installation and training of e-Neighbor		●	●	○
Baseline, 6-, 12-, and 18-month data collection		●	●	●
Embedded treatment fidelity/process evaluation		●	●	●
Embedded post-RCT semi-structured interviews			●	●
Quantitative, qualitative, and mixed analysis			●	●
Dissemination				●

NOTE: ADRD = Alzheimer's disease or a related dementia; RCT = randomized controlled trial;
● = primary focus; ○ = ongoing but less intensive

9.0 Study Population

9.1 Inclusion Criteria:
The following inclusion criteria will be applied for 200 persons with ADRD: 1) English speaking; 2) physician diagnosis of ADRD (Alzheimer's disease, Lewy Body disease, fronto-temporal dementia, or stroke/vascular dementia; mild cognitive impairment only); 3) not currently receiving care or case management services; and 4) 55 years of age and over. Caregivers of persons with ADRD must: 1) speak English; 2) be 21 years of age and over; 3) self-identify as someone who provides help to the person with ADRD because of their cognitive impairments; 4) self-identify as the person most responsible for providing hands-on care to the person with ADRD; 5) plan to remain in the area for at least 18 months in order to reduce possible loss to follow-up; and 6) indicate a willingness to use eNeighbor.

9.2 Exclusion Criteria: Anyone who does not fit the inclusion criteria will be excluded.

9.3 Screening: If caregivers agree to participate, the PI or research coordinators will initiate a brief screening procedure applying the inclusion criteria above.

10.0 Vulnerable Populations

10.1 Vulnerable Populations:

Population / Group	Identify whether any of the following populations will be primary focus of the research

	(targeted), included but not the focus of the research or excluded from participation in the study.
Children	Excluded
Pregnant women/fetuses/neonates	included but not the focus
Prisoners	Excluded
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Primary focus of the research
Non-English speakers	Excluded
Those unable to read (illiterate)	Excluded
Employees of the researcher	Excluded
Students of the researcher	Excluded
Undervalued or disenfranchised social group	included but not the focus
Active members of the military (service members), DoD personnel (including civilian employees)	included but not the focus
Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded

Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	included but not the focus
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	included but not the focus
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Excluded
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded

10.2 Additional Safeguards:

All participants in the above table that are listed as "included but not the focus" could be included in the study by chance. However, these vulnerable groups are not sought out during recruitment and we do not ask potential participants if they belong to one of the above groups or not. Thus, extra safeguards are not put in place to protect these groups since we would not know if they were included in the research or not. Given our study population of interest, it is unlikely for participants to be a part of the groups listed as "included but not the focus," besides adults lacking the capacity to consent or have a diminished capacity to consent which is addressed below.

Adults lacking the capacity to consent or have a diminished capacity to consent are one of the primary groups of participants to be recruited to the study. Specific safeguards to protect this population include signing of a consent form by the caregiver or a LAR (Legally Authorized Representative). Additionally, the person with memory loss either consents or assents to the research based on their SLUM and Capacity to Consent scores – see more detail in the consent section below.

10.3 If research includes potential for direct benefit to participant, provide rationale for any exclusions indicated in the table above:

Some individuals in the above vulnerable groups are excluded because they are not our population of interest (i.e. ADRD does not impact children) or because participating in such research would potentially be risky for them.

11.0 Number of Participants

11.1 Number of Participants to be Consented:

We aim to enroll 200 ADRD caregivers and 200 individuals with ADRD in our study.

12.0 Recruitment Methods

12.1 Recruitment Process:

The Principal Investigator (PI) will initiate email, telephone, or mail contact with ADRD caregivers on the University of Minnesota Caregiver Registry (IRB# 1007S85812) or others recruited by the PI or research coordinators via various advertisements, community presentations, and other outreach/enrollment efforts who potentially meet the project inclusion criteria. In addition, the PI or research coordinators will ask professional caregivers on the Registry to identify potential ADRD caregivers for recruitment purposes.

12.2 Source of Participants:

Dr. Gaugler has created a University of Minnesota Caregiver Registry that includes family and professional caregivers who have participated in his free annual community education conference, “Caring for a Person with Memory Loss” (CPWML). Approximately 200-350 persons attend each CPWML conference. Attendees are invited to complete a brief form which enrolls them in the Registry and gives Dr. Gaugler and his research staff permission to contact and invite them to participate in his studies. We will periodically send project recruitment materials to members of the caregiver registry.

In addition to general recruitment assistance, the PI or research coordinators will ask professional care providers in the Registry (many of whom provide care to under-represented older persons) to identify ADRD caregivers of diverse ethnic or racial origin and geographic location to enhance the inclusion of AHRQ Priority Populations. These recruitment efforts will be facilitated by the Minnesota Board on Aging (MBA), the Minnesota-North Dakota Alzheimer’s Association regional office, and other community organizations. For example, the MBA will help us promote this study through Area Agencies on Aging, many of which serve ethnic and racially diverse older adults as well rural ADRD caregivers. Cumulatively, these various outreach efforts are expected to result in a sample that includes approximately 40 diverse and under-represented ADRD caregivers (20% of the sample). Additional recruitment efforts will take place via advertisements in local print, radio, and internet media sources including websites of local and national organizations.

12.3 Identification of Potential Participants:

Family and professional caregivers on The University of Minnesota Caregiver Registry (IRB# 1007S85812) have provided permission for Dr. Gaugler or his research team to contact them to invite them to participate in his ongoing or future research projects. Other enrollment procedures will rely on participants to contact Dr. Gaugler or the research coordinators if they are interested; this will also protect participants' privacy.

During initial enrollment contacts, the PI or research coordinators will describe the eNeighbor monitoring system, explain study procedures, and invite potential ADRD caregivers to participate. Caregivers will be offered the opportunity to ask any questions about the study procedures. If caregivers agree to participate, the PI or research coordinators will initiate a brief screening procedure applying the inclusion criteria above. Participants will self-identify in response to recruitment efforts.

The PI and research coordinators will be in first contact with potential participants. Additionally, professional care providers in the Registry may promote this study and therefore be the first contact with potential participants. Potential participants will not be identified using medical records or other source of protected records.

12.4 Recruitment Materials: See materials submitted in ETHOS.

12.5 Payment: Participants are not compensated for participating in the study.

13 Withdrawal of Participants

13.1 Withdrawal Circumstances:

We will emphasize to all participants that they do not have to complete any question they do not want to answer, and that the interview may be terminated at any time according to their wishes. We will stress to ADRD caregivers that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota or other entities. If a participant wishes to withdraw from the study because they are no longer interested in participating or they are no longer able to participate, we will follow the procedures described below.

13.2 Withdrawal Procedures:

In instances where ADRD caregivers wish to withdraw from the study we will determine and document the reason for study withdrawal, and if the caregiver agrees we will administer regular, brief surveys (either online or over the telephone) to collect data on outcome variables (identical to the regular follow-up interviews/surveys; **see Appendix for form location**).

13.3 Termination Procedures:

In instances where ADRD caregivers are terminated from the study, we will determine and document the reason for termination and ask the caregiver to return the eNeighbor system (if applicable). We would not send the caregiver any follow-up surveys/interviews.

14 Risks to Participants

14.1 Foreseeable Risks:

The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver a relative with Alzheimer's disease and related dementia (ADRD). Since the research team has considerable experience providing psychosocial support to dementia caregivers on various research protocols, serious psychological risks are unlikely to occur. The potential social or legal risks for the participants relate only to possible violations of confidentiality. As noted above, Healthsense, Inc. as instituted a robust and secure data privacy system for the remote health monitoring technology.

14.2 Reproduction Risks: Not applicable

14.3 Risks to Others: Not applicable

15 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: Not applicable

16 Potential Benefits to Participants

16.1.1 Potential Benefits: There are no direct benefits of participating in the study.

17 Statistical Considerations

17.1 Data Analysis Plan:

Intensive longitudinal analysis procedures (growth curve modeling) will be utilized to capitalize on the randomized design and the multiple waves of data that will be collected.

17.2 Power Analysis:

The number of ADRD caregivers to be enrolled to address study hypotheses was determined using power analysis procedures that take into account the hierarchical analytic design of the study.[68] In this framework, the researcher identifies the Type I error rate (e.g., $p < .05$) to differentiate between a null and alternative test hypothesis, a suitable level of statistical power (.80 is considered an excellent power value), and the expected difference between the two study groups in order to determine the number of ADRD caregivers to enroll into the project. We sought a sample size that would be sufficient to detect a group difference of 0.50 standard deviation units. This is considered to be a "medium" effect size[69] and is a reasonable benchmark to evaluate the efficacy of a new behavioral intervention in comparison to an attention control condition. Using these specifications, a sample size of 200 ADRD caregivers (factoring in the anticipated 20% attrition rate) was found sufficient. As noted in various recommendations for mixed

methods sampling, 30 participants is considered an adequate sample size for semi-structured interview protocols to ensure the richness and depth of open-ended data collected.[70,71]

17.3 Statistical Analysis:

Analysis of Specific Aim1: Tests of Hypotheses 1-3.

Data available at baseline, 6 months, 12 months, and 18 months will allow for individual growth curve models that examine change in ADRD caregiver outcomes.[72,73] Multilevel analysis approaches are available that support growth curve modeling. In this context, growth curve modeling is an example of a 2-stage modeling process consisting of 1) a within-subjects model across time; and 2) a between-subjects model that incorporates caregiver and person with ADRD covariates.[74,75] The primary independent variable in the proposed investigation consists of an indicator variable for random assignment into the eNeighbor treatment condition or the attention care control. IBM SPSS Statistics 21[76] will be used to conduct these analyses, as it supports multilevel and growth curve modeling procedures. Dr. Gaugler, the PI, has extensive experience conducting longitudinal and growth curve analyses in his prior research on ADRD caregiving.[46,80,81,88]

Our proposed analyses will provide in-depth tests of Hypotheses 1 and 2 and partially test Hypothesis 3 (i.e., rates of change in ADRD caregivers' self-efficacy, competence, subjective stress, depressive symptoms, and frequency of negative health transitions and service use). In one set of outcome evaluations, the baseline value will be included as a covariate, and time will be "centered" at 6-months post-baseline. This scales the intercept effect to be a main effect of eNeighbor group assignment and allows the eNeighbor treatment and the attention control groups to have different 6-, 12-, and 18-month change trajectories, or an expanded eNeighbor treatment*time interaction effect. After establishing that the individual growth parameter estimates have significant variance around the mean trajectories of change in key dependent variables, an eNeighbor treatment vs. attention care control group indicator will be added as the key independent variable to predict intercepts and rates of change in outcomes. Additional analyses will determine if covariates (e.g., stress process model covariates including context of care indicators, primary objective stressors, and resources) significantly vary across the eNeighbor treatment and attention control groups at baseline and over time via growth curve modeling procedures. If statistically significant variations between the eNeighbor treatment and control groups are found, initial status and rate of change parameters for these covariates will be included in all tests to provide additional statistical control.

Cox proportional hazard survival analyses will determine whether participation in the eNeighbor treatment group results in significantly less time to nursing home admission (e.g., admission into a 24-hour nursing home facility for at least 90 days), overnight hospitalization, emergency room use, and negative health transitions (falls, wandering) when compared to persons with ADRD in the attention control group (Specific Aim 1/Hypothesis 3). The Cox proportional hazards model is defined as the product of an unknown function of time and the exponent of a linear combination of risk variables. eNeighbor treatment vs. attention control group membership will be the

independent variable of interest in the test of Hypothesis 3; time to nursing home admission, overnight hospitalization, emergency room use, and occurrence of a fall or a wandering event will serve as the dependent variables. Date of randomization will serve as baseline. Additional variables will serve as covariates, including time-invariant and time-varying measurements of stress process covariates. Likelihood ratio tests and partial odds ratios will be examined in order to determine the degree to which these variables explain the observed effects of eNeighbor on time to dependent variable occurrence.

Variations in eNeighbor Use and Setting

Empirical treatment fidelity data and context of care measures that assess heterogeneity in the use of eNeighbor within the treatment condition (e.g., frequency and duration of sensor alerts and myHealthsense website use; diverse home characteristics) will be included as a series of additional Specific Aim 1 analyses. These analyses will explore the effects of variations in eNeighbor use on the outcomes hypothesized above for persons with ADRD and their family caregivers.

Specific Aim 1/Hypothesis 4

The cost-effectiveness of the remote monitoring technology intervention will be assessed by comparing costs of implementation and healthcare utilization between persons with ADRD in the treatment condition and those in the attention control. The analysis will be conducted from the perspective of the payer (i.e., the public). Costs in the numerator of the incremental cost-effectiveness ratio (ICER) will be determined by identifying the differences in Medicare and Medicaid expenditures for persons with ADRD across the eNeighbor treatment and attention control groups using aggregated ("rolled up") Medicare and Medicaid claims matched to the individual participant by Social Security number for the 18 months of participation. Because the differences in costs derive from a randomized trial, an evaluation of the difference in mean costs can determine significance. In addition, the direct costs of the intervention will be included as the cost of the remote sensor hardware, staff time (i.e., the Director of Nursing and Technology, who will track her hourly effort related to monitoring eNeighbor activities and assisting ADRD caregivers over a 1.5-year period), and installation costs over the 18-month study period.

The differences in effectiveness included in the denominator of the ICER will be measured using 5 ADRD caregiver and person with ADRD outcome measures: a) the standard cut-point of "moderate or higher" burden on the Zarit Burden Interview;[77] b) the standard cut-point of "major depression" on the Center for Epidemiological Studies Depression scale;[78] c) fall (occurred or not); d) wandering event (occurred or not); e) nursing home admission (placed or not); f) hospitalization (overnight use or not); and g) emergency room use (used or not). Significant differences in cost will be investigated. Sensitivity analysis will be performed where parameter uncertainty exists. Where possible, evaluation of these ICERs will be based on comparisons in prior literature to determine the overall costs and effectiveness of eNeighbor.

Analysis: Specific Aim 2

Specific Aim 2 analyses will primarily focus on thematic content analysis of open-ended data to examine eNeighbor utility and mechanisms of benefit. As noted by experienced methodologists, systematic reading and rereading of qualitative content and hand coding of a significant proportion of this content is necessary in order to develop an understanding of meanings in their conversational or observational contexts.[79,80] Specifically, the PI and research coordinator with the help of Dr. Garcia (Co-Investigator) will independently develop coding categories together with descriptors (via hand-coding and NVivo) and will generate a shared coding scheme that will reflect the primary categories of the transcription. Through repetition of this procedure, a consensus perspective on appropriate coding categories and themes will be modified and developed. These themes will provide insights as to the eNeighbor's implementation and use (i.e., treatment fidelity/process evaluation embedded component) and mechanisms of benefit (i.e., semi-structured interview embedded component).

Grounded theory techniques described by Morse[81] and Strauss and Corbin[79] will guide the analyses of qualitative data in Specific Aim 2. These approaches allow participants to construct meanings, perceptions, and behaviors from their own vantage points. All open-ended data collected will be first read by the PI and the research coordinator to identify textual elements that emerge repeatedly (i.e., codes); these codes will then be clustered into larger categories that are later used to construct major thematic elements from the text (with the use of nVivo 10 analytic software). During weekly meetings in the analysis phase of the proposed project, the PI and research coordinator along with Dr. Garcia will discuss their own identified codes to reach a consensus about specific codes, categories, and themes that emerge from the qualitative data (these decisions will be noted in an audit trail). In addition, patterns that link particular themes will be identified and discussed in successive meetings between the PI, research coordinator, and Dr. Garcia to identify more complex processes of eNeighbor use or health monitoring technology's pathways to benefit for persons with ADRD and their family caregivers. During monthly team meetings, the development of codes, categories, and themes will be reviewed with the project Consultants to yield any additional input into these project components. The multiple team meetings and discussions will allow for an exploration of alternative interpretations of the qualitative data and will also provide a check regarding the quality and richness of the data collected during the embedded mixed methods components. Additional mixed methods analyses[57,58] will take place. The thematic codes and categories of implementation/use and mechanisms of benefit will be cross-tabulated with the empirical data from the randomized controlled evaluation to determine whether the findings diverge, converge, or highlight pathways toward additional questions and analysis.[57] This comparative, mixed method analysis approach may suggest that those who reported greater decreases in subjective stress during health monitoring technology use may indicate certain themes more often than ADRD caregivers who report greater increases in stress.

Specific Aim 3 Analysis Plan

Brief background data will be collected from Community Advisory Board (CAB) members (sociodemographics, professional experience, duration of dementia care, etc.). Analyses of these

descriptive quantitative data will include descriptive statistics such as frequency tables, means, and other univariate statistics. Additional strategies will include thematic content analysis of open-ended data (e.g., meeting discussions) as described above. Analysis of CAB meeting open-ended data will help us to identify the main themes related to how health monitoring technology can be designed, delivered, and evaluated to achieve the greatest utility for persons with ADRD and their family caregivers.

Planned Interim Analyses

Not applicable; if these are done, they will be conducted at the 6-, 12-, and 18-month intervals; given how the qualitative data component of the mixed methods research design is structured, these findings will not be fully available until the final months of the 5-year project.

17.4 Data Integrity:

Data will be anonymized approximately 3-5 years following the completion of this project. Specific data collection methods and types are described in detail earlier. Study records will be kept indefinitely, in order to encourage data sharing submitted to the Agency for Healthcare Research and Quality.

18 Health Information and Privacy Compliance

18.1 Select which of the following is applicable to your research:

☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☒ I am requesting that all research participants sign a HIPCO approved HIPAA

Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

Appropriate Use for Research:

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☐ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

☐ Other. Describe:

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

18.4 Approximate number of records required for review:

N/A; not reviewing records.

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☒ Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants. When participants consent or assent to participating in the research, they are asked whether or not they agree to communicate with the research team via unencrypted email. If a participant does not agree to communicate this way, the team can send encrypted emails to participants.

18.6 Access to participants

The participants consent or assent to providing information to the research team for research purposes only.

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☐ In REDCap (recap.ahc.umn.edu)

☐ Store ☐ Analyze ☐ Share

☒ In Qualtrics (qualtrics.umn.edu)

☒ Store ☐ Analyze ☒ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☒ In the University's Box Secure Storage (box.umn.edu)

☒ Store ☐ Analyze ☒ Share

☒ In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

S:\Public_Health_Center-on-Aging_Gaugler\A Proactive Health Monitoring Intervention for Dementia Caregivers The eNeighbor

IT Support Contact: Troy Karkula karku003@umn.edu

☒ Store ☒ Analyze ☒ Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☒ Other. Online survey data will be collected and stored in Google Forms.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartform (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☐I will use a desktop or laptop not previously listed

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.8 Consultants. Vendors. Third Parties. Data will be collected and stored by MyHealthsense. MyHealthsense provides scheduled reports to the family caregiver and the nurse care manager that summarizes eNeighbor sensor activity and links this information to the person with ADRD's electronic health record

Additionally, Production Transcripts is a professional transcription service that will be used to transcribe audio recordings of qualitative interviews. Audio recordings will be securely uploaded to their secure website and the transcripts will be securely shared with the research team once completed.

18.9 Links to identifiable data: N/A

18.10 Sharing of Data with Research Team Members. Data will be shared with research team members using Box, AHC Server, Google Forms, and Qualtrics.

18.11 Storage of Documents. Paper forms of the data will be located in a locked file cabinet in D350 Mayo (the PI's research office) only accessible to the PI, research coordinators, and other approved research staff. Unless the data are being filed or accessed, these cabinets will remain locked. All electronic data will be maintained on the PI's office computer and the shared project folder. Per University of Minnesota and AHC-IS data security guidelines, all data on the PI's computer in D350 Mayo and the research coordinators' computers (located in D351 Mayo) are protected by strong password only accessible to the PI, research coordinators, or the Co-Investigators for data analysis purposes.

18.12 Disposal of Documents: The data will be maintained on the PI's and research coordinators' computers and in the secure project folder for approximately 2-3 years, which is the time anticipated it will take to disseminate any and all research papers or presentations from these data. Data will be anonymized approximately 3-5 years following the completion of this project.

19 Confidentiality

19.1 Data Security**:**

All information obtained from the participants will remain strictly confidential and will not be released except at the express written request of the study participant. All electronic data will be maintained on Dr. Gaugler's office computer and the shared project folder. Per University of Minnesota and the Academic Health Center-Information Systems data security guidelines, all data on Dr. Gaugler's computer in D350 Mayo and the research staff's computers (located in D351 Mayo) are protected by strong password only accessible to Dr. Gaugler or the research team. The data will be maintained on Dr. Gaugler's research team's computers and on the secure project folder for approximately 2-3 years which is the time anticipated it will take to disseminate any and all research papers or presentations from these data. Similarly, paper forms of the data will be located in a locked file cabinet in D351 Mayo (Dr. Gaugler's research office suite) only

accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

With respect to private information entered into the online portal of the eNeighbor myHealthsense site, the design of the system includes a structure of permissions with password protection to limit access to material so only ADRD caregivers, invited family members or health care professionals, the research staff (the PI or research coordinators), and the Director of Nursing and Technology can view sensitive information.

All of Dr. Gaugler's staff are required to use VPN and Remote Desktop Connection to access study data stored on the secure server, and to save all study-related data on the same folder; they are not to download, view, or save any project-related data on their personal laptops or any mobile data storage device.

A copy of the consent form or other research study related documents will not be placed in a participant's medical, employment, or educational records.

20 Provisions to Monitor the Data to Ensure the Safety of Participants

20.11 Data Integrity Monitoring.

Dr. Gaugler (the PI) and the research coordinators will have primary responsibility for managing all study data. Research assistants who work under the supervision of Dr. Gaugler in the Families and LTC Projects at the University of Minnesota may also enter, clean, and assist the PI and research coordinators manage data as appropriate during the course of the project.

Data will be derived from surveys/interviews with ADRD caregivers (an online, telephone, or mail survey option will be offered to interested caregivers). Additional open-ended data will be collected during quarterly CAB meetings and follow-up surveys/interviews (the latter if needed). The Principal Investigator (PI) and research coordinators will be responsible for all data collection procedures. The Director of Nursing and Technology (DNT; Sharon Blume; Kristen Werner) will also generate monthly usage reports on eNeighbor system use to facilitate our analysis of process of use.

Names and contact information are included in the Registry, and the PI and research coordinators will plan on creating a tracking file for the purposes of interview reminders and completion of the various data collection procedures. However, it is important to note that in the data analysis files, no identifying information will be entered or included.

All electronic data will be maintained on the PI's office computer, research coordinators computers, and the shared project folder. Per University of Minnesota and AHC-IS data security guidelines, all data on the PI's and research coordinators'

computers in D350/D351 Mayo are protected by strong password only accessible to the PI, research coordinator, or the Co-Investigators for data analysis purposes. The data will be maintained on the PI's and research coordinators' computers and in the secure project folder for approximately 2-3 years, which is the time anticipated it will take to disseminate any and all research papers or presentations from these data. Similarly, paper forms of the data will be located in a locked file cabinet D351 Mayo (the PI's research office suite) only accessible to the PI, research coordinators, research assistants, and other approved research staff. Unless the data are being filed or accessed, these cabinets will remain locked.

Per email communication with David Norman of AHC-IS Server Operations, 8/28/13, based on the PI's inquiry regarding data security of the SoN secure data servers:

"Although we do have some servers running with hardware encryption, the bulk of our servers do not have it. The Nursing shared and Nursing User servers are two that do not run hardware encryption. With that said, I just want to reassure you that your data is safe and secure. I have attached a document that details the AHC-Information Systems server standards for you to review if you wish." **(See Appendix)**

"Hardware encryption only beneficial if a physical hard drive is stolen. If you have an AHC-IS supported laptop, for example, we require hardware encryption. This is prevent someone who may have stolen a laptop from connecting your laptop hard drive in to another computer and accessing the data. With servers and server storage, this works differently.

"First off, the servers and associated storage are stored in an enterprise class data center which is physically restricted and monitored and is not on campus. Second, all your data is stored on various large scale storage appliances. Data is written to these appliances not to a single hard drive, but across potentially hundreds. If an individual were to somehow get one of these hard drives, it would be useless to them. This is because they would not be able to access your data because they won't have enough of your data to reconstruct your files because they are written across all those drives.

"If you have a IRB or research requirement that requires hardware encryption, we do have a few servers running hardware encryption that may be available depending on how much storage you need. Please let me know.

Thank you,

Mike Norman
AHC-IS Server Operations"

20.12 Data Safety Monitoring.

As this project will pose minimal risks to study participants the Principal Investigator (PI), Dr. Gaugler, will serve as the primary monitoring entity of this study. The proposed study involves no invasive procedures and there will be no physical risks to study participants.

Additional monitoring support will be provided by the Independent Study Monitor (ISM), Dr. Ann Garwick, PhD, RN, LP, LMFT, FAAN. Dr. Garwick is Professor, Senior Executive Associate Dean for Research, Cora Meidl Siehl Endowed Chair in Nursing Research, and Director of Center for Child and Family Health Promotion Research in the University of Minnesota School of Nursing. Dr. Garwick has provided data monitoring support and oversight to Dr. Gaugler previous 5-year R01 project evaluating a comprehensive psychosocial intervention for adult child caregivers of persons with dementia (R01 AG022066) as well two projects funded by the Eli Lily Company.

In addition to ongoing review of protocol and human subjects research compliance during weekly project meetings with staff (see *Project Timeline*), the PI will generate an annual report starting at the conclusion of Year 2.

If a caregiver is in crisis because of their care situation or some other reason, Dr. Gaugler, with the permission, we will then contact the appropriate resource person in an external agency (e.g., the Alzheimer's Association). Based on the research team's experience working with their caregiving families, we expect no or very few such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the state senior abuse hotline will be contacted to protect the rights of persons with dementia and their families.

Annual audit reports. The responsibility of Dr. Gaugler (who also has oversight for the data management and analysis of the project) will include the production of an audit report that will highlight the results of the audit analysis as well as study progress. In addition, Dr. Gaugler will provide information on any deviations from the approved protocol (e.g., deviations in adhering to study eligibility criteria), error rates, and any other issues related to the progress of the study. The ISM will review the audit report to ensure ongoing quality control, and will work with Dr. Gaugler, if needed, to ascertain if audited cases deviate from the approved study protocol. In instances of adverse events occurring (see below), the ISM, the AHRQ project officer, and the University of Minnesota IRB will be notified immediately.

The audit reports will include the following:

1. Table of contents
2. Narrative/trial summary
    a. Summary of main findings
    b. Discussion of issues or problems

c. Report preparation procedures

3. Study description
    a. Project organizational chart, personnel
    b. Brief statement of purpose of trial
    c. Projected timetable and schedule
4. Study administration
    a. Recruitment and participant status
        i. Figure 1: Enrollment by year or month of study
    b. Forms status
        i. Status of forms (e.g., consent, completing of screener, baseline assessment battery, etc.)

Reporting Adverse Events and Unanticipated Problems

In addition to ongoing monitoring of protocol and human subjects compliance and reporting and the production of quarterly case audits to the ISM, Dr. Gaugler will generate safety reports on an ongoing basis that will list adverse events, serious events, unexpected events, events related to or associated with the intervention, and the potential causality of the intervention to the event for each participant if they occur. Taken from the September 2002 National Institutes of Mental Health policy on Data and Safety Monitoring in Clinical Trials and the Guidance on Reporting Adverse Events to Institutional Review Board for NIH-Supported Multicenter Trials (as suggested in the Policy of the National Institute of Nursing Research for Data and Safety Monitoring of Clinical Trials), the definition of each event is as follows:

Adverse event. Any untoward medical occurrence in a patient or clinical investigation participant which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of [an intervention], whether or not considered related to the [interventions].
Serious adverse event. Any adverse experience that results in any of the following outcomes: death, a life threatening experience, inpatient hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse drug experience when based upon appropriate medical judgment, they may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
Unexpected. Any adverse experience, the specificity or severity of which is not consistent with the risks information described in the [protocol or consent documents].
Related to (or associated with) the intervention. There is a reasonable possibility that the experience may have been caused by the intervention.

Causality. A reasonable possibility that the product is etiologically related to the adverse event. Causality assessment includes, for example, assessment of temporal relationships, dechallenge/rechallenge information, association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, plausibility, etc.

In the instance of an adverse event, Dr. Gaugler will classify whether the event is unexpected, adverse, or seriously adverse, whether the event is unexpected or related to the intervention, and what potentially caused the event. Dr. Gaugler will review study-related data on an ongoing basis and will alert the ISM, University of Minnesota IRB, and the AHRQ program officer as well as AHRQ (via the DSM report) if these events occur. Specifically, the PI will utilize an adverse event form that will provide detail on the occurrence (who, what, when, where, why if relevant) of any adverse, serious adverse, unexpected/unanticipated event and whether these events were related to the remote health monitoring technology.

As part of his professional service, the PI serves as editor-in-chief for the *Journal of Applied Gerontology* and sits on an additional three editorial boards of leading journals in gerontology. This proximity to cutting-edge research on family caregiving interventions, in addition to his regular review of the literature he conducts to support his various dissemination efforts, will allow the PI to assess developments and issues related to the use of technology tools for ADRD caregivers. If these developments reveal any potential threats to participate safety or other concerns that require protocol modification, these issues will be addressed in the annual DSM reports provided to the ISM and the University of Minnesota IRB.

21 Compensation for Research-Related Injury

21.1.1 Compensation for Research-Related Injury: N/A
21.1.2 Contract Language: N/A

22 Consent Process

22.1 Consent Process (when consent will be obtained):

Within two weeks following the completion of eligibility screening, consent/assent procedures and baseline interviews will be scheduled within 2 weeks for eligible caregivers. Signed informed consent from the eligible family caregiver will take place. Signed informed consent will be offered in-person, via mail, or if deemed most convenient to the family caregiver, via an online consent form. The following IRB approved script will also be administered either in-person or via the telephone in instances where a participating caregiver wishes to complete the consent form via mail or online.

"We are examining the effectiveness of health monitoring technology for family caregivers of persons with memory loss, and we are asking whether you would be interested in helping us with this project. We expect that this technology can help feel family caregivers feel more secure and confident about their relative's care, will experience reduced stress, and can help their relative stay at home longer.

"We are asking you to sit down with me to first review and sign the consent form and also to have your relative complete a brief cognitive screening procedure and then complete verbal assent to complete this project. Over the next few days you will be randomly assigned, like the flip of a coin to the group that receives the health monitoring technology system for your relative or the usual care control group. If you are in the group that receives health monitoring technology, we will ask you to work with the Director of Nursing Technology to conduct a visit to the home where your relative with memory loss lives to install the health monitoring technology and learn how to use it. If you are selected to receive health monitoring technology, I will be contacting you monthly to complete some checklists to see how the sensors are working for you and your relative, and then at 6-, 12-, and 18-months to complete a survey and some additional open-ended questions. Everyone will also be asked to help us complete interviews at 6-, 12-, and 18-months. For those assigned to the health monitoring group, we may ask you near the end of the project to sit down with me for around an hour or so to see how well the health monitoring system worked for you or your relative. Also, if you are selected to not receive the health monitoring technology, at the end of this project <mention how long until the end of the project> we will offer the technology to you for free on a first-come, first-serve basis.

"How does this sound? Is this something you might be interested in helping us out with? <if no, then the PI or RC will thank them and end the interview process>"

We will add the following questions to ascertain comprehension of participants:

- "Explain to me what we are asking you to do as part of this project."
- "What are some of the challenges you think will come up if you decide to participate?"
- "Let's review how the eNeighbor system works, and then you can ask me questions about it."
- "Do you have any other questions about your privacy and confidentiality, your rights as a research participant, or any other aspect of participation that I can try and help answer?"

If a legally authorized representative (LAR) for the person with ADRD is identified other than the family caregiver, we will also obtain signed consent from this individual. For the purposes of efficiency, we will offer an online consent form to review and approve. All online consent and HIPAA forms will be administered via the secure University of Minnesota Google Docs application.

In addition to administering informed consent forms to family caregivers and LARs, we will additionally provide HIPAA forms (either in-person or via mail and online formats) for the family

caregiver and LAR to review and sign. To complete this procedure, the Family Caregiver Consent Form, the LAR Consent Form, and the HIPAA form will be utilized (see Appendix).

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): N/A

22.4 Non-English Speaking Participants: N/A; only English speaking participants are eligible for the study.

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A; participants must be 21 years of age or over.

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

Persons with memory loss who receive a score of 20 or above on the brief St. Louis University Mental Status examination (SLUMS; moderate/mild cognitive impairment; see Appendix for the tool as well as a possible introductory script, transcribed from http://www.youtube.com/watch?v=P32_zvyXTw8), signed verbal assent to continue with the research procedures will be collected. If a person with ADRD scores below 20 on the SLUMS, verbal assent only will be obtained.

For remote/telephone consent procedures, the Capacity to Consent Form would be used; if a person with memory loss scores over 14.5 on this tool, we would ask them to complete a person with memory loss (PWML) version of the consent and HIPAA forms, guiding them to do so over the telephone. If PWMLs score below 14.5, the PWML would complete oral assent to participate. Consent of the family caregiver will then take place (note: if the family caregiver is not the power of attorney/legally authorized representative of the person with ADRD, then signed consent must be obtained from that person as well; if multiple family members of the person with ADRD wish to participate in the data collection procedures outlined below they may do so, but signed consent is necessary from each participating family caregiver). See next section, 22.7, for more details.

22.7 Adults Unable to Consent:

22.7.1.1 Permission: Permission is gathered from primary caregivers or LARs.

22.7.1.2 Assent:

Following the securing of consent of primary caregivers and LARs, Verbal Assent of persons with ADRD will take place (see Appendix). While ideally this may take place simultaneously with the consent procedures above, there may be a delay in time (hopefully no more than several days) between when consent is secured from family caregivers and LARs and assent of the person with ADRD. For those individuals who receive a score of 20 or above on the brief St. Louis University

Mental Status examination (SLUMS; moderate/mild cognitive impairment; see Appendix for the tool as well as a possible introductory script, transcribed from http://www.youtube.com/watch?v=P32_zvyXTw8), signed verbal assent to continue with the research procedures will be collected. If a person with ADRD scores below 20 on the SLUMS, verbal assent only as well as consent of the caregiver (and, if necessary, the LAR) will take place. In this circumstance, the PI or RCs will print the name of the person with memory loss (PWML), then sign and date the assent form. In instances where the person with memory loss (PWML) declines the SLUMS, the PI or RC will ask the PWML to sign and date the verbal assent form. In some instances, the PWML may wish to sign and date a consent form as well as HIPAA form; they may do so if they wish and in such instances this will substitute for a signed verbal assent form. If the PWML is absent from the consent meeting (e.g., is asleep) or is non-communicative or non-verbal, the PI or RCs should not attempt to obtain verbal assent, but instead determine whether the PWML is exhibiting behaviors that suggest agitation or disagreement with participation (e.g., see Batchelor-Assage et al., 2014 for approach to do so). If this is not the case, then consent and HIPAA forms signed by the caregiver/LAR is sufficient for enrollment.

Furthermore, we will administer a verbal assent procedure prior to or following each 6-month interview/survey (i.e., at baseline, 6 months, and 12 months) for those in the eNeighbor treatment group. The rationale for this approach is that since persons with dementia in the control group do not engage in any way with the research procedures or researchers themselves following baseline (i.e., family caregivers complete all surveys), assent is likely not needed in such circumstances as participants in the control group are essentially participating in a family caregiving study. As persons with memory loss in the treatment condition are experiencing the installation and operation of the eNeighbor remote monitoring system in their homes, ongoing verbal assent is necessary for these individuals for the duration of the study follow-up period (i.e., at baseline, 6 months, and 12 months; by completion of the 18-month follow-up surveys/interviews the study procedures are complete and no further assent is needed).

23 Setting

23.1 Research Sites: The research team will conduct research in the D350 Mayo office suite. Research procedures will therefore take place in this location unless otherwise specified, such as in a participant's home or over the phone. The Community Advisory Board is described in section 17 under the "*Specific Aim 3 Analysis Plan" heading***.**

23.1 International Research: N/A; not applicable

23.2 Community Based Participatory Research: N/A; not applicable

24 Multi-Site Research

N/A; not applicable

25 Coordinating Center Research

N/A; not applicable

26 Resources Available

26.1 Resources Available:

The Principal Investigator (PI), Joseph E. Gaugler, PhD, has a long track-record of conducting research on the longitudinal ramifications of dementia caregiving and designing, implementing, and evaluating randomized controlled evaluations of ADRD caregiver interventions (see attached Biosketch). He is serving or has served as PI on multiple AHRQ, National Institutes of Health (NIH), and Alzheimer's Association (AA) grant projects addressing these issues in the past decade (NIH: K02 AG029480R01, R01 AG022066, R21 AG026525, R03 AG20786, R03 CA099515; AA: NIRG-00-2249, IIRG-02-3567; R01 HS013181). He has built on these well-established research foci to apply everyday technologies to assist family and formal caregivers assist persons with dementia (AHRQ: R03 HS020948; R43 NR010642 as Co-Investigator; R44 AG023451-02 as Consultant). As part of his current 5-year K02 project (AG029480) Dr. Gaugler has spent the last 5 years obtaining expertise in mixed methods research and is the founder and director of the Mixed Methods Interdisciplinary Graduate Group at the University of Minnesota.[64] As part of his academic appointment in The School of Public Health, Dr. Gaugler will have the necessary time to devote to the proposed project. The teaching load is flexible and based on external support for Dr. Gaugler's research time. Service expectations include standard membership on School of Public Health and university committees. Due to the advantageous research environment provided by The School of Public Health, Dr. Gaugler can devote up to 95% of his time to research projects and he will have the necessary effort available to make the current project a success.

Dr. Gaugler's secure suite in the Mayo Building includes his own office, three other connected office spaces, a meeting room, and a file area that house nine of his research team members (e.g., two research coordinators, five graduate research assistants, and two additional research assistants). Dr. Gaugler's office suites are equipped with secure computers (including the necessary statistical software), two printers (including one color), web cameras, telephone access, and ample secure file space to conduct the proposed study. The computers have LAN access. Dr. Gaugler's suite is a private location to conduct research participant interviews when needed as well as collect and manage any related human subjects research data.

Kathleen Buckwalter, PhD, RN, FAAN, Consultant, is recognized internationally for her research in geropsychiatric nursing, particularly interventions for behavioral and psychological symptoms in persons with dementia and their formal (long-term care staff) and family caregivers (R01 NR03234, NIA/Rural Aging Center; Administration on Aging, NIMH; Alzheimer's Association, Division of Nursing, DHHS; NINR F33 award, all as PI). Her extensive expertise will facilitate the dissemination of the evaluation results to appropriate scientific and clinical venues.

Bonnie Westra, PhD, RN, FAAN, FACMI (Co-Investigator) will provide health informatics expertise in the effective delivery, use, and evaluation of eNeighbor. She is a member of the Minnesota e-Health Advisory Board, the American Medical Informatics Association Board, and co-chairs the Alliance for Nursing Informatics. She will assist the research team in addressing facilitators and barriers to installation, utilization, and evaluation of the eNeighbor.

The Lutheran Home Association (TLHA) of Belle Plaine, MN has utilized the eNeighbor wellness and communication monitoring system within congregate, independent living, and home settings throughout Minnesota and Wisconsin for over five years. The Director of Nursing and Technology of TLHA, Melissa Mewes, has begun to establish experience in providing nursing care management and technical oversight of the eNeighbor in TLHA's residential and community settings. TLHA will collaborate with the research team to purchase, install, and implement eNeighbor for the purposes of the proposed evaluation (see Letters of Support).

The research team also includes George Demiris, PhD, FACMI, Consultant, who lends extensive expertise in health informatics and information technology in chronic disease. Dr. Demiris is currently the PI of an NINR R01 project (NR012213) that will test interventions for family caregivers of hospice patients that are delivered through tele-health. His expertise in these "smart home" applications will directly facilitate the implementation, evaluation, and analysis of how and why eNeighbor benefits persons with ADRD and their family caregivers.

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