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A. Introduction/Hypothesis

Two of the most challenging conditions that negatively affect persons with dementia (PWD) living in the community are: (1) weight loss leading to frailty, and (2) social isolation leading to diminished quality of life (QOL). Lack of caregiver (CG) skills related to meals, dysfunctional CG and PWD behaviors during meals, and diminished PWD social skills leading to isolation are well-documented factors influencing nutritional outcomes. This study will test the efficacy of an intervention that empowers CGs and volunteers or staff in respite care centers (RCCs) who interact with PWD during mealtime. Specifically, a train-the-trainer program, **Partners at Meals (PaM)** derived from the theoretically-based **C3P Model of Changing the Place** (home or RCC), **Changing the People** (CG or volunteer) and **Changing the Person** (PWD) will be used to improve nutritional outcomes and QOL. Family members are the primary CGs of community dwelling PWD. We **hypothesize** our intervention will: (1) improve quality of life by better equipping family caregivers and respite care providers to manage a chronic illness with significant burden (Alzheimer's disease and related dementias), (2) improve palliative care for this terminal illness while some change is feasible, and (3) enhance innovation in a community-based practice (Respite Care Centers). As such, the products of this study are of high significance.

Family-managed care is critical in promoting quality of life (QOL) and health in Alzheimer's disease and other dementias. The Partners at Meals (PaM) intervention emphasizes focusing on more than just "changing" a PWD, but also intervening with the People with whom they interact and Place where meals occur. With this intervention, CGs and volunteers or staff at RCCs partner and modify mealtime at a point when the PWD is still able to express preferences and engage in the meal process, and develop a PWD-centered plan of mealtime care. Of note, our pilot work indicated that CG's report of mealtime behavior may be inaccurate because CG and other family members may overlook key cues/triggers to dysfunctional behavior. Thus, to **improve this identification process, a secure and HIPAA-compliant telehealth component (Doxy.me)** is used to record dysfunctional behaviors displayed by the PWD on a 'tablet'. The CG interacts with their "partner' volunteer, the RCC staff or MUSC Interventionst (AIM 4) either through a real-time connection or sharing of the recorded file so that together, they can problem-solve issues and modify the plan of care. This CG-volunteer/ staff member partnership also fosters consistency across settings (AIMS 1-3), as well as imparts skills and self-efficacy for care management for both parties, improves QOL for the CG and the PWD, improves mealtime outcomes for the PWD, and promotes better health outcomes.

Research design. A randomized cluster-design trial will be conducted in two large RCCs with six sites that serve primarily white and African American PWDs. RCCs will be randomized to the **intervention condition (Partners at Meals**; 2 sites) or **['enhanced usual care' (EUC)]** (4 sites). The primary unit of analysis is the PWD and CG: 60 PWDs, 60 CGs will be enrolled; it is estimated that up to 60 volunteers/staff/managers may be enrolled. The CG and RCC volunteer or staff member is another dyad for analysis, as is the RCC volunteer/staff member and the PWD. Additionally, RCC Managers at both PaM and EUC sites will be interviewed regarding barriers to implementation, ways to enhance the project, and possible causes of discharge of PWD from the study related to nutritional problems.

Additionally, to explore the feasibility of program replication and widespread adoption, an online

global survey of Respite Care Providers and their respective agencies will be conducted on the use of telehealth/videoconferencing technologies to deliver individualized educational support services to families in-the-home.

Partners at Meals (experimental condition) uses the C3P Model to direct change in three key areas (place, person, PWD) whether at the RCC or in the home. In the intervention sites, project staff will train the RCC volunteers or staff members, who will train CGs to more effectively manage meals based on assessment at the Center, and will subsequently use the telehealth solution in the home. Tailoring the plan to the home is critical to family-managed sustainability. The intervention will be delivered through each CG-volunteer /staff member dyad, and each PWD-CG dyad will be enrolled for 6 months. CGs and staff/volunteers in the EUC condition will have training focused on CG needs alone for support from family and others to manage care. A comprehensive process evaluation plan will be used to monitor implementation and foster dissemination.

Specific Aims:
Aim 1: To use a repeated-measures, randomized control design to assess the relative efficacy of Partners at Meals (PaM) vs. enhanced usual condition (EUC) in terms of the following PWD outcomes at baseline, and one-month intervals: nutritional status (weight, photography of pre- and post-food consumed); dysfunctional behaviors at meals (Edinburgh Feeding in Dementia scale XL with additional fields and questions added); quality of life (QOL-AD)
Main hypothesis: Participation in PaM will be associated with improved weight maintenance and decreased dysfunctional mealtime behaviors (the latter of which is the presumed mechanism of change).
Aim 2: To assess the relative efficacy of the Intervention vs. EUC in terms of the following. CG: quality of life (Euro-QOL), burden (Zarit Burden Scale), depression (CES-D), and self-efficacy for managing meals at home; b) RCC volunteer or staff: self-efficacy for training and management of mealtime issues; c) RCC director/manager: satisfaction with the program and willingness to maintain the program post-funding.
Aim 3: Conduct a process evaluation and content analysis to assure adherence, feasibility (e.g. using the telehealth tablet at home), reach, and maintenance to inform dissemination and adoption.
Exploratory Aim 4: To assess efficacy and outcomes of PaM when research staff implements the Intervention.

B. Significance and Innovation:
This trial examines patient-centered (PWD) outcomes when changes occur in behavior and in the environment. We lay the groundwork to examine the effectiveness and sustainability of a train-the-trainer program that could be disseminated and adopted by national organizations and community agencies through various media to manage mealtimes for this vulnerable population. With the demographic changes and resulting CG burden, comes the need for changes in the way health services are delivered. Tailored and dynamic plans that manage meals need to be developed, and care needs to be delivered in the community, where older people prefer to live and where resources are accessible and tailored to the culture and context. Along these lines, the PaM intervention focuses on two community sites – the home where meals are delivered by the CG, and the RCC where volunteers and staff assist with meals. Our implementation model uses

the train-the-trainer approach (train volunteers or staff to then train CGs) to deliver an intervention posited to change QOL issues for both the CG and the PWD, as well changing nutrition-related outcomes in the PWD. Several major nutritional enhancement initiatives to date have focused on CGs or PWDs but not both, as does the PaM program. There have been some successes among community-based programs that improved CGs health parameters and their ability to handle behavioral issues. However, studies are needed that describe capacity-building community interventions for the CG that influence PWD health parameters beyond QOL, which is notably influenced by CG health. Although our intervention is targeted to Respite centers, it could be easily extended to Adult Day Centers (medical model) that provide respite services to families. The impact of the proposed study is translational as it effectively builds upon the foundational NIH supported studies (REACH, Savvy Caregiver, NYUCI) one of which, the Savvy Caregiver, has been translated into a 'transportable version', something we feel we are close to achieving in this efficacy study and will use a component of in our 'enhanced usual care' group. Furthermore, this study addresses an unexplored important area – patient-centered outcomes related to a dyadic interaction - impact on PWD health. The focus to date on CGs outcomes implicitly assumes that change in that domain will yield positive results for 'patients'. If PWD health benefits are demonstrated, this may lead to a potential policy implications related to CG support.

Innovations proposed by this study are five: a potential to change how and where services in dementia caregiving are delivered; potential to demonstrate a novel Train-the-Trainer model using volunteers or staff-CG dyads supported by a tele-health intervention; a focus on multiple dyads (i.e., PWD-CG, CG-volunteers or staff, volunteers or staff -PWD); the use of technology to enhance management of a disease that often leaves CGs isolated and unsupported; and a development of a low-cost sustainable intervention.

C. Rationale and Approach:

Study Overview:

Collaborating with the 2 respite care organizations and up to 180 subjects, a cluster design will be used to determine the efficacy of the Partners at Meals (PaM) train-the-trainer program compared to enhanced usual care (EUC). Two groupings of sites will be created in attempt to balance size and racial distribution: the largest site, which is racially diverse (The ARK), will be paired with a site (in the Respite Care Charleston system), which is not diverse: Together they will be one Site for treatment condition and analysis. The other four sites in the Respite Care Charleston system that together have approximately the same diversity and size, will be joined to create a second Site. These two Sites will then be randomized to PaM and EUC. All subjects (PWD, CG and RCC volunteers) will be followed for 6 months or until discharge or voluntary termination. The biostatistician will determine the cluster randomization. An ongoing process, impact and outcome monitoring plan is planned.

We will conduct an **'enhanced usual condition'** training to identify ways that CGs communicate with family and friends to delegate challenging aspects of caregiving. Inspired by a unit of the Savvy Caregiver, the EUC will include a 30-minute presentation at sites with a follow-up 30-minute role-play regarding identifying challenging issues, ways of communication and ways to share those elements of caregiving that could be accomplished by others. When the site 'comes on board', the Program Manager will deliver the training and repeated every 6

months while the project is in progress for new CGs. Additionally, the staff of the EUC sites will be included in the teaching, and will facilitate discussion with the CGs during the interim. The program staff will attend the EUC site's support group every two months (or more frequently if needed) to see if CGs need guidance and discuss issues with the EUC staff.

Further, every attempt will be made to include PWDs with similar levels of cognitive/behavioral disabilities in both the PaM and EUC conditions; however, since this is cluster design, we cannot assure an equal balance.

In order to further assess the feasibility aim of program replication and widespread adoption, an online global survey of Respite Care Providers and their respective agencies will be conducted on the use of telehealth/videoconferencing technologies to deliver individualized educational support services to families in-the-home. The researcher devised survey will examine provider attitudes and opinions towards using these technologies to deliver individualized educational support services to families at their respite RCCs.

D. Research Design and Method:

AIMS 1,2 and 3

Recruitment, enrollment, participant eligibility South Carolina is largely a rural state with more than 1/3 of the population identifying themselves as African American (AA). We chose two agencies that serve a diverse group of families at five sites in Charleston, Berkeley and Dorchester counties. The sites chosen are largely in Medically Underserved Areas of South Carolina. Both agencies and Executive Directors (PL, JH) have long-standing relationships with the PI (TK) and have been the sites of prior research and shared funding. Furthermore, our team has a long-standing relationship of improving care in the community, supporting each other in submissions to foundations and state agencies, teaching staff and families, acting as sites for data collection, and assisting with fund-raising for close to 15 years.

The intervention is designed to benefit important target groups: persons with dementia (PWD); home caregivers (CG); volunteers or staff at the RCC sites (volunteers or staff); and RCC administrators/managers. In the centers, the Program Manager will work with the RCC Manager and volunteers or staff to identify PWD and CGs that might be willing to volunteer. They will support this effort by announcing the study in their web-based newsletter, through take-home fliers, and announcing the study at support groups where the PI and Co-PI (TK, SQ) and Program Manager will make planned visits to answer questions and demonstrate the tablet platform. Due to the 6-month project length/dyad, we will over-enroll by 25%.

Exploratory AIM 4 Design Overview

Exploratory AIM 4 includes MUSC research project staff to implement the intervention to CG and PWDS residing at home and receiving respite services. The past 14 months brought limitations to in-person meeting and programming in respite care centers affecting clients, volunteers and staff alike. Electronic platforms including Telehealth are now more commonly used and will be used to eliminate some of those barriers by making the intervention available to those not ready or able to engage in respite center programming or attending respite centers currently experiencing fewer Volunteers prior to the COVID pandemic.

Recruitment, enrollment, participant eligibility South Carolina is largely a rural state with more than 1/3 of the population identifying themselves as African American (AA). We recruit in through partnerships with agencies that serve a diverse group of families often in Medically Underserved Areas of South Carolina. Councils on Aging, homehealths, community centers and formal and informal respite centers are all places where Project Staff has formed connections to support and recruit for this project through web-based newsletters, through take-home fliers, social media announcements and announcing the study at support groups.

AIMS 1, 2 and 3 Eligibility criteria for the Volunteers or Staff; be a regular volunteer or staff with current affiliation of working or have worked at RCC within the last 12 months and is amenable to commit to the 6 month length of the study; able to read and speak English, identify as comfortable in the teacher/coach role, and demonstrate ability to use televideo and photograph.

(All AIMS) Eligibility criteria for Persons with Dementia (PWD): aged ≥ 45 years; diagnosis of Alzheimer's disease or related dementia with mild to moderate stage as demonstrated by the Functional Assessment Staging Scale (FAST) of 4 or greater; absence of wasting disorders (e.g., HIV/AIDS, heart or renal failure or COPD, end-stage cancer) ; some supervision required or dysfunctional behavior present (e.g., redirection); not receiving enteral feeding or active treatment by a speech pathologist/therapist; not diagnosed with dysphagia as identified by CG or on RCC Intake Sheet. Those enrolled in or qualifying for hospice will not be included.
Eligibility criteria for Caregiver (CG): is not paid for services; provides 4 hours or more of care/day; assists with ADLs including meals; be able to speak and read English. This study will not enroll persons for whom English is not their primary language. We acknowledge this essentially excludes older Hispanic persons who are solely Spanish speaking. However, we plan to create a culturally tailored intervention for this population in future work. **AIM 4 Have or have access to computer with internet connection.**

Eligibility criteria for the Administrators/Managers: assumes an administrative position within the respite care site (PaM or EUC) who has worked with the organization for at least 3 months and plans to be in place for at least 9 more months.

The introduction of the study and consenting processes are described in Protection of Human Subjects.

Intervention (Partners at Meals):
(AIMS 1,2,3) The intervention (PaM) is a train-the-trainer process. This process is primarily overseen by the PI (TK); she will also be available for further training and consultation. The intervention begins with 3 initial sessions (each 90-minutes over 2 weeks) by the project staff trained in adult education and will occur in the intervention sites; and they will be repeated as needed in each RCC for all new volunteers. These **initial sessions** will include: an introduction to dementia and mealtime issues along with an evaluation; principles of adult education; and application and refinement of assessment and teaching skills with an evaluation. There will be **booster sessions** (90-minutes) after the first 6 weeks of training or as needed with project staff for all volunteers that include: challenges of implementation; application and refinement of

assessment and teaching skills. There will also be **observation of the volunteer or RCC staff-CG dyad** by the research project staff and RD (initially) and monthly by the project staff based on feedback from the RCC staff and CG through self-report questionnaires to include skills in assessment, mealtime issues and teaching. The plan will be reviewed during the first month, then monthly for the remainder of the 6-month intervention. Thus, the mealtime intervention is occurring, being evaluated and modified monthly based on the Place/ People/ Person of the Partners at Meals model.

Furthermore, under the supervision of project staff trained in adult education and the Registered Dietician (RD) the intervention delivered by the RCC volunteer or staff with the CG and PWD dyad will be **tailored to the PWD based on the initial assessment** of health conditions, nutrient intake (initially assessed a pre-post measure of food consumed at the RCC and at home), mealtime behaviors (EdFED XL), and perceived quality of life (QoL-AD) . Cultural factors will be ascertained via structured checklist that will allow further modification (e.g., avoidance of meat/fish products, food blessing rituals, eating of hot and cold foods with certain medical conditions). Perceived barriers, preferences, motivation and confidence in making change will be assessed by the Program Manager and Registered Dietitian (RD). Working with the Program Manager and the RD, the **RCC volunteer / staff or MUSC Project Staff (AIM 4) and CG will devise an <u>initial</u> plan of care for mealtimes**. An RD was chosen to be a part of the initial planning since the PWD who attend RCC programs may have co-morbidities as well as pharmacological therapy that may influence nutritional status and diet choice. Furthermore, the RD will use **assessment of nutrients and calories consumed based on digital pre-and post-photos (taken on the tablet) and food logs** that may warrant changes in the plan based on health changes or as other information is available, e.g. food insecurity.

The project staff **under the supervision of the PI (SQ) will be trained in the use of the tele-**health component in of the intervention; she will also be available for further training and consultation. Research Staff will then train the volunteers or RCC Staff and the volunteers or RCC Staff will train the CGs in an initial training and at the same times for booster sessions and observations as the mealtime plan (above). After instruction in the use of the tablet, the CG will make monthly photos and films of a breakfast, lunch and dinner using the tablet provided. These images will either be **sent via a password-protected HIPAA compliant system – Doxy.me** to be evaluated by the Volunteer or RCC Staff and the research staff. Alternatively, the tablet can be brought to the respite care site and images downloaded there. In partnership with the Volunteer or RCC Staff, and research staff, a plan will be made to either continue the activities in the current plan or to revise it. The **plan will be made initially after enrollment based on the tele-health images and the evaluation measures** (see next section)**,** then **monthly** for the remainder of the 6-month intervention; the CG and Volunteer or RCC Staff will document their agreed upon plan with the goal of the CG becoming the 'lead' in the planning as time progresses to promote sustainability. During the intervention, the CG and Volunteer or RCC Staff or MUSC Project Staff (AIM 4) will **meet at least monthly** at the RCC in a private room or via DOXY.ME on the Tablet to review progress and resolve issues; the research project staff will attend the first two of these meetings to assure fidelity and facilitate the process (the RD may be consulted during these times or more frequently if needed). Thus, the mealtime intervention is occurring, being evaluated and modified monthly, based on the Place/ People/ Person of the Partners at Meals model. The RCC administrator/manager, staff and volunteers (and possibly the

RD) will have planned interactions with the Program Manager at one-month intervals to assess use of resources, skills and beliefs of RCC staff, satisfaction with the program and suggestions for improvement.

Administrators/Managers at the respite sites **will be interviewed** by the Program Manager every 3 months that the study is in place for satisfaction, willingness to continue the program after completion, any CG or volunteer dissatisfaction, and are asked for data regarding discharge or hospitalization of study participants to determine if the cause could be related to nutrition-related changes. The Administrator/Manager and the project staff will 'check-in' every month, or more often if needed, to report any urgent problems or issues that need a timely resolution. However, the Administrators/Managers will not be consented as they are not research subjects but engaged in research (Offsite form attached) and we will be collecting feasibility and evaluation/satisfaction information from them. **Formal evaluation** of the Volunteer or RCC Staff, CG and PWD will occur at baseline, monthly and at the end of enrollment (6 months) or earlier if the CG or PWD withdraw or are withdrawn (see next section).

If requested, a step-by-step outline of the sessions used to train the Volunteer or RCC Staff, and then the CG by the Volunteer or-RCC Staff as well as 'booster' sessions can be provided to the IRB, as well as weekly and monthly review activities accomplished by research team members.

Measures, data sources and collection. As noted in the Aims, there are key outcome measures of interest as well as mediating and moderating variables to address secondary aims. This briefly summarizes the primary outcome measures, describes the dependent measures to address the primary study aims and summarizes all measures, collection mode and timing**. All data will be collected at baseline, monthly and when completed – at 6 months** to approximate the effect of the PaM or EUC on the groups separately and in unison. All participants at both the PaM and EUC sites will receive all measures. The primary measures against which the study is powered lie with the PWD and are **weight change** and **change in dysfunctional behavior**.

1. Person with Dementia measures:
Demographics collected only at baseline:

- Functional Assessment Staging Scale – level of independence in physical activities
- Mini-Mental Status Examination – rates level of dementia
- Characteristics – age, race/ethnicity, primary diagnosis/ health problems with focus on swallowing problems and possible dysphagia

Outcomes collected baseline, monthly and completion

- Body weight and caloric intake – weight before meal in street clothing less outer garments; intake measured by images taken with tablet pre- and post-meals at pre-arranged times
- Edinburgh Feeding in Dementia Scale (EdFED XL with added questions) – 24-item scale for dysfunctional meal-related behaviors (images from the tablet may assist in validating behaviors in question)
- Quality of Life in Alzheimer's Disease (QOL-AD) – 13 item instrument used in person with MMSE as low as 4

2. Caregiver measures:
Demographics collected only at baseline

- Age, race/ethnicity, employment, relation to PWD, living arrangement, hours/day caring for PWD

Outcomes collected baseline, monthly and completion

- Center for Epidemiological Studies – Depression Scale (CES-D) – widely used in CG studies
- Zarit 12-item Burden Scale – rated 0 – 4, used in prior CG studies
- European Quality of Life (Euro-QL) – measures health-related quality of life
- Self-efficacy for Change – based on CP3 Model (developed in pilot work)

3. Volunteer or RCC Staff measures (AIMS 1,2 and 3):

Demographics collected only at baseline

- Age, race/ethnicity, preparation for volunteer role including coursework or classes or personal experience as CG, frequency of attendance, years in role

Outcomes

- Self-efficacy for Change – based on CP3 Model instrument (developed in pilot work)
- Performance measures – self-report of fidelity to treatment, carry out or change mealtime plan, address questions, training issues, progress and participation (developed in pilot work)

4. RCC Administrator/Managers measures

Demographics collected only at baseline

- Age, education, training, years in role, roles and responsibilities, role as CG

Outcomes

- Overall satisfaction of staff and CGs
- Satisfaction with implementation issues, satisfaction with program, willingness to continue
- Discharge status of any PWDs in study – to institutional care, hospitalized related to nutrition-related problems

Online Global Survey of RCC providers

An online global survey of RCC providers will be conducted using a researcher developed survey instrument. The survey will explore RCC telehealth/video conferencing capabilities, their use pre and post the onset of the COVID-19 pandemic, and RCC provider attitudes and opinions towards communicating and delivering individualized and in-the home educational support services to caregivers and their families with these types of technologies.

The survey itself will be conducted via an online REDCap survey link that will be widely and electronically disseminated through local, state, national and international network of RCC provider agencies and member associations – who will in turn share the link and opportunity to participate in the survey with their members on their listserves and organizational websites. No PHI will be collected, a waiver of HIPAA authorization and consent will be utilized, as written consent is deemed impractical for a study of this design. Survey instructions will however be devised in accordance with Federal Regulations and MUSC IRB policy: - so, as to include information about the study, its purpose, the demands, risks, and a statement that by submitting their responses that the individual is voluntarily agreeing to participate in the research study. We are aiming to sample at least 120 participants, globally. As no identifiable PHI will be collected,

the risks associated with this participation in this portion of the study are considered minimal. Study compensation will not be provided for survey participation.

Eligibility criteria includes:

- aged 18 years and older;
- male and female employees at RCCs;
- ability to read and understand English; and,
- must have internet access.

Statistical analyses:
Responses to all items are not required to complete the survey. All responses will be evaluated with descriptive analyses under the intention-to-treat principal (ITT). Descriptive analyses will include frequency tables for categorical variables and mean, standard deviation, minimum, 1st quartile, median, 3rd quartile, and maximum for continuous variables. Data will be stratified by demographic variables. Additional analyses will evaluate the association among survey elements using appropriate statistical techniques based on the nature of the data and the research question(s). Categorical variables will be compared with other categorical variables using the chi-square or Fisher's Exact test and with continuous variables using ANOVA or a non-parametric alternative. Associations between pairs of continuous variables will be assessed using the Pearson or Spearman Correlation Coefficient. Finally, generalized linear models may be used for exploratory statistical modeling of outcomes of interest from this survey. Survey results will be shared with member associations and organizations, who will in turn share them with their members, ie. the survey respondents.

E. Protection of Human Subjects

1. Risk to subjects:

a. Sample
The proposed study will include 60 persons with dementia (PWD) and 60 caregivers (CGs) from 5 respite care centers (RCCs), approximately 33-57 ADC volunteers or staff and administrators/managers (will participate but are not considered subjects). The total number of persons counted for the Enrollment Tables is 180 persons. Both the PWD and his/her CG will be enrolled in this study and the PWD must attend one of the RCC sites for care at least once weekly. Additionally, volunteers will be enrolled who are long-time (defined as volunteering for at least 3 months or longer), and are present at least weekly. RCC Staff will have current affiliation with or have worked at the RCC with the last 12 months and are amenable to commit to the 6 month length of the study.

This is a cluster-randomized trial so each RCC whether in the EUC or PaM groups will be added every 2 months. For both types of conditions, the involvement of these participants includes: recruitment, consent and enrollment into the study; gathering of baseline data including an analysis of the percent of food eaten pre- and post-meals via a still photo, other assessments collected by an in-depth interview that will take about 1 hour. At this point in the **Intervention (PaM) group**, a train-the-trainer program will now be shared with RCC staff in the intervention site and within two weeks, under the direction of the Program Manager and with input from the

Registered Dietician, the RCC volunteer or RCC Staff will work with the CG to devise an initial plan of care for the PWD; this plan will be operationalized both at home and in the RCC (see Intervention – Partners at Meals). Additional training for new volunteer and booster sessions are planned. Monthly the RCC volunteer or RCC Staff and CG 'partnership' (dyad) will meet to determine if the plan is still working, and if adjustments need to be made with the help of the Program Manager or his/her designated staff member, and Registered Dietician, if needed. The intervention lasts 6 months and during that time, data are collected every month. Reasons for withdrawal are: death, institutionalization, and discharge from the RCC. Additionally, the administrator/manager of the RCC will be interviewed every 3 months that the project is ongoing (could be up to 2.5 years) to determine their satisfaction with the project, use of resources, and willingness to sustain the project.

Those in the **Enhanced Usual Care (EUC) group** will have data collected at the same intervals (baseline, monthly or withdrawal) and the administrator/manager will be interviewed every 3 months. At the conclusion of the project in each site for those in the EUC sites, the Program Manager will provide the initial training sessions to the RCC volunteers at these sites.

The persons with dementia (PWD) and the caregivers (CG) could be considered vulnerable groups. Enrollment including the informed consent process and their continued participation will be based on several issues. All conversations, assessments and consenting will occur in a private room in the RCCs. The PI is very familiar will all of these sites and they all have a private room. The voluntariness of this research will be stressed every month that a CG completes their assessment; if a CG does not complete the forms requested every month after a second request, they will be asked by the Program Manager (not the RCC staff) if they consider the study to be in any way a burden, and will be withdrawn unless they state they wish to continue. PWD will be asked to assent to the Informed Consent and will be asked their assent to continue in the study every month. If at two separate times they decline, the PWD will be withdrawn from the study.

All CGs enrolled in the study, whether in the PaM or EUC arm, will receive $50 at enrollment and **$50 per month for every month** they are enrolled in the trial. It is expected that since the CGs live with or on the same property as the PWD, that this money will be considered shared. RCC volunteers or RCC Staff receive **$100 for every CG with whom they partner**. Volunteers or RCC Staff receive $100 for each PWD/CG dyad they work with for at least one month; there is no further remuneration. It is possible that over the life of the project within any agency, the volunteer may work with more than one PWD/CG dyad and thus be eligible for $100 for each dyad with whom they assist. The total remuneration will be based on the total number; for example, if a volunteer works with 3 PWD/CG dyads, they would receive $300. **The total number of dyads that any one volunteer** or RCC Staff **can work with is 5 and thus the maximum reimbursement would be $500. (**This is below the $600 limit for IRS reporting.) For every year that the site has participants enrolled in the study, they will receive **$10,000 to provide for the extra resources, time, and data collection** that this study will impose.

To be eligible for the study, **potential PWDs will need to be**: aged 45+ years; receives 4 or more hours daily of care; Functional Assessment Staging (FAST) score of ≥4 with supervision required at mealtimes; not enrolled in hospice; not receiving enteral feeding or active treatment by a speech pathologist; not diagnosed with dysphagia. **Caregivers will need to be**: someone

who lives with or near the PWD who is also enrolled in this study; providing 4 hours of care/day; assisting with ADLs including meals. **RCC volunteers must be** long-term volunteers (at least 3 months) and must be present at the RCC at least weekly. RCC Staff that participate in the study will have current affiliation with or have worked at the RCC with the last 12 months and are amenable to commit to the 6 month length of the study.

Administrators/managers will be the Administrator/manager of record.

b. Sources of materials:
Research materials will be obtained directly from participant in-person or telephone interviews, direct observation with checklists, and direct standing weight obtained at the RCC. Data collected directly from participants that will be recorded include social, psychological, medical, functional, and health factors related to nutritional intake, weight, and dietary intake. All information obtained will be used solely for research purposes and participant confidentiality will be assured. This will be explicitly disclosed in the Informed Consent Form and carefully reviewed with potential participants. Private information, including name, address, telephone number, and address that are individually identifiable will be collected from study participants for the purposes of this research. Such private information will be coded and each individual will be assigned a study identification number. A key will be created to decipher the code. Only the PI and Co-I, Program Manager, Research Assistant, and Registered Dietitian will have access to this code. This is because they will be contacting caregivers in their homes. Furthermore, all data will be stored in the MUSC secure REDCap database, which was used successfully in our SCTR-funded pilot study.

c. Potential risks and planned protection:
This study involves the criteria for minimal potential risk to participants. Risks of the intervention are primarily those associated with collection of confidential information. Additionally, it is possible that some of the suggestions offered by the Program Manager and Registered Dietitian may not be part of a participant's usual routine and these may cause psychological distress. Because the intervention is guided by participants' preferences and individual circumstances, the likelihood of this occurring is low. It is also possible that participant may feel tired or burdened while participating in the study. This risk is also low based upon our past experience in researching CGs and PWDs. We are careful to ask about ostensible indicators of swallowing problems – choking, coughing, and turning the head or resistance to assistance. In discussion with Dr. Bonnie Martin-Harris, a leader in the field of dysphagia and Past President of the Dysphagia Research Society (personal communication, July, 2015), there will be no swallow screening in this project. The current training intervention directs any RCC staff or CG who observes indicators of swallowing problems to contact their healthcare provider immediately; Dr. Martin-Harris felt that this precaution was sufficient. Dr. Martin-Harris's successor, **Dr. Heather Bonilla – also an expert SLP clinician and researcher, has agreed to sit on our DSM group.** Additionally, if any PWD is found to be losing more than 5% of their body weight during the 6 months of the study, we will contact the CG and ask them to notify the PWD's healthcare provider.

2. Adequacy of Protection against Risks

a. Recruitment and Informed Consent

At this point, the Administrator/Manager of the RCC will be given an opportunity to ask any questions, and will be consented. Once the sites are established and matched, the PI and Program Manager will visit all sites and hold an informational session at a time convenient for staff, volunteers and CGs; we realize there may be multiple meetings required. We will publicize the study in newsletters and fliers sent home. We will then screen all interested volunteers and CGs and question the CGs generally about the PWDs mental and functional capacity. Every RCC site has private rooms and we will conduct initial meetings and all interviews in these private rooms. After meeting all eligibility requirements, we will approach the RCC administrators, volunteers, CGs and PWD regarding consent.

Due to scheduling and coordination challenges with CGs at the RCC during their normal hours of operation, we will employ both face-to-face in-person consenting as well as remote Electronic consenting.

In a private room within the RCC at a time agreeable to the potential participant, the Program Manager will describe the study protocol and informed consent in detail, including reading the informed consent form. She/he will ask the potential participant (RCC volunteer or RCC Staff, CG, and PWD if able) if he or she has any questions and if they understand the consent form. She/he will ask the participant to describe their perception of what they have read or been read in order to ensure informed consent. Extra care will be taken to ensure that the participant understands that he or she is agreeing to participate in a cluster randomized controlled trial. Care will be taken to ensure that he or she does not believe they will be receiving treatment in the study or that continued receipt RCC services is dependent upon participation in the study. Additionally, the consent form will explicitly describe that adverse health information (e.g., weight loss, possible dysphagia) related to dementia will be shared with the health provider, if the CG agrees. Past studies conducted by the PI affirm that PWD should at encouraged to assent at least monthly, and whenever possible consent to research if legally able; if not, consent will be given on their behalf by someone legally empowered to do so. Once RCC volunteers, CGs, and PWDs are consented and HIPAA forms are completed for the CG and PWD, we will randomize the sites.

Electronic or e-Consenting will be performed on eligible CGs and PWDs that want to participate in the study but are unwilling for whatever reason and/or unable to attend a face-to-face informed consent meeting at the Center. Families identified through the study recruitment processes that fall into this category will already have spoken with the researchers, have been introduced to the study and its demands, as well as had their initial questions answered. After speaking with the researchers, families that are further interested in study participation will be asked to provide an email address at which they will receive a REDCap survey link containing a scanned image of the currently approved Informed Consent document (developed from the MUSC REDCap e-consent template). Families will be able to take as much time as they like to read the consent document together in the comfort and privacy of their own home or at a place and time of their choosing. Prior to providing their physical e-consent, the researchers will coordinate with these families; so as to be on the telephone and be available to further answer any questions that they may have during the e-consent process. Should a participant have any questions or concerns about the study, the researchers will address these issues to the best of

their abilities and knowledge. Upon submitting the e-consent, a REDCap trigger will immediately notify the researchers, who will then provide their countersignature to the document.

Participants will be able to download a copy of their executed informed e-consent/HIPAA authorization forms directly to their own computer, or have copies emailed to them. They will also be given the option to have a copy of their executed e-form mailed to them should they elect to do so. A copy of the executed e-consent will also be stored in the participant's electronic case record for monitoring and audit purposes.

b. Protection against risks including confidentiality:
Risks to confidentiality will be protected by coding participant records as described above. Additionally, all study participant records will be kept in the secure REDCap System – "a mature, secure web application for building and managing online surveys and databases. All transactions are securely delivered to the application using SSL (SHA-1th RSA Encryption;; 2048-bits). It is then transmitted internally (behind the MUSC firewall to the database server.) All transactions are logged at the server layer (http logging), application layer (REDCap logs activity to a database table), and the database layer (using both query and binary logging.) Whenever possible, all data entry will be made directly into tablets fitted with the REDCap secure application." Any signed documents will have the signature page scanned and uploaded into REDCap. A separate Regulatory Binder will also be kept in a locked cabinet in the PI's (TK) locked office.

Regarding protection against other forms of risk (psychological, physical, social, etc.), several safeguards will be in place. If at any time during any interaction with study staff, a participant exhibits or expresses burden or fatigue, the session will be interrupted and arrangements will be made to resume at a later date. If any of the CGs report a level of burden of depression that is considered serious, we will ask them to report this to their healthcare provider as soon as possible or offer to make the report with their permission. If a PWD's weight is reduced by 5% or greater, or displays increased agitation during the intervention, we will inform the CG and ask to inform their healthcare provider. The PWD will be withdrawn from the study if the CG or the provider decide this is the best course.

c. Payment to participants:
As noted in Section 1.a - All CGs enrolled in the study, whether in the PaM or EUC arm, will receive $50 per month for every month they are enrolled in the trial. It is expected that since the CGs live with or on the same property as the PWD, that this money will be considered shared. RCC volunteers receive $100 for every CG they partner with – this will be paid at the conclusion of the volunteer training ($50) and another $50 after the third month of pairing with each Caregiver. Administrator/managers will not receive any direct reimbursement. We support a community-engagement approach to research and have always shared our funding with our community partners based on an estimate cost to the agency.

3. Potential Benefits of the Proposed Research to the Subjects and Others:
The benefits to participants of participating in the study are that PWD may increase caloric intake and stabilization or increase in weight. Their interaction with the CG and RCC volunteer

or RCC Staff at meals may improve their QOL. This may result in prevention of unintentional weight loss, improved function, reduced morbidity and mortality, and decreased adverse outcomes, including morbidity, institutionalization, and mortality. The benefit to others is that if this program is proven effective, other PWDs and CGs might benefit as well from its future implementation. The intervention could result in improved mental health and QOL of CGs, and the ability of RCC staff to influence the knowledge, skills and behaviors of CGs and PWDs on other issues. Administrators/managers could better manage problem issues and consider the use of tele-health as a meaningful way of communicating and assisting clients.

4. Importance of Knowledge to be Gained:

Information gathered from this study could lend support to policies designed to enhance the nutritional status of PWD, and mental health indicators of their CGs; it could provide a valuable way to increasing knowledge and skills of CGs and use RCCs as a mechanism to offer more integrated training and treatment in their facilities. Information gathered in this study could be used by foundation and organizations serving PWD such as the Alzheimer's Association, the Brookdale Foundation or various state agencies that deliver care to older adults such as the Lieutenant Governor's State of South Carolina Office on Aging to disseminate training programs specifically for community-based programs. The minimal risks involved in this study are reasonable in relation to important information that a non-invasive cost-effective intervention might provide.

a. Dissemination plan:

The investigators of this study plan to share the results with appropriate audiences – both scientific and
community based. We plan to submit abstracts to the following conferences (at least 1 annually):
1) Gerontological Society of America (November)
2) International Academy on Nutrition and Aging on Nutrition and Alzheimer's Disease (July)
3) American Association of Public Health (November)
4) Academy of Nutrition and Dietetics (October/November)
5) Alzheimer's Association Annual Meeting (July)
6) Local conferences that involve community organizations and ethnic/minority communities

Planned publications include:
1) The Gerontologist
2) The Journals of Gerontology: Health Sciences
3) Journal of Nutrition, Health & Aging
4) Journal of Applied Gerontology
5) Journal of Clinical Bioinformatics
6) Journal of Telemedicine and Telecare

The material resources used for this study (Train-the-Trainer Manual, videos, brochures, PowerPoint presentations, "Playbooks") will be shared with the community and academic partners, NIH, and the general public. Findings from this study will be disseminated and shared with community and academic partners, NIH and the general public via professional and lay publications, presentations and forums, web-sites, newsletters, or other mechanisms.

References (key – full list of 101 references can be furnished)

Administration on Aging. A Profile of Older Americans: 2014. Washington DC: US Department of Health and Human Services; 2014 [15].

Amella E Mealtime difficulties. In: Evidence-based geriatric nursing protocols for best practice. National Clearinghouse Guidelines (AHRQ). 2008. Available from: http://www.guideline.gov/summary/summary.aspx?doc_id=12267&nbr=006351&string=mealtime+AND+difficulties.

Amella EJ, Aselage MB. Facilitating ADLs by caregivers of persons with dementia: The C3P Model. Occupational Therapy & Health Care. 2014;28(1):51-61. PMCID: PMC4487525.

Bellg A, Resnick B, Minicucci D, Obedegbe G, Ernst D, Borrelli B, et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol. 2004; 23(5):443-51.

Gaskill D, Isenring E, Black L, Hassall S, Bauer J. Maintaining nutrition in aged care residents with a train-the-trainer intervention and nutrition coordinator. Journal of Nutrition, Health and Aging. 2009;13(10):913-7.

Gaugler J, Kane R, Kane R. Early community-based service utilization and its effects on institutionalization in dementia caregiving. The Gerontologist. 2005;45:177-˘85.

Hepburn K, Lewis M, Tornatore J, Sherman C, Bremer K. The Savvy Caregiver Program: The demonstrated effectiveness of a transportable dementia caregiver psychoeducational program. Journal of Gerontological Nursing. 2007;33(3):30-6.

Locher J, Bales C, Ellis A, Lawrence J, Newton L, Ritchie C, et al. A theoretically based behavioral nutrition intervention for community elders at high risk: The B-NICE randomized controlled clinical trial. Journal of Nutrition Gerontology & Geriatrics. 2011;30(4):384-402. PMCID: PMC3495161

Instruments:

Bedard M, Molloy D, Squire L, Dubois S, Lever J, O'Donnel M. The **Zarit Burden Interview**: a new short version and screening version. The Gerontologist. 2001; 41:652-7.

EuroQol. What is **EQ-5D**? Rotterdam, The Netherlands: EuroQol Group; 2009. Available from: http://www.euroqol.org/home.html

Folstein M, Folstein S, McHugh P. "**Mini-Mental State**": A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12:189-95

Radloff L. The **CES-D scale**: a self-report depression scale for research in the general population. Applied Psychological Measurement. 1977; 1:385-401.

Reisburg B, Ferris S, deLeon M, Crook T. The **Global Deterioration Scale** for assessment of

primary dementia. American Journal of Psychiatry. 1982;139:1136-9. (FAST Scale)

Serrano-Aguilar P, Lopez-Bastida J, Yanes-Lopez V. Impact on health-related quality of life and perceived burden of informal caregivers of individuals with Alzheimer's disease. Neuroepidemiology. 2006;27(3):136-42.

Watson R, Green S, Legg L. The **Edinburgh Feeding Evaluation in Dementia Scale #2** (EdFED #2): convergent and discriminant validity. Clinical Effectiveness in Nursing. 2001;5(1):44-6.

Watson R, MacDonald J, McReady T. The **Edinburgh Feeding Evaluation in Dementia Scale #2** (EdFED #2): inter- and intra-rater reliability. Clinical Effectiveness in Nursing. 2001;5(4):184-6.

5. Data Safety Monitoring Plan – (2/14/17 an 8-page DSMP was filed with the NIH/NINR, is copied here and added to final documents at close of this IRB application)

DATA AND SAFETY MONITORING PLAN (DSMP)

We proposed a Data Safety Monitoring Committee due to the lower risk of this study and have received no feedback from NINR (funder) to the contrary.

SECTION A. Monitoring Entity

Considering the study rationale, population, procedures, and the risk: benefit profile, the overall risk level for participation in this study is classified as: **Minimum Risk.** The study will employ the use of a Safety Monitoring Committee (SMC) that will meet semi-annually across all years of the study. The SMC members are charged with reviewing safety and trial progress and providing recommendations to the PIs and MUSC IRB with respect to study continuation modification, and termination.

1) Data Safety Monitoring Committee (DSMC)

The study's SMC is comprised of the following individual members:

- Heather Bonilha, PhD CCC-SLP, Dysphagia Expert (DE) and SMC Chair
- Frank Treiber, PhD, Technology for Healthy Lifestyle Expert (TE)
- Martina Mueller, PhD, Biostatistician (BS)
- Kathryn VanRavenstein, PhD, RN, Clinical Expert (CE)
- Mohan Madisetti, MS, Project Manager (PM)

2) Individual Roles and Responsibilities

Principal Investigators, (PIs). As PIs, Drs. Kelechi and Qanungo will overall be responsible for the immediate protection of all human participant study participants.

Dysphagia Expert (DE), **Dr. Bonilha** who is the Medical Director for Speech-Language Pathology for the MUSC hospital/clinic enterprise, and specializes in the areas of swallowing and voice disorders will serve as Chair of the SMC. Because of the slight chance of a person

with mild to moderate developing dysphagia, Dr. Bonilha's expertise will be valuable. As a member, Dr. Bonilha will also correspond semi-annually with the other members of the SMC to review de-identified cumulative AE study data to assess any impact on the safety of participants or on the ethics of the study and provide expert safety recommendations. Dr. Bonilha has no real or apparent conflict of interest that would affect her performance in this role on the study.

Technology for Healthy Lifestyle Expert (TE), **Dr. Treiber** is the MUSC Endowed Chair for the South Carolina Centers of Economic Excellence (CoEE) Technology Center to Advance Healthful Lifestyles and will serve as a member of the SMC. Dr. Treiber has a long history of extramural funding from the NIH and uses technology – particularly telehealth modalities to reach marginalized groups that otherwise would not receive innovations in healthy lifestyles. Because of his community telehealth expertise, Dr. Treiber's expertise will be helpful. As a member, Dr. Treiber will also correspond semi-annually with the other members of the SMC to review de-identified cumulative AE study data to assess any impact on the safety of participants or on the ethics of the study and provide expert safety recommendations. Dr. Treiber has no real or apparent conflict of interest that would affect his performance in this role on the study.

Biostatistician, (BS). **Dr. Mueller** will be responsible for conducting semi-annual interim data analyses, generating semi-annual AE safety reports from the electronic study research database and disseminating de-identified information to all members of the SMC. The interim data analyses will only include safety related results; analyses in regards to study outcome will not be performed. The interim AE safety reports will provide typology, frequency data and outcomes of all reported and documented AEs in the electronic study database. As a member of the SMC, Dr. Mueller will also participate in semi-annual SMC meetings.

Clinical Expert (CE), **Dr. VanRavenstein** is an Assistant Professor at College of Nursing and certified by the American Nurses Credentialing Center as a Family Nurse Practitioner. As a nurse practitioner, she has a diverse practice background in the areas of family and internal medicine, urology, orthopedics, cardiovascular surgery, retail and community health. She is a P20 funded researcher focusing on mHealth applications for the promotion of qualitity life among aging populations. Dr. VanRavenstein will correspond semi-annually with the SMC to review de-identified cumulative adverse event (AE) study data to assess any impact on the safety of participants or on the ethics of the study.

Project Manager, (PM). **Mr. Madisetti** will be responsible for the classification of all reported adverse events (AE) and ensuring that all serious adverse events (SAE) are forwarded to the PIs and CE in real time and in compliance with MUSC IRB and NINR's reporting requirements. In addition, and in conjunction with the PIs, the PM will be responsible for amending the protocol in accordance with the SMC recommendations, submitting reportable SAEs to the IRB, and submitting annual Progress Reports to the NIH/NINR through MUSC's ORSP. As part of the SMC, he/she will be responsible for: conducting monthly internal quality control audits on all participant records and notifying the PIs of any deficiencies; assisting in the generation of ad hoc participant data safety reports as requested; and, the forwarding of reportable SAE to the NIH/NINR Program Official through MUSC's ORSP within 72hrs of IRB review and acknowledgement. The PM will also be responsible for following up on reported AEs to monitor outcomes and provide for the continuity of care for study participants.

SECTION B. Procedures for Safety, Risk and Confidentiality

1) Monitoring Study Safety

From the initial screening of participant by inclusion and exclusion criteria to the informed consent process to the provision of participant study instruction to staff training in Good Clinical Practices (GCP) and regulations pertaining to the Conduct of Human Participant Research to weekly contact with participants to internal quality control audits and protocol fidelity monitoring to the real-time review of AE by the CE and SMC to the oversight of MUSC's IRB, procedures for monitoring study safety are consistently afforded throughout study. Since persons with dementia may have impaired judgement for decision making, their Legally Authorized Representative (LAR) will be included in all information sharing and decision-making related to this study. Specific procedures include:

- All participants will be screened for inclusion and exclusion per the protocol.
- All participants will be fully informed as to all known risks and the possibility of risk from study participation in the informed consent process. These risks are minimal.
- AEs and changes in medical status will be elicited at every participant visit and contact.
- All participants will be given a 24 hrs. AE reporting phone number to the research assistant and instructed to notify the PIs of any/all suspected or experienced adverse events whether they believe them to be related to the intervention or not.
- The CE will have access to real-time AE study data and will be able to provide immediate recommendations to the PIs and PM.
- The PM will track all reported participant AEs through to resolution. Please see Section C. 1 – 4.
- The BS shall generate semi-annual AE reports for the PIS and SMC to review.
- The PM will conduct a quarterly internal quality control audit of the study and all participant records to ensure compliance with MUSC IRB regulations and notify the PIs of any deficiencies; the PM will work with the PM to correct any errors.
- The PIs and/or designee will observe and evaluate ten (10%) percent of eligibility screening visits, informed consents and study instructions performed by IRB approved study personnel and provide feedback and/or retraining of study personnel if fidelity to both applicable federal regulations and the protocol is not observed.
- All investigators and researchers will maintain active CITI training.
- Investigator performance and compliance will be provided for through MUSC IRB and ORI study oversight.
- All reportable events, including protocol deviations will be forwarded to the NIH/NINR Program Official through MUSC's OSRP within 72hrs of IRB review and acknowledgement.

2) Minimizing Research-Associated Risk

Diligent study safety monitoring will be conducted by the PIs and all members of the SMC throughout the conduct of this study in compliance with the following required elements of MUSC IRB's continuing review process:

1. Tracking and follow-up of participant accrual including withdrawn consents will minimize risk by identifying, disclosing, and mitigating any potentially unknown risk(s) of harm to study participants. These risks are minimal.

2. Timely and appropriate reporting of informed consent process deficiencies, protocol deviations, privacy breaches, conflicts of interest, and/or changes in personnel.
3. Ongoing soliciting, monitoring and appropriate reporting of adverse event activities.
4. Timely and appropriate IRB submission of safety-related documents such as audit reports, sponsor progress reports, ISM reports, and other materials or communications that might impact the safe conduct of this study.
5. Active cooperation with the IRB, ACO, sponsor, and other applicable entities in the event of a random or for-cause internal or external audit.

Institution-Wide Assurances
This protocol will be conducted fully in keeping with the signed MUSC IRB Principal Investigator Statement of Assurance and Department Chair's Statement of Assurance, when submitted to the IRB as a required component of the MUSC IRB Human Research Review Application. An application will be submitted to the MUSC IRB if/when this project is approved and funded by NIH/NINR. Assurances include the following safety-related agreements, signed and dated by the PIs.

3) Protecting Confidentiality of Participant Data
Participant Screening and Enrollment. All data from participants screened for the study will be entered into electronic study database. Designated research staff will collect, gather, and enter required data (written informed consent, HIPAA Authorization, medical history and demographics) onto study data forms. Screened patients who do not meet study eligibility will have specific screening data entered into the study database. The collected data will be helpful in examining the patient population and feasibility of enrollment criteria and will include gender, age, race and reason for exclusion. All dates will be shifted and other Personal Health Information (PHI) will be removed from the study database upon study completion. All data obtained from this study will be used for research purposes only and will comply with Federal HIPAA regulations. Master Screening and Enrollment Logs will be maintained by the PM and will be used to prepare reports on accrual and attrition for the PIs and SMC.

Case Report Forms. All proposed study specific case report forms (source documents) for data collection will be designed by the PM in concert with the PIs and BS, and transferred by the PM into electronic Case Report Forms (eCRFs) for use in the study's REDCap database. These study specific eCRFs source documents (study logs for correspondence, contact with provider, compensation and other forms such as pre-eligibility screens) will be coded by the participant's unique study ID# for all data collected including study instruments will be maintained in the participant research record and/or their electronic medical record that will be made accessible to study monitors. Completed instruments that require signature on a paper CRF will be scanned and uploaded into the study database to all for remote electronic safety monitoring as well as maintained on file in accordance with MUSC policies and applicable Federal Regulations for the Conduct of Human Participant Research.

Binders. The PM will prepare and maintain a participant-specific binder for each participant containing all non-eCRFs records. A regulatory file will also be maintained to include the IRB-approved Protocol, original Informed Consent documents, HIPAA forms and other study-related regulatory documents. All paper research records and CRFs will be maintained in a locked file

cabinet, stored in a room for research files that is accessible only via a password protected entry system that features security cameras, within the College of Nursing. Access to the research records, study database and PHI's will be restricted to study personnel as approved by the PIs and MUSC IRB. As with all studies conducted at MUSC, this study is also eligible for a random audit by MUSC Office of Compliance.

Data Processing. This study will use Research Electronic Data Capture (REDCap) for data capture and management. REDCap is a software toolset and workflow methodology for the electronic collection and management of research and clinical trials data. REDCap provides secure, web-based, flexible applications, including real-time validation rules with automated data type and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, SATA, R and Microsoft Excel. The study-specific REDCap electronic database will be designed and developed by the PM in concert with the BS. The provision of REDCap is made available through the South Carolina Clinical & Translational Research (SCTR) Institute at MUSC with NIH Grant awards UL1RR029882 and UL1TR000062.

Data Security. Ensuring data security, compliance with 45 CFR 46 and maintaining the integrity of PHI is a top priority. MUSC has Standard Operating Procedures (SOP) to ensure a high level of data security while coordinating electronic and paper data management activities for clinical research trials. The REDCap study database will be hosted in the Biomedical Informatics secure data center at MUSC, a secure environment for data systems and servers on campus, and includes firewall, redundancy, failover capability, backups and extensive security checks. The secure data center has strict access control; only authorized core personnel may access the facility un-escorted. Only authorized users are allowed to connect to the network, and the security of the network is actively monitored. Power and environmental controls have several layers of backups, from interruptible power supplies to alternate and redundant feeds to the local utility company. The REDCap system administrator contributes to the maintenance of institutional disaster recovery and business continuity plans. Load balancers and a highly fault tolerant SAN infrastructure contribute to high availability.

The REDCap system itself has several additional layers of protection including password protection. Access to the data and its security is managed institutionally by sponsored login IDs through a Shibboleth login with an MUSC issued NetID and features a user account management filter that controls who can access the data and to what degree. All personnel must pass an employment background check before being issued an ID. Password complexity, history and expiration standards are implemented at the institutional level. Access to individual REDCap projects and their data is managed by the owner of the project. All transactions are securely delivered to the application using Secure Sockets Layer (SSL – SHA-1 with RSA Encryption; 2048-bits). It is then transmitted internally (behind the firewall) to the database server. All transactions are logged at the server layer (httpd logging), application layers (REDCap logs activity to a database table), and the database layer, using both query and binary logging. This feature provides audit trails for all changes, queries, data exports and reports. MUSC Information security policies are available at: https://mainweb-v.musc.edu/security/policy/

Data Entry. Only MUSC IRB approved study personnel that are authorized to have access to the REDCap study database will be granted password access. Study personnel using computers

that are connected to the Internet will directly enter data into the remotely housed database. As such, no electronic study data will be stored on hardrives and/or any portable electronic devices. Additionally, all personnel with access to the database will have current University of Miami CITI training in the Conduct of Human Subject Protections, and their respective institution's HIPAA and Information Security trainings that are completed annually. Each participant will be assigned a unique study identifier, all PHIs will be masked, and data exports will be limited to the PIs, the PM and the BS for generating reports and the conduct of statistical data analysis.

Data Monitoring. Ongoing quality control procedures will be implemented for data collection, storage and processing. The PM will conduct monthly monitoring of the study database and generate a report for the PIs to review at team meetings. Standing agenda items for these meetings will include participant recruitment and retention, AE's, protocol deviations, data integrity and overall study conduct. The PM will work to resolve and validate discrepant data. Discrepancies that warrant clarification will be sent to appropriate parties for review and resolution. All data entry and changes made in the study database by authorized study personnel will be automatically logged by REDCap, and provide a transparent visible audit trail for reviewers.

SECTION C.
Procedures for Identifying, Reviewing and Reporting Adverse Events
1) Identifying. Potential minimum risks identified for participants are outlined in the Protection of Human Participants and will also be outlined in the IRB-approved informed consent document. Additional unknown risks may occur and, if so, will be identified through diligent monitoring by the PM and the frontline research team throughout the conduct of this study. During the informed consent process, participants will be advised of the potential minimum risks of participation as identified in the IRB-approved informed consent document and reminded throughout the study that the researchers should be promptly informed about any concerns regarding potential side effects, adverse events, or clinical deterioration. Participants will also be instructed to notify the PIs and/or designee of any suspected adverse events immediately if possible. Throughout the course of study enrollment, at each study visit, the researchers will elicit information about experienced AEs and monitor participant progress. The PM will maintain an electronic record of all reported adverse events and notify the PM and CM of all reportable events as they occur. The CM will have real-time access to the study database to review and monitor all SAEs that were reported as related to the intervention. The PM will generate and provide de-identified semi-annual administrative human participant safety reports for the SMC to review participant progress, accrual and attrition rates. Additionally, the BS will generate semi-annual safety reports for the SMC to provide for the monitoring of the frequency of all reported side effects and AEs.

2) Reviewing. Adverse events will be assessed and evaluated by the members of the SMC according to the following MUSC's IRB Adverse Event Reporting Policy http://academicdepartments.musc.edu/research/ori/irb/HRPP/HRPP%20Guide%20Section%204.7:

- Expected/Anticipated—Identified in nature, severity, or frequency in the current protocol, informed consent, investigator brochure, or with other current risk information.
- Unexpected/Unanticipated—Not identified in nature, severity, or frequency in the current

protocol, informed consent, investigator brochure, or with other current risk information.

- More Prevalent—Occurs more frequently than anticipated or at a higher prevalence than expected.
- Serious—Results in death, is life threatening, requires inpatient hospitalization or prolongs existing hospitalization, results in persistent or significant disability/incapacity, cancer, overdose, or causes a congenital anomaly/birth defect.

The relationship of adverse events to study participation will be determined by the SMC according to the MUSC IRB Adverse Event Reporting Policy:

- Unrelated—There is not a reasonable possibility that the adverse event may have been caused by the drug, device or intervention.
- Possibly Related—The adverse event may have been caused by the drug, device, or intervention, however there is insufficient information to determine the likelihood of this possibility.
- Related—There is a reasonable possibility that the adverse event may have been caused by the drug, device or intervention.

3) Reporting. All reportable AE, SAE and unanticipated problems experienced by participants will be reported to the NIH/NINR and MUSC IRB in compliance with their Adverse Event Reporting Policy requirements, using the IRB's password protected on-line secure server adverse event reporting system. Within 24 hours after a reportable AE, SAE or unanticipated problem has been reported by the participant, it will be initially graded by the PM, forwarded to the study's CE for review and approval, and then will be submitted by the PIs to MUSC IRB. The Institutional Official(s) will review the event and discuss the report with the IRB Chair and the Director of the Office of Research Integrity. After IRB review and acknowledgement, the PIS will further review, and the PM will forward a copy of the reportable AE, SAE or unanticipated problem and IRB acknowledgement letter to the NIH/NINR Program Officer through MUSC's OSRP. The activities will be reported to the NIH/NINR within 72hrs. In addition, all cumulative reportable AE, SAE and unanticipated problems included in the ISM reports will be submitted to the NIH/NINR in the PI's Annual Progress Reports.

4) Examples of Potential Reportable Adverse Events: In accordance with MUSC IRB Adverse Event Reporting Policy, an AE is reportable is it meets all of the following criteria: 1) is unexpected 2) is related and/or possibly related, and 3) is serious and/or suggests that the research places participants or others at a greater risk of physical or psychological harm than was previously known or recognized. Additionally, per MUSC's policy all participant deaths, protocol deviations, complaints about the research, and breaches of confidentiality are reportable events. From our previous work among this comorbid population, an **example of an AE** would be less than 5% weight loss due to progression of cardiac disease in a person with dementia. Depending on the severity, the possible steps to be taken include referral to a medical provider, and/or withdrawing the participant from the study and inviting him or her to restart after acute symptoms subside. An **example of an SAE** would be the death of a caregiver participant from acute renal failure, which although would be viewed as unexpected and unrelated to the intervention is nonetheless a reportable serious event. No further steps would be taken except to review, grade and report the event to all applicable agencies. An **example of an unanticipated problem** would be the participant volunteer has a car accident with loss of transportation but only

slight injury (bruising/contusions). The steps in this case would be to withdraw the volunteer participant from the study and invite him or her to restart the study after the transportation is reestablished and injuries have healed. These events and problems will be reported in accordance with the IRB and NIH/NINR policy as noted in Section C.3.

SECTION D. Multi-site Monitoring and Compliance
This is not a multi-site study.

SECTION E. Assessment of External Factors
The PIs will conduct a semi-annual assessment of external factors through a review of literature related to new developments in the areas of nutrition, swallowing, mealtime interventions and other approaches that may have an impact on the safety of participants or on the ethics of the study. To determine whether any changes are necessitated to the study protocol, the SMC will review any identified literature or product safety data that may pose as a potential impact to the risk benefit ratio study and/or safety of study participants.

SECTION F. Interim Analysis
Based upon our prior extensive research in this field among this same population and the minimal risk associated with the intervention, there is no stopping rule for this study. Accordingly, interim futility analysis will not be performed. However, the BS and PM will generate semi-annual qualitative interim analysis reports on: a) adverse events; and b) data obtained during phone call and returned end-of-study surveys to understand issues related to the uptake, usability, and adoption of new feeding techniques as the dementia progresses. We will evaluate the screening and enrollment procedures, barriers to participation and retention, including, safety, adherence, acceptability, technology problems (iPad failures, internet security, etc.) encountered if any, and user feedback from all types of participants. The information gained from this structured process will inform the design for an implementation/dissemination study aimed to facilitate the Partners at Meals model broadly through a non-profit organization such as the Alzheimer's Association or the Brookdale Foundation, such that it becomes the standard of care of people with dementia living in the community.