Title: A Mobile Informatics Solution to Aid in Memory; NCT04700540

# Protocol

This protocol version (V19) was IRB approved on 9/29/2023.

**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

**Which ancillary reviews do I need and when do I need them?**

Refer to HRP-309 for more information about these ancillary reviews.

| Select yes or no | Does your study… | *If yes…* | Impact on IRB Review |
|---|---|---|---|
| ☐ **Yes**<br>✓ **No** | Include Gillette resources, staff or locations | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*<br>*research@gillettechildrens.com* | **Required prior to IRB submission** |
| ☐ **Yes**<br>✓ **No** | Involve Epic, or Fairview patients, staff, locations, or resources? | *The Fairview ancillary review will be assigned to your study by IRB staff*<br>*Contact:* ancillaryreview@Fairview.org | **Approval must be received prior to IRB committee/ designated review.**<br><br>**Consider seeking approval prior to IRB submission.** |
| ☐ **Yes**<br>✓ **No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection? | *STOP – Complete the Medical Template Protocol (HRP-590)*<br><br>*The regulatory ancillary review will be assigned to your study by IRB staff*<br>*Contact: medreg@umn.edu*<br>*See https://policy.umn.edu/research/indide* | |
| ☐ **Yes**<br>✓ **No** | Require Scientific Review? Not sure? See guidance in the Investigator Manual (HRP-103). | *ONLY REQUIRED BIOMEDICAL RESEARCH REVIEWED BY FULL COMMITTEE* | |
| ☐ **Yes**<br>✓ **No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco? | *Complete the CPRC application process.*<br>*Contact: ccprc@umn.edu* | |
| ☐ **Yes**<br>✓ **No** | Include the use of radiation?<br>(x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *Complete the AURPC Human Use Application and follow instructions on the form for submission to the AURPC committee.*<br>*Contact: barmstro@umn.edu* | **Approval from these committees must be received prior to IRB approval;** |
| ☐ **Yes**<br>✓ **No** | Use the Center for Magnetic Resonance Research (CMRR) as a study location? | *Complete the CMRR pre-IRB ancillary review*<br>*Contact: ande2445@umn.edu* | |

| | | | |
|---|---|---|---|
| ☐ **Yes**<br>✓ **No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *STOP – Complete the Medical Template Protocol (HRP-590)* | **These groups each have their own application process.** |
| ☐ **Yes**<br>✓ **No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *STOP – Complete the Medical Template Protocol (HRP-590)* | |
| ✓ **Yes**<br>☐ **No** | Include PHI or are you requesting a HIPAA waiver? | *If yes, HIPCO will conduct a review of this protocol.*<br>*Contact: privacy@umn.edu* | |
| ☐ **Yes**<br>✓ **No** | Use data from CTSI Best Practices Integrated Informatics Core (BPIC)<br>Formerly the AHC Information Exchange (AHC-IE)? | *The Information Exchange ancillary review will be assigned to your study by IRB staff*<br>*Contact: bpic@umn.edu* | **Approval must be received prior to IRB approval.**<br><br>**These groups do not have a separate application process but additional information from the study team may be required.** |
| ☐ **Yes**<br>✓ **No** | Use the Biorepository and Laboratory Services to collect tissue for research? | *STOP – Complete the Medical Template Protocol (HRP-590)*<br>*The BLS ancillary review will be assigned to your study by IRB staff. Contact: Jenny Pham Pham0435@umn.edu* | |
| ☐ **Yes**<br>✓ **No** | Have a PI or study team member with a conflict of interest? | *The CoI ancillary review will be assigned to your study by IRB staff*<br>*Contact: becca002@umn.edu* | |
| ✓ **Yes**<br>☐ **No** | Need to be registered on clinicaltrials.gov? | *If you select "No" in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*<br>*Contact: kmmccorm@umn.edu* | |
| ☐ **Yes**<br>✓ **No** | Require registration in OnCore? | *If you select "No" or "I Don't Know" in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*<br>*Contact: oncore@umn.edu* | **Does not affect IRB approval.** |

**PROTOCOL COVER PAGE**

| | |
|---|---|
| **Protocol Title** | A Mobile Informatics Solution to Aid in Memory |
| | Name: Jude Mikal |

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|---|---|
| **Principal Investigator/Faculty Advisor** | Department: School of Public Health, Health Policy & Management |
| | Telephone Number: 385-212-4185 |
| | Email Address: jpmikal@umn.edu |
| **Student Investigator** | Name: N/A |
| | Current Academic Status (Student, Fellow, Resident): |
| | Department: |
| | Telephone Number: |
| | Institutional Email Address: |
| **Scientific Assessment** | I believe Scientific Assessment is not required. |
| **Version Number/Date:** | Version 19, date: 8/31/2023 |

**REVISION HISTORY**

| Revision # | Version Date | Summary of Changes | Consent Change? |
|---|---|---|---|
| 2 | 2 | Phase 1 updates: Focus groups instead of interviews | Yes: phase 1 consent at focus group session instead of at time of screening and enrollment. |
| 3 | 2/26/2020 | Change in cognitive assessment tool and added details about phase 1 focus groups. Added context of care survey for care partners to complete. | Change in cognitive assessment tool |
| 4 | 3/2/2020 | 1. Clarification provided on using Mini-Cog and UBACC in consent process.<br>2. Clarification on Baseline and 3 month survey | Clarification provided on using Mini-Cog and UBACC |
| 5 | 5/6/2020 | Focus Groups will now be conducted via Zoom meetings. If needed, dyadic interviews will also be conducted with participants in place of focus groups. Questions were added to phase I about changes in technology use due to the COVID-19 pandemic. | Yes: consent in phase 1 will now be conducted via Zoom, so consent will occur verbally with the caregiver and PWMC. |
| 6 | 5/24/2020 | No focus groups will be conducted, instead only dyadic interviews will be conducted. The SR Checklist survey will be administered verbally during the interview instead of after the interview via mail or web. | No |
| 7 | 12/22/2020 | Updating protocol and materials with new Primary Investigator (switched from Dr. Joseph Gaugler to Dr. Jude Mikal). Changes reflect that Dr. Gaugler was responsible for Phase 1 of the study while Dr. Mikal is responsible for Phase 2 of the study. | No |
| 8 | 3/28/2022 | Updated to new protocol template version available from the UMN IRB. No changes were made to content of the protocol, unless it was not specified by the previous protocol. | No |

| | | | |
|---|---|---|---|
| 9 | 5/25/2022 | Phase 1 specific content is colored green for ease of review (content was not changed since phase 1 has concluded).<br>Specific changes made to Phase 2 content: Updated staff changes, added brief pilot testing to ensure the study is not launched for multiple dyads before the technology has been debugged, added details about survey administration, added details about administering the UBACC before the follow-up surveys to ensure ongoing PWMC consent/assent, updated scales/information collected in the surveys, updated eligibility criteria so that the PWMC must live in the community, The TICS-40 will be administered to assess level of dementia severity and screen out participants who have severe dementia or no cognitive impairment, and added recruitment opportunities. | Yes: updated consent forms for CP and PWMC and a PWMC assent form; created CP and PWMC consent scripts for reviewing consent form over the phone; added details about administering the UBACC to PWMC prior to each survey to ensure ongoing consent or assent. |
| 10 | 7/1/2022 | The survey has been broken into Care Person and PWMC surveys, and more specifically baseline and follow-up surveys have been created for each participant type to better assess the SR based on results from Phase 1. Additionally, the semi-structured interview, UBACC and email/telephone script have been revised for Phase 2. An infographic has been created to share phase 1 results with phase 1 participants. A screener form including the TICS-40 questions has been developed along with additional recruitment materials (emails, fliers, newspaper, and Facebook ads). Cover letters for email and mail communication have been created for Phase 2 as well as telephone scripts, for communicating with participants throughout the study duration. Details have been | Yes, the UBACC has been edited so that desired participant answers are updated for Phase 2. Additionally, consent processes are detailed further in the protocol. |

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|---|---|---|---|
| | | added about the RA's blinding to randomization and survey data collection procedures. | |
| 11 | 9/2/2022 | 1) Updated the protocol's secure storage information (section 18) because the storage system intended for use has changed. 2) Also updated the protocol to reflect incentive payments of $50 for 20 semi structured interviews. Previously, only the survey payments were listed. 3) Updated incentive payments to be paid via Visa Debit Cards instead of Greenphire ClinCards. 4) Uploaded updated consent forms and consent scripts to include semi structured interview payment and Visa card instead of Clincard. 5) Uploaded updated cover letter templates to reflect semi structured interview and visa card payment were fitting. 6) Added Emily Merkel, research assistant, and Yun Leng Wong, research assistant, to the study. | Yes: updated consent forms and scripts to include $50 participant payment if chosen for a semi structured interview and changed Clincard to Visa card. Process of consenting remains the same. |
| 12 | 11/10/2022 | 1) Updated the recruitment section of protocol (12) to include snowball recruitment and recruitment via professional network who works with target population. 2) Updated protocol to reflect reminder procedures for survey follow-up. | No. |
| 13 | 12/13/2022 | 1)Specified the type of follow up surveys (Regular follow up, Bereavement or Long Term Care Transition), that would be administered to caregivers depending on their response to the disposition (section 5.2 note).<br>2)Specified the possibility of potential participants screening themselves out informally before completing a screener, due to the natural progression of conversation. | No. |
| 14 | 1/25/2023 | Edited inclusion criteria to remove criteria that they must remain in the | No. |

| | | | |
|---|---|---|---|
| | | same area for next 6 months. Decided this is not required for the technology to work appropriately and may help with recruitment. | |
| 15 | 2/14/2023 | 1. Changed participant payment to Amazon gift card to allow for appropriately prorated amounts for those who do not complete all surveys, and to minimize fees that participants will face (as seen with Visa cards). Added further details about prorated amounts.<br>2. Updated Data Baking to allow for data sharing, which aligns with the grant and approved consent forms. This discrepancy was noticed in review of data sharing requirements. | |
| 16 | 3/30/2023 | The protocol has been updated to include national recruitment websites and registries fitting to the population. | no |
| 17 | 4/12/2023 | Updated protocol to include an informed consent and rights summary to be read to the dyad before the semistructured interview. | no |
| 19 | 9/1/2023 | Updated the protocol to allow semi structured interviews following the 3-month follow up time point. Interviews will be conducted at 3 month or at 6 month with selected intervention participants to allow us to reach the goal of 20 interviews and have a more robust response due to the limitations imposed by study funding and timeline. All other procedures will remain the same.<br>Also per the IRB's request, the care partner and pwmc full consent forms were updated to include NIH "Certificate of Confidentiality" text. | Yes: added certificate of confidentiality text. |

## Table of Contents

**ABBREVIATIONS/DEFINITIONS**

| Abbreviation | Full Text |
|---|---|
| AD | Alzheimer's Disease |
| ADRD | Alzheimer's Disease and Related Dementias |
| AME | Advanced Medical Electronics |
| PWMC | Person with Memory Concerns |
| RA | Research Assistant |
| RCT | Randomized Controlled Trial |
| SR | Smartwatch Reminder |
| MCI | Mild Cognitive Impairment |
| UBACC | University of California, San Diego Brief Assessment of Capacity to Consent |
| TICS | Telephone Interview for Cognitive Status |
| LTFU | Lost to follow up |

# 1.0 Objectives

1.1 Purpose:

We propose to develop an informatics system to assist people with memory impairment. Early stages of Alzheimer's and Alzheimer's related dementia often causes memory concerns. Persons with Memory Concern often cannot match names with faces or cannot recognize faces with a sure feeling of familiarity. Persons with Memory Concern (PWMC) may have difficulty remembering the names of family members and friends or may address them with a wrong name. They recognize the faces they see daily, such as a spouse or caregiver, but they may confuse visiting friends and grandchildren. The inability to remember names or relationships contributes to isolation and deeply affects their social lives. The proposed solution is a Smartwatch Reminder (SR) system to conspicuously provide this information to the PWMC when needed. This system will automatically transmit pictures and relevant information to a smartwatch worn by the PWMC when family or friends visit. The system will be evaluated on the target persons with memory concern population to measure engagement and improvements in social interactions and well-being.

**Phase I Aims:**

*Aim1:* The phase I will develop a prototype SR system with limited features. It will work on one model of smartphone and smartwatch. The prototype system can be used to get feedback from potential users.

*Aim 2:* Examine the feasibility of the SR system for PWMC.

The result of Phase I will include user feedback that demonstrates the acceptability and perceived utility of the system.

**Phase II Aims:**

*Aim 3:* Phase II will develop smartphone and smartwatch apps designed to work with the popular products of 2022. The project will provide a smartwatch and tablet for dyads in the treatment group. Family, friends, etc. of the treatment group participants will be able to download a smartphone app from an online store. Instructional material will be created to show the suggested information that can be entered into the app.

*Aim 4:* Evaluate whether the Smartwatch Reminders exerts positive benefits for PWMCs' social engagement and well-being via an embedded experimental mixed methods design that combines the collection and analysis of qualitative data within a traditional randomized controlled trial (RCT) design.

# 2.0 Background

**2.1 Significance of Research Question/Purpose:** Millions of Americans have dementia, the loss of mental functions, e.g., thinking, memory, and reasoning, which interferes with

their daily functioning. While some cases of dementia are caused by medical conditions that can be treated, most cannot be reversed. Hence, the focus switches from treatment to palliative care, i.e., developing a plan to make life easier and more comfortable for individuals with dementia and their caregivers. The proposed project will develop an important tool to improve the well-being for persons with dementia. There are three types of strategies that have been utilized to assist people with memory problems: repetitive drill and practice, internal strategies for remembering, and external aids to cue or assist people with remembering(1). Only the third strategy, using an external tool, has been demonstrated to improve social interactions for patients with AD(1-4).

**2.2 Preliminary Data:** AME Corp. working with Dr. Joseph Gaugler at the University of Minnesota has recently completed a study of the use of a smartwatch to display the names of people in the vicinity that were identified by face recognition. AME called this system a Social Support Assistant (SSA). The SSA consisted of a smartwatch and a body worn device with a camera. The bodyworn device had a database of face images of the friends and family of the PWMC. Face recognition software in the bodyworn device matched the faces of people who approached the PWMC to the database. Each time a new face match occurred the picture and name would appear on the smartwatch. Other information could also appear to identify the relationship that person has with the PWMC. A phone app was developed that automated the creation of the face image database for the device worn by the PWMC's. This app allowed a new person to take selfies of their face at different angles to optimize the face recognition success. Another person could also use the app to take the pictures if the new person being enrolled could not do it themselves. The testing successfully showed that PWMC liked using reminders about friends and family.

**2.3 Existing Literature:** A recent review of intelligent assistive technology describes the products that have been or are under development for persons with dementia(5). It is significant that none of these devices has been tested in a clinical study with dementia subjects(5). There are also no electronic devices proposed to assist PWMC with the recognition of other persons. While little has been developed or tested for PWMC, electronic devices that store information and prompt users to attend to the information with alarm and messaging features have been tested with patients with memory impairments due to other neurological conditions with promising results(2). For all devices being developed for PWMC, it is important to consider their familiarity with the type of device prior to their disease due to their limited ability to learn new information(2). Aids that are simple to use and utilize familiar interfaces are most likely to be successful(2).

## 3.0 Study Endpoints/Events/Outcomes

### 3.1 Primary Endpoint/Event/Outcome:

**Phase I:** Twenty care partners will complete a system review checklist and context of care items in a dyadic interview setting. The intervention will be considered successful if at

least 75% of participants score an average of 4 (out of 5) points or higher on the checklist, indicating that SR met their needs (i.e., indicated agree or strongly agree that the SR was useful, acceptable, and feasible overall). This threshold has been used as a benchmark for success in prior research evaluating technological interventions for PWMC and their care partners(6-8). If the criteria for success are not met, the technology will be refined based on feedback and suggestions from PWMC and care partners, before conducting additional testing with the improved prototypes. Ample qualitative feedback will be available via the dyadic interviews to guide such refinement.

**Phase II:** Baseline and 6 month data will be used in a 2x2 repeated measures analysis of covariance to examine whether use of the SR results in statistically significant changes in PWMC negative health transitions and , social interaction, pleasant events, social stress, loneliness, relationship closeness, and community engagement and care partner well-being, such as social support, depression and burden (9). The primary independent variable in the proposed investigation consists of an indicator variable for random assignment into the SR treatment condition or the attention control group. Additional analyses will determine if covariates (context of care, mobile device proficiency, and dementia severity indicators) significantly vary across the SR treatment and attention control groups at baseline and over 6-months. If statistically significant variations between the SR treatment and control groups are found, baseline and/or change scores for these covariates will be included in all repeated measures analyses of covariance tests to provide additional statistical control.

3.2 **Secondary Endpoint(s)/Event(s)/Outcome(s):** We will apply a parallel convergent mixed methods design. Quantitative and qualitative data will be collected and analyzed separately, and then paired side-by-side for comparison(10, 11). Quantitative analyses are expected to provide breadth in presenting group-level trends, while qualitative analyses will provide insight into variation within these trends, and allow study participants to identify meaningful SR components for themselves. After independent quantitative and qualitative analyses, the results will be paired side by side for comparison. Researchers will identify and iteratively discuss areas of convergence and divergence to validate the results(10-13). 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(12, 13). This comparative, mixed method analysis approach may suggest how and why PWMCs experience the greatest benefit while using the SR.

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

4.1 **Description:** Researchers will interact with study participants during Phase I and Phase II (Table 1). In Phase I, researchers will enroll 20 PWMC and their care partners to participate in a dyadic interview session. The dyadic interviews will occur via the HIPAA-compliant video conferencing platform, Zoom. The interviews will begin with questions

about the participants' technology use prior to and during the COVID-19 pandemic then participants will watch a brief instructional video followed by a question and answer session on the smartwatch technology, a verbally administered survey, and end with a semi-structured discussion about the SR. In Phase II, researchers will enroll 100 PWMC and their care partners to participate in initial, 3-month, and 6-month surveys. Half of the dyads will be randomly assigned to receive the smartwatch technology for a 6-month period and the other half will be randomly assigned to the usual care control group. 20 PWMC and their care partners who receive the smartwatch technology will be asked to participate in a semi-structured interview in the month following their 3 or 6-month survey.

*Table 1.* Phase I and II Schedule for AME Developers and UMN-Affiliate Researchers

| | Months 1-6 | Months 7-12 | Months 13-24 | Months 25-36 |
|---|---|---|---|---|
| *Project Management: Weekly Web Conference and Annual In-Person Meetings* | ● | ● | ● | ● |
| ● Recruit and train RA<br>● Build Smartwatch Reminder<br>● Data management and entry protocols | ● | ○ | ○ | ○ |
| *Phase I (Months 1-12)* | | | | |
| ● Enroll 20 PWMC and their care partners | ● | ○ | | |
| ● Complete dyadic interviews | ● | ○ | | |
| ● Analyze Phase I qual/quan data<br>● Refine Smartwatch Reminder content and protocol for Phase II | ○ | ● | | |
| *Phase II (Months 12-36)* | | | | |
| ● Enroll 100 PWMC and their care partners | | | ● | ○ |
| ● Complete initial, 3-month, 6-month, and embedded qual data collection | | | ● | ● |
| ● Analyze qual/quan data | | | ○ | ● |
| ● Disseminate Phase II findings | | | ○ | ● |

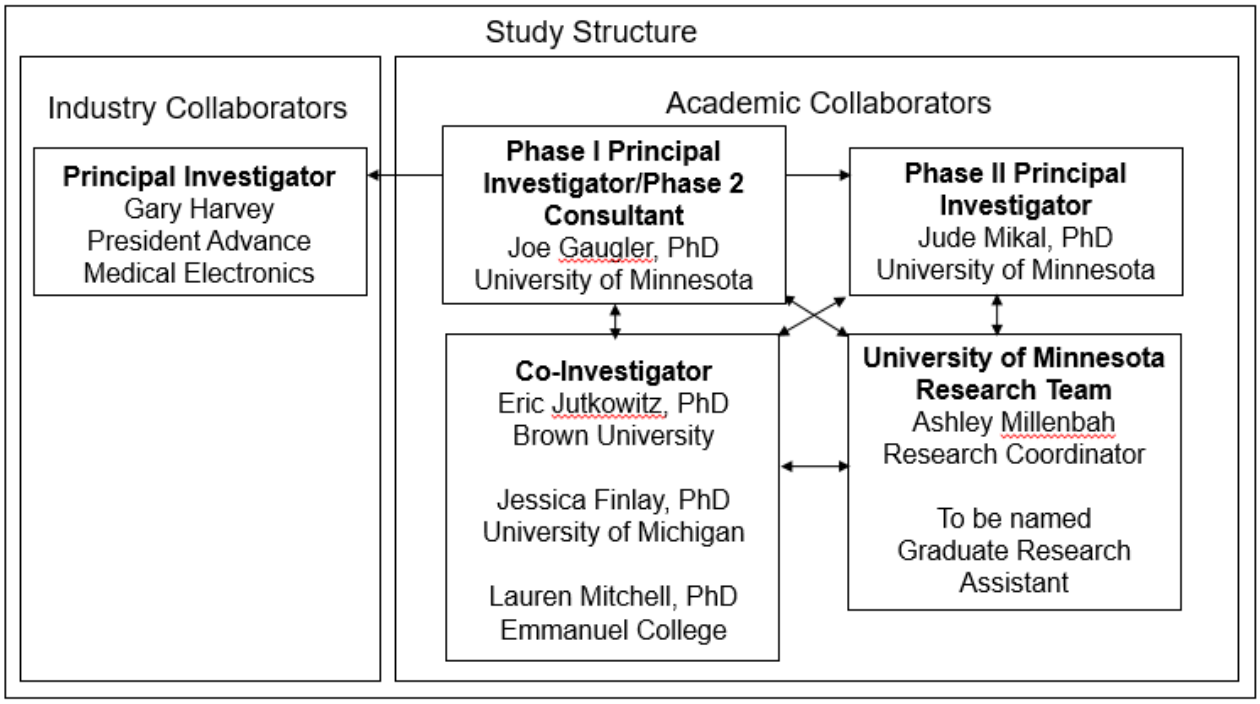
NOTE: RA = research assistant; PWMC = persons with memory concerns; qual = qualitative; quan = quantitative; ● = primary focus; ○ = secondary focus

## 5.0 Procedures Involved

5.1 **Study Design:** The proposed study will enable us to investigate the utility of the Smartwatch Reminder for individuals with varying degrees of memory concern. We will evaluate the immediate utility of the Smartwatch for persons with memory concern, and determine the extent to which participants practice using the system in the three months after it is introduced. By including participants with mild-to-moderate cognitive impairment we will also ascertain the feasibility of starting to use the Smartwatch system at a time when participants may immediately benefit from the cues and information provided by the system. Through interview questions, we will probe PWMC and their care partners to understand if using the Smartwatch in the early stages of cognitive decline is a valuable experience and if they would consider using the Smartwatch as the PWMC experiences cognitive decline.

AME has assembled an interdisciplinary team with the necessary skills to achieve the objectives of the project and effectively carry out the study design (Figure 1). Mr. Havey at AME is an experienced Primary Investigator with decades of project management and electronics engineering experience. AME's Dan Hedin has worked on multiple smartphone and smartwatch projects and has published papers on them. Greg Seifert and Paul Gibson at AME are the Technical Managers on the study. AME has also partnered with Matt Knutson, Louis Barrett and Kevin Kramer as engineers.

*Figure 1.* Structure of Industry and Academic Study Collaborators




The Principal Investigator in Phase I, Dr. Gaugler, PhD, at the University of Minnesota has an established track-record of conducting research on PWMC and their care partners. He has built on his well-established research foci to apply novel technologies that assist family and professional caregivers of persons with dementia. The Principal Investigator in Phase II, Dr. Jude Mikal, at the University of Minnesota has acted as a consultant to faculty

and investigative teams in the areas of project development, research design, and grant development. In addition, he is an expert in qualitative research methods, transition-related stress, computer-mediated communication and computer-mediated social support. Collaborating Co-Investigators on this project include Dr. Mitchell (PhD and Assistant Professor of Psychology at Emmanuel College), Dr. Finlay (PhD and Postdoctoral Research Fellow in the University of Michigan Institute for Social Research), and Dr. Jutkowitz (PhD and Assistant Professor in the Brown School of Public Health and researcher at the Center of Innovation in Long-Term Services and Supports at the Providence VA Medical Center). The Co-Is have collaborated extensively with Dr. Gaugler and each other on multiple evaluations of interventions and services for PWMC, including innovative technological interventions in dementia care projects. This includes evaluating a remote activity monitoring program that installed sensors in the home of a PWMC. Each investigator also has independent expertise in qualitative, quantitative, and mixed-methods research and participation in multiple randomized trials. Dr. Mitchell is a psychologist with expertise in social support and adult development, and a focus on mixed methods. Dr. Finlay is a health geographer and environmental gerontologist whose methodological expertise include global positioning systems tracking, in-person and virtual geospatial audits, interviews, surveys, and cognitive and physical testing. Dr. Jutkowitz is a health services researcher focused on understanding the cost and value of care provided to individuals with PWMC. His prior work includes conducting a cost-effectiveness study alongside a randomized trial evaluating a dementia caregiver support program and evaluating the effect of cognitive decline on time spent providing informal caregiver. Our team of collaborators is well-positioned to conduct an evaluation of the Smartwatch Reminder (SR).

### 5.2 Study Procedures:

*Phase I Feasibility Pilot Study*

**Overview.** The objective of Phase I is to make an initial, limited assessment of the value of the Smartwatch Reminder (SR) for PWMC and their care partners.

**Phase I Sample Size.** The academic team will purposively sample 20 dyads (PWMC and their care partners) of varying kin relationships (adult child vs. spouse), gender, and race/ethnicity to participate in Phase I feasibility testing.

**Phase I Procedure.** A parallel-convergent mixed methods design (QUAN+QUAL) will be used to generate qualitative and quantitative data on the feasibility and utility of the SR system.

1. **Initial Contact:** During initial contacts with potential participants, the RA will explain the study procedures and invite care partners to participate in the study. Care partners will have the opportunity to ask questions about the study procedures.
2. **Enrollment:** If the care partner agrees to participate, the RA will screen the participant and schedule the dyad for a dyadic interview session (see Section 9, “Study

Population"). An email will be sent to the participants containing an instructional pamphlet to read over before the interview.

3. **Consent:** The RA will first ensure that the dyad is able to use the video conferencing platform and troubleshoot any issues that may have occurred. The RA will then obtain informed consent from the care provider and PWMC (see Section 21, "Consent Process").
4. **Dyadic Interview Sessions:** The RA will digitally record each session. Audio recordings will be transcribed by a professional transcriptionist. The interview will begin with the context of care questions (see Appendix). Participants will then be asked questions on technology use prior to and during the COVID-19 pandemic. The RA will then play a video on how to use the SR system to the PWMC and their care partner. Next, participants will ask the RA questions they have about how the technology works (e.g., navigating the smartphone app; entering new profiles, photos, and information; using the smartwatch to identify the caregiver and other persons nearby).

Immediately after the SR tutorial, participants will be asked to complete a brief survey including the SR checklist to evaluate their perceptions of the technology. Questions will be asked verbally during the interview session. The SR checklist includes Likert items designed to measure both the PWMC and care partners' perceptions of the performance of SR in terms of ease of use, clarity, and quality of information provided.

The RA will then ask the participants semi-structured questions to elicit open-ended data on the feasibility and utility of SR (see Appendix). The interview questions include prompts about technology more generally to elicit feedback about opportunities and barriers for technology to assist care partners and PWMC in navigating everyday life. This will provide a more comprehensive perspective regarding the feasibility and use of the SR system. Participants will provide in-depth information on the reasons why PWMC and care partners felt the SR will or will not be easy to use, and will point out barriers or facilitators to use that will be critical to address when refining SR prior to Phase II.

*Phase I Data Collection.*

**18-item system review checklist.** This will be completed verbally by care partners and PWMCs during the dyadic interviews. The checklist includes Likert items designed to measure both the PWMC and care partners' perceptions of the performance of SR in terms of ease of use, clarity, and quality of information provided.

**Context of care.** Questions will be completed verbally during the dyadic interviews. Care partners and PWMCs can complete the context of care variables. It includes items on geographic location, time since diagnosis, type of dementia diagnosis, Medicaid status, living arrangement of the PWMC, and demographics of the PWMC and the care partner.

**Semi-structured questions.** The RA will conduct dyadic interviews with Phase I participants to elicit open-ended data on the feasibility and utility of SR. Questions will also elicit feedback on how participants' technology use has changed due to the COVID-19

pandemic. The semi-structured questions will provide in-depth information on the reasons why PWMC and care partners felt the SR was or was not easy to use, and will point out barriers or facilitators to use that will be critical to address when refining SR prior to Phase II (33).

***Phase II. Evaluate the Smartwatch Reminder Efficacy***

**Overview of Phase II.** The primary goal of the SR is to facilitate social interaction for PWMC by providing facial recognition of family, friends, and other key people. In this Phase II study, the SR will be evaluated to determine whether it provides positive benefits for PWMC's social interactions and well-being.

**Phase II Sample Size.** 100 dyads (PWMCs and their care partners) will be enrolled. Half of the PWMCs will be randomly assigned to the intervention group (i.e., use of SR) and half to the attention control group. The intervention group will receive the SR.

**Procedure.** An embedded experimental mixed methods design ([QUAN+qual]→[QUAN+qual])(12) will be utilized to combine the collection and analysis of qualitative data within a traditional randomized controlled trial design(12). This will assist the project team in examining the process of the SR's implementation during the evaluation to determine whether or not and why the SR worked for PWMCs and their care partners(12, 34, 35).

**Pilot Testing.** Prior to initiating full recruitment, we will pilot test the Smartwatch System technology among 1-2 dyads. This will ensure that any possible bugs in the Smartwatch System are worked out before many more dyads are enrolled and given the technology. If no or very minimal problems are found, the 1-2 dyads would remain in the study and be included in the total of 100 dyads recruited. If many problems are found, the 1-2 dyads would remain in the study, but their data would not be used, so 100 more dyads would still need to be recruited.

1. **Initial Contact:** During initial contacts with potential participants, the RA (or, if needed, Drs. Mitchell, Mikal and Jutkowitz or the research coordinators) will explain the study procedures and invite care partners to participate in the study. Care partners will have the opportunity to ask questions about the study procedures.
2. **Enrollment:** If the care partner agrees to participate, the RA will schedule a brief screening and enrollment procedure using the inclusion criteria (see Section 9, "Study Population"). The RA will obtain informed consent/assent from the care partner and PWMC (see Section 21, "Consent Process").
3. **Baseline survey:** Following enrollment, a baseline survey will be administered to both the CP and PWMC (either online in Qualtrics or via mail, if preferred) within 2 weeks of enrollment (see Appendix). The RA will administer this prior to exposure to the intervention/attention control.
4. **Randomization:** Following completion of the baseline survey, PWMC and their care partners will be randomly assigned to the SR treatment condition that receives full access

to the SR along with the training procedures 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 Dr. Mikal. For those in the SR treatment group, the research coordinator will schedule a time to introduce the SR to the PWMC and the care partner via Zoom or telephone.

To ensure blinding is maintained, the RA will not have access to the password-protected database containing participants' group assignment, and will not review survey data completion (which would un-blind the RA since all of the treatment participant follow-up surveys will contain the system review and all control participant follow-up surveys will not). Additionally, opaque, sealed envelopes will be created for the research coordinator to reveal which group each participant was randomized into. The outside of each envelope will be labeled with a dyad's ID and the inside will contain their group assignment, which will ensure integrity of the randomization order since no one will be able to change the order once the envelopes are created.

5. **3-month survey or contact call:** A survey will be administered (either online in Qualtrics or via mail, if preferred) by the RA to all participating care partners and PWMC 3 months following enrollment. A brief disposition survey will be administered before the 3- and 6-month follow-up surveys to determine if the PWMC has moved or passed away. A system review of the SR will be assessed via a checklist and open-ended questions (see Appendix) and will be sent only to dyads in the intervention group in their follow-up survey (the RA will remain blinded because they will email participants personalized links to the survey which do not indicate whether the participant is receiving the SR system review or not in their follow-up survey). The attention control group will receive a 3-month contact call from the research coordinator. Based on our prior experience, PWMC and care partners in an attention control group will often seek information and psychosocial support during these calls. We will provide free information resources (e.g., brochures or websites of the Alzheimer's Association). See section 10.2 about re-assessing each PWMC's capacity to consent at each time point.
6. **6-month survey or contact call:** A survey will be administered (either online in Qualtrics or via mail, if preferred) by the RA to all participating care partners and PWMC 6 months following enrollment. A brief disposition survey will be administered before the 3- and 6-month follow-up surveys to determine if the PWMC has moved or passed away. Additionally, a system review of the SR will be administered by the RA to participating care partners and PWMC in the intervention group 6 months following enrollment (while remaining blinded). The attention control group will receive a 6-month contact call from the research coordinator.
7. **Data tracking for 6 months:** Detailed data on frequency and duration of use by PWMC and their care partners will be tracked directly by the SR, allowing for an analysis of exact utilization and practicality (i.e., how long and often PWMC and their care partners actually use the technology). This data will be shared with us securely via Box by AME.
8. **Semi-structured interview:** 20 semi-structured interviews will take place up to one month after completion of the final 6-month follow-up survey with intervention group participants only. Due to a change in study funding and timeline, as of 9/1/23, to meet the

20 semi-structured interviews, some semi-structured interviews will now take place following the 3-month follow up survey with intervention participants. Dyads will complete only one interview at 3 or 6 months, not at each time point.

***Note:*** Baseline and follow-up surveys and interviews will be in a format that is convenient to care partners and PWMCs: through online or mail formats, whichever is desired by the individual. Each baseline survey is anticipated to take no more than 45 minutes to complete with follow-up surveys expected to take approximately 20-30 minutes to complete. If the PWMC has passed away or moved into a long-term care facility as determined by the brief disposition survey at 3- or 6-months, the PWMC would not be administered any additional surveys and the care partner would receive shortened follow-up surveys if they agree to continue, depending on the person with memory concern's scenario (bereavement or transition to a long term care/assisted living facility).

The RA will complete disposition calls or emails ±7 days prior to a scheduled follow-up survey. The RA will contact care partners within 1 week of a missed survey to resend, and update participants' contact information as needed throughout the project. RA will follow up with CG and PWMC via email reminders at 1, 2 and 3 weeks past the date a survey was sent if it is still incomplete. Additionally, at 3 weeks RA/RC will try to contact dyad via phone. If no response, participants will be considered lost to follow up (LTFU) for that time point.

Note: If LTFU occurs at baseline, the dyad will be withdrawn from study as they were not randomized.

An annual project newsletter will be sent to all participants to provide updates on study progress as well as provide seasonal caregiving tips. Finally, in order to provide additional rapport and incentive to participate in the attention control group, all PWMC and care partner dyads in the proposed project will be provided with up to a $100 participation incentive following completion of their 6-month survey (see more information in Payment section 12.5). Those in the treatment group who are selected for and complete a semi-structured interview will receive an additional $50 participation incentive.

***Phase II Data Collection.***

The RA will administer the baseline and follow-up surveys at 3- and 6-months, and will be blinded to randomization. Completion of these follow-ups may occur outside of the timeframe for initial contact based on participant scheduling needs.

**Baseline, 3-Month and 6-Month Survey.** The RA will administer all surveys (see Appendix). The surveys are designed to collect information from both PWMC and care partners. The selected measures have strong psychometric properties, sensitivity to change, and clinical relevance in the evaluation of health technology such as SR. Our past experience in distributing surveys of similar length indicate that they take PWMC and their care partners approximately 20-45 minutes to complete. Mean and sum scores will be calculated for all scales.

- Context of care (baseline only). Care partners will complete context of care variables include geographic location, time since diagnosis, type of dementia diagnosis, Medicaid status, living arrangement of the PWMC, and demographics of the PWMC and the care partner.
- Dementia severity. Care partners will complete validated measures of dementia severity including the PWMC's dependence on assistance with 6 activity of daily living tasks and dependence on assistance with 6 instrumental activity of daily living tasks(16-18, 50-52). An 8-item scale will assess the intensity of PWMCs' memory losses, communication deficits, and recognition failures at each time point (memory impairment)(19, 20). From the Dementia Severity Rating Scale, we are using one item about the PWMC's recognition of others (53). Additionally, during screening, the PWMC will complete the Telephone Interview for Cognitive Status (TICS-40) developed from the Aging, Demographics, and Memory Study), which will assess their level of dementia severity at the beginning of the study (50).
- Social interaction. Questionnaires will be administered to care partners to determine the frequency and quality of PWMCs' interaction in six different areas: in-person visits; telephone/video calls; traditional mail correspondence, text messaging, or email;, and social media. Per the recommendations of prior research on informal long-term care, a prior week estimate will be completed that includes frequency and duration of each activity(22). A 7-day time-window was chosen as it is less prone to recall error. In addition to frequency data, satisfaction with the quality of interaction will be assessed on a simple 5-point scale, similar to prior reliable measures utilized in Alzheimer's disease and related dementias care partner intervention studies(23).
- Pleasant Events/Social Engagement. Care partners will complete the Pleasant Events Schedule-AD (PES-AD) Short Version (24, 25) for PWMCs. The PES-AD Short Version includes 20 items of events and activities for PWMCs. As originally constructed, the items of the PES-AD were within the capacity of individuals suffering from the earlier/milder stages of dementia, and thus were appropriate for inclusion in this Phase II project(24, 25). Items are rated according to their frequency during the past month and how much the PWMC enjoys the activity. An overall summary score assessing frequency of engagement in enjoyable activities is generated by multiplying each frequency and enjoyment item with each other and summing the resulting responses. The PES-AD has demonstrated excellent reliability and validity(24, 25).
- Global Health. The PWMCs' overall health and quality of life are being measured using the PROMIS Scale v1.2 – Global Health (26). This assesses various aspects of health and life, such as ratings of mood, satisfaction with social activities/relationships, average pain, etc. through a series of 10 questions asked of the PWMC.
- Mobile Device Proficiency and social media use. The Mobile Device Proficiency Questionnaire (MDPQ-16; short form) is a 16-item scale used to measure how proficient the CP and PWMC are using various new technologies, such as tablets and their different features (27). The CPs' social media usage is also being measured using 3 questions developed by the research team.

- Social Support/Loneliness. Socioemotional support will be measured on a five-item scale to assess the affective assistance provided to the care partners by relatives or friends at each time point(19, 20). The Lubben Social Network Scale-6 (LSNS-6) is a six-item scale that assesses social isolation among the CP and PWMC (55). Loneliness will be measured with the 3-item Short Scale for Measuring Loneliness in Large Surveys(28).
- Care partner well-being. The 11-item Eriksonian Psychosocial Stage Inventory - Identity scale(29) will be administered to assess changes in identity coherence. The 10-item Center for Epidemiological Studies-Depression scale will be used to measure care partner depressive symptoms(30, 31).
- Relationship closeness. A 6-item measure of Relationship Closeness (32) will be used to evaluate the quality of the relationship between the PWMC and their care partner. This 6-item measure is part of the Stress Process Model for Residential Care (SPM-RC), developed by Whitlatch and colleagues and based on the Stress Process Model (SPM) for dementia caregiving. The measure assesses caregiver agreement with statements about their relationship with their relative using a 4-point Likert scale (1=strongly disagree, 4=strongly agree). Higher scores indicate a closer relationship (range 6-24).
- Community engagement. A 15-item survey developed specifically for the project will evaluate the PWMC's typical social interactions and destinations accessed outside of the home. The survey evaluates average frequency of leaving the home; socializing in-person with family and friends; and destinations accessed including senior centers, gyms and recreational facilities, educational classes, libraries, faith services, club meetings, coffee shops/cafes, and parks. Following the 15-item survey, an open-ended question to be applied post-baseline asks in which situations the SR system was and was not useful, and why.
- Caregiving Burden. A short version of the Burden Scale for Family Caregivers (BSFC-s) is a valid measure of subjective burden among family caregivers and is measured using 10-items on a 4-point scale (54).

Phase II will also feature 20 semi-structured interviews with purposively sampled dyads who are randomly assigned to receive SR. These interviews will take place up to one month after completion of the final 6-month follow-up survey. As of 8/31/2023 due to funding and timeline changes, interviews may also take place up to one month after completion of the 3-month follow-up survey. Dyads will only complete an interview at one time point (not both). It was determined that interviews at 3 months will be as rich in data as the 6 month surveys. A sequential mixed methods sampling approach will be utilized(36) where the results of the first methodological strand will inform the selection of participants in this second methodological strand. Specifically, the academic collaborators (led by Dr. Mikal) will purposively select 10 dyads who report average system review checklist scores between 4 and 5 (i.e., SR met their needs) and 10 dyads who indicate average system review checklist scores of 3 and below (i.e., neutral and below regarding SR meeting their needs). A stratified purposive sampling approach will be applied: the academic collaborators will identify family care partners of different kin

relationship (care partner is spouse vs. adult child), PWMC with varying dementia severity (middle versus late stage dementia symptomatology), caregiver gender, and racial or ethnic background of caregivers to participate.

The open-ended responses of the semi-structured interviews will provide in-depth information on the reasons why dyads felt SR did or did not enhance their interactions with each other and their friends and family. The research assistant will schedule and conduct the semi-structured interviews and will digitally record each one with permission. If permission to record the interview is not granted, relevant field notes will be taken during and immediately following the interview. Audio recordings will be transcribed by a professional transcriptionist into a Microsoft Word file which will then be uploaded to NVivo (37) for subsequent analysis. This mixed methods design will allow the research team to link the efficacy results of the study to the thematic categories developed from the semi-structured interviews.

**5.3 Follow-Up:** N/A: The study team will not conduct long-term follow up with study participants.

**5.4 Individually Identifiable Health Information:** N/A: The research team will not access any medical records or other sources of private information about participants, apart from the information provided directly by participants in surveys, interviews, or direct communication with research team members.

## 6.0 Data Banking

6.1 Storage and Access: Any datasets generated and/or analyzed and published or placed in a data repository will be de-identified.

6.2 Data: See 6.1.

6.3 Release/Sharing: 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 [unless permitted by law or regulatory oversight].

## 7.0 Sharing of Results with Participants

7.1 A report of the study findings will be provided to participants via an infographic. The report will only include aggregated findings and de-identified participant quotes (no other individual-level data).

## 8.0 Study Duration

8.1 Phase I: Each individual participant will take part in Phase I of the study one time for a dyadic interview. We anticipate taking 6 months to enroll all 20 participants. We expect all study procedures and data analysis to take 12 months total.

Phase II: Each participant will take part in the study for a total of about 6 months (data collection at enrollment, 3, and 6 months). We anticipate taking 12 months to enroll all 100 dyads. All study procedures and data analysis are anticipated to be completed within 24 months.

## 9.0 Study Population

**9.1 Inclusion Criteria:** Inclusion criteria for PWMC are as follows: 1) English speaking; 2) a physician diagnosis of early-stage Alzheimer's disease or mild-to-moderate cognitive impairment; 3) live in the community (including at home with or without the care partner, in a retirement community, etc.); 4) no history of serious mental illness (i.e., any major psychiatric disorder) and 5) must have some level of cellular connection in their place of residence (if known).

Care partners of PWMC must: 1) speak English; 2) be 21 years of age and over; 3) self-identify as someone who provides assistance to the PWMC because of their memory loss (these individuals are called ''care partners,'' as these individuals may or may not provide the intensive hands-on care typical of ''caregivers''); and 5) indicate a willingness to use the smartwatch system as well as to being randomized to a control group.

**9.2 Exclusion Criteria:** Those who do not meet the criteria above will be excluded. Additionally, PWMC with severe or no dementia are not eligible.

**9.3 Screening:** Potential participants will complete a brief screening survey prior to enrollment, including items assessing each of the inclusion criteria listed above. Those who are considered eligible based on their responses will be invited to participate in the study. It is possible that potential participant informally screen as ineligible before completing a screener due to the natural progression of conversation via telephone or email. In these instances we would not continue to formally screener with those who we know are already ineligible.

In Phase II, PWMC will be administered the TICS-40 (Telephone Interview for Cognitive Status-developed for the Aging, Demographics, and Memory Study) via Zoom or the telephone during screening (50). The TICS-40 is a brief, 17-item screening tool, with scores ranging from 0 to 40, that is used to screen for different levels of cognitive impairment. According to a crosswalk between the Mini-Mental State Exam and the TICS-40, cutoff TICS-40 scores for mild dementia are 17-24, for moderate dementia are 6-16, and severe dementia are 0-5 (51, 52). Individuals with scores indicating presence of mild or moderate dementia (scores from 6 to 24) will be eligible to participate in the research. Individuals without the presence of dementia or with severe dementia will not be eligible.

## 10 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 | Excluded |

| | |
|---|---|
| research during a stressful situation such as emergency room setting, childbirth (labor), etc. | |
| 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:

The smartwatch technology being tested in this study is designed to be used by persons with mild-to-moderate dementia severity. Testing the feasibility and utility of the technology for persons with mild or moderate cognitive impairment is therefore an important research objective. It is anticipated that the technology will be most useful to individuals whose memory has deteriorated enough to benefit from the cues and reminders provided by the smartwatch. Therefore, moderate cognitive impairment may represent the least degree of impairment compatible with the aims of the study. By including participants with mild-to-moderate cognitive impairment, we will learn whether the technology is feasible for various stages of cognitive impairment, whether the technology provides improvements in social interactions, and whether there are modifications that might improve the utility of the technology for PWMC.

Due to the natural progression of AD/ADRD and the length of the study, PWMC will be reassessed for their capacity to consent and re-assent or re-consent to participate in

the research at 3- and 6-month time points. We will use the UCSD Brief Assessment of Capacity to Consent to determine whether participants are capable of providing consent for themselves. Those who are not able to provide consent will be asked to re-assent to participate, in which case, assent will be documented by asked the participant to verbally sign an assent form (attached). Those who are able to provide consent will be asked to re-consent to participate using the brief follow-up consent form (attached).

Since the study involves no invasive procedures, there will be no physical risks to study participants. Thus, no research-related injuries need to be disclosed as none are expected. The consideration of need is potentially stressful, and thus there are possible psychological risks for the PWMC and care partners. However, the research team has considerable experience providing psychosocial support to Alzheimer's disease and related dementia caregivers on various research protocols, so 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.

Participants with impaired capacity to consent will be closely monitored when first introduced to the smartwatch technology and taught how to use it; given that this technology is non-invasive, additional monitoring in Phase II will take place at the 3- and 6-month survey interviews. Participants with memory concerns will be withdrawn from the study if they appear unduly distressed.

We will use the UCSD Brief Assessment of Capacity to Consent to determine whether participants are capable of providing consent for themselves. Those who are not able to provide consent personally will be asked to assent to participate. In that case, assent will be documented by asking the participant to verbally sign an assent form (attached). All potential participants will be informed of the research objectives and procedures to the greatest extent that is compatible with their understanding.

Though not specifically targeted for inclusion, participants from some of the above groups (indicated in the table) may be allowed to participate, as indicated in the table. Participants will be reminded that all study procedures are voluntary and will not impact the care they receive from any institution. We do not anticipate any individuals from the above noted groups to have increased risk from participating in the proposed research, such as an increased risk of coercion, etc. Thus, our standard protocol practices (i.e. data security, confidentiality procedures, etc.) provide reasonable protections to these vulnerable participants.

The research does involve cognitively impaired adults, or adults with fluctuating, diminished, or lacking capacity to consent, this the (CHECKLIST: Cognitively Impaired Adults (HRP-417)) below has been reviewed.

**10.2.1** This population must be included in the research study because they are part of the target population. By including this population in the research, we will learn whether or not the Smartwatch Reminder technology is

helpful to PWMC and in what ways it may be helpful to them, as well as their care partners.

**10.2.2** Persons with Memory Concerns are being included in the study if they have the capacity to consent or not, because we need to know if individuals with lesser and higher degrees of cognitive impairment benefit from the SR or not. Individuals with severe cognitive impairment, such as late-stage dementia are not included in our study because we do not expect the SR to provide any benefit to this group.

**10.2.3** 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 their family caregiver. Additionally, the person with memory loss either consents or assents to the research before each survey based on their 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 or because they would be ineligible (i.e. must live in the community therefore prisoners would be ineligible).

## 11 Number of Participants

**11.1** Number of Participants to be Consented:

Phase I: 20 dyads, or 40 participants
Phase II: 100 dyads, or 200 participants

## 12 Recruitment Methods

**12.1** Recruitment Process: Participants will be recruited in various in-person and online ways using the approved text and images. In person recruitment opportunities may include advertisements at memory clubs and programs for PWMC, through the Care Options Network, and at the annual Caring for People with Memory Loss Conference. Additionally, virtual recruitment via advertisement in the University of Minnesota Caregiver Registry and via newsletters shared by colleagues and professionals in this area of work are engaged with the target population. The research coordinators, Dr. Mikal, Dr. Mitchell, Dr. Finlay, or Dr. Jutkowitz will initiate email, telephone, or mail contact with family members on the Registry and who respond to an advertisement, or those who complete a permission to contact form

(sent out via emails, shared at the conference, via newsletters, etc.; attached). In addition, Dr. Mikal, Dr. Mitchell, Dr. Finlay, or Dr. Jutkowitz will ask professional care providers on the Registry to identify potential family members for recruitment purposes, including family members of diverse ethnic or racial origin and geographic location (given that many provide care to under-represented older persons). Snowball recruitment among potential/enrolled participants may also be used. In this case, following the initial screening conversation, potential participants may be asked if they know of anyone else who might be fitting for the study. If so, UMN staff will share an approved flyer for the [potential] participant to then share. If needed, participants will be recruited via ads on facebook and newspapers, on the National Institutes of Health-supported website called researchmatch.org, and other national research recruiting sites and registries fitting for this population (such as Banner Health and FTD Disorders Registry LLC). Using this method, only those who are interested are contacted.

Registration forms for educational presentations (by study staff or other agencies) may include an opportunity for individuals interested to provide their permission for the research team to contact them to share additional information about the study. *[Thus, by nature of this, UMN staff or other agency staff involved in planning, hosting, or post-webinar certificates will have access to the names/contact information of those indicating interest in receiving more information about the study].* Presentation "polls" may offer an additional opportunity for presentation attendees to provide permission for contact. Presentation slides may also be used during these community presentations to increase outreach. Hard copy permission forms may also be presented at in-person presentations.

*Note: General promotional materials/text (emails/newsletters/flyers/etc) are shared in the context of general promotional recruitment efforts. However, study staff do not pursue individualized study-related contact with potential participants until contact is made by an interested individual or a permission form/request for information is obtained.*

**12.2** Source of Participants: Participants will be community members who respond to a recruitment source listed in 12.1. Dr. Gaugler and his evaluation team developed and actively maintain the Caregiver Registry based on their community outreach and education efforts on Alzheimer's disease and related dementias. All individuals in the Registry have provided permission for Dr. Gaugler and his team to contact them to participate in research. The registry includes 675 family members of PWMCs and 316 professionals as of August 2018, and calls for new registry participants occur annually from March to June.

**12.3** Identification of Potential Participants: Individuals will self-identify as potential participants. Dr. Gaugler has developed and maintains the University of Minnesota Caregiver Registry based on his various community outreach and education efforts on Alzheimer's disease and related dementias (#1007S85812). All individuals in the Registry have provided permission for Dr. Gaugler and his research staff to contact

them to participate in research. Dr. Gaugler has conducted several prior and ongoing evaluations of early-stage dementia support programs throughout the Minneapolis/St. Paul area and works with several memory clubs and programs for PWMC. . Dr. Gaugler also directs the Center for Healthy Aging and Innovation which hosts events among our target population, which may also be used for recruitment. Finally, Dr. Gaugler is a member of the Care Options Network, and will post an invitation to participate to Network members. No medical records will be used to identify potential participants.

**12.3.1** For information contained in private/protected records, explain how the researcher has legitimate access to these records: N/A

**12.3.2** Dr. Mikal, Dr. Mitchell, Dr. Finlay, Dr. Jutkowitz, the research coordinators, or the research assistant will make initial contact with potential participants who respond to advertisements or complete a permission to contact form.

**12.3.3** No medical records will be used to identify potential participants.

**12.4** Recruitment Materials: Flyers, emails, ads, and phone calls will be used for recruitment. A copy of the flyer and email/phone script are included in the IRB application.

**12.5** Payment: In order to provide additional rapport and incentive to participate, all care partner and PWMC dyads in the proposed project will be provided with up to a $100 participation incentive. Those who are selected and complete a semi structured interview will be provided an additional $50 participation incentive. Compensation will be mailed after completion of participation (following the dyadic interview for Phase I, and after the 6 month assessment for Phase II). For phase II, dyads will receive a prorated amount based on the number of surveys completed ($33.00 for one, $66.00 for two, or $100.00 for all three) The dyads will be compensated using Amazon gift cards.

## 13 Withdrawal of Participants

**13.1** Withdrawal Circumstances: If instances of elder abuse or mistreatment are identified or reported to the research team, the Minnesota Adult Abuse Reporting Center will be contacted (1-844-880-1574) and the participant will be withdrawn from the study without their consent.

Withdrawal Procedures: In instances where care partners or PWMCs wish to withdraw from the study, we will determine the reason for study withdrawal, and whether or not the care partner or PWMC agrees to still complete regular, brief surveys (either online or over the phone) to collect data on outcome variables. Data prior to withdrawal will be used in subsequent analyses unless the dyad does not wish for their data to be included at all.

**13.2** Termination Procedures: Following completion of the Phase II study period, participants will be asked to return the SR technology to the research team. We will thank them for participating and distribute compensation. After all participants have completed their study period, we will clean and analyze the data, and generate reports of the findings. Data will be securely stored for 5 years or until all dissemination efforts have been completed.

## 14 Risks to Participants

**14.1** Foreseeable Risks: 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 PWMC and care partner. Since research team has considerable experience providing psychosocial support to Alzheimer's disease and related 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.

Complete privacy cannot be guaranteed while using Zoom video conferencing, as some tools keep participant data, and we cannot guarantee others are not keeping a log of the discussion. Additional steps will be taken by password protecting these dyadic interviews.

The experience of the University of Minnesota research team 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 fifteen years that Dr. Gaugler has operated various protocols related to dementia caregiving research. Additionally, as another safeguard, participants will receive a list of ADRD and caregiving resources (approved) at each time point with their baseline and follow-up surveys, during a time where sensitive questions may prompt emotional responses related to current and future situations. RA 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 care partners or PWMCs 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.

In the event a care partner or PWMC does become upset during the interview process, the RA will contact the PI who will be available for consultation. If a participant is in crisis because of their care situation or some other reason, research staff will be instructed to consult with the PI. With the participant'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 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 Ombudsman will be notified to protect the rights of persons with dementia and their families.

There is a possibility that data collected by AME from the technology, such as location, could be lost. This is very unlikely to occur, but participants will be made aware of this risk prior to consenting.

**14.2** Reproduction Risks: N/A

**14.3** Risks to Others: N/A

## 15 Incomplete Disclosure or Deception

**15.2** Incomplete Disclosure or Deception:

This study will not use incomplete disclosure or deception.

## 16 Potential Benefits to Participants

**16.1** Potential Benefits: We anticipate that using the smartwatch technology will benefit participants by improving social interactions and well-being.

## 17 Statistical Considerations

**17.1** Data Analysis Plan:

**Phase I Quantitative Analysis:** As the aim of Phase I is to examine the feasibility, acceptability, and utility of Smartwatch Reminder, the quantitative analyses of Phase I will largely rely on descriptive statistics. Specifically, Phase I quantitative analyses will utilize frequency tables and means to examine sample characteristics and item-level responses to the 18-item system review checklist and context of care items (see appendix). Mean scores for each item, as well as an overall summary score for each participant, will be calculated.

**Phase I Qualitative Analysis:** Analyses of qualitative treatment fidelity data will primarily focus on thematic content analysis of open-ended data to examine Smartwatch 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(38, 39). Grounded theory techniques described by Morse(38) and Strauss and Corbin(39) will guide the analyses of qualitative data in this evaluation. These approaches allow participants to construct meanings, perceptions, and behaviors from their own vantage points. Dr. Mitchell and Dr. Finlay will lead open-coding of all available qualitative data: the interview transcripts and RA field notes. All qualitative data will be thematically analyzed using Braun and Clarke's (2006) six steps of thematic analysis: (1) familiarization; (2) generation of initial codes; (3) search for themes; (4) review themes; (5) define and name themes; and (6) write up of themes analyzed. Researchers will follow an iterative process to continually identify themes, linkages, and explanations. Regular debriefing and audit trails (clear pathways detailing how the data are collected and managed) will enhance transparency and credibility(40). All open-ended data collected will be first read by Dr. Mitchell and Dr. Finlay 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). These themes will provide insights as to the SR's implementation and use (i.e., treatment fidelity/process evaluation embedded component) and mechanisms of benefit (i.e., semi-structured interview embedded component). During weekly meetings in the analysis phase of the proposed project, Dr. Mitchell and Dr. Finlay 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 Dr. Mitchell and Dr. Finlay to identify more complex processes of Smartwatch use or this technology's pathways to benefit PWMC and their care partners. During monthly team meetings, the development of codes, categories, and themes will be reviewed with the other academic investigators (Drs. Gaugler and Jutkowitz) and the AME team 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.

**Phase II Quantitative Analysis:** Data available at baseline and 6 months will allow for a 2x2 repeated measures analysis of covariance to examine whether use of the SR results in statistically significant changes in PWMC negative health transitions and , social interaction, pleasant events, social stress, loneliness, , relationship closeness, and community engagement and care partner well-being, such as social support, depression and burden (9). The primary independent variable in the proposed investigation consists of an indicator variable for random assignment into the SR treatment condition or the attention control group. IBM SPSS Statistics 21(41) will be used to conduct these analyses, as it supports a range of univariate, bivariate, and multivariate statistical analysis procedures. The team has extensive experience conducting longitudinal analyses on their prior research on dementia(5, 6, 42-44). Our proposed analyses will provide in-depth tests of the study hypotheses. Outcomes will include statistical significance of within-subjects, or 6-month change, in those in the Smartwatch Reminder treatment or control groups on key outcome variables (see above). Additional analyses will determine if covariates (context of care, mobile device proficiency,  and dementia severity indicators) significantly vary across the SR treatment and attention control groups at baseline and over 6-months. If statistically significant variations between the SR treatment and control groups are found, baseline and/or change scores for these covariates will be included in all repeated measures analyses of covariance tests to provide additional statistical control.

**Variations in SR use and setting:** Empirical treatment fidelity data and context of care measures that assess heterogeneity in the use of SR within the treatment condition (e.g., frequency and duration of SR use) will be included as a series of additional analyses. These analyses will explore the effects of variations in SR use on the outcomes hypothesized above for PWMCs and their care partners.

**Phase II Qualitative Analysis:** The methods described in Phase I Qualitative Analysis will be applied to the open-ended system review checklist responses, as well as the interviews gathered at the end of Phase II.

**Phase II mixed methods analysis**: Researchers will apply a parallel convergent mixed methods design. Quantitative and qualitative data will be collected and analyzed separately, and then paired side-by-side for comparison(10, 11). Quantitative analyses are expected to provide breadth in presenting group-level trends, while qualitative analyses will provide insight into variation within these trends, and allow study participants to identify meaningful SR components for themselves. After independent quantitative and qualitative analyses, the results will be paired side by side for comparison. Researchers will identify and iteratively discuss areas of convergence

and divergence to validate the results(10-13). 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(12, 13). This comparative, mixed method analysis approach may suggest how and why PWMCs experience the greatest benefit while using the SRS.

**17.2** Power Analysis:

Phase I: The purpose of Phase I is to evaluate feasibility and utility of the SR system, and to identify areas for potential improvement of the technology. The sample size of 20 dyads is appropriate for these objectives.

Phase II: A repeated measures analysis of covariance (ANCOVA) will be utilized to capitalize on the randomized design and the two sets of data that will be collected. The number of PWMC-care partner dyads to be enrolled to address study hypotheses was determined using power analysis procedures(45, 46). A sample size of 100 to identify a medium statistical effect (standardized regression coefficient = 0.15) at a suitable level of statistical power (0.80 is considered an excellent power value) is able to effectively incorporate up to 6 baseline covariates that vary significantly across the randomly assigned Smartwatch Reminder treatment and control conditions if they exist (as random assignment is often used to ensure statistically comparable treatment and control conditions, we feel this is a conservative estimate of baseline covariates)(46). Specifically, we relied on statistical power tables by the expert statistician Cohen(46) to conduct our assessment of power. As noted in Table 2 of Cohen (1992)(45), an alpha level of .05, a medium effect size of .15 (as opposed to using specific measures, Cohen operationalized a medium effect size of .15 as one that is observable, and a survey across the social sciences suggested that this proposed effect size was close to the average of observed effects), and a multiple regression model (similar to an ANCOVA) that includes up to 6 covariates requires a sample size of 97. For these reasons, an expected sample size of 100 PWMC and care partner dyads will be sufficient to conduct the Phase II efficacy evaluation. We anticipate having less than a 3% attrition rate which will ensure we maintain sufficient power. As noted in various recommendations for mixed methods sampling, 20 participants is considered an adequate sample size for semi-structured interview protocols to ensure the richness and depth of open-ended data collected(36, 47).

**17.3** Statistical Analysis:

Statistical analyses used will include calculation of frequencies, bivariate correlations, t-tests, chi-square tests, and repeated measures ANCOVA as detailed above.

**17.3** Data Integrity:

Several steps will be taken to ensure data quality. The psychometric properties of the study measures are generally well-established; however, additional steps will be taken to ensure the reliability and validity of the study measures. For example, internal reliability will be established with Cronbach's alpha (α) estimates for each measure and subscale. In addition, construct validity will be comprehensively assessed with a confirmatory factor analysis. In this particular method, individual items of each measure are loaded onto their latent construct. Indices of fit in structural equation models (e.g., Root Mean Square Error of Approximation = .05, Goodness of Fit Index =.97, Non-Normative Fit Index = .93 and Comparative Fit Index = .97; 'excellent' fit is demonstrated in models where p > .05, RMSEA < .05, GFI >.92, NNFI >.95 and CFI > .95)(32) then act as tests of significance for the construct validity of each measure. These procedures will help to establish the psychometric qualities of each tool beyond their utilization in prior study. Each outcome variable will be examined to determine if skewness exists or outliers are present. Normal probability plots and histograms of each dependent variable will be analyzed; this step is necessary because individual outcome variables must have near-normal distributions in order to be included in subsequent models. If the outcome variables are not normally distributed, the original variables can be subjected to algebraic transformations or other standard transformation techniques to meet model assumptions(9).

## 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: N/A, not reviewing records

**18.4** Approximate number of records required for review:

N/A

**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.

Participants will be communicated with via telephone, Zoom, mail, and email. As part of the consent form, participants will agree or not to use unencrypted email for communication throughout the study. If a participant requests the use of encrypted emails, we will do so. PHI will not be sent to participants via any form of communication.

**18.6** Access to participants

Only participants who have consented and agreed to participate in the research will be included. 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.

**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: https://remote-access.ahc.umn.edu S:\Public_Health_Center-on-Aging\Mikal\Smartwatch Memory Aid Troy Karkula

✔ Store ✔ Analyze ✔ Share

In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:
All data will be stored in an AHC-IE Data Shelter which is a virtual Windows server that provides researchers a secure environment in which to work with clinical data. All viewing and manipulation of the data will take place within the Data Shelter. All data is password protected and only personnel named on our IRB protocol will be given permission to login to the Shelter to view and analyze the requested data. Furthermore, per the policies of the AHC-IE, only authorized users who have completed HIPAA training will be granted access. The data will be maintained in the AHC-IE Data Shelter for 2-3 years after the conclusion of Phase II, which is the time

anticipated it will take to disseminate any and all research papers or presentations from these data.

Store Analyze Share

✓ Other.

Similarly, paper forms of the data will be located in a locked file cabinet in Dr. Mikal's research office only accessible to him, and other approved research staff. Unless the data are being filed or accessed, these cabinets will remain locked.

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: Semi-structured interview recordings will be sent to ProductionTranscripts for transcription. Audio recordings and transcripts are shared between the UMN and ProductionTranscripts via ProductionTranscripts' secure transfer website. De-identified transcripts may be analyzed in NVivo software, which is on the AHC Secure Server. On the AHC Secure Server, participant data may be analyzed using SPSS or R.

**18.9** Links to identifiable data: 2-3 years after phase II is completed, any identifiable data and the link will be destroyed.

**18.10** Sharing of Data with Research Team Members. Team members will have access to data on the server, Qualtrics, Box, and paper forms in Dr. Mikal's office, as indicated above.

**18.11** Storage of Documents: paper forms of the data will be located in a locked file cabinet in Dr. Mikal's research office only accessible to him and other approved research staff. Unless the data are being filed or accessed, these cabinets will remain locked.

**18.12** Disposal of Documents: Identifiable data will be destroyed 2-3 years after the conclusion of phase II in order to disseminate findings.

## 19 Confidentiality

### 19.1 Data Security:

A copy of the consent form or other research study information will not be placed in the participants' medical, employment, or educational records.

The research team will not access any medical records or other sources of private information about participants, apart from the information provided directly by participants in surveys, interviews, or direct communication with research team members.

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

### 20.1 Data Integrity Monitoring.

As the proposed project will pose minimal risks to study participants the Principal Investigator (Dr. Gaugler in Phase I and Dr. Mikal in Phase II) and Co-Investigators, Dr. Mitchell, Dr. Finlay, and Dr. Jutkowitz, will serve as the primary monitoring entities of this study.

In addition to ongoing review of protocol and human subjects research compliance during weekly project meetings with research staff, the research coordinators and the Co-Is (Dr. Mitchell, Dr. Finlay, and Dr. Jutkowitz) will generate quarterly reports (every 3 months) and will randomly audit 3 cases every 3 months to ensure that each case complies with Institutional Review Board (IRB) requirements, including use of IRB-approved forms (particularly the verbal consent form) and that each staff person on the proposed project adheres to the study protocol. In both weekly meetings and quarterly audit reports, the Co-Is will actively work with project staff to minimize research-associated risk and protect confidentiality of participant data (see Protection of Human Research Subjects).

The research coordinators and the Co-Is, Dr. Mitchell, Dr. Finlay, and Dr. Jutkowitz, (who have oversight for the data management and analysis of the project), will produce a quarterly audit report that will highlight the results of the audit analysis as well as study progress. In addition, the report 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 PI will review the audit report to ensure ongoing quality control, and will work with the Co-Is if needed, to ascertain if audited cases deviate from the approved study protocol. Audit reports are described in more detail below.

As noted above, 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 PWMC and their care partners. However, potential participants with a history of serious mental illness (i.e., any major psychiatric disorder) will not be included in the study and 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.

*Quarterly audit reports.* The research coordinators and the Co-Is, Dr. Mitchell, Dr. Finlay, and Dr. Jutkowitz (who also have oversight for the data management and analysis of the project), will produce a quarterly audit report that will highlight the results of the audit analysis as well as study progress. In addition, the report 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 PI will review the audit report to ensure ongoing quality control, and will work with the Co-Is if needed, to ascertain if audited cases deviate from the approved study protocol. In instances of adverse events occurring, related to the intervention (see below), the PI, the NIA project officer, and the University of Minnesota IRB will be notified immediately.

The audit reports will include the following: Table of contents, Narrative/trial summary, Summary of main findings, Discussion of issues or problems, Report preparation procedures, Study description, Project organizational chart, personnel, Brief statement of purpose of trial, Projected timetable and schedule, Study administration, Recruitment and participant status, Table 1: Enrollment by year or month of study, Figure 1: Comparison of target to actual enrollment by month, Forms status (e.g., consent, completing of screener, baseline assessment battery, etc.).

**20.2** Data Safety Monitoring.

*Monitoring study safety.* In both weekly meetings and quarterly audit reports, the Co-Is will actively work with project staff to minimize research-associated risk and protect confidentiality of participant data (see Protection of Human Research Subjects). Research staff 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 participants 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.

In the event a participant does become upset during the interview process, research staff will contact the PI, who will be available for consultation. If a participant is in crisis because of their care situation or some other reason, research staff will be instructed to consult with the PI. With the participant'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 persons with dementia 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 Ombudsman will be notified to protect the rights of persons with dementia and their families.

*Reporting Adverse Events and Unanticipated Problems.* In addition to ongoing monitoring of protocol and human subjects compliance and reporting and the production of bi-annual case audits to the PI, the Co-Is 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, the Co-Is 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. The Co-Is will review study-related data on an ongoing basis and will alert the PI, University of Minnesota IRB, and the NIA program officer as well as NIA if these events occur. Specifically, the Co-Is 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 Smartwatch Reminder system. All adverse event reports and any additional documentation will be further provided and collated in the quarterly audit reports for review by the PI, University of Minnesota IRB, and the NIA project officer.

## 21 Compensation for Research-Related Injury

**21.1** Compensation for Research-Related Injury:

The research involves no greater than Minimal Risk to participants, and research-related injury is not anticipated.

**21.2** Contract Language: N/A

## 22 Consent Process

**22.1** Consent Process (when consent will be obtained):

In Phase I, care partners and PWMC will take part in a brief consent and enrollment procedure via Zoom, during the first hour of the dyadic interview. The research staff will read the verbal consent form verbatim over Zoom to the care partners, and give them the opportunity to ask questions prior to consenting to participate. Care partners will be asked to provide verbal consent to participate after the consent form is read to them verbatim. Completed consent forms will be emailed to care partners and PWMC for their records. In Phase II, care partners will be asked to provide verbal consent to participate. After volunteering to participate, the RA will schedule a brief screening, consent and enrollment procedure to take place either via Zoom or telephone.

In Phase I and II, we will use the UCSD Brief Assessment of Capacity to Consent (UBACC) to determine whether PWMC participants are capable of providing consent for themselves. In phase I, we will also administer a cognitive screening test called the Mini-Cog to screen for presence of dementia. In Phase I, these will be administered via Zoom. The UCSD Brief Assessment of Capacity to Consent will be administered verbally, as usual in Phases I and II. In Phase II, individuals with a UBACC score of 14.5 or higher are considered able to have the capacity to consent and will be asked to consent to participation. While individuals with a UBACC score lower than 14.5 do not and will be asked to assent to participation. In Phase II, assent will be documented by asking the participant to verbally sign an assent form after it is read verbatim to them. Afterwards, the assent form will be emailed to the participant for their records. All potential participants will be informed of the research objectives and procedures to the greatest extent that is compatible with their understanding.

All questions in the Mini-Cog are administered verbally except for one question that requires drawing of an analog clock face. To administer this question will ask the care partner to draw a circle on a standard sheet of paper so the PWMC can complete the assessment by drawing the clock face on the circle. The RA will show the care partner a piece of paper with a circle drawn on it for reference to ensure proper circle size. Those with a Mini-Cog score of 3 or higher and are able to provide consent personally will be asked to provide verbal consent for Phase I. Those who are not able to provide consent personally or with a Mini-Cog score of 2 or below will be asked to assent to participate. In that case, assent will be documented by asking the participant to verbally sign an assent form after it is read verbatim in Phase I (attached). In Phase I, the

assent form will be emailed to the participant for their records. All potential participants will be informed of the research objectives and procedures to the greatest extent that is compatible with their understanding. Participants with impaired capacity to consent will be closely monitored, and will be withdrawn from the study if they appear unduly distressed. We will re-administer the UBACC during follow-up with Phase II participants who are PWMC to ensure ongoing consent or assent to participation.

In Phase II, dyads will be encouraged to go through the consent process together at the same time, such as on Zoom. However, not all dyads will live together or have access to Zoom technology. Therefore, CP and PWMC will have the option of consenting over the phone. Additionally, CP will have the option of filling out their consent form online in Qualtrics once it has been summarized for them over the phone. Given the nature of administering the UBACC and the consent/assent process for PWMC, they can only provide consent/assent over the phone or Zoom.

Due to the natural progression of AD/ADRD and the length of the study, PWMC will be reassessed for their capacity to consent and re-assent or re-consent to participate in the research at 3- and 6-month time points. We will read a script to the CP over the telephone to communicate our follow-up procedures. We will then use the UCSD Brief Assessment of Capacity to Consent to determine whether PWMC are capable of providing consent for themselves. Those who are not able to provide consent will be asked to re-assent to participate, in which case, assent will be documented by asking the participant to verbally sign an assent form (attached). Those who are able to provide consent will be asked to re-consent to participate using the brief follow-up consent form (attached). Prior to beginning the semi-structured interview (within one month of the 3 or 6-month PWMC reassent/consent), a brief Informed Particpation statement will be read to the Care Partner and Person with Memory Concerns, then allowing each of them to ask questions or decide not to participate. If needed, the research coordinator or research assistant will resend the 3 or 6 month consent/re-assent form for full details.

**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):

Due to COVID-19 concerns for the vulnerable population being studied and to improve convenience for dyads, UMN staff will administer a verbal consent form to participants via Zoom or the telephone using a consent script. A verbal consent or assent form will be administered to PWMC, as determined by scores on the UCSD Brief Assessment of Capacity to Consent, via Zoom using a script. As all scripts state, participants will be asked if they have any questions regarding the study prior to asking for their consent or assent to participate. The research staff will document the care partner and PWMC's's verbal consent or assent by

signing the form. This consent and assent forms will be completed by the research team or participants electronically via Qualtrics.
The consent and assent forms/scripts were developed using IRB-templates. If a participant enrolls, a copy of the completed consent or assent form (signed by the research team if consenting online) will be emailed to the participant for their records.
The study does not involve newborn dried blood spots.

**22.4** Non-English Speaking Participants:

N/A – All participants will be English-speaking

**22.5** Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

N/A – All participants will be over the age of 18.

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

Care partners will be asked to provide verbal consent to participate. We will use the UCSD Brief Assessment of Capacity to Consent to determine whether PWMC participants are capable of providing consent for themselves. Those who are not able to provide consent personally will be asked to assent to participate. In that case, assent will be documented by asking the participant to verbally sign an assent form after it is read verbatim (attached). All potential participants will be informed of the research objectives and procedures to the greatest extent that is compatible with their understanding.

**22.7** Adults Unable to Consent:

22.7.1 Permission:

The care partner enrolling in the study with the care recipient will be responsible for signing with the person with diminished capacity to consent.

22.7.2 Assent:

As noted above, we will use the UCSD Brief Assessment of Capacity to Consent to determine whether PWMC participants are capable of providing consent for themselves. Those who are not able to provide consent personally will be asked to assent to participate. In that case, assent will be documented by asking the participant to verbally sign an assent form after it is read verbatim (attached).

22.7.3 Dissent:

The assent form will not be verbally signed by the person with diminished capacity to consent if they do not assent to participate in the research.

## 23 Setting

**23.3** Research Sites:

Participants will be recruited through the University of Minnesota Caregiver Registry. Dr. Gaugler and his evaluation team developed and actively maintain the Registry based on their community outreach and education efforts on Alzheimer's disease and related dementias. All individuals in the Registry have provided permission for Dr. Gaugler and his team to contact them to participate in research. The registry includes 675 family members of PWMCs and 316 professionals as of August 2018, and calls for new registry participants occur annually from March to June. The RA, Dr. Mikal, Dr. Mitchell, or Dr. Jutkowitz will initiate email, telephone, or mail contact with family members on the Registry. In addition, Dr. Mikal, Dr. Mitchell, or Dr. Jutkowitz will ask professional care providers on the Registry to identify potential family members for recruitment purposes, including family members of diverse ethnic or racial origin and geographic location (given that many provide care to under-represented older persons). In addition, Dr. Gaugler has conducted several prior and ongoing evaluations of early-stage dementia support programs throughout the Minneapolis/St. Paul area and works with several memory clubs and programs for PWMC. Dr. Gaugler will contact each of these programs, in addition to the early-stage services coordinator at the Minnesota-North Dakota Alzheimer's Association Regional Office with whom he has collaborated to further identify PWMCs and their care partners for the proposed project. Dr. Gaugler also holds an annual Caring For Persons with Memory Loss Conference where participants will be recruited. Dr. Gaugler also directs the Center for Healthy Aging and Innovation which hosts events among our target population, which may also be used for recruitment. Participants may also be recruited via ads on Facebook or in newspapers. Finally, Dr. Gaugler is a member of the Care Options Network, and will post an invitation to participate to Network members.

In Phase I, interaction with participants will take place in a HIPAA-compliant video conferencing platform, Zoom. In Phase II, interaction with participants will take place via telephone, email or Zoom communication. In other instances, if requested, interaction may take place in a private office room in Mayo Memorial Building (Dr. Mikal's research office) .

**23.4** International Research:

N/A – the research will only take place in Minnesota

**23.5** Community Based Participatory Research:

N/A – the research will not involve community-based partners

## 24 Multi-Site Research

N/A

## 25 Coordinating Center Research

N/A

## 26 Resources Available

**26.3** Resources Available:

Advanced Medical Electronics (AME) has a 9,220 square foot office and engineering facility in Maple Grove, Minnesota. Design work will take place in this facility. A complete set of tools and resources are maintained in this facility for the design, testing, and manufacturing of electronic medical devices and their associated software packages. AME is well equipped with electronic test equipment including digital oscilloscopes, logic analyzers, frequency analyzers, signal sources, digital meters, and power supplies. AME maintains a prototype fabrication capability for electronics circuit assembly, metal-working, and plastic fabrication. Mechanical design tools include a full CAD seat of Pro-E. AME owns several embedded processor emulator systems to support the development of embedded code. AME maintains a suite of Silvaco, Inc. integrated circuit design CAD tools. More details for AME resources available to support the proposed research and development tasks are provided below in the equipment section.

Dr. Gaugler is a Professor and Dr. Mikal is a Research Scientist at the University of Minnesota's School of Public Health. The School of Public Health is among the top schools of public health in the nation. For the last four out of five years, the School has attracted more National Institutes of Health research funding than any other public university school of public health. The School has strong links to the community in our backyard and around the globe and has ranked in the top ten among public university schools of public health in total grants and contracts. The Division of Health Policy and Management's educational programs feature five majors and dozens of opportunities for joint degrees and certificates. The Division has extensive research and educational management capabilities, including a full-time administrator, several full-time student administrators, a financial management staff, computer services (including programmer/analysts), and an available publications staff. At present there are over 75 research projects underway totaling over $50 million dollars and employing over 90 research assistants.

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