Study Protocol

A Randomized Controlled Trial of Visual Cues, Signage, and Spaced Retrieval Education within Long Term Care Communities to Assist with Wayfinding

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Protocol Changes Log

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A Randomized Controlled Trial of Visual Cues, Signage, and Spaced Retrieval Education within Long Term Care Communities to Assist with Wayfinding

Principal Investigator: Davis, Rebecca

Brush, Jennifer	Co-Investigator, Faculty/Staff
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Event		
IRB Amendment (#11216)	Remove Pamela Taubert & Sue Borstein; Extend data collection for an additional year; Acknowledge October 14, 2022 DSMB Report/no revisions to research needed	12/14/2022
IRB Amendment (#10826)	Add Carol Rausch & Josh Selwyn	6/2/2022
IRB Amendment (#10815)	Remove Elizabeth Hill, Elizabeth Martin, Viktoria Basso, Paige Bekker	5/30/2022
IRB Amendment (#10676)	Remove Valerie Conley	4/12/2022
IRB Amendment (#10665)	Remove Michelle Salem	4/6/2022
IRB Amendment (#10462)	Enrollment letter v Nov 2021; Medical release letter sent after enrollment v Nov 2021; Alternative process for obtaining medical history; Change in Process for reassessment of consent capacity	1/24/22
IRB Amendment (#10250)	Add Viktoria Basso - IRB	10/28/21
IRB Amendment (#10223)	Acknowledge September 2021 DSMB	10/25/21
IRB Amendment (#10128)	Expanded data collection visit windows	9/29/21
IRB Amendment (#10108)	Add Elizabeth Martin	9/13/21
IRB Amendment (#10011)	Add Pam Taubert; Allow in-person research interactions at 3 locations: Jennings-Garfield, Jennings-Brecksville, Danbury.	8/17/2021

IRB Amendment (#9923)	Approval to send LAR letter accompanying IC form; LAR letter v1.0. LAR recruitment phone script V1.	6/28/2021
IRB Amendment (# 9883)	Add Kim Francis, Jessica Abbott. Permission to follow the rules of each research site as they relate to COVID. Revised IC version 9.0.	6/22/2021
IRB Amendment (#9732)	Approved for COVID alert level 2. Remove Emily Bourassa, Lisa Mayher, Pamela Taubert. Change in protocol for IC process due to delays in enrollment after COVID. Additional information for location tracking. Permission to restart interactions at Clark, Sunset, and PVP.	5/3/2021
IRB Amendment (#9338)	Addition of design opinion survey for all residents and staff; waiver of documentation of consent (for this mod)	12/11/2020
IRB Amendment (#9072)	Modification to reconsent process and new consent capacity assessment tool. Variable added in the demographic questionnaire. Gift cards for less than $40 can be given to those who don't want to share their SS#. COVID-19 procedures for re-engaging in research.	7/14/2020
IRB Amendment (#8975)	All research interactions and recruitment on HOLD due to COVID. Participant notification postcard approved.	3/25/2020
IRB Amendment (#8957)	COVID-19 related: Month 6 can occur up to Month 10	3/20/2020
IRB Amendment (#8887)	Approval to work with Promotions Office to create a recruitment video. Additional recruitment materials include TV slide, brochures. Added Danbury as research location.	2/18/2020
IRB Amendment (#8865)	Add Pamela Taubert and remove Megan Owens	2/6/2020
IRB Amendment (#8829)	IC version 7; addition of Jennings at Garfield and Jennings at Brecksville	1/28/2020
IRB Amendment (#8761)	Add Anita Jones; Recruitment materials V 4.0	1/02/2020
IRB Amendment (#8741)	Remove Lucille Yurko	12/10/2019
IRB Amendment (#8566)	Add Elizabeth Hill and Paige Greer; Add Park Village Pines; Researchers can verify participant activities with caregiver; Revised IC V6.0	9/20/2019
IRB Amendment (#8552)	Revised IC V5.0; Change in randomization; waiver of documentation of consent in specific circumstances.	9/9/2019
IRB Amendment (#8428)	Transition of study to Revised Common Rule; added retention plan V1; Revised IC V4.0	7/19/2019

IRB Amendment (#8332)	Add Lisa Mayher & Sue Borstein; Revised protocol v4.1; Reading screening form v2.0 5/13/19; Community presentation, v1 5/20/19; Wayfinding brochure for staff, v2 5/22/19; inclusion of 3 additional sites; DSMP, v2.0	5/24/2019
IRB Amendment (#8319)	Adapted Recruitment Materials V3 dated 5/16/19	5/24/2019
IRB Amendment (#8287)	Add GR data collectors, revised recruitment and intervention, revised continuing assent script and SR CRF, research handout of center staff	5/7/2019
IRB Amendment (#8097)	Revised protocol V 2.1; Revised ICF V 2.1 dated 11/6/2018; Updates to informed consent process; Updates to data collection process; Use of REDCap	2/22/2019
IRB Continuing Review (#7787)		11/5/2018
IRB Amendment (#7787)	Add Lucille Yurko & Megan Owens; Revised Inclusion criteria; Additional document revisions	9/13/2018
IRB Amendment (#7750)	Add Emily Bourassa	8/24/208
IRB Amendment (#7546)	Concordance review for protocol and grant	5/24/2018
IRB Initial Submission (#1052)		12/14/2017
IRB New Project (#7169)		12/3/1207

6. Purpose of Research

The overall goal of this project is to assess the contribution of cues and spaced retrieval education on wayfinding ability and life space in persons with wayfinding impairment who live in long term care communities in a randomized controlled trial. We will select nine senior assisted living residences and recruit 137 residents identified as having wayfinding problems who can move themselves and communicate. We will randomize the facilities to one of three arms 1) Control (no changes); 2) Cued (salient environmental landmarks and signage placed at key decision points) plus staff training on use of the cues and 3) Cued plus Spaced- Retrieval education. Subject characteristics including mobility, demographic variables, activities of daily living, and cognitive ability will be measured along with life space mobility (spatial extent of mobility). We will test all subjects' wayfinding ability (primary outcome) and life space (secondary outcome) at baseline and at 1, 3, 6, and 12, months. We will compare wayfinding performance over time among the 3 trial arms.

The specific aims are:

Aim 1: To examine the effect of salient cues with and without spaced retrieval education on wayfinding ability initially and over time in older adults who have wayfinding deficits in long term care communities. HO1: Subjects will have improved wayfinding (faster, more accurate) in the cued condition versus the control condition at months 1, 3, 6, and 12; and post intervention compared to pre intervention.

HO2: Subjects in the cued condition + Spaced Retrieval education will have improved wayfinding ability compared to the control and cue alone condition at times 1, 3, 6, and 12 months.

Aim 2: To determine the effects of salient visual cues and spaced retrieval training on life space.

H03: Subjects in the cued conditions will have larger life spaces than those in the control condition at times 1,3, 6 and 12 months.

H04: Wayfinding ability will be positively correlated with larger life space over time.

Exploratory Aim 3: To determine which subject characteristics are most amenable to the intervention; and which subject characteristics place persons at risk for less responsiveness to the intervention so that the intervention can be appropriately targeted.

The significance and innovation of this project is that it may provide one of the first research supported nonpharmacological interventions for the problem of wayfinding for persons in existing long term care communities.

7. Subject Population Description

7a. Subject Population description

Please enter the anticipated number of subjects.

137

Please provide justification for why the number of subjects to be recruited is appropriate.

The sample size for this study was determined based on Specific Aim 1, Hypotheses H01 and H02 for the pairwise comparisons of the trial arms. In the prior R15-funded study of the PI, the effect size for the difference in wayfinding time observed under cue versus no cue condition was 0.42 (a reduction of 8 minutes on average, with a standard deviation of 19 minutes). In the proposed study, wayfinding will be measured at baseline, 1, 3, 6, and 12 months. Since baseline measure will be used as a covariate in the analysis of repeated measures of outcomes (see the analysis section), the adjusted standard deviation in this analysis would be smaller than unadjusted. Assuming correlation of 0.4 between pairs of repeated measures, the effect size adjusted for the design of the proposed trial and analysis strategy is 0.67, which would be detected with power 0.8 or greater in two-sided tests using 0.05 level of significance with the sample size of 36 per group. Next, this sample size was adjusted to account for clustering of participants within care communities using a conservative estimate of the intraclass correlation coefficient (ICC) of 0.0012. The resulting design effect factor is 1.042 yields the sample size requirement of 38 per group, or 114 total. Finally, to account for projected 20% attrition, 137 participants will need to be recruited. This corresponds to the average recruitment goal of 11 participants per care community. The participating care communities stated that they have 10 to 30 available participants satisfying the inclusion criteria; therefore the required sample size is feasible.

Briefly describe the subject population characteristics (i.e., age ranges, and where appropriate, gender, ethnic background, and health status).

Planned enrollment includes men and women 62 years and older. For NIH our enrollment table includes an ethnic and racial mix of subjects in alignment with the population in the cities in which the study is being conducted - however, the sample is a convenience sample.

7b. Vulnerable Populations

Will any vulnerable populations be recruited for this study? These include, but are not limited to, children under the age of 18, prisoners, mentally disabled persons, economically disadvantaged, or pregnant persons.

Yes

Please indicate the vulnerable population(s) involved.

Cognitively impaired persons

Please enter a justification for use of the vulnerable population(s) identified above.

The majority of subjects will have a cognitive disorder that affects their ability to find their way within the long term care communities such as Alzheimer's disease. We expect many of the participants to have health issues related to their age, including arthritis, heart disease, or other frequently diagnosed conditions among older adults. Long-term care community residents were selected for this study because they are the population at risk for wayfinding problems due to their health and cognitive issues, and they live in large and complex environments.

8. Research Procedures and Methods

8a. Recruitment and Selection of Subjects

Briefly describe how participants will be recruited.

The researchers have obtained agreements with 12 care communities to conduct the study. Study brochures will be distributed in the communities by the community contacts. In each care community, a designated employee of the community will be asked to approach residents who have been identified by the nursing staff as having wayfinding problems. They will ask the residents if they would be interested in being in a research study that will assess their ability to find their way in the care community, with the goal of learning ways to improve care communities to make them better for wayfinding. If the resident is not his or her own decision maker, the employee will contact the decision maker and ask permission for someone from the research team to contact the decision maker.

The program manager (Grand Rapids) or site coordinator (Cleveland) will contact those who are interested, and an appointment will be made with the decision maker and potential subject. The study will be explained in lay terms. Consent capacity will be assessed using the Evaluation to Sign Consent Measure. Those who do not have consent capacity will be asked to give assent if they wish to participate in the study, and the decision maker for the subject will sign the informed consent document if he/she agrees. Assent will be attained at each data collection period during the year-long study.

In addition, we will be recruiting 4-6 care staff members from each of the Arm 2 and Arm 3 communities for focus groups/interviews. We will ask the staff who are caring for the subjects (direct and indirect

care staff who have interacted with the subjects over the past year) if they would be interested in participating. If so, they will be scheduled for a focus group or individual interview.

Describe the criteria you will use to determine which subjects will be included and which excluded.

Inclusion criteria include: 1) age 62 or older who are living in 1 of 12 senior residential communities (independent or assisted living) in study; 2) wayfinding impairment identified by the subject or staff and exhibited at baseline, including problems finding their way among three defined locations (these may differ among care communities); 3) able to move self either independently by walking or using mobility aids (self-mobile; any mobility aids are acceptable); 4) able to communicate with researchers and follow directions; and 5) able to see and read signs in English. Exclusion criteria include: 1) chronic health conditions that impair the ability to participate in the study, such as severe COPD (limiting movement) or terminal illness; and 2) signs of rapid deterioration in health during the past 6 months as evidenced by staff communication or medical records.

For the care staff interviews, the only inclusion criteria is that they provided care in the form of direct care or therapy, activity, during the past year for at least one research subject.

Describe any circumstances under which there could be a *perception* of consent coercion and/or undue influence by the researcher(s), and indicate how such influences will be minimized.

The program manager (Grand Rapids) or site coordinator (Cleveland) will contact those who are interested, and an appointment will be made with the decision maker and potential subject. The study will be explained in lay terms. Consent capacity will be assessed using the Evaluation to Sign Consent Measure 1. Those who do not have consent capacity will be asked to give assent if they wish to participate in the study, and the decision maker for the subject will sign the informed consent document if he/she agrees. Assent will be attained at each data collection period during the year-long study.

IRB Amendment to 8A # 9338 - 12/11/20

We are recruiting two new groups of participants 1) residents of the long-term care communities in which we added signage and art work; and 2) staff from these same long-term care facilities. Paper surveys will be distributed via the community contact to staff, or via email Qualtrics link by the community contact. Because all staff may have interaction with residents who are wayfinding (i.e. receptionists, care providers, therapists, etc.) we will send to all staff. The goal of these surveys is to determine the usefulness and acceptability of the design changes (signs and cues) to the staff and residents.

IRB Amendment to 8A #8287 - 5/24/19

IRB Amendment #8287 (5/7/2019) revised the recruitment strategy to include that the designated employee at each community will share times study staff would be available in person to explain the study and answer questions either individually or in groups. The Community Presentation was created to assist in explaining the study to groups of residents in the community. Study staff may also present educational information on Wayfinding, Long-Term Care Community design for dementia, and general information on clinical trials and research. Direct recruitment for the study will be limited to the information presented in the attached PowerPoint slides and the study brochure.

2) When presenting staff at one of our communities with the Wayfinding Handout for Staff, it was suggested that we include that the signs and cues in the community will be temporary. This revision was made to the handout.

IRB Amendment to 8A. #8287 - 5/7/2019

In addition to obtaining permission for the program manager or site coordinator to contact interested residents, the designated employee at each community will share times study staff will be available in person to explain the study and answer questions either individually or in groups. Interested residents can be introduced to study staff in person and then screened and enrolled at designated times in the community if they are their own decision maker. If the resident is not his or her own decision maker, the designated employee will have contacted the decision maker and asked permission for someone from the research team to contact the decision maker. The program manager or site coordinator will let the interested resident know that they will speak with the decision maker about the study and then schedule the enrollment meeting.

IRB Amendment to 8a. #7787 - 9/13/2018

Inclusion criteria 5, "able to see and read signs in English," was removed.

8b. Research Location(s)/General Data Protection Regulation (GDPR)

Will any portion of the research take place outside of GVSU?

Yes

Please describe the outside location(s) and how you will obtain permission to utilize the location(s)

We have two cities in which there are 12 senior communities (independent and assisted living) in which the study will take place. We have permission to use these communities. Letter from the communities are attached.

8c. Consent/Assent Process Description

Provide a description of the process for obtaining consent/assent of the subjects or their representatives.

Individuals who have indicated interest in participating in the study will be contacted by the program manager/site coordinator and screened over the phone for interest and an appointment scheduled with the interested residents and their decision makers. At the appointment, the data collector will explain the study, including the time commitment, study protocol, and potential risks and benefits. The data collectors will conduct an assessment of consent capacity (the Evaluation to Sign Consent Measure; ESCM) for those who indicate interest in participating.

If the participant has consent capacity, he or she will be asked to sign the informed consent document after having any questions answered (if he/she agrees).If the participant does not have consent capacity, the legal decision maker or closest family member who acts as the decision maker in regard to health care matters (with permission of the participant) will be informed of the study and asked if they would like to give consent to enroll the participant. Assent will be obtained from the participant prior to consent from the decision maker. Participants will be reminded about the study at each data point over the year, and assent obtained. If participants express a desire to withdraw, or have any indication of discomfort, they will be withdrawn (or rescheduled if the discomfort is temporary). The participants will also be told that they are free to withdraw at any time during the study. The instructions for the study, including their right to withdraw at any time, will be repeated to the individuals each day of testing.

How will you ensure that the voluntary nature of participation is apparent to the subjects?

Please see above. We will obtain assent from the subjects at each time period during the study (see script). For subjects who are assessed as having consent capacity upon study enrollment, we will reassess this capacity at the 6 month data collection time period (using our previously described protocol) or more frequently if subjects appears confused or not to recall the study when we meet with them (although no guidelines exist, this appears reasonable based on the researcher's knowledge of the progression of the disease). If subjects' consent capacity declines during this time period we will obtain consent from their LAR and assent from the individual as previously explained prior to any data collection.

How will you ensure that a subject can freely withdraw from the research aspects of the study without concern about being penalized?

Please see description above. We will also obtain assent each time we see the subjects; and we will observe them for discomfort and ask them if they wish to continue if we are concerned.

IRB Amendment to 8c. #10462 - 1/24/2022

At Month 6 and 12, we will not reassess the participant using the Evaluation to Consent Measure unless there is a noted cognitive change that dictates the use of the Measure. The team will obtain assent as usual.

IRB Amendment to 8c. #10462 - 1/24/2022

Developed an alternative process for obtaining medical history data from persons who live in Assisted Living Residences. Use a generic (GVSU template) HIPAA form, and to request that the nursing staff at the AL provide the information to use using a form. This request has 3 parts; a letter to the nurse at the site; a form; and a process. Using this process does not alter anything on the ICD because we do not specify which health care provider we will be using.

IRB amendment to 8c. #9883 - 6/22/2021

Version 9.0 IC: Removed the statement about asking for authorization to release information AT THE END of the study.
Added the RCI email address versus HRRC.

Some subjects were enrolled right before the shutdown at several sites. These subjects gave informed consent and were enrolled but no other data collection was done prior to the shutdown. To resume the study:

a) We will check with site contacts to see if the previously enrolled subjects are still residing at the care site.
b). For those who are residing there, the data collector will reintroduce him/herself, explain the study again, and ask if the subject is still interested in participating. If yes, then the data collector will follow the study procedure for assessing consent capacity using the Evaluation to Sign Consent Measure. If subjects who previously enrolled, and had consent, are still willing to participate; we will write a note in REDCap indicating that the discussion occurred; ECM showed consent capacity was still present, and the subject agreed to participate in the study. For those who did not have consent capacity initially but were enrolled via assent and permission from a LAR, we will also explain the study, obtain assent again if the subject is interested, and contact the LAR to obtain permission to resume the study. A note in REDCap will be made.

IRB Amendment to 8c. #9338 - 12/11/20

Two new consent information documents - one for residents of the community sites; and one for employees. Waiver of signature of informed consent. The parent project was approved under expedited review. The rationale for the waiver is that signed informed consent would be the only identifier linked to the subject. In addition, this study is of no real risk to subjects, and this type of study procedure would normally be reviewed under exempt criteria whereby a signature for IC is not usually required.

IRB Amendment to 8c. #9072 - 7/14/2020

Will forgo the reassessment of consent capacity using the same protocol as initial enrollment; informed consent discussion and Evaluation to Sign Consent Measure (ESCM). Assessing for consent capacity will only occur for participants who have a decrease in MoCA score by 2 points at the 6-month data collection period (a decrease in MoCA score from Month 1 to Month 3 will be used for participants who did not complete 6-month data collection due to COVID-19). The Reconsent Measure tool will be used after the 6-month data collection period to re-assess for consent capacity.

IRB Amendment to 8c. #8552 - 9/9/2019

Mail the informed consent (as per our procedure), and call them to initiate discussion and answer any questions about the research (using the IRB approved script). If, after one week, we have not received the signed informed consent document, we will call them again, and ask if they are still interested, and answer any questions and again ask them to return the form in the mail. If, after this reminder call, the informed consent document is not obtained within one more week, we will again call and ask for their interest and questions, and to remind them to mail the IC. If, after one more week, the IC is not obtained, we will again call, review any questions, and ask for verbal permission for the subject to participate in the research. If they agree, we will sign the IC document and mail a copy to the LAR. If the LAR should have concerns, we will address those (as we would in any other circumstance).

IRB Amendment to 8c. #8097 - 2/22/2019

"Individuals who have indicated interest in participating in the study will be contacted by the program manager/site coordinator and screened over the phone for interest and an appointment scheduled with the interested residents and their decision makers. At the appointment, the data collector will explain the study, including the time commitment, study protocol, and potential risks and benefits. An infographic of the key elements of informed consent will be used in conjunction with the inform consent document. The data collectors will conduct an assessment of consent capacity (the Evaluation to Sign Consent Measure; ESCM) for those who indicate interest in participating and do not have a legally authorized representative (LAR). The LAR is a person legally authorized to make medical decisions for the participant. If the participant has a LAR who is unable to be present, written consent will be obtained from the LAR prior to the enrollment appointment.

If the participant has consent capacity, he or she will be asked to sign the informed consent document after having any questions answered (if he/she agrees). If the participant does not have consent capacity, the decision maker will be the durable medical power of attorney, or the closest family decision maker (GVSU Human Research Review Policy 813, *Research involving participants with questionable consent capacity and/or legally authorized representatives)*. With permission of the participant, the decision maker will be informed of the study and asked if they would like to give consent to enroll the participant. Assent will be obtained from the participant prior to consent from the decision maker unless the participant's LAR has given written consent prior to the enrollment appointment. If the LAR has given prior written consent, assent will be obtained from the participant before continuing enrollment. Participants will be reminded about the study at each data point over the year (1, 3, 6, and 12 months), and assent obtained. If participants express a desire to withdraw, or have any indication of

discomfort, they will be withdrawn (or rescheduled if the discomfort is temporary). The participants will also be told that they are free to withdraw at any time during the study. The instructions for the study, including their right to withdraw at any time, will be repeated to the individuals each day of testing."

8d. Nature and Timing of Research Activities

Please describe the frequency and length of time subjects will be involved in the study.

Subjects will be in the study for one year, and data will be collected at 0, 1, 3, 6, and 12 months. Subjects in Arm 3 of the study will also participate in twelve 30-minute spaced retrieval education classes over 4 weeks during the first month of the study.

The focus group/staff interviews will take place once at the completion of the one-year study period at each study site

Describe step-by-step what will occur during your project. Include a description of the data you are collecting, how it will be collected, and how it will be analyzed.

The rigor of the study will be facilitated by a longitudinal cluster randomized controlled trial design. The study will be conducted at 12 independent and assisted living senior communities. Of the 12 communities, nine are medium (<50 residents) to large (>51 residents) continuing care retirement communities (independent living, assisted living, and skilled nursing in one community) and three are smaller assisted living communities (20-40 residents). Most are typical senior communities with double loaded hallways, congregate dining room(s), multiple activity rooms, and other common areas (letters indicating interest in participating are included with this package). The rationale for conducting the experiment in these communities is that: 1) this study falls within Stage III of the NIA's Stage Model for Behavioral Intervention Development (NIA, n.d.). As such, the rationale for conducting the study within senior living communities is to provide a more homogeneous population and setting order to establish internal validity of the interventions prior to establishing external validity in a larger population; 2) there is a significant need for studies supporting measures to improve wayfinding in these communities due to the complexity of their design and poor quality and quantity of evidence; 3) there is a large population of individuals with cognitive decline who live in these communities. Environmental design that supports engagement has been linked to an improved quality of life thus this population stands to benefit from the study results.

The study will be conducted as follows:

1. Prior to beginning the study, the care communities will be grouped based on their similarity of purpose (Assisted living (AL), or Independent living (IL) and size.

2. The IL communities will be randomly assigned to waves 1, 2 or 3 (three per wave). The AL communities will be assigned to wave

3. Three routes, which vary with respect to complexity (low, medium, and high complexity), will be chosen based on the space syntax assessment for each community using a computer program that calculates space syntax. Space syntax gives numerical values of complexity for routes in terms of length of path, number of path intersections, visibility of destinations, connectedness of spaces (direct connection versus indirect connection through intermediate spaces) and salience of existing cuing

(number, size, contrast, location and distinctiveness of cues).The rationale for choosing the routes based on space syntax is so that similarly complex routes can be compared among communities with different building design, and so that a range of complexity of routes is provided.

4. Subjects will be recruited and enrolled from each of the three communities prior to the intervention (see Human Subjects section).

5. After enrollment, the care communities will be randomized to either the control (Arm 1), Cued (Arm 2) or Cued Plus SR (Arm 3) condition. The rationale for randomizing after enrollment is to reduce potential selection bias due to the type of participants that agree to be in the study based on being in the intervention group or not.

6. At baseline, all enrolled subjects will undergo measurements of wayfinding ability, health, cognition, mobility and life space.

7. Arms 2 and 3 of the will have salient visual cues (colorful, familiar objects), including pictures, signage, statues and nature elements placed throughout the care community at key decision points (Figure 1). Arm 3 will additionally receive SR education, which uses a procedural memory cue over increasingly longer spaces of time. The control care communities will receive no change in décor or training (described below).

8. Wayfinding performance (primary outcome) will be compared between the participants in the care communities repeatedly over a period of 12 months (baseline, 1, 3, 6 and 12 months). The rationale for the time frame of outcome measures is to determine the effects of the interventions initially and over time. This information will be essential to understanding the timing and dosage of the interventions. Most studies that examine wayfinding only look at initial learning or short term retention; we seek to address this problem by assessing the impact of the intervention over a sustained period of time. Subjects will have their life space (secondary outcome) measured via a questionnaire. In addition, one community from each arm (for a total of three communities) will have life space measured via a mobility tracking device at these time frames.

9. Randomization will occur in the same manner in Waves 2-4 with enrollment of residents from nine additional care communities (three in each Wave). Each Wave will have similar communities in terms of space syntax and level of care. Randomization in this manner, a control comparison group, and careful measurement of the complexity of the communities and the subjects' baseline characteristics will provide a rigorous and reproducible study.

Description of ARMS. ARM 1 is the control condition, in which there will be no modifications to décor or signage in the existing care community, and no education on wayfinding. However, subjects will receive the same testing that is provided for the other arms at the designated time periods. ARM 2 consists of adding cues to the environment along the routes being measured for wayfinding. The cues will be comprised of pictures, objects, and signage (described below). The care community staff, residents, and visitors will be given a brochure indicating the purpose for the cues and suggesting ways in which individuals can use the cues for wayfinding. ARM 3 is the cues + spaced retrieval education. This condition will have cues as in ARM 2 added to the care communities. In addition, a spaced retrieval (SR) memory intervention strategy will be implemented individually for each resident participating in the study to help them remember the presence and function of the environmental wayfinding cues.

Standardized procedure for adding cues to environment to ensure reproducibility. The procedure for adding the salient cues and signage to the care communities includes the following. All study routes within the senior communities will be systematically evaluated by the research team using space syntax to identify important locations for cues. A comprehensive cuing framework that uses colorful and identifiable objects as well as colorful and legible signage that differentiates different aspects of the community will be developed for each of three chosen routes from the residents' apartments/rooms. Signage and cues will be specifically placed at key decision points (i.e. where hallways intersect and a decision about which way to go must be made) and at key areas to identify hallways for route finding, such as at the end of a hallway. Once a cue framework and design is developed, it will be reviewed with care community personnel by the investigators to ensure their acceptance. Cues will be designed to easily added to the building without significant modifications (e.g. they will be lightweight) and of sufficient quality to least at least 1 year (study period). The cues will be placed in the key areas adhering to building codes and other regulations. A brochure will be given to residents and staff (and available to guests) that explains the purpose of the cues. Brochures are a common way for care communities to communicate with building users about changes that are taking place, and they are something care communities can easily implement along with the signage/cuing.

Description of Spaced Retrieval Intervention. Spaced Retrieval (SR) is an evidence-based memory strategy that is used to teach individuals with memory loss new or previously known information (Brush & Camp, 1998; Benigas, Brush & Elliot, 2016). SR is a single procedure that involves selecting information to be learned, telling the information to the person, and then asking for immediate recall. Recall then is elicited in expanding time intervals. SR emphasizes setting the person up for success by beginning with short time intervals between practices and then systematically increasing the time between each practice as the person successfully recalls the details he or she needs to remember. It can be used to help individuals lead more independent lives by enhancing memory for personally relevant information and improving behaviors, such as less repetitive questioning, better orientation and wayfinding, greater engagement in activities, improved appointment keeping, safe ambulation, transfer and safer swallowing behaviors. Achievement of these goals can promote independence and reduce anxiety, as well as improve person-staff interactions. SR has been shown to be effective across a variety of types of dementia and has been used successfully with persons in their homes, in adult day centers, and in skilled nursing communities. It can be implemented during practice sessions with speech-language pathologists, or other health care professionals, and then maintained by family caregivers or nursing care staff. The ultimate goal of SR is retention of and ability to recall information over very long intervals of time (weeks, months, etc.).

Standardized procedure for Spaced Retrieval training. The standard protocol for Spaced Retrieval requires an individualized, predetermined, exact question to be presented for testing, with correct retention being judged as an immediate, predetermined, exact response. Upon success, the same test question is presented at expanding time intervals measured in seconds (e.g., 10, 20, 40, 60). Once the item is recalled at 60 seconds the time is doubled with each test trial (e.g., 2-minutes, 4-minutes, 8-minutes, etc.). If the targeted response is not recalled immediately, errorless learning is utilized by providing the person with the correct response, prompting the person to repeat it, and the time until the next test trial is reduced to the last successful time interval. Jennifer Brush, who is an expert on SR, will teach the technique to the research staff and monitor its implementation. Participants in the study will receive twelve 30- minute individualized SR practice sessions spread over 4 weeks for each

wayfinding cue that they need to learn. The prompt question will be consistent for each participant (e.g., "What do you look for help you find the _____room") and the target response and accompanying behavior will be individualized depending on the route and the cue the person needs to remember. Data will be recorded for each prompt question and target response using the procedure and data record sheets as described in the Spaced Retrieval manual. Subjects will be trained one route at a time.

Measures. Variables within the conceptual model and control variables will be assessed by the measures described below. The primary independent variable for this study is the cue condition intervention (cues; cues plus SR education) versus the control group. The dependent variables are measures of wayfinding performance and life space. Covariates include age, diagnoses, mobility, independence in activities of daily living (ADL), measures of cognitive ability, and gender. In addition, measures of feasibility will include assessment of tolerance to the measures and acceptance of the cues by the care community.

Control Variables

The control variables will be measured at baseline and will provide added control for pre-intervention influences so that the effect of trial arms will be rigorously isolated over and above other factors. The cognitive variables (working memory, cognitive status), independence in ADL's , and mobility aids will also be measured at each time period (1,3, 6, and 12 months) to account for changes over time which may affect wayfinding performance.

• Cognitive Status. The Montreal Cognitive Assessment (MoCA) is a 10 minute, 30 point instrument that tests short term memory recall, visuospatial abilities, executive functioning, attention, concentration and working memory, language, and orientation. The internal consistency (Cronbach's alpha) reported as .83. The MoCA has reported sensitivity for identifying mild cognitive impairment at 90% and AD 100% which is much more sensitive than the MMSE. In addition, the Mini Mental Status Examination (MMSE) will be administered. The MMSE is an 11-item (30 point) screening tool that assesses orientation, attention, immediate and short-term recall, language, and spatial ability. A cut score of up to 27 has been shown to have sensitivity of .89 and specificity of 0.91 in identifying those with dementia. The MMSE will be used along with the MoCA to describe the overall cognition of the subjects.

• Working Memory. The Digit Span tests will be used to assess working memory and attention, as these factors have been shown to impact spatial learning ability. Subjects are asked to repeat an increasingly larger series of numbers in the Digit Span Forwards test (DSF). In the Digit Span Backwards (DSB) test, subjects repeat the numbers in reverse order. Normal scores for the DSF test are > 5 and > 4 for DSB. Test-retest reliability of the digit span tests range from.

• Age. Age will be included on the demographic questionnaire and reported in years.

• Education: This will be included on the demographic questionnaire and recorded as years of school completed. Education is important to control for as it is often associated with cognitive performance.

• Sex. Sex will be a dichotomous variable on the demographic questionnaire with 2 responses: male or female. The purpose of including this variable is that the male sex has frequently been shown to have an advantage in wayfinding tasks. In addition, males have been shown to use different wayfinding strategies than females; and may be less reliant on cues.

• Mobility aids used: This will be measured by asking the subjects to identify the mobility aids they use in everyday activities, including: 1) No aids 2) Cane 3) Walker 4) Wheelchair and 5) Scooter and 6) Other.

• Activities of daily living (ADL) ability. The Katz Index of Independence in Activities of Daily Living 56 scale will be used to measure the ability of the subject to perform daily functions, such as bathing, eating, dressing, and toileting. The subject is rated as having total independence (1 point) or needing help (0 points) on six ADL's for a maximum score of 6. High scores indicate more independence in function. This scale has been used extensively for measurement of functional ability in older adults and has been shown to have predictive validity 57. This scale will provide information about differences in level of dependence of the subjects which may be related to their wayfinding performance.

• Diagnoses. To determine any medical diagnoses that could impact wayfinding ability, including neurological diseases such as stroke, Parkinson's disease, Alzheimer's disease, and others, the primary health care provider for each participant will be contacted (after permission/HIPAA release is obtained) and asked to send a list of all medical diagnoses.

• Reading ability: Subjects will have a brief reading test to determine their ability to read signage (different size fonts) and comprehend it. This test requires subjects to read prompts at various font sizes and perform the associated action (i.e. "Pat your head"). This data will be used to determine the subjects' ability to read and comprehend the signage40.

Feasibility Measures

Since this is a pilot RCT requested by PAR-16-365, Pilot Clinical Trials for the Spectrum of Alzheimer's Disease and Age Related Cognitive Decline, several measures of feasibility are included. Of primary concern is the tolerance of the testing by the subjects, acceptance of the cues by the residents within the communities; and the opinion of the usefulness of the cues by the LTC staff. The measures of feasibility are:

• The number of participants who could complete the entire study which will be obtained by the tracking study participation and attrition.

• Reason for attrition will be collected ongoing in the study by the data collectors.

• Resident acceptance of cues will be assessed using an anonymous questionnaire for all residents within the community at the completion of the study. Since a primary concern of many LTC communities is to provide a decorative and pleasing décor, it will be important to ascertain that the cues used within the care communities are acceptable. The survey will give important information about the preferences of the residents.

• Staff opinions of the utility of the cues will be assessed using focus groups and individual interviews. The staff within the community will be queried about their opinions about the usefulness of the cues for assisting residents in wayfinding; as well as their thoughts on the decorative element of the cues.

Study Outcomes (Dependent Variables)

Primary Outcome: Wayfinding Performance. Wayfinding is the ability of participants to find their way to key locations and back to the starting point (bedroom, dining area; and back to starting place). Wayfinding performance will be measured at times 0, 1, 3, 6 and 12 months using the method of Brush

et al. Subjects will be asked to show the route from his or her bedroom to Location 1: from the Location 1 to the Location 2; and from Location 2 to the participant's. Two research assistants will walk with the participant to obtain the following measures:

1) Time to move from one location to another/distance. Time will be measured for each of the three routes along with the total distance in (feet/yards) of the path. The average speed of covering this distance will be calculated as v = (total distance) / (total time), thus standardizing variation in distance and the resulting time that could be present among different care communities. If elevators are present, time will be stopped once the participant reaches the elevator and uses it, and time measurement will be resumed upon exiting the elevator. If subjects make a wrong turn, they will be corrected and 2 minutes added for each time they are corrected.

2) Errors are defined as the percent of errors made (wrong turns) based on the number of possible turns. Depending upon the route selected by the subject, the number of possible turns is variable so that the percentage of wrong terms will be calculated.

Secondary Outcome: Life Space. Life space is defined as the spatial extent of mobility within an environment, and varies from a small life space (limited to one's room) to a large life space (travels outside of the care community). Life space will be measured using a modified version of Tinetti's Nursing Home Life-Space Diameter at times 0, 1, 3, 6, and 12 months. The tool is a survey that asks subjects or their caregivers to state how often per day (in the past 2 weeks) an individual moves within spaces, including their own rooms, outside the room but within the unit/hallway/floor, outside the unit/hallway/floor but within the care community, and outside the care community. Frequency is rated on a scale from 0 = never to 5 (> 3 times/day) for each level of life space. Scores for each life space are summed, with the total ranging from 0-50 and higher scores representing more mobility and a larger life space. Tinetti reported test-retest reliability of the measure with r=.922-951 using different nurse raters.

A weakness of Tinetti's tool is the reliance on self-report; thus we will use an electronic tracking device to measure life space on a subsample of subjects for one community from each of the arms for years 2-4 of the study (one community for each Arm; Y2 = Arm 1; Y3=Arm2; and Y4 = Arm 3). Tracking devices have been used in healthcare and manufacturing for years, but have only recently been used in long term care. Primarily they have been used to identify when individuals with dementia elope from buildings or areas. Except for one small study involving hard wired monitoring devices, mobility tracking has not been used to measure life space. There is at least one system available that provides a wearable technology (wristband) and "anchors", which are devices that plug into the community's wall outlets. The system uses Bluetooth to identify the participant's location inside to a location to accuracy within 10 feet. The system provides real time tracking and reporting which can be used to track life space. Secure data is stored in the cloud. Because this technology is relatively new, we did not want to rely on it solely. But it would give a much more accurate and detailed report of locational information than the Tinetti measure and provide valuable information about the effect of cues on life space.

Procedure for Tracking: The participants will be instructed to go about their activities as normal. The tracking devices will be placed on the individuals and data will be collected for one week at baseline (prior to interventions); and for one week at each measurement time. For Arm 3 subjects, monitoring will be ceased during the spaced retrieval training time periods. The wristbands can be worn 24 hours/day (they are waterproof), so the participants will be asked to leave the devices on for each week. Study staff will monitor the use of the trackers daily during data collection. If a band is lost, it will be

replaced. Using the tracking device analytics, we will measure the life space of the participants within the community using the zones described in Tinetti's Nursing Home Life-Space Diameter. In addition, we will measure the time spent at each life space zone.

DATA collection for staff focus groups or interviews:

Care staff who are interested in participating in the focus groups or interviews will be given one of two times for a focus group. If this time does not work, they will be asked to participate in an individual interview. The researchers will abide by the administrator's wishes (at each site) regarding whether or not participants may participate in the focus groups during their work shifts. Individual interviews will be scheduled at the convenience of the interviewee. Please see attached research tools for questions. The interviews will be recorded digitally.

Has text/survey validity and/or reliability been demonstrated?

Yes – please see above.

Please describe the training and experience of person(s) administering the treatment and performing data collection/assessment, and describe the relevance of this to human subject protections.

The research team for this study has the expertise necessary to implement this proposed project. The PI has lead three studies on salient cues and wayfinding in aging and/or Alzheimer's disease, including an NIH funded study. Dr. Calkins is an internationally known and well respected expert on design for dementia, and has led numerous studies in long term care environments including several key studies on wayfinding. Dr. Sikorskii is a biostatistician who has extensive experience and success in the analysis of outcomes and processes within randomized controlled trials, including cluster trials with multiple arms. Jennifer Brush, a speech-language pathologist, is nationally known for her work on spaced retrieval, and has recently conducted a study on signage and wayfinding in persons with dementia in long term care. She has extensive experience in leading and conducting research in long term care.

Will subjects be compensated for their participant in the study?

Yes

Please describe the compensation. (Payment should be reasonable and prorated with partial payment to those who withdraw before completion of the research.)

Subjects will receive a $10 store card per wayfinding measurement session plus an additional $10 at the end of the study. This adds up to $60 per subject (if they complete all sessions).

There will be no compensation for the staff participating in the focus groups.

IRB Amendment to 8D #9732 - 5/3/2021

Location tracking will be done by having the subjects wear a "fit bit" type of bracelet for one week at each data collection time frame. Subjects will be instructed to keep the bracelet on for the entire week. A data collector will assist the resident in applying the bracelet if necessary. At the end of the week, the bracelet will be collected, placed in a plastic bag, and locked in the research office. Subjects will wear the same bracelet (it is associated with their subject ID). The data is transmitted, de-identified, to a server placed in the facilities. The server can be dialed into by the researcher, who can monitor if there is no activity by the subject and intervene if necessary. The use of the tracking device is already in the current informed consent document. The subject will be given instructions about caring for the device (they can bathe with it on, they should wear it all the time, etc.) and we will check with them daily to make sure everything is going OK. Like all parts of our study, they can refuse this at any time.

IRB Amendment to 8d #9338 - 12/11/20

Section 8d of the original protocol submission included: "• Resident acceptance of cues will be assessed using an anonymous questionnaire for all residents within the community at the completion of the study. Since a primary concern of many LTC communities is to provide a decorative and pleasing décor, it will be important to ascertain that the cues used within the care communities are acceptable. The survey will give important information about the preferences of the residents.
• Staff opinions of the utility of the cues will be assessed using focus groups and individual interviews. The staff within the community will be queried about their opinions about the usefulness of the cues for assisting residents in wayfinding; as well as their thoughts on the decorative element of the cues."

The tools have been developed at this time as six LTC communities in the study are being closed out due to COVID 19 visitor restrictions and because the year-long study has come to a close in these sites. Also due to COVID-19, staff opinions will be assessed using a survey rather than focus groups and interviews. We do not feel staff have the time nor feel a focus group or interview on the signs and artwork is a priority at this time. We are also unable to conduct any in-person interviews or focus groups; therefore, we would like to use a survey to collect this information. Paper surveys will be distributed via the community contact to staff, or via email Qualtrics link by the community contact. Because all staff may have interaction with residents who are wayfinding (i.e. receptionists, care providers, therapists, etc.) we will send to all staff. The goal of these surveys is to determine the usefulness and acceptability of the design changes (signs and cues) to the staff and residents.

IRB Amendment to 8d. #9072 - 7/14/2020

Additional variable on the demographic questionnaire: "How many years have you lived in the community?"

IRB Amendment to 8d. #8957 - 3/20/2020

Amendment to 8D #8. Due to COVID-19, the 6month data collection period can occur up to the 10th month of the trial in each community.

IRB Amendment to 8d. #8566 - 9/20/2019

Caregivers on the floors may be asked about activities (i.e. the Life space questionnaire or Katz activities of daily living; or about safe mobility for our study) when we do not feel that the subject is able to answer the question.

IRB Amendment to 8d. #8552 - 9/9/2019

9) Randomization will be prior to enrollment but the Arm assignment will not be told to the communities, data collectors, or participants until after enrollment.

IRB Amendment to 8d. #8332 - 5/20/2019

1) Reading ability: Subject in Arm 3 will have a brief reading test to determine their ability to read different size fonts. The test requires subjects to read prompts at various font sizes. This data will be used to determine the

subjects' ability to read the visual aid used in Spaced Retrieval. All Subjects in all arms will have a brief reading test to determine their ability to read signage from a distance of 10 feet. This data will be used to determine the subjects' ability to read the signage.

IRB Amendment to 8d. #8097 - 2/22/2019

1) Addition of data collection timeline to study step #8

"Wayfinding performance (primary outcome) will be compared between the participants in the care communities repeatedly over a period of 12 months (baseline, 1, 3, 6 and 12 months). Subjects may be scheduled two weeks after or two weeks before the exact 1, 3, 6, and 12-month date to accommodate for scheduling conflicts. The rationale for the time frame of outcome measures is to determine the effects of the interventions initially and over time. This information will be essential to understanding the timing and dosage of the interventions. Most studies that examine wayfinding only look at initial learning or short-term retention; we seek to address this problem by assessing the impact of the intervention over a sustained period of time. Subjects will have their life space (secondary outcome) measured via a questionnaire. In addition, one community from each arm (for a total of three communities) will have Life space measured via a mobility tracking device at these time frames."

2) Addition of visual aid use in Spaced Retrieval standardized procedure

"Standardized procedure for Spaced Retrieval training. The standard protocol for Spaced Retrieval requires an individualized, predetermined, exact question to be presented for testing, with correct retention being judged as an immediate, predetermined, exact response. Upon success, the same test question is presented at expanding time intervals measured in seconds (e.g., 10, 20, 40, 60). Once the item is recalled at 60 seconds the time is doubled with each test trial (e.g., 2-minutes, 4-minutes, 8-minutes, etc.). If the targeted response is not recalled immediately, errorless learning is utilized by providing the person with the correct response, prompting the person to repeat it, and the time until the next test trial is reduced to the last successful time interval. Jennifer Brush, who is an expert on SR, will teach the technique to the research staff and monitor its implementation. Participants in the study will receive twelve 30- minute individualized SR practice sessions spread over 4 weeks for each wayfinding cue that they need to learn. The prompt question will be consistent for each participant (e.g., "What do you look for help you find the _____room") and the target response and accompanying behavior will be individualized depending on the route and the cue the person needs to remember. Participants will receive a visual aid of each wayfinding cue once they successfully recall the targeted response at the 2-minute interval. Data will be recorded for each prompt question and target response using the procedure and data record sheets as described in the Spaced Retrieval manual. Subjects will be trained one route at a time."

3) Removal of the Mini Mental Status Examination (MMSE) under control variables: cognitive status

"• Cognitive Status. The Montreal Cognitive Assessment (MoCA) is a 10-minute, 30-point instrument that tests short term memory recall, visuospatial abilities, executive functioning, attention, concentration and working memory, language, and orientation. The internal consistency (Cronbach's alpha) reported as .83. The MoCA has reported sensitivity for identifying mild cognitive impairment at 90% and AD 100% which is much more sensitive than the MMSE~~. In addition, the Mini Mental Status Examination (MMSE) will be administered. The MMSE is an 11-item (30 point) screening tool that assesses orientation, attention, immediate and short-term recall, language, and spatial ability.52 A cut score of up to 27 has been shown to have sensitivity of .89 and specificity of 0.91 in identifying those with dementia.53 The MMSE will be used along with the MoCA to describe the overall cognition of the subjects.~~"

4) Change in language under primary outcome: wayfinding performance

"Primary Outcome: Wayfinding Performance. Wayfinding is the ability of participants to find their way to key locations and back to the starting point (bedroom, dining area; and back to starting place).

Wayfinding performance will be measured at times 0, 1, 3, 6 and 12 months using the method of Brush et a. Subjects will be asked to show the route from ~~his or her bedroom to Location 1: from the Location 1 to the Location 2; and from Location 2 to the participant's bedroom~~ a predetermined starting location to a predetermined destination. Two research assistants will walk with the participant to obtain the following measures:

5) Addition of qualitative data collection during wayfinding

Behaviors will be recorded while subjects travel the route. Behaviors recorded will include: 1) Subject asks for a rest, 2) Subject looks at cue card (visual aid), 3) Subject asks for directions, 4) Subject is confused or frustrated.

9. Personal Identifiable Information/Deception/Potential Modifications

9a. Personal Identifiable Information

Will personal identifiable information and/or protected health information be collected during this study?

Yes

Please select the type of personal identifiable information being collected.

Names

All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes Telephone numbers

Social security numbers

Please describe who will have access to the data.

Since this is a longitudinal study, we have to keep a record of all subjects' names, addresses, contact information, etc. In addition, we will be collecting data from their medical record about their diagnoses (we need to know if they have diagnoses that would explain some of their wayfinding problems, such as Alzheimer's disease).

The project manager (Grand Rapids), site coordinator (Cleveland), PI, co-investigators, and data collectors will have access to this information.

SS# are collected because our business office requires it.

How will the personal identifiable data initially be obtained?

We will obtain HIPAA release (see ICD) for the PHI. For the phone numbers and addresses, we will ask that interested participants call us, and ask them (or their legal guardians) for this information. We will collect this in our demographic information sheet.

For the SS# we will ask the subjects (or legal guardians) to fill out a card that has their name and number on it - we will place this in a sealed envelope and lock it in a drawer separate from the data. It will ONLY be opened if needed for business office purposes.

For how long will subjects' identifying information be linked to the data and how will the data be destroyed?

We will link it for the year-long study. The SS numbers have to be kept for at least 7 years for the business office.

Where and how will the data be stored?

All forms will be de-identified and stored in a locked file cabinet in the research offices. The identified forms (keys with addresses and contact numbers) will be kept separate from the data, and only accessed by study staff when needed for scheduling and data collection visits. Informed consent documents will be kept separate from the data and stored in a locked file drawer.

What steps will you take to protect the data? How will you guard it from improper use and disclosure?

4. Privacy and Confidentiality. We have measures to ensure privacy. Private data, such as cognitive tests, will be collected in a private area given to us by the long term care community for this purpose.

a. Protecting Confidentiality. Study subjects will be assigned a numerical code upon enrollment. This number will then become the identifier of records for all participants. This number will be transferred along with the name, address, and telephone number of the participant to the data collector. After data collection, the identifiable information will be removed from the paper documents (except for the informed consent form and HIPAA form which will be stored in a locked file cabinet separate from the study data).

b. Security Procedures for Collection, Transfer, and Storage of Electronic Data –Electronic data will be in a format needed by supporting software. Computers used to collect and send data during the study implementation can use encrypted data files. Data received or stored at the central location are password-protected. Electronic copies of forms will be stored on dedicated, secure servers with appropriate firewalls. The system can use 128-bit encryption (AES-CCM) to transfer data between internal servers and Federal Information Process Standard (FIPS) 140-1 to transfer data between the servers and collection points. Data stored within the server can be encrypted and require additional password for access. Servers are scanned for viruses, and systems are in place to detect attempts at unauthorized entry. The server and data is backed up nightly to back-up servers. Daily backups are kept onsite at a different physical location for up to one month. A monthly copy of the backup data can be stored on an externally hosted cloud designed for long term storage until the study is finished and the data is no longer needed.

c. Security Procedures for Collection, Transfer, and Storage of Paper and Electronic Data – The informed consent document, enrollment forms, HIPAA release, and pen and paper tests will all be done on paper. These documents will all be de-identified upon receipt and stored in a locked file cabinet using the subjects' assigned ID number. The study data (such as pen and paper tests) will be coded and entered into a database. Only the project manager, site coordinator, and PI will be able to see identifiers in the electronic data. The electronic data will be stored on the secure computer network which is password protected as described above.

d. Wayfinding data. The wayfinding data will be recorded using a computer application on an iPad that will allow for the data collectors to input wayfinding behavior along the study routes. This data will not have any identifiable information attached to it. The subject wayfinding data will be stored on a

password protected network and downloaded by the PI or project manager/site coordinator using a password so that data can be inputted into the data base for analysis.

e. Recorded data. The digitally recorded focus group data will be transcribed into Atlas.ti and all identifiers removed. Digitally recorded

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IRB Amendment to 9a. #8097 - 2/22/2019

1) Addition of use of Institution HIPAA Authorization for Release of Health Information for Research Purposes

"We will obtain HIPAA Authorization for Release of Health Information for Research Purposes, included in the Informed Consent Document for the PHI. The participant, LAR, or other designated representative will be asked to sign institution specific HIPAA Authorizations when applicable. For the phone numbers and addresses, we will ask that interested participants call us, and ask them (or their legal guardians) for this information. We will collect this in our demographic information sheet."

2) Addition of REDCap for Electronic Data Storage

Electronic data will be captured and stored in REDCap. REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data (including 21 CFR Part 11, FISMA, and HIPAA-compliant environments), it is specifically geared to support online or offline data capture for research studies and operations. The GVSU instance of REDCap is housed on university servers, thus ensuring the collected information is protected behind university firewalls. Access to the system is granted at the user level to certain projects and even certain data fields within a project.

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10. COVID-19 Modifications

IRB Amendment to 8D #9883 - 6/22/2021

Revised COVID procedures to follow rules of site, as below:
1) All study staff will complete the applicable modules of the CDC Nursing Home Infection Preventionist Training Course (https://www.train.org/cdctrain/training_plan/3814) prior to re-engaging in research activities. Modules to be taken include: Infection Prevention and Control Program, Principles of Standard Precautions, Principles of Transmission-Based Precautions, Hand Hygiene, Respiratory Hygiene and Cough Etiquette, Environmental Cleaning and Disinfection.

2) UNTIL NO LONGER REQUIRED BY GVSU and the RESEARCH SITE, Study staff will be required to screen for COVID-19 symptoms each day prior to entering the community. They will use the screening required by the LTC community. If for some reason screening is not required by the community (this is not the case at this time, but in the near future) we will require them to submit the GVSU required COVID screen and notify the Project manager if positive. We will cancel our visit with participants if we have experienced any COVID-19 symptom up to 48 hours before the scheduled visit. If study staff has symptoms or diagnosis of COVID-19, we will follow the return to work recommendations for health care providers by the CDC or by the community: https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

3) UNTIL NO LONGER REQUIRED BY THE RESEARCH SITE (based on appropriate government regulations/policies) All equipment will be disinfected prior to entering the community as well as in between participant visits. Equipment includes; tablet, stopwatch, clipboard, pens, and bag handle.

4) Study staff will follow 1) each research site's infection control protocols as well as 2) the CDC recommended precautions to reduce the spread of COVID-19 (covering cough/sneeze with tissue or crook of elbow, frequently washing hands for 20 seconds, using >60% alcohol-based hand sanitizer, etc.).

5) UNLESS/UNTIL NO LONGER REQUIRED (based on appropriate government regulations/policies) study staff will wear masks/face coverings as required by the long term care community (some require surgical masks, others require double masking, some require mask plus face shields; SOME DO NOT REQUIRE MASKS). Subjects will be asked first if they desire our staff to wear masks; and if so they will wear a mask.

6) UNLESS/UNTIL NO LONGER REQUIRED (based on appropriate government regulations/policies) study staff will keep 6 feet of distance except during the transfer of research material (paper assessments), when pushing a wheelchair, or when a participant feels unsteady during wayfinding. At such time as government policies and site policies do not have social distancing, subjects will be asked if they desire us to stay 6 feet away, and if so we will.

7) UNLESS/UNTIL NO LONGER REQUIRED (based on appropriate government regulations/policies) we ask participants to wear a mask when they are medically able to do so. We will provide them if needed. We also ask that participants wash their hands or use alcohol-based hand sanitizer before and after their visit with us.

8) UNLESS/UNTIL NO LONGER REQUIRED (based on appropriate government and specific site regulations/policies) the participants will be screened for COVID symptoms at each meeting with them by asking the following questions. If any COVID-19 symptoms are mentioned, the data collector will not proceed (most all residents have been vaccinated).
1. Have you been within 6 feet of someone with COVID-19 symptoms in the past 14 days?
2. Have you recently developed a cough?
3. Have you recently developed shortness of breath?
4. Have you recently developed extreme tiredness, especially when combined with any other symptoms?
5. Have you recently experienced a loss of appetite/sense of taste/sense of smell?
6. Have you recently developed diarrhea or nausea?

9. The LTC communities have different policies and procedures related to what happens when someone in their community tests positive for COVID. For example, in one facility, visitation is not allowed in the nursing home section of the building; but is allowed in the independent living section and assisted living so long as the infected person is isolated. We have asked the sites to tell us if there is an outbreak at the site; if it is in an area we are in (most frequently it would be staff as most residents are vaccinated) we will make a determination of the risk to staff and place the study on hold if needed.

10) If a participant decides at any time that they feel safer not completing a study visit, we will respect that decision and will delay the visit or withdraw the participant at their request.

IRB Amendment #9732 - 5/3/2021

Permission to restart using COVID precautions:

1) All study staff will complete the applicable modules of the CDC Nursing Home Infection Preventionist Training Course (https://www.train.org/cdctrain/training_plan/3814) prior to re-engaging in research activities. Modules to be taken include: Infection Prevention and Control Program, Principles of Standard Precautions, Principles of Transmission-Based Precautions, Hand Hygiene, Respiratory Hygiene and Cough Etiquette, Environmental Cleaning and Disinfection.

   2) Study staff will be required to screen for COVID-19 symptoms each day prior to entering the community. They will use the screening required by the LTC community. If for some reason screening is

not required by the community (this is not the case at this time, but in the near future) we will require them to submit the GVSU required COVID screen and notify the Project manager if positive. We will cancel our visit with participants if we have experienced any COVID-19 symptom up to 48 hours before the scheduled visit. If study staff has symptoms or diagnosis of COVID-19, we will follow the return to work recommendations for health care providers by the CDC or by the community: https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

3) All equipment will be disinfected prior to entering the community as well as in between participant visits. Equipment includes; tablet, stopwatch, clipboard, pens, and bag handle.

4) Study staff will follow 1) each research site's infection control protocols as well as 2) the CDC recommended precautions to reduce the spread of COVID-19 (covering cough/sneeze with tissue or crook of elbow, frequently washing hands for 20 seconds, using >60% alcohol-based hand sanitizer, etc.).

5) Study staff will wear masks/face coverings as required by the long term care community (some require surgical masks, others require double masking, some require mask plus face shields).

6) Study staff will keep 6 feet of distance except during the transfer of research material (paper assessments), when pushing a wheelchair, or when a participant feels unsteady during wayfinding.

7) We ask participants to wear a mask when they are medically able to do so. We will provide them if needed. We also ask that participants wash their hands or use alcohol-based hand sanitizer before and after their visit with us.

8) Participants will be screened for COVID symptoms at each meeting with them by asking the following questions. If any COVID-19 symptoms are mentioned, the data collector will not proceed (most all residents have been vaccinated).
1. Have you been within 6 feet of someone with COVID-19 symptoms in the past 14 days?
2. Have you recently developed a cough?
3. Have you recently developed shortness of breath?
4. Have you recently developed extreme tiredness, especially when combined with any other symptoms?
5. Have you recently experienced a loss of appetite/sense of taste/sense of smell?
6. Have you recently developed diarrhea or nausea?

9) The LTC communities have different policies and procedures related to what happens when someone in their community tests positive for COVID. For example, in one facility, visitation is not allowed in the nursing home section of the building; but is allowed in the independent living section and assisted living so long as the infected person is isolated. We have asked the sites to tell us if there is an outbreak at the site; if it is in an area we are in (most frequently it would be staff as most residents are vaccinated) we will make a determination of the risk to staff and place the study on hold if needed.

10) If a participant decides at any time that they feel safer not completing a study visit, we will respect that decision and will delay the visit or withdraw the participant at their request.

IRB Amendment #9072- 7/14/2020

This following portion of the amendment is addressing changes to our protocols due to the COVID-19 virus. We were in the middle of the study at the time of the pandemic. We halted data collection and recruitment. We are expecting some of our sites to be open to visitors soon (per our Ohio researcher partners, July 1, 2020) and this amendment is preparing for resumption of month 6 data collection for existing subjects; and continued recruitment and enrollment (and other study activities) for new sites. We expect Michigan sites to allow us to resume later but these changes will apply there as well as sites open up. List of changes:

1) We will be submitting letters/emails from the Long-Term Care Communities where research activities are taking place as we receive them and visitor restrictions are lifted. We will only reengage in research activities after communicating with each site, sharing our COVID-19 prevention procedures, reviewing and training our data collectors on the community specific COVID-19 prevention procedures, and receiving notice that we may re-enter the community.

2) We will provide the attached COVID-19 handout and discuss with the participant and/or their LAR the following information. After reviewing the handout with the participant and/or their LAR, we will ask if they would like to continue in the study.

3) All study staff will complete the applicable modules of the CDC Nursing Home Infection Preventionist Training Course (https://www.train.org/cdctrain/training_plan/3814) prior to reengaging in research activities. Modules to be taken include: Infection Prevention and Control Program, Principles of Standard Precautions, Principles of Transmission-Based Precautions, Hand Hygiene, Respiratory Hygiene and Cough Etiquette, Environmental Cleaning and Disinfection.

4) SOPs for study staff related to COVID-19 and accompanying documents include the following: a) Study Staff Screening and Reporting (Screening Tool attached): Study staff will be required to use the attached screening log (individual) each day prior to entering the community. Study staff will take a picture of the log and send to the site coordinator each day before entering. The Site Coordinator will use the department log to record all study staff self-assessments. b) Disinfection equipment (Checklist attached): All equipment will be disinfected prior to entering the community as well as in between participant visits. c) PPE, distancing, and hygiene: Study staff will follow the CDC recommended precautions to reduce the spread of COVID-19 (covering cough/sneeze with tissue or crook of elbow, frequently washing hands for 20 seconds, using >60% alcohol-based hand sanitizer, etc.). Study staff will not visit any other buildings/LTC community sites prior to entering the current community for the day. Study staff will be provided 2 cloth masks that will be doffed prior to entering the community each day. Study staff will change clothes once leaving the building and put those clothes, as well as their mask, in a plastic bag to wash each night when they return home. Staff will keep 6 feet of distance except during the transfer of research material (COVID-19 Handout, Informed Consent, and Montreal Cognitive Assessment), when pushing a wheelchair, or when a participant feels unsteady during wayfinding. d) Meeting space and participant flow management: For the assessment portion of data collection, participants will be asked to come to a designated room in each community where the meeting space (i.e. table) is disinfected after each participant visit. Study staff will not meet or visit participants in their rooms. In order to reduce risk of exposure to both the study staff and communities, one data collector will be assigned per community for data collection and will wait 2 weeks after completing data collection in one community to enter into another community.

IRB Amendment #10128 - 9/29/2022

We are requesting to expand our data collection visit windows. Currently, we visit our study sites post intervention at Months 1, 3, 6, and 12. The visit windows for these visits are one week prior to - one week after month 1; and 2 weeks prior to - 2 weeks after months 3, 6 and 12. At this time, we have baseline data in 3 new sites, and have instituted our intervention. We have found out that due to COVID, some sites are required to close for 10 days at a time (for example, if there is an exposure, or if someone tests positive). Then the sites do testi29 of all residents and staff during that time. We (and other visitors) are usually not allowed in and we also have specified in our protocol that we do not go into sites if they are closed to visitors.

Thus, to avoid missing data in sites, we propose to expand our visit windows to one month prior to the next visit window for visits 1, and 6 and for one month after Month 12. We will keep the other visits on the current timeline (not expanding the length of the trial). Thus, for example, if a site is closed for two weeks during Month 1; we will have until one month before Month 3 to collect Month 1 data.

We are hoping we won't have to do this often, but we have no way of predicting what will happen with COVID. This will allow us to continue the trial and get longitudinal data. The statistician has been consulted to assist us with dealing with the varying timelines. Dates are collected for each measurement time period.