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| **Protocol Title** | Utilizing Senior Companions to Enhance Dementia Care Services and Supports: R61 Phase; NCT03667924 |
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| | Institutional Email Address: |
| **Scientific Assessment** | Nationally-based, federal funding organizations |
| **Version Number/Date:** | v15 / 10/28/22 |

**PROTOCOL COVER PAGE**

**REVISION HISTORY**

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| 1 (Mod 8452) | Version 2: 12/18/2018 | Updated Senior Companion baseline survey measures, office and data storage locations, language regarding incentive payments | Yes |
| 2 (Mod 9760) | Version 3: 3/14/2019 | Protocol review to align with intervention development and updated study procedures; Consent and procedure updates; addition of 3 new study staff | Yes |
| 3 (Mod 10054) | Version 4: 4/2/19 | Protocol review to align with intervention development and updated study procedures (screening, consent, delivery of training); update in study staff | Yes |
| 4 (Mod 10627) | Version 5: 5/2/19 | Protocol update for intervention development/delivery of training (allowing for facilitation of online CARES training in a group setting, sequence of study events) | No |
| 5 (Mod 11234) | Version 6: 6/4/2019 | Protocol update for change to consent (for PWML) and development of screeners, surveys, training evaluation | Yes |
| 6 (MOD 12402) | Version 7: 7/31/19 | Protocol update to allow for survey completion modality based on participant preference. Changes to eligibility screening process (inclusion of participants concerned about memory loss (no diagnosis), inclusion of clients from community setting, inclusion of LSS volunteer companions from | No |

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| | | programs other than Senior Companion (such as Neighbor to Neighbor, etc.), and exclusion of caregivers/clients with untreated psychiatric disorders). Updated protocol modification dates to reflect submission dates. | |
| 7 (MOD 13796) | Version 8: 10/9/19 | Consent: GRA names removed, terminology updated to focus on "memory concerns", monthly check-ins in person or via phone as able; Eligibility: added eligibility criteria of 55+years for clients and 21+ years for volunteers and caregivers | Yes |
| 8 | Version 9: 12/27/19 | Protocol updated to:<br>1. Reflect updates to "Permission to Contact" form/processes.<br>2. Add that enrolled companions are provided a "checklist" reviewing project trainings and process for sharing information with clients<br>3. Provide clarification that additional volunteer companions within the specified regions (previously stated as estimated n=20) may be enrolled as needed to meet client/caregiver recruitment targets<br>4. Remove study milestones that are | No |

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| | | identified to occur in a particular month of the study timeframe (as companions are enrolled on a rolling basis and follow up is administered per protocol accordingly) | |
| 9 | Version 10: 2/20/2020 | Update to screening criteria (AD8 to be used instead of TICS-M for client); addition of alternate version of assent for client participation with no surveys/interview; clarification of data collection measures based on survey modality | Yes (added alternative assent for no surveys/interview) |
| 10 | Version 11: 3/11/2020 | Update to screening procedures [client eligibility questions to be completed by caregiver if/when applicable]. Added option for volunteer baseline to be completed via phone as needed. | |
| 11 | Version 12: 3/22/2020 | Update to reflect project-specific precautions related to COVID-19 and post-bereavement procedures. | |
| 12 | Version 13: 6/17/2020 | No consistent use/administration of project milestones checklist (given COVID-related study modifications); removal of Community Advisory Board Meeting timeframes and criteria for study report/summary; updates to encrypted phone recording devices and transcription service; extension of COVID precautions through end of | No |

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| | | study timeframe (August 2020); update to timeframe for maintenance of study data | |
| 13 | Version 14: 8/10/2020 | Ensuring upload of intervention materials for 4-part training | |
| 14 | Version 15: 10/28/22 | Study now completed; modification to update consistency of version date listed in header for ClinicalTrials; clarification of assent process | No |

## Table of Contents

**ABBREVIATIONS/DEFINITIONS**

- ADRD: Alzheimer's Disease and Related Dementias
- LSS-MN: Lutheran Social Service of Minnesota
- PCP: Primary Care Companion
- SC: Senior Companion
- SCP: Senior Companion Program
- PI: Principal Investigator
- DHR: Dementia Healthcare Research
- NIA National Institute on Aging
- NIH: National Institutes of Health
- LTSS: Long-Term Services and Supports
- PWML: Person with memory loss
- HCBS: home and community-based services
- RCP: Regional Program Coordinator
- LAR: legally authorized representative
- ISM: independent study monitor
- CAB: community advisory board
- CMSS: CARES® Memory Support Specialist

## 1.0 Objectives

This project will evaluate a novel adaption of the Senior Companion Program (SCP) administered by Lutheran Social Service of Minnesota to assist families better manage their relatives' Alzheimer's disease or related dementias (ADRDs); identify and facilitate use of community-based long-term services and supports (LTSS); and improve engagement with healthcare providers. This intervention, called the PorchLight Project has the following aims:
Specific Aim 1. Implement PorchLight Project for 25 persons with ADRD or memory concerns (collectively, persons with memory loss [PWML]) and/or their caregivers in one urban and rural region of Minnesota. A convergent parallel mixed methods design [(QUAN+QUAL)-->QUAL] will be utilized to examine the feasibility, acceptability, and utility of PorchLight Project for 25 families and their SC-Ds (n = 20) over a 3-month period (i.e., Stage I of the NIH Stage Model).

Specific Aim 2. Refine PorchLight Project delivery and implementation for efficacy evaluation. Activities to support this aim will include assessment of R61 milestones and incorporation of R61 findings to refine the PorchLight Project prior to efficacy evaluation. Through stakeholder engagement with the Dementia Healthcare Research Advisory Group (DHR) as well as analysis of the various quantitative and qualitative data elements collected during this Phase, we will finalize and refine effective training approaches for PorchLight Project Senior Companions (SCs), identify and confirm stakeholder-centric measures, and enhance the overall implementation of the PorchLight Project to inform a subsequent R33 Phase.

## 2.0 Background

The public health implications of Alzheimer's disease or related dementias (ADRDs) are significant. Approximately 10% of Americans over the age of 65 have ADRD, with this percentage escalating to 32% for those over the age of 85.(1) The multi-year progression of ADRD has placed considerable pressure on the U.S. healthcare system, as persons with ADRD account for considerably higher healthcare costs than individuals without ADRD.(1-3) These concerns have led some to ask: how are we going to live with ADRD?(4, 5)

Public health efforts to address ADRD are limited. The inability of formal healthcare systems to effectively identify ADRD and the lack of suitable care or case management often result in families remaining unaware of important community-based, long-term services and supports (LTSS) that could help to mitigate the negative effects of ADRD.(6, 7) Approaches that: a) identify community-residing older persons with potential memory impairment; b) assist their families in navigating the healthcare system; and c) facilitate the identification of appropriate community-based LTSS could result in more effective management of ADRD.(4, 8-10)

Funded by the Corporation for National and Community Service, The Senior Companion Program (SCP) is one of three National Senior Service Corps programs. The SCP places volunteers in the homes of frail older adults to serve as companions, to provide assistance with activities of daily living, and to provide respite to family caregivers.(11-14) The SCP features 12,190 Senior Companions serving 43,000 frail older clients and 6,650 families throughout the U.S. in 2017.(15) Although several efforts have attempted to utilize the SCP to develop psychoeducational, multi-session interventions for dementia family caregivers in smaller scale studies,(16) the use of SCP as a possible public health intervention to engage PWML, identify LTSS in the community, and facilitate healthcare system interactions is heretofore untapped. Utilization of lay/peer intervention providers in the community to reach older persons and their families who struggle with memory loss or ADRD may offer a novel, cost efficient method to reach those in need. Such an approach may also serve as a fulcrum around which formal healthcare delivery and community-based LTSS are better integrated for PWML and their families, which is a core tenet of effective chronic disease care.(17, 18)

## 3.0 Study Endpoints/Events/Outcomes

**Outcomes**

**Primary:**

- Utilization of LTSS by PWML
    - Baseline, 1-month, 3-month
    - Community-based service utilization of PWML will be assessed by asking participants to identify (from a fixed list of options) fifteen different home and community-based services (HCBS).
- Quality of primary care interactions
    - Baseline, 1-month, 3-month
    - A 3-item measure of quality of interaction during primary care provider encounters
- Caregiver Distress: Burden
    - Baseline, 1-month, 3-month
    - Caregiver distress will be ascertained with the 22-item Zarit Burden Interview.
- Caregiver Distress: Depressive symptoms
    - Baseline, 1-month, 3-month
    - Caregiver distress will be ascertained with the 20-item Center for Epidemiological Studies-Depression scale.
- PWML Well-being
    - Baseline, 1-month, 3-month

- We will assess the PWML health related quality of life using the EQ-5D-5L. These measures will be used to generate the PWML health utility that will inform the cost-effectiveness analysis.

- PWML Depression
  - Baseline, 1-month, 3-month
  - PWML Depression will be ascertained using the 15-item Geriatric Depression Scale Short Form
- PWML Quality of Life
  - Baseline, 1-month, 3-month
  - PWML Quality of Life will be ascertained using the 13-item Quality of Life AD-Measure

**Secondary:**

- Caregiver self-efficacy
  - Baseline, 1-month, 3-month
  - An 8-item measure of caregiver self-efficacy.

Note: Depending on time point, participants can elect to complete surveys in-person, hard copy, or online. As needed, minor verbiage changes have been made to allow for online completion.

## 4.0 Study Intervention(s)/Interaction(s)

**Study Intervention**

Senior Companions (or other LSS-MN volunteers providing senior companionship services) who deliver the PorchLight Project will first complete the CARES® Dementia Care Specialist training modules developed by HealthCare Interactive. The CARES® interactive modules are designed to provide education, tools, and resources to help professionals from various disciplines as well as families provide more person-centered, effective care across the spectrum of ADRD. The CARES® modules are developed specifically for those with lower health literacy. The CARES® Approach is based on the following principles: C – Connect with the Person, A – Assess Behavior, R – Respond Appropriately, E – Evaluate What Works, and S – Share with Others. Among the unique and helpful features of the CARES® modules are care scenarios with real professionals, family members, and persons with ADRD as well as a wide variety of textual, audio, and visual resources, passive and active learning modes, interviews in streaming video, and resources for interactive feedback and interpersonal follow up.(19-24) Research supported by a series of Small Business Innovation Research grants authored by the Chief Executive Officer of Healthcare Interactive (John Hobday) and the PI (Joseph E. Gaugler, PhD) have demonstrated these modules' strong feasibility, utility, and potential to inform practice change among diverse users.(19-24) Many states that require dementia-specific training for long-term care providers

recognize completion of the CARES® Dementia Basics module alone as a necessary training requirement. The Alzheimer's Association also offers the CARES® modules as its essentiALZ® training certification program.

Volunteer companions who deliver the PorchLight Project, as well as their Regional Program Coordinator (RPCs), will complete the first three modules of the CARES® program (Dementia Basics; Dementia-Related Behavior; Dementia Care for Families). Completion of the CARES® modules are self-paced, and can be completed individually or in a group setting. We will provide 20 tablets as needed to facilitate SCs' training.

In addition to the CARES training, SCs will be asked to complete four additional trainings provided by Dr. Gaugler's team that will cover the following topics: 1) overview of the PorchLight Program, recruitment and approach, 2) Review of the National Consensus Guidelines on Palliative Care,(25) 3) Review of the list of guided questions, and 4) Review of journaling approach and LTSS resources. The National Consensus Guidelines on Palliative Care are evidence-based recommendations to provide a holistic palliative care model. For the purpose of our project, these guidelines will be adapted for the lay person delivering care (SCs). SCs will participate in these training sessions either in person or via web and/or teleconference. These sessions will offer the opportunity to integrate and demonstrate the learning obtained in the CARES® modules. CARES® reminders, resources, tips, and slides used for this training, along with space for note-taking, are provided in a binder and/or bag with the project logo. As needed, additional resources are given on request.

After completing these trainings and passing a knowledge check exam (a score of 90% or greater; the exam can be retaken at no additional cost if needed), SCs will receive a certificate of "CARES® Memory Support Specialist" (CMSS).

The 3rd component of the PorchLight Project training will include monthly check-ins (discussions and case review as applicable) with Senior Companions and the University of Minnesota (UMN) research team (the Principal Investigator/PI, research coordinator, or research assistant) via phone and/or in person. (26-29)SCs who deliver the PorchLight Project will also be trained to identify community-based LTSS. A particular emphasis of SC engagement is to identify the strengths and needs of the PWML as well as their family caregiving system via semi-structured guides that assess elicit preferences for physical, family, social, cultural, financial/legal, and spiritual care. [28]

Monthly check-ins will largely focus on review of specific cases (as applicable), discussion of challenges and potential solutions, provision of additional education as needed, and ensuring that SCs are regularly engaged with PWML

and family members throughout PorchLight Project delivery. We have successfully utilized this approach in a current national pragmatic trial that implements a staff-delivered family care management program in adult day service programs ("ADS Plus," R01 AG049692; PIs: Gitlin and Gaugler).

A project "checklist" will be available to enrolled companions as needed (offered during training or at monthly check in sessions) to facilitate completion of project training and the process for sharing information with their clients.

## 5.0 Procedures Involved

A parallel convergent mixed methods design [(QUAN+QUAL)-->QUAL] will be used to generate qualitative and quantitative data on the feasibility and utility of the PorchLight Project across two Senior Companion Program (SCP) regions served by Lutheran Social Service of Minnesota (LSS-MN) (Stage I of the NIH Stage Model). The R61 procedure will begin with the project biostatistician, Dr. Roth, randomly assigning the 12 RPCs to one of two groups: a PorchLight Project "treatment" region or a SCP usual care region. A re-randomization procedure will be used to ensure balance between Regional Program Coordinators (RPCs) who are assigned to intervention or control conditions on 3 important regional/RPC-level covariates: 1) whether the RPC has oversight within the Minneapolis-St.Paul 7-county region; 2) whether the region includes 20 or more SCPs; and 3) whether the RPC has 3 or more years of experience in this position. The re-randomization procedure has been used successfully in our ongoing ADS Plus trial (R01 AG049692). It involves conducting multiple possible randomizations (e.g. 20) before the trial is initiated, then selecting the one randomization assignment solution that achieves optimal balance on these pre-specified covariates. Two of the RPCs randomly assigned to a PorchLight Project treatment region will be randomly selected again to initially implement the proposed intervention: one from the Twin Cities metropolitan area and one from a region outside of the Twin Cities area.

The 2 randomly selected RPCs and the volunteer companions under their supervision (estimated n = 20) will be invited to participate in this study after reviewing the PorchLight Project research procedures with them. Additional volunteer companions in the selected regions may be invited to participate as needed to meet the PWML and/or caregiver recruitment targets. If they voluntarily agree to participate, they will be asked to sign an informed consent form (hard copy or electronic), complete a baseline survey (hard copy, via phone, or electronic), and then undergo the training period. The training features CARES® modules and the additional 4-part PorchLight Project training sessions delivered in person or via teleconference/web conference sessions described in the Research Plan. Following this training period, recruitment and enrollment of

PWML and their family caregivers in the PorchLight Project will begin. This will result in an anticipated sample of 25 PWML and/or their family caregivers.

Following a description of the study by the SC, the UMN research coordinator or graduate research assistant would complete the screening process and consent/assent (similar to our other IRB approved protocols [e.g., 1401S47541]). Consent would be reviewed with the research staff. The UMN research coordinator or graduate research assistant will administer a baseline survey to PWML. This can be conducted in-person, via telephone, or in hard copy. As applicable, the enrolled caregiver will also complete a survey. After completion of the baseline survey, the SC will engage with the PWML and caregiver to provide routine SCP respite and support in addition to: a) referral of the person with PWML and family member to recommended long-term services and supports (LTSS) in their community; b) assistance for the person with PWMLs and their family caregiver to navigate and interact with healthcare providers; and c) provision of guidance, support, and education/resources informed by in-home visits or telephone consultations (i.e., the PorchLight Project). As part of the feasibility testing procedures, the volunteer companions will complete a usage log and journal entry following each contact with PWML and their family caregivers to summarize: a) the length and method of contact; b) the main issues that are raised by caregivers or PWML when receiving PorchLight Project support; c) types of support provided by the SC; and d) how family members and PWML react to/receive the various recommendations and services provided by the companion. A detailed list of procedures is listed below for each type of participant.

The research team will utilize additional approaches to assess the feasibility and utility of the PorchLight Project implementation among 25 clients and family caregivers of PWML. During the training period the standardized CARES® training program will be administered. Following the PorchLight training, an anonymous post-session satisfaction survey will be administered to assess the usefulness of the CARES® and PorchLight trainings and provide the companions with a forum to provide suggestions. We will also monitor turnover of SCs. A review checklist of the PorchLight Project, based on similar, reliable checklists Dr. Gaugler has used in his various dementia caregiving interventions will be administered to participating PWML and caregivers at 1 month and 3 months following completion of the baseline survey.

Several data collection strategies will be employed to determine the degree to which participants use and apply the PorchLight Project service recommendations to their everyday care situations and how they perceive the utility of the PorchLight Project overall (see list below). The research coordinator or graduate research assistants will conduct a brief semi-structured interview

with PMWLs and/or their caregivers 3 months following baseline to explore how the application of the PorchLight Project was conducted. The open-ended responses will provide information about how PWML and/or their caregivers felt about volunteer companion visits and the resources they facilitated, and will point out how the program can be improved in the R33 Phase. A similar interview will be conducted with volunteer companions who implemented the PorchLight Project (estimated n = 20) to understand their experience in the project and suggestions for improvement. The interview will take place 3 months following the client/caregiver enrollment.

List of procedures by type of participant *[Note: Depending on time point, participants can elect to complete surveys in-person, hard copy, via telephone, or online. As needed, minor verbiage changes have been made to allow for online completion]:*

A. Volunteer companions:
    0) Assess eligibility
    1) Sign a consent form
    2) Complete a brief background survey
    3) Complete project training
        i. 3 CARES® modules (Basics, Behavior and Families)
        ii. Take the CARES knowledge check exam (re-take is optional at no additional cost)
        iii. 4-part project training in person or via web/teleconference
            1. "CARES® Memory Support Specialist" certificate
    4) Recruitment and enrollment of PWML and caregivers
        i. Use flyer, information sheets and Documentation of Permission Form
    5) 3-month work with client (intervention)
        i. Log of contact to monitor turn over
        ii. Journal
        iii. Monthly case review and check-in
        iv. Brief semi-structured interview
B. PWML
    0) Assess eligibility, complete consent/assent (use UBACC to assess capacity to consent as necessary)
    1) If providing study team with data, PWML is asked to complete a survey at baseline, 1- and 3-months containing:
        i. Demographics/context of care [baseline only]
        ii. Cognitive assessment [baseline in-person only] – 5-item Mini Cog
        iii. Physical assessment [baseline in-person only]—Timed Up-and-Go
        iv. Activities of daily living [baseline only]

v. Utilization of LTSS by PWML - Community-based service utilization of PWML will be assessed by participant identify (from a fixed list of options) fifteen different home and community-based services (HCBS).
vi. Quality of primary care provider interactions - A 3-item measure of quality of interaction during primary care provider encounters
vii. PWML well-being We will assess the PWML health related quality of life using the EQ-5D-5L. These measures will be used to generate the PWML health utility that will inform the cost-effectiveness analysis.
viii. PWML depression – 15-item Geriatric Depression Scale Short Form
ix. PWML quality of life – 13-item Quality of Life AD-Measure
x. 15-item PorchLight Project Evaluation [1- and 3-months only]

2) Brief semi-structured interview

C.) Caregiver [if applicable]

0) Assess eligibility, complete consent
1) Complete a a survey at baseline, 1- and 3-months containing:
   i. Demographics, activities of daily living, memory impairment [baseline only]
   ii. Utilization of LTSS by PWML - Community-based service utilization of PWML will be assessed by asking family caregivers to identify (from a fixed list of options) fifteen different home and community-based services (HCBS).
   iii. Quality of primary care provider interactions - A 3-item measure of quality of interaction during primary care provider encounters
   iv. Caregiver Distress: Burden - Caregiver distress will be ascertained with the 22-item Zarit Burden Interview.
   v. Caregiver Distress: Depressive symptoms - Caregiver distress will be ascertained with the 20-item Center for Epidemiological Studies-Depression scale.
   vi. PWML well-being - We will assess the PWML health related quality of life using the EQ-5D-5L. Measures will be used to generate the PWML health utility that will inform the cost-effectiveness analysis.
   vii. Caregiver self-efficacy-An 8-item measure of caregiver self-efficacy.
   i. 17-item PorchLight Project Evaluation [1- and 3-months only]
2) Brief semi-structured interview

## 6.0 Data Banking

**Release and Sharing**

N/A

## 7.0 Sharing of Results with Participants

Since a variety of findings will be derived from the project, results will be disseminated via several mechanisms throughout the final months of the project. First, a user-friendly summary of the findings will be made available to all research participants and other key stakeholders such as the national office of Lutheran Social Service, the Dementia Healthcare Advisory Board, the Minnesota Brain Aging Research Consortium, the National Institute of Aging, and collaborating organizations that assist PWML and their family caregivers (e.g., the Alzheimer's Association, the Family Caregiver Alliance, the Rosalynn Carter Caregiver Institute). The report will illustrate how community organizations and other long-term service and support (LTSS) providers can utilize the PorchLight Project model to effectively and proactively engage with persons with memory loss and their family members in the community. Dr. Gaugler will also be available to provide lectures and overviews of the results to interested organizations in Minnesota and in other regions of the U.S. (e.g., via Zoom web conference meetings).

Multiple peer-reviewed manuscripts and presentations will also be produced from this study, and these academic dissemination efforts will be directed to top forums in gerontology, geriatrics, Public Health, and related disciplines. Clinical geriatrics and community-based health journals will also be identified for dissemination purposes in order to maximize the practice impact of this project and will create a strong foundation for subsequent scientific or service development efforts. To augment these resource sharing and dissemination activities, Dr. Gaugler will utilize social media to expand the reach of the project findings. Dr. Gaugler will post any scientific manuscripts, poster presentations, webinars, or final reports of the proposed project to his Experts@Minnesota profile site. The utilization of social networking and other Web 2.0 features will further dissemination both within and beyond the academic and service contexts of the project team.

## 8.0 Study Duration

The total study duration will be 2 years. Volunteer companions will participate for approximately 12-16 months, depending on the number of eligible clients they identify. Volunteers may participate in study activities (including monthly

check in calls) through the end of the study timeframe in August 2020. PWML and caregivers will participate for approximately 3-4 months.

## 9.0 Study Population

The inclusion criterion for volunteer senior companions is to 1) be a current volunteer through LSS-MN 2) be willing to complete the CARES® modules and 4-part training session provided by UMN research staff and 3) be 21 years of age or older.

The inclusion criteria for the PWML will be based on one of the following scenarios: 1) the person or their caregiver are concerned about the person's memory loss, 2) the person has a physician diagnosis of ADRD, 3) the caregiver (or PWML) scores 2 or greater on the AD8,(30) a validated screening interview that includes 8 yes/no items. *Note: The AD8 will be administered as needed, if other criteria had not been previously met in the discussion with the client and/or caregiver.* The PWML must be 55 years of age or older. As needed, a caregiver may assist to provide data to determine a client's eligibility.

The inclusion criteria for the caregiver will be based on them caring for a PMWL at least in part related to their cognitive impairment. Their care recipient must be eligible per the inclusion criteria specified above. The clients/caregivers do not need to be receiving LSS services to be eligible.

Further, a PWML or caregiver will be ineligible if they live with a current diagnosis of a serious psychiatric illness, their symptoms have worsened in the last 6 months, and they don't receive steady, ongoing treatment for those symptoms.

Inclusion criteria for the caregiver is that the individual is 1) 21 years of age or older, 2) self-identifies as someone who provides help to the PWML because of their cognitive impairments, and 3) the care recipient is eligible for the study as per the above criteria.

To initiate participant recruitment, interested volunteer companions will reach out to the UMN study staff directly, or provide documented verbal or written permission to be contacted by UMN study staff. Following the volunteer's enrollment and training, the volunteer companions, LSS staff, and/or UMN study team will present details about the study to clients and/or caregivers either in-person (e.g., monthly meetings, at community outreach events) or over the telephone. If the client and/or caregiver agree, the SC, LSS staff, or UMN study staff person will record their verbal or written permission to be contacted by study staff using a hard copy or electronic form. Permission may also be obtained from community contacts interested in receiving senior companionship

(i.e., potential new clients). Alternatively, interested individuals may also contact the UMN research team directly to discuss the study.

Following discussion with the interested individual, as applicable, the UMN team may reach out to the contact's caregiver or care recipient without completion of an additional contact form. The UMN study staff will describe the study process in-depth to the client and/or eligible family caregiver and obtain signed consent/verbal assent to participate.

## 10.0 Vulnerable Populations

☐ Children
☐ Pregnant women/Fetuses/Neonates
☐ Prisoners
x 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
☐ Approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.
x Disadvantaged in the distribution of social goods and services such as income, housing, or healthcare
☐ Serious health condition for which there are no satisfactory standard treatments
☐ Fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior)
☐ Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research
☐ Undervalued or disenfranchised social group
☐ Members of the military
☐ Non-English speakers
☐ Those unable to read (illiterate)
☐ Employees of the researcher
☐ Students of the researcher
None of the above

Additional Safeguards:
In creating our research design and sampling procedures, an important objective was to preserve the privacy, confidentiality, and autonomy of all participants. Following discussion of the study with a volunteer companion, regional coordinator, and/or study staff, interested PWML and/or caregivers will be asked to provide permission to be contacted by study staff with more information.

Verbal permission will be recorded by LSS or UMN staff person using either a hard copy or electronic form. Alternatively, the potential participant may complete their own form or contact the UMN research team directly if they so choose. Study staff will reach out to introduce the study to the PWML, family caregiver [if applicable], and legally authorized representative (LAR) [if applicable]. If they are interested, staff will provide potential participants with the consent materials. Staff will review the consent materials in detail with each potential participant, including a description of the types of assessments to be obtained and time required.

After reviewing consent with the PWML, staff will administer a capacity to consent questionnaire (San Diego Brief Assessment of Capacity to Consent [UBACC]),(33). If the PWML scores above the threshold for capacity to consent, they will be asked to consent to participate if they so choose. If the PWML scores below the threshold, they will be asked to verbally assent to participate if they so choose. *(Note: Since the consent form was shared and/or reviewed with clients with memory loss prior to UBACC administration, staff would not review the assent form additionally (containing similar, but abbreviated information) prior to obtaining verbal permission regarding their interest in participation if they were unable to consent).* In the case of PWML assent, signed consent will be obtained from the family caregiver or LAR. Participants who are eligible to consent will sign the consent form in electronic or hard copy. If the PWML scores below the threshold and does not have a caregiver or LAR, they are not eligible to participate in the study.

Alternatively, if a caregiver is interested in enrolling in the project, and the client (or family) prefers that the client not complete data collection procedures (surveys/interviews), the research team will review an alternate assent form with the involved client, and enroll the caregiver separately. As needed (if the client does not participate in the full screening process separately), the research team may obtain data necessary to determine eligibility of the client from the involved caregiver or LAR. Additionally, if the eligible client is not participating in data collection surveys/interviews, the team would not assess the client's capacity to consent (verbal assent for study involvement in this manner would be obtained).

More details (and a diagram detailing the consent/assent procedures) are provided in the Consent Process section (22.0) below.

Staff will review consent materials (and assent materials, if applicable) with all potential participants and give them the opportunity to ask questions. Potential participants may decide to review materials further and ask questions of staff and investigators at a time that is convenient to them. Participants who are

eligible to consent will sign the consent form in electronic or hard copy. In the case of assent, the process and the participant's decision will be documented by study staff (no participant signature will be obtained). The study staff or Dr. Gaugler will also sign the hard copy consent form and/or assent form.

The experience of the research team and the exclusion of participants with serious psychiatric illness will minimize the possibility of psychological risks. The unlikelihood of such problems is evident from the absence of any clinically significant problems during the past 13 years that the research team has operated various protocols related to dementia caregiving intervention research. The research coordinator and research assistant will be trained to interview in ways that are non-threatening, friendly, and respectful. 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 caregivers, PWML, and SCs that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota, Lutheran Social Service of Minnesota (LSS-MN) or other entities.

In the event a caregiver or PWML does become upset during the interview process, the research coordinator or research assistant will contact Dr. Gaugler, who will be available for consultation. If a caregiver or PWML is in crisis because of their care situation or some other reason, research staff will be instructed to consult with Dr. Gaugler. With the caregiver's PWML's 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 very few or no such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the Adult Protection office/officer will be contacted in the appropriate county.

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 an AHC-IS secure shared project folder. Per University of Minnesota and the Academic Health Center-Information Systems data security guidelines, all data for this project will only be accessed via this secure server. The data will be maintained on the secure project folder for approximately 3-5 years, which is the time, anticipated it would take to disseminate 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 Memorial Building (Dr. Gaugler's research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

We believe participation will yield benefits for participants. Participation in the PorchLight Project will provide PWML and their caregivers with improved ability to identify supportive, community-based services and better navigate healthcare systems for the PWML. Caregivers and PWML will be paid $25 following their successful completion of each survey and interview in the proposed study. Each enrolled caregiver and PWML is eligible for up to $100 in incentives.

The evidence base of dementia caregiver interventions and dementia specialty care has advanced considerably, but linking PWML and their family members to available community-based LTSS remain underdeveloped. In particular, engaging with underserved persons with dementia and their families earlier in the disease process could help to improve caregiving outcomes, enhance community-based LTSS utilization, and assist families better navigate the healthcare system.

We have attached the CHECKLIST: Cognitively Impaired Adults (HRP-417) to the ETHOS IRB application for further documentation of safeguards.

**COVID19 Precautions:**

The following precautions were implemented to promote the safety of PorchLight project participants and research staff during the COVID19 outbreak. Participants and new contacts affected by these precautions were notified. Precautions initiated March 2020 and will be continued through the end of study timeframe (August 2020).

1.) Volunteer companion check-in meetings via phone/conference call only
2.) Delayed (or incomplete) training for volunteer companions unable to complete training online
3.) Volunteer companions not required to visit their client for research purposes; Routine client visits by LSS volunteers may exist per LSS discretion outside of the research collaboration.
4.) Delayed enrollment of new volunteer companions for those unable to complete the process electronically/via phone
5.) No enrollment of new PorchLight clients/caregivers. No in-person visits by study staff will be conducted during this time.
6) Research team available via phone for project participants

## 11.0 Number of Participants

25 family caregivers and/or PWML; 20 SCs.

## 12.0 Recruitment Methods

For SCs:

The source of potential participants are current or new LSS-MN volunteer companions who express interest in the PorchLight Project. If they verbally agree to be contacted by the UMN research team, the person obtaining their verbal agreement (e.g., regional coordinator, LSS or UMN study staff, another Senior Companion, or the potential participant themselves) will document it, and the UMN research team will proceed to reach out to them to discuss the study further, as well as schedule a formal screening and consent process. Current SCs who undergo the training described above will then become "CARES® Memory Support Specialists (CMSS)".

For PWMLs and/or their caregivers:
Potential participants will be initially identified by SCs, regional coordinators, and/or UMN and LSS study staff who engage with clients/caregivers. They may also share project information and obtain verbal permission to be contacted by those in the community interested in receiving companionship. SCs, regional coordinators, or UMN and LSS study staff will briefly describe the study, share a flyer and information sheet, and if the person agrees to be contacted by the UMN research team, record their verbal permission to be contacted using a hard copy or electronic form. Alternatively, the potential participant may complete their own form or contact the UMN research team directly if they so choose. Records of permission to be contacted will be transferred to the UMN research team in hard or electronic copy (e.g., via Qualtrics).

As part of their volunteer roles, volunteer companions regularly meet with (in-person or over the telephone) older persons to provide respite and support in their homes. The PorchLight Project is building off of this model to provide SCs with more specialized training and education in dementia and dementia care to better meet the needs of older persons they may be helping who have memory issues. Volunteer companions, as part of their volunteer outreach role, will continue to engage with older persons to provide respite and relief (that is hypothesized as more effective based on their dementia care training), and as outlined in this protocol will present the opportunity to participate in the research project to these older persons. If they agree to share their contact information with the UMN research team, we will then proceed to reach out to them to schedule a formal screening and consent process.

All SCP clients that a SC may visit may be approached in regards to their participation in this project. Depending on the home situation of the SCP client, either the person with memory loss (PWML), the caregiver, or both will be approached. The SCs do not have to make a decision on who to approach; all screening for eligibility will take place by the UMN research coordinator or research assistants.

*Note: Volunteer companions will be alerted by the project team if one of their clients enrolls in the project.*

SCs, regional coordinators, and/or UMN and LSS study staff will provide existing and potential new clients and/or caregivers with information on the PorchLight Project. The UMN team will provide SCs, regional coordinators, and LSS study staff with study flyers/information sheets and forms they can use to record a client or caregiver's verbal permission to be contacted by the UMN research team. The client or caregiver may complete their own form or contact the UMN research team directly if they so choose.

**Recruitment Materials**

We will be using flyers and information sheets describing the study.

**Payment**

Participating caregivers and/or PWMLs will also be asked to complete 1- and 3-month outcome surveys (see below) and will be offered an incentive of $25 to complete the baseline, 1-month, and 3-month surveys, as well as a semi-structured exit interview (for a total of $100 possible).

## 13.0 Withdrawal of Participants

**Withdrawal Circumstances**

Participants would withdraw from the study if they indicate to the research coordinator they no longer wish to participate, either over the phone, email, or in writing.

**Withdrawal Procedures**

Our previous dementia caregiver intervention work at UMN has featured low loss to follow-up,(34-36) and we will take several similar steps to address attrition bias and enhance retention. If a PWML has died, caregiver follow-up interviews will include queries to determine when the event occurred. An enrolled caregiver, if applicable, would be asked to complete the next follow-up survey, as well as the final telephone-interview, in order to collect as much information on outcome variables that are appropriate (i.e., intention to treat principle, which is a feature of pragmatic trial design (37, 38)). Additional follow-up surveys would be omitted. In instances where participants wish to withdraw from the study we will determine the reason for study withdrawal. All data collection/contact of these individuals will cease. However, the research team will continue to use the data participants did provide in the intervals leading up to the decision to withdraw, per intention to treat principle.

**Termination Procedures**

There is no intention to terminate any participant's participation in the research study, however if this were to occur, the procedures that would be carried out would be similar to those if the participant requested to withdraw, or was lost to follow up. Data from participants who were terminated would be used up until the point of their termination.

## 14.0 Risks to Participants

Since the study involves no invasive procedures, there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver. However, the research team has considerable experience providing psychosocial support to dementia caregivers on various protocols and serious psychological risks are unlikely to occur based on this experience. The potential social or legal risks for the participants relate only to possible violations of confidentiality. Given the procedures outlined below, such risks are highly unlikely.

In creating our research design and sampling procedures, an important objective was to preserve the privacy, confidentiality, and autonomy of all participants.

As indicated above, the experience of the research team and the exclusion of PWML and caregivers with serious psychiatric illness will minimize the possibility of psychological risks. The unlikelihood of such problems is evident from the absence of any clinically significant problems during the past 13 years that the research team has operated various protocols related to dementia caregiving intervention research. The research coordinator and research assistants will be trained to interview in ways that are non-threatening, friendly, and respectful. 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 caregivers, PWMLs, and SC-Ds that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota, Lutheran Social Service of Minnesota (LSS-MN) or other entities.

In the event a caregiver or PWML does become upset during the interview process, the research coordinator or research assistant will contact Dr. Gaugler, who will be available for consultation. If a caregiver or PWML is in crisis because of their care situation or some other reason, research staff will be instructed to consult with Dr. Gaugler. With the caregiver's 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 very few or no such instances to occur. If a member of the research team does identify neglect or other potentially

inappropriate care practices, the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

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 an AHC-IS secure server and data accessed by Dr. Gaugler or the project team will only occur via this server. The data will be maintained on the secure AHC-IS server for approximately 3-5 years, which is the time, anticipated it would take to disseminate 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 Memorial building (Dr. Gaugler's research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

## 15.0 Incomplete Disclosure or Deception

This study will not include incomplete disclosure or deception.

## 16.0 Potential Benefits to Participants

We believe participation will yield benefits for participants. Participation in the PorchLight Project will provide persons with dementia and their caregivers with improved ability to identify supportive, community-based services and better navigate healthcare systems for the PWML. Caregivers or PWMLs will be paid $25 following their successful completion of each survey and interview in the proposed study (for a total of $100 possible).

## 17.0 Data Management

### Data Analysis Plan

As this project will feature quantitative analyses that describe feasibility and utility of the PorchLight Project, the proposed sample size of 25 family caregivers of PWML (and/or PWML themselves) will be sufficient. As noted in various recommendations, a sample of 25 PWML (and/or their caregivers) and 20 SCs (estimated) who deliver the intervention is appropriate to ensure rich data derived for the semi-structured interviews proposed. Additional volunteer companions may be enrolled in order to reach the target sample of PWML and/or caregivers.

As a major objective of this project is to examine the feasibility, acceptablity, and utility of the PorchLight Project intervention, quantitative analyses will large rely on descriptive statistics. Specifically, quantitative analyses will utilize frequency tables and means to examine sample characteristics and item-level responses to the PorchLight Project review checklist. Where appropriate, bivariate analyses

may also be conducted (e.g., paired T-Tests; Chi-square analyses) to examine factors associated with caregivers' perceptions of utility and feasibility of the PorchLight Project at the 1- and 3-month follow-ups. Sex as a biological variable. The gender of the caregiver and PWML will be included to examine whether women or men caregivers and care recipients are more likely to indicate acceptability and utility of the PorchLight Project over a 3-month period in bivariate analyses.

The multiple team meetings and discussions will allow for an exploration of alternative interpretations of the qualitative data and provide a check regarding the quality and richness of the data collected. Following the collection of all quantitative data and in preparation for analysis, all data are screened for outliers and normality and other data screening procedures will be employed as appropriate for the planned analysis. The research coordinator and research assistants will also follow up with participants if needed in instances of extensive missing data on surveys to ensure as complete data as possible.

## 18.0 Confidentiality

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 an AHC-IS secure server folder and a Box folder backup. Per University of Minnesota and the School of Public Health security guidelines, participant data will be maintained on the AHC-IS secure project folder for approximately 3-5 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 Memorial Building (Dr. Gaugler's research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

The PI, research coordinator, and graduate research assistants 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. Any hard copy forms collected by LSS-MN staff (e.g., SCs) will be maintained in a locked file cabinet at LSS-MN and will be transferred securely to Dr. Gaugler and D351 Mayo at the conclusion of the project. SCs will be asked not to collect or record any personal health information on their clients.

Similar to our other IRB-approved protocols, we will utilize a secure (or encrypted) telephone-based recording system to conduct semi-structured interviews. The XBlue X-7 or Olympus DS-2600 recording systems have the ability

to record both sides of a telephone conversation. The device connects to a computer for upload to a secure environment. The recordings are saved to the UMN Box Desktop App and the AHC-IS project server folder. Recorded telephone interviews will be transcribed using Production Transcripts services.

## 19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

As the proposed project will pose minimal risks to study participants, the Principal Investigator (PI), Dr. Gaugler, will serve as the primary monitoring entity of this study. As noted in the Protection of Human Research Subjects section, the proposed study involves no invasive procedures and there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the PWML or caregiver. However, potential participants with a history of serious mental illness (i.e., any major psychiatric disorder) will not be included in the study. Specifically, if a participant indicates they have clinical depression or a similar mental illness whose: a) symptoms have exacerbated in the last six months, and b) are not receiving steady, ongoing pharmacological or other treatment for these symptoms during the screening procedure, they will be excluded from our project. Further, 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. With respect to private information entered, the design of the system will include a structure of permissions with password protection to limit access to materials so only dementia caregivers and the research staff can view sensitive information.

Additional monitoring support will be provided by the Independent Study Monitor (ISM), Dr. Tim Beebe, Mayo Professor and Head of the Division of Health Policy and Management in the University of Minnesota School of Public Health.

*A. Data and Safety Monitoring Procedures: Monitoring Study Safety*

*B1. Monitoring study safety.* In addition to ongoing review of the protocol and human subjects research compliance during weekly project meetings with staff, the PI (Dr. Gaugler) will generate annual reports to ensure that each case complies with Institutional Review Board (IRB) requirements, including use of IRB-approved forms (particularly the consent form), and that each staff person on the proposed project adheres to the study protocol. In both weekly meetings and audit reports, Dr. Gaugler will actively work with project staff to minimize research-associated risk and protect confidentiality of participant data (see Protection of Human Research Subjects section). The research coordinator and research assistants will be trained to interview in ways that are non-threatening, friendly, and respectful. 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 PWML, their caregivers, and SCs who deliver the intervention that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota, Lutheran Social Service of Minnesota (LSS-MN), or other entities.

In the event that a caregiver does become upset during the survey or interview process, the research coordinator or research assistant will contact Dr. Gaugler, who will be available for consultation. If a caregiver is in crisis because of their care situation or for some other reason, research staff will be instructed to consult with Dr. Gaugler. With the caregiver's 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 very few or no such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

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 School of Public Health shared project folder. Per University of Minnesota and the Academic Health Center-Information Systems data security guidelines, all data on Dr. Gaugler's AHC shared server are protected by strong passwords only accessible to Dr. Gaugler or the research team. The data will be maintained on Dr. Gaugler's AHC server folder for approximately 3-5 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 Building (Dr. Gaugler's research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

*B2. Annual audit reports.* The responsibility of Dr. Gaugler (who also have oversight for the data management and analysis of the project) will include the production of an annual 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 University of Minnesota IRB will be notified.

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. Table 1: Enrollment by year or month of study
        ii. Figure 1: Comparison of target to actual enrollment by month
    b. Forms status
        i. Status of forms (e.g., consent, completing of screener, baseline assessment battery, etc.)

*B3. Reporting Adverse Events and Unanticipated Problems*

In addition to ongoing monitoring of protocol and human subjects compliance and reporting and the production of annual case audits, Dr. Gaugler will generate safety reports on an ongoing basis that will list adverse events, serious events, unanticipated events, events related to or associated with the intervention, and the potential causality of the intervention to the event for each participant should they occur. Taken from the 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 that 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.

Unanticipated Problem. 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 unanticipated, adverse, or seriously adverse, whether the event is unanticipated or related to the intervention, and what potentially caused the event. Dr. Gaugler will review study-related data on an ongoing basis, will alert the University of Minnesota IRB as they occur, and will document adverse events in their annual report for the ISM and NIA program officer if these events occur. Specifically, Dr. Gaugler 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, unanticipated event/problem, and whether these events were related to participation in the proposed project. If adverse events occur during the R61 Phase of the project, the PI will review and report adverse events to the Institutional Review Board at the University of Minnesota. In our annual Data Safety and Monitoring Report, we will provide these adverse reports to the Independent Study Monitor to review and approve via a signed cover letter. The final, approved Data Safety and Monitoring Report would then be sent to the Program Officer at NIA for review.

*B4. Procedures to Ensure Compliance with the Monitoring Plan across Study Sites*

Not applicable.

*B5. Assessment of External Factors*

Dr. Gaugler, via his own research experience as well as his editorial board service, is kept abreast of developments in ADRD caregiver interventions. 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 research team to assess issues related to the delivery of community-based services and supports to PWMLs and their family caregivers. If such developments reveal any potential threats to participant

safety or other concerns that require protocol modification, these issues will be addressed in the annual audit reports provided to the ISM and the University of Minnesota IRB.

*B6. Plans for Interim Analysis*
There are no planned interim/futility analyses. Interim analyses are not planned because in the R61 Phase of this project, there is no randomly assigned control condition; the objective of the R61 Phase is to initially implement and refine the PorchLight Project's content, structure, and delivery where needed in preparation for the subsequent R33 Phase (years 3-5). For these reasons, we did not deem futility analyses appropriate.

## 20.0 Provisions to Protect the Privacy Interests of Participants

**Protecting Privacy**

As noted in the recruitment and enrollment process above, the University of Minnesota research team will not reach out to participants for screening or enrolling purposes unless those potentially interested share their permission to be contacted.

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 an AHC-IS secure shared server. The data will be maintained on the secure server 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 Memorial Building (Dr. Gaugler's research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked. Also, all correspondence that contains protected health information will take place via encrypted email, and the entirety of the research team will have completed HIPAA and CITI training prior to conducting human subjects research.

**Access to Participants**

Our research team is not permitted to access medical records. Any private information that the research team is allowed to have access to will need to be provided by the participant. This includes, but is not limited to, survey responses, semi-structured interview responses, and contact information.

## 21.0 Compensation for Research-Related Injury

This research does not involve greater than Minimal Risk to participants, so there is no compensation.

## 22.0 Consent Process

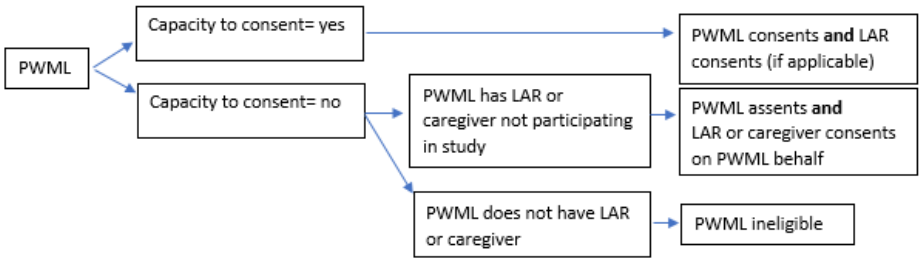
In this study, we will adapt the consent process to fit the needs of each participant situation as detailed in the figure below.

Briefly, clients and caregivers will be asked to consent individually. If a PWML is interested in participating, they will be asked to consent or assent depending on their capacity to consent and the availability of a caregiver or LAR. During the informed consent process, study staff will explain the project in detail including a description of the types of assessments to be obtained and the time required. Study staff will then administer a capacity to consent questionnaire for the PWML (San Diego Brief Assessment of Capacity to Consent [UBACC]),(33); if the PWML scores above the threshold for capacity to consent, they will be asked to sign the consent form if they choose to participate. If the PWML scores below the threshold, then consent will be obtained from the LAR or caregiver and the PWML will verbally assent to study participation if they choose to participate (UMN team will document that verbal permission was obtained via the assent form). If the PWML scores below the threshold and there is no LAR or caregiver involved, the PWML will not be eligible to participate.

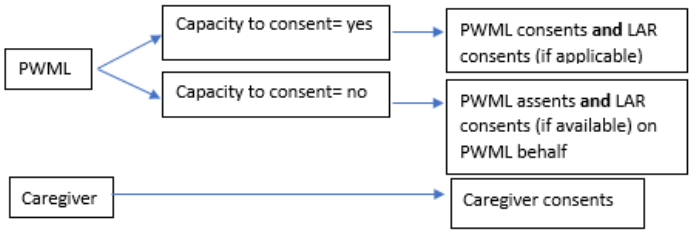
Alternatively, if a caregiver is interested in enrolling in the project, and the client prefers not to complete data collection procedures (surveys/interviews), the research team will review an alternate assent form with the involved client, and enroll the caregiver separately. In this scenario, the client's capacity to consent is not assessed. The figure below reviews the study consent/assent procedures for clients (PWML) and their caregivers.

**Consent Flow Chart: Porchlight Project**

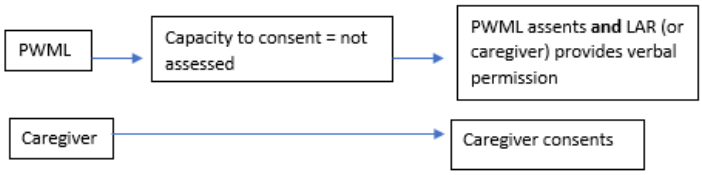
1. **Scenario 1: Person with memory loss (PWML) enrolling in study alone [With data collection]**




2. **Scenario 2: Caregiver and person with memory loss (PWML) enrolling in study together [With data collection]**




3. **Scenario 3: Caregiver enrolling [PWML receiving intervention/does not participate in research surveys or interview]**




The participant will review the study consent form and will have the opportunity to ask questions prior to consenting. Study staff will review the assent form with the PWML if they score below the capacity score on the UBACC. Potential participants may also decide to review the consent/assent form further and ask questions of the staff and investigators at a time that is convenient to them. Study staff or Dr. Gaugler will also sign the consent form and assent form.

Participants will identified through the Senior Companion Program (SCP) and other programs providing senior companionship services at Lutheran Social Service of Minnesota (LSS-MN), so we will rely on a combination of LSS-MN input and direct query of individuals to determine the LAR and their contact information.

Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): N/A
Non-English Speaking Participants: N/A
Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A
Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: Yes, please see above.

**Adults Unable to Consent**

Please see above.

## 23.0 Setting

Our research will be conducted at the University of Minnesota, School of Public Health, Division of Health Policy and Management, D351 Mayo Memorial Building, 420 Delaware St. S.E., Minneapolis, MN 55455.
We will collaborate with a community partner, LSS-MN, to deliver the proposed intervention and identify participants for the study. These potential participants will be forwarded to Dr. Gaugler's research team at the University of Minnesota, where they will then begin the process of eligibility screening. All research procedures will be conducted at the University of Minnesota, School of Public Health, Division of Health Policy and Management, D351 Mayo Memorial Building, 420 Delaware St. S.E., Minneapolis, MN 55455.

A gap highlighted in the design, evaluation, and translation of dementia interventions is the lack of stakeholder engagement throughout the scientific process.(39, 40) Stakeholder engagement is important in the design, development, and evaluation of pragmatic trials. For these reasons, we will adopt various strategies outlined by AHRQ(41) and others to engage stakeholders to refine and enhance the implementation of the PorchLight Project's for PWML and their family members. A Community Advisory Board (CAB) consisting of family members and care professionals, will offer stakeholder input.

During periodic meetings (approximately 2 hours each), the CAB will review the aims to evaluate progress. Each meeting will also include time to discuss concerns so that as a group the DHR can propose mechanisms to resolve issues during the implementation and evaluation of the PorchLight Project. The philosophy underpinning the CAB meetings is one of balanced communication, mutual respect, and an interaction process where all viewpoints are heard and discussed openly. The UMN research coordinator or graduate research assistants will moderate and digitally record all meetings and interviews to provide an additional source of qualitative data on stakeholder perspectives. Open sharing of meeting transcripts with all CAB members to review and edit will also occur to

further establish a transparent environment. At the outset and throughout the course of the project, the CAB's role as key collaborator on the PorchLight Project will be emphasized. The CAB meetings will serve to engage key stakeholders from different organizations, care specialties, and communities to further position the PorchLight Project as an innovative approach to assist PWML and their family caregivers.

The CARES® interactive online modules (as previously described) are designed to provide education, tools, and resources to help professionals from various disciplines as well as families provide more person-centered, effective care across the spectrum of ADRD. The CARES® modules are developed specifically for those with lower health literacy.

International Research: N/A

Community Based Participatory Research: N/A

## 24.0 Multi-Site Research: N/A

## 25.0 Resources Available

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 9 of his research team members (e.g., two research coordinators, five graduate research assistants, and two additional research assistant). 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.

In the event a caregiver does become upset during the interview process, the research coordinator or research assistant will contact Dr. Gaugler, who will be available for consultation. If a caregiver is in crisis because of their care situation

or some other reason, research staff will be instructed to consult with Dr. Gaugler. With the caregiver's 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 very few or no such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

## 26.0 References

### Bibliography and References Cited

1. Alzheimer's Association. 2017 Alzheimer's Disease Facts and Figures. Chicago, IL; 2017.
2. Phelan EA, Borson S, Grothaus L, Balch S, Larson EB. Association of incident dementia with hospitalizations. Jama. 2012;307(2):165-72.
3. Jutkowitz E, Kane RL, Gaugler JE, MacLehose RF, Dowd B, Kuntz KM. Societal and Family Lifetime Cost of Dementia: Implications for Policy. J Am Geriatr Soc. 2017;65(10):2169-75.
4. Karlawish J. How are we going to live with Alzheimer's disease? Health affairs (Project Hope). 2014;33(4):541-6.
5. Gaugler JE, Jutkowitz E, Peterson CM. An overview of dementia caregiving in the United States. . Generations. 2017;September 13 (Fall (ACL Supplement)):37-44.
6. Borson S, Chodosh J. Developing dementia-capable health care systems: a 12-step program. Clinics in geriatric medicine. 2014;30(3):395-420.
7. Gaugler JE, Zarit SH, Pearlin LI. The onset of dementia caregiving and its longitudinal implications. Psychology and Aging. 2003;18:171-80.
8. Callahan CM, Sachs GA, LaMantia MA, Unroe KT, Arling G, Boustani MA. Redesigning Systems Of Care For Older Adults With Alzheimer's Disease. Health affairs. 2014;33(4):626-32.
9. French DD, LaMantia MA, Livin LR, Herceg D, Alder CA, Boustani MA. Healthy Aging Brain Center improved care coordination and produced net savings. Health affairs (Project Hope). 2014;33(4):613-8.
10. Tan ZS, Jennings L, Reuben D. Coordinated care management for dementia in a large academic health system. Health affairs (Project Hope). 2014;33(4):619-25.
11. Butler SS. Evaluating the Senior Companion Program: a mixed-method approach. J Gerontol Soc Work. 2006;47(1-2):45-70.
12. Rabiner DJ, Scheffler S, Koetse E, Palermo J, Ponzi E, Burt S, et al. The Impact of the Senior Companion Program on Quality of Life Outcomes for Frail Older Adults and Their Families. Home Health Care Serv Q. 2004;22(4):1-26.
13. Rabiner DJ, Scheffler S, Koetse E, Palermo J, Ponzi E, Burt S, et al. The impact of the senior companion program on quality of life outcomes for frail older adults and their families. Home Health Care Serv Q. 2003;22(4):1-26.
14. Lee CF, Gray LC. Respite service to family caregivers by the senior companion program: an urban-rural comparison. J Appl Gerontol. 1992;11(4):395-406.

15. Service CfNaC. Senior Corps Fact Sheet Washington, DC: Corporation for National and Community Service; 2017 [Available from: https://www.nationalservice.gov/newsroom/marketing/fact-sheets/senior-corps.
16. Fields NL, Xu L, Richardson VE, Parekh R, Ivey D, Feinhals G, et al. The Senior Companion Program Plus: A culturally tailored psychoeducational training program (innovative practice). Dementia (London). 2016:1471301216685626.
17. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. The Milbank quarterly. 1996;74(4):511-44.
18. Epping-Jordan JE, Pruitt SD, Bengoa R, Wagner EH. Improving the quality of health care for chronic conditions. Quality & safety in health care. 2004;13(4):299-305.
19. Hobday JV, Gaugler JE, Mittelman MS. Feasibility and Utility of Online Dementia Care Training for Hospital Staff: The CARES(R) Dementia-Friendly Hospital Program. Research in gerontological nursing. 2017:1-8.
20. Gaugler JE, Hobday JV, Robbins JC, Barclay MP. Direct Care Worker Training to Respond to the Behavior of Individuals With Dementia: The CARES(R) Dementia-Related Behavior Online Program. Gerontology & geriatric medicine. 2016;2:2333721415626888.
21. Gaugler JE, Hobday JV, Robbins JC, Barclay MP. CARES((R)) Dementia Care for Families: Effects of Online, Psychoeducational Training on Knowledge of Person-Centered Care and Satisfaction. Journal of gerontological nursing. 2015;41(10):18-24.
22. Gaugler JE, Hobday JV, Savik K. The CARES((R)) Observational Tool: A valid and reliable instrument to assess person-centered dementia care. Geriatric nursing (New York, NY). 2013.
23. Hobday JV, Savik K, Gaugler JE. An internet-based multimedia education prototype to enhance late-stage dementia care: formative research results. Geriatric nursing (New York, NY). 2010;31(6):402-11.
24. Hobday JV, Savik K, Smith S, Gaugler JE. Feasibility of Internet Training for Care Staff of Residents with Dementia. Journal of gerontological nursing. 2010:1-8.
25. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National consensus project clinical practice guidelines for quality palliative care guidelines. Journal of palliative medicine. 2018;21(12):1684-9.
26. Shippee ND, Shippee TP, Mobley PD, Fernstrom KM, Britt HR. Effect of a Whole-Person Model of Care on Patient Experience in Patients With Complex Chronic Illness in Late Life. Am J Hosp Palliat Care. 2018;35(1):104-9.
27. Shippee T, Shippee N, Fernstrom K, Mobley P, Frazer M, Jou J, et al. Quality of Life for Late Life Patients: Mixed-Methods Evaluation of a Whole-Person Approach for Patients With Chronic Illnesses. J Appl Gerontol. 2017:733464817732511.
28. Anderson EW, Frazer MS, Schellinger SE. Combining Best Practices and Patient, Caregiver, and Healthcare Provider Perspectives for Late-Life Supportive Care: LifeCourse. J Nurs Adm. 2017;47(11):551-7.
29. Schellinger S, Cain CL, Shibrowski K, Elumba D, Rosenberg E. Building New Teams for Late Life Care: Lessons From LifeCourse. Am J Hosp Palliat Care. 2016;33(6):561-7.
30. Galvin JE, Roe CM, Powlishta KK, Coats MA, Muich SJ, Grant E, et al. The AD8: a brief informant interview to detect dementia. Neurology. 2005;65(4):559-64.
31. Brandt J, Spencer M, Folstein M. The telephone interview for cognitive status. Neuropsychiatry, Neuropsychology, and Behavioral Neurology. 1988;1:111-7.

32. Knopman DS, Roberts RO, Geda YE, Pankratz VS, Christianson TJ, Petersen RC, et al. Validation of the telephone interview for cognitive status-modified in subjects with normal cognition, mild cognitive impairment, or dementia. Neuroepidemiology. 2010;34(1):34-42.
33. Jeste DV, Palmer BW, Appelbaum PS, Golshan S, Glorioso D, Dunn LB, et al. A new brief instrument for assessing decisional capacity for clinical research. Archives of General Psychiatry. 2007;64(8):966-74.
34. Gaugler JE, Reese M, Mittelman MS. Effects of the NYU caregiver intervention-adult child on residential care placement. The Gerontologist. 2013;53(6):985-97.
35. Gaugler JE, Reese M, Mittelman MS. Effects of the Minnesota Adaptation of the NYU Caregiver Intervention on Depressive Symptoms and Quality of Life for Adult Child Caregivers of Persons with Dementia. The American Journal of Geriatric Psychiatry : Official Journal of the American Association for Geriatric Psychiatry. 2015;23(11):1179-92.
36. Gaugler JE, Reese M, Mittelman MS. Effects of the Minnesota Adaptation of the NYU Caregiver Intervention on Primary Subjective Stress of Adult Child Caregivers of Persons With Dementia. The Gerontologist. 2016;56(3):461-74.
37. Forbes G, Loudon K, Treweek S, Taylor SJC, Eldridge S. Understanding the applicability of results from primary care trials: lessons learned from applying PRECIS-2. J Clin Epidemiol. 2017;90:119-26.
38. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. Bmj. 2015;350:h2147.
39. Wethington E, Burgio LD. Translational research on caregiving: Missing links in the translation process. In: Gaugler JE, Kane RL, editors. Family caregiving in the new normal. Philadelphia, PA: Elsevier, Inc.; 2015. p. 193-210.
40. Gove D, Diaz-Ponce A, Georges J, Moniz-Cook E, Mountain G, Chattat R, et al. Alzheimer Europe's position on involving people with dementia in research through PPI (patient and public involvement). Aging Ment Health. 2017:1-7.
41. Viswanathan M, Ammerman A, Eng E, Garlehner G, Lohr KN, Griffith D, et al. Community-based participatory research: assessing the evidence. Evidence report/technology assessment (Summary). 2004;(99)(99):1-8.