A Tailored Technology Intervention for Diverse Caregivers of AD Patients

National Clinical Trials Number: **NCT03049501**

Study Number: 20130460

Version: 2.3

Date: May 30, 2018

1) Protocol Title

A Tailored Technology Intervention for Diverse Caregivers of AD Patients

2) Objectives*

An increasing number of adults in the U.S. provide care to someone aged 50+ years with Alzheimer's Disease (AD) or dementia. Numerous intervention programs have been developed to address the needs of caregivers and several studies have demonstrated small to moderate effects in improving both caregiver and patient outcomes. However, the impact of these programs has been shown to vary according to the characteristic of the caregiver. In addition, despite the availability of these programs, barriers such as transportation problems, insufficient support from others, lack of knowledge about available services, and cultural beliefs often limit caregivers, especially minority caregivers, from participating in intervention programs and accessing needed resources. Computer and communication technologies may help remove these barriers and enhance caregiver access to needed programs and services. However, the effectiveness of technology-based intervention programs needs to be rigorously evaluated with diverse caregiver groups given the increasing numbers of elders from minority populations, and ethnic/cultural differences in response to the caregiving situation. The aims of this study are to evaluate the acceptability and efficacy of a culturally tailored technology-based psychosocial intervention for reducing the stress and burden and enhancing quality of life of diverse family caregivers of AD patients. The intervention is designed to address known areas of caregiver risk and to foster the ability of caregivers to leverage the type of supports they need for themselves and the AD patient. The target population is Black/African American, Hispanic, and White non-Hispanic family caregivers of AD patients. These diverse cultural groups are predominant in the greater Miami community and in the larger United States older adult population. We will recruit and randomly assign 240 dyads (80 from each ethnic group) to one of two groups: 1) The Telecare Intervention Condition or 2) An Attention Control Nutrition Condition. The intervention will be home-based and delivered over 6 months using notebook technology in Spanish or English. Participants will be assessed at baseline, post-intervention (6 months after baseline), and six months later (12 months after baseline). Measures will include indices of distress, burden, health and social support and caregiving efficacy. We will also gather information on differences in response to the intervention among the three ethnic groups and the cost-effectiveness of the intervention. In addition, we will conduct moderation analyses to examine the influence of other caregiver characteristics (e.g., age; relationship to the patient; coping mechanisms) on responsiveness to the intervention and mediation analyses to identify specify components of the intervention that are linked to outcomes.

This is behavioral intervention designed to help caregivers. We believe it's a not greater than minimal risk study.

3) Background*

Alzheimer's disease (AD) is a devastating disease that erodes the quality of life and functioning of the patient, generates high levels of stress and burden on family caregivers, and results in substantial economic burdens to society. The number of individuals with AD is increasing rapidly. Today, 5.4 million Americans have AD and

the majority of these individuals (5.2 million) are aged 65 and over. It is estimated that by 2025 there will be about 6.7 million people with AD or some other form of dementia and somewhere between 11-16 million by 2050[1]. Most people with AD are cared for at home by a family member or friend. In 2011, 15 million family members or friends provided about 17 billion hours of unpaid care for persons with AD or dementia and the prevalence of family caregivers is projected to increase in concert with the projected increase in number of AD patients. Although family caregivers provide a great service to their loved one and to society, they often do so at great personal cost. Many caregivers experience adverse emotional and physical health consequences such as depression, anxiety, compromised health, and mortality. In 2011, Alzheimer's and dementia caregivers incurred $8.7 billion in additional healthcare costs due to the impact of caregiving on their own health. Caregiving also often disrupts social and family relationships and employment activities. It is estimated that the annual cost of informal caregiving in terms of lost productivity to U.S. businesses is $17.1 to $33 billion annually. Many caregivers also report that they lack the knowledge, tools and skills they need to provide care to the patient and manage their own stress [1,2,3,4,5,6,11].

There have been numerous studies testing interventions designed to alleviate caregiver burden and depression and other health-related effects of caregiving. Overall, these studies have demonstrated small to moderate effects in reducing caregiver burden, lowering depression, and delaying institutionalization. Generally, the findings suggest that treatment programs that are individually delivered, as opposed to group format and those with higher dosage, are more effective for outcomes such as caregiver depression. Further, interventions that are comprehensive and address more aspects of caregiving have been found to be more effective than those interventions that are narrower in focus [12].

The literature also indicates that the impact of these programs is uneven across different cultural/ethnic caregiver minority groups. For example, the Resources for Enhancing Alzheimer's Caregiver Health (REACH II) trial evaluated a multi-component intervention that provided education, support, and skill building, which was tailored to the risk profile of the caregiver. Overall, caregivers who received the intervention had significant improvements in burden, depression, social support, health and self-care and management of patient behaviors [9]. However, the efficacy of the intervention varied according to the ethnic or cultural background of the caregiver. Overall, the data indicated that the intervention improved the quality of life for Hispanic and White caregivers. For Black caregivers, there was a significant difference in the intervention effect by relationship indicating that the intervention was beneficial to spousal caregivers but not other family members. Other investigators [8,13,14] have also found that the efficacy of various caregiver programs varies according to the racial/ethnic or cultural background of the caregiver.

Barriers such as transportation problems, insufficient support from others, lack of knowledge about available services, and cultural beliefs also limit caregivers, especially minority caregivers, from participating in intervention programs and obtaining needed support. For example, Black/African American caregivers are less likely to use formal support services [15] and Hispanic caregivers access long term care services at lower rates [16]. Language barriers among Hispanics caregivers may also result in reduced access to educational materials and services. In our recently completed Videocare study, which

targeted Black/African American and Hispanic caregivers, a majority of the caregivers indicated they did not have information about AD or dementia, had concerns about their health and indicated that they needed help dealing with the care recipient's behavior problems such as verbal aggression. Clearly, there is a need to identify innovative intervention approaches that overcome barriers to access and meet the needs of diverse caregiver populations.

We and others [17] have found that technology holds a promising role as a mechanism for delivering intervention programs to caregivers [7,8,9,10]. Technology offers a flexible format that allows for easy tailoring to meet individual needs and preferences and an increased ability to deliver and access information and support on demand, asynchronously and over long distances. However, more rigorous evaluation of technology-based interventions is warranted especially with diverse caregiver groups since socio-demographic factors such as ethnicity/culture can have a significant influence on caregiver needs, preferences in terms of support, and caregiver outcomes. For example, Black/African American caregivers tend to report lower burden, lower depression and greater satisfaction within the caregiving role and are more likely to see caregiving as a natural part of the aging process than White caregivers. However, they also have more health problems and are less likely to engage in healthy behaviors. Whereas Hispanic caregivers tend to report higher levels of depression than White caregivers, they are similar to Black/African American caregivers, reporting worse health. Minority caregivers also typically report engaging in more hours of care and providing more help with basic ADL activities [1, 18]. Ethnic and cultural differences in the caregiving experience are also moderated by other variables such as age and relationship to the care recipient and mediating, by differences in coping styles, social support and familism [18, 19, 20]. For example, in a further analysis of the REACH II data we found that caregiver's age, available social support and religious coping moderated the effects of the intervention for Hispanics and Black/African Americans. These differences, among and within ethnic/racial groups in response to caregiving, need to be understood and accounted for in caregiver intervention programs. This is a pressing issue, given that the number of older adults from minority cultures is projected to significantly increase and the incidence of chronic conditions such as AD is higher among Black/African American and Hispanic older adult populations.

The aims of this project are to gather systematic data on the acceptability, and efficacy of a culturally tailored psycho-social intervention program that targets diverse racial/ethnic caregiver groups. The intervention is guided by the stress-process model of caregiving [21] which views the consequences of caregiving as resulting from the interrelationships among several factors including the socioeconomic characteristics and resources of the caregiver, the primary and secondary stressors to which they have been exposed and their appraisal of these stressors. Recent studies [22] indicate that this model as a whole appears to fit across different racial/ethnic groups.

The intervention also builds on the evidence-based REACH II program [9], modified and implemented via technology in the VideoCare project. The intervention represents a multi-component and structured, but tailored intervention approach, whereby the emphasis of the intervention is tailored to meet the specific needs of the individual [9, 10]. It is designed to enhance knowledge, resources and formal and informal support and reduce known areas of risk (eg, emotional distress; lack of social support).

The intervention program will be delivered through an interactive computer interface and uses computer tablet technology as a mechanism for intervention delivery. Technology offers several advantages such as increased access to information and support, especially for those who have mobility restrictions or live in isolated or remote locations. Further, the technology offers unparalleled flexibility in the presentation of information and facilitates tailoring of intervention content according to an individual's needs and interests. Although the Internet is also increasingly being used as a media for the delivery of healthcare services and information, there has not been rigorous, systematic evaluation of Internet-based interventions for caregivers of AD patients, especially within minority groups. In addition, using a web-based platform will facilitate longer-term wide scale implementation of the intervention.

The overall goal of this project is to develop an intervention program for AD caregivers that is efficacious, feasible and practical and can be implemented broadly in the community. The proposed intervention program aims to: 1) reduce the stress and burden and improve the physical, psychological and emotional well-being of diverse populations of AD caregivers; and 2) enhance the skills of and access to formal and informal support for these caregivers. The project will also increase our understanding about the caregiving experiences and needs of minority caregivers. Ultimately, the gains from the intervention program could result in improved health, quality of life and decreased health care costs for both caregivers and AD patients.

Reference

1. Alzheimer's Association. (2012). *Alzheimer's disease facts and figures*.
2. Pinquart, M. & Sorensen, S. (2003a). Differences between caregivers and noncaregivers in psychological health and psychical health: A meta analysis. *Psychology and Aging, 18*, 250-267.
3. Pinquart, M. & Sorensen, S (2003b). Associations of stressors and uplifts of caregiving with caregiver burden and depressive mood; A meta-analysis. *Journal of Gerontology B Psychological Sciences, 58*, P112-128.
4. Pinquart, M. & Sorensen, S. (2007). Correlates of psychical health of informal caregivers; A meta-analysis. *Journal of Gerontology B Psychological Sicnes, 62*, P126-137.
5. Schulz, R., O'Brien, T. A., Bookwala, J., & Fleissner, K. (1995). Psychiatric and physical morbidity effects of dementia caregiving: Prevalence, correlates, and causes. *The Geronlogists, 35*, 771-791.
6. Schulz, R. & Matire, L. M. (2004). Family caregiving of persons with dementia: prevalence, health effects, and support strategies. *American Journal of Geriatric Psychiatry, 12,* 240-249.
7. Czaja, S. J., & Rubert, M. P. (2002). Telecommunications technology as an aid to family caregivers of persons with dementia. *Psychosomatic Medicine, 64*, 469-476
8. Eisdorfer, C., Czaja, S. J., Loewenstein, D. A., Rubert, M. P., Arguelles, S., Mitrani, V. B., & Szapocznik, J. (2003). The effect of a family therapy and technology-based intervention on caregiver depression. *The Gerontologist, 43*, 521-531
9. Belle, S. H., Burgio, L., Burns, R., Coon, D., Czaja, S. J., Gallagher-Thompson, D., et al. (2006) Enhancing the quality of life of dementia caregivers from different ethnic or racial groups. *Annals of Internal Medicine, 145,* 727-738.
10. Czaja, S. J., Perdomo, D., Nair, S., & Schulz, R. (2011). *A technology-based psycho-educational intervention for minority AD caregivers*. Poster presented International Conference on Alzheimer's Disease, Paris, France.
11. Family Caregiver Alliance. (2012). *Selected caregiver statistics*. Available online at http://www.caregiver.org/caregiver/jsp/content_node.jsp?nodeid=439.
12. Sorensen, S., Pinquart, M., & Duberstein, P. (2002.). How effective are interventions with caregivers? An updated meta-analysis. *The Gerontologist, 42*, 356-372.
13. Burgio, L., Stevens, A., Guy, D., Roth, D. L., & Haley, W. E. (2003). Impact of two psychosocial interventions on White and African American family caregivers of individuals with dementia. *The Gerontologist, 43*, P568-P579.

14. Gitlin, L., Belle, S. H., Burgio, L., Czaja, S. J., et al (2003). Effect of multi-component interventions on caregiver burden and depression: The REACH multisite initiative at 6-month follow-up. Resources for Enhancing Alzheimer's Caregiver Health (REACH). *Psychology and Aging, 18*, P361-P374.
15. Miller, B., & Guo, S. (2000).Social support for spouse caregivers of persons with dementia. *Journal of Gerontology Psychological Sciences, 55*, S163-S172.
16. Aranda, M. O. & Night, B. G. (1997). The influence of ethnicity and culture on the caregiver stress and coping process: A sociocultural review and analysis. *The Gerontologist, 37*, 342-354
17. Demiris, G., Oliver, D. R., Hensel, B., Dickey, G., Rantz, M., & Skubic, M. (2008). Use of videophones for distant caregiving: an enriching experience for families and residents in long-term care. *Journal of Gerontological Nursing, 34*, 50-55.
18. Pinquart, M., & Sorensen, S. (2005). Ethnic differences in stressors, resources, and psychological outcomes of family caregiving: A meta-analysis. *The Gerontologist, 45*, 90-106.
19. Knight, B. G. & Sayegh, P. (2010). Cultural values and caregiving: the updated sociocultural stress and coping model. *Journal of Gerontology: Psychological Sciences, 65B*, 5-13.
20. Lee, C. C., Czaja, S. J., & Schulz, R. (2010). The moderating influence of demographic characteristics, social support, and religious coping on the effectiveness of a multicomponent psychosocial caregiver intervention in three racial ethnic groups. *Journal of Gerontology: Psychological Sciences, 65B*, 185-194.
21. Pearlin, L.I., Mullin, J.T., Semple, S.J., & Skaff, M.M. (1990). Caregiving and the stress process: An overview of concepts and their measures. *The Gerontologist, 43,* 583-594.
22. Hilgeman, M. M., Durkin, D. W., Sun, F., DeCoster, J., Allen, R. S., Gallagher-thompson, D., & Burgio, L. D. (2009). Testing a theoretical model of the stress process in Alzheimer's caregivers with race as a moderator. *The Gerontologist, 49*, 248-261.

4) Inclusion and Exclusion Criteria*

The study is only enrolling normal healthy volunteers. Systematically, the study will exclude:

1. People who are not providing care to a loved one with Alzheimer's disease or dementia because caregivers of other condition/illness will have different needs that are not being addressed in our study.
2. Adults who are not able to consent, individuals who are not yet adults, pregnant women or prisoners.

Study related exclusion criteria:
1. Not providing care to a loved one with Alzheimer disease or dementia
2. Not speak English or Spanish
3. Have cognitive deficit
4. Have terminal illness
5. Plan to place their loved one in a facility
6. Plan to move away in the next 12 months

Study related inclusion criteria:
1. Speak and understand English or Spanish
2. Provide care to a loved with memory decline
3. Not having terminal illness/condition
4. 18+ yrs old

5) Procedures Involved*

The study population will include White, Hispanic and Black/African American caregivers. We anticipate to screen a maximum of 350 participants and to study about 280 participants. We expect 240 participants to complete the study.

The study will be conducted in English or Spanish. We will recruit and randomly assign, following a baseline assessment, 240 (80 per ethnic group) dyads to one of two groups: 1) The Telecare Intervention Condition (TC) or 2) A Nutrition Attention Control Condition (NAC). The entire study is home-based. The intervention will be delivered over 6 months using computer tablet technology in Spanish or English. Assessments will occur at baseline, six months (after completion of the intervention) and at twelve months from baseline.

Interested participants can contact us via telephone or email. One of our research associates (RA) will provide more information about the study to the potential participants. A verbal consent will be obtained from the potential participant in order to ask them a series of questions to determine their eligibility criteria. If the participant is eligible for the study, an appointment will be provided, and one of our research associates will visit the participant and conduct the baseline assessment at the participants' homes in their preferred language (Spanish or English). The assessments (baseline and 2 follow-ups) last between 2 and 3 hours. We will be using Qualtrics (online survey/data collection service that UM has subscription to) to administer the assessments. The assessment consists of a series of socio-demographic questions (e.g., age, education, ethnicity, occupation, living arrangement), psycho-social questions (e.g., social support, depression, burden, formal care and services), caregiver readiness questions (e.g., familism scale, self-efficacy, preparedness), and physical and functional health questions (SF-12, ADL/IADL, quality of sleep, risks appraisal, quality of life). In case of technical failure, paper and pencil format of the assessment will be used.

During the baseline home visit, the RA will go over the written informed consent with the participant. The assessment will not begin unless the participant has a fully understanding of the informed consent form and has signed the form. Some assessments (randomly) will be recorded for quality assurance purposes.

The care-receivers will also complete a brief interview about their memory (e.g., today's date, spelling the word "world", doing subtractions, recalling words, and drawing pictures). Before initializing the interview, the research associate will go over the informed consent form with the care-receiver. The interview will last about 15 minutes. There are a total of 3 interviews (baseline, 2 follow-ups). They will be scheduled around the same time of the assessments with the participant. These interviews can be conducted in English or Spanish and with or without the participant's (caregiver's) presence. In the event the care-receiver can't comprehend or give consent to the interview, the research associate will get the assent from the participant before proceeding with the interview.

Upon the completion of the baseline, participants will be notified by the Project Coordinator or designee about their randomization condition: TC or NAC condition. During first intervention session, all participants will receive a tablet equipped with WiFi access. The RA will provide a brief tutorial on the usage of the tablet before starting the activities of the intervention. The TC condition will consist of multimedia (text, voice and video clips, real time interactions) features that will be placed within a customized website. The components will include: skill-building sessions and modules; an annotated resource guide; an annotated reading list; an "ask a question" feature, information and tips, expert educational seminars (video), and structured support group sessions (6 sessions). All the sessions (home-based, one-on-one, and support group sessions) will last about 60-90 minutes. The participants in the NAC condition will have access to resource

and information tips on topics related to Nutrition. The NAC condition is significantly less interactive than the TC condition as it is the comparison condition of the study. All participants regardless of their randomization condition will receive total of 8 sessions. The first and last sessions will be home based, and the rest are via tablet using videoconferencing feature.

Participants will keep the tablet for additional 6 months post intervention period. They will be encouraged to continue accessing the sites and use the available features. The last assessment (12^{th} month) will be very similar to the initial assessment with the addition of evaluation and usability questionnaires. The tablets will be retrieved from the participants after the 12^{th} month follow-up.

We have implemented different kind of follow-up assessments for the caregiving depending on their caregiving status. This might happen in the 6^{th} month or 12^{th} month assessment point.

- Regular battery: for caregivers who are still caring for their loved homes at their homes.
- Placement battery: for caregivers who placed their loved ones in a facility (e.g., nursing home, ALF).
- Bereavement battery: for caregivers who's loved one passed away during the study.
- Discontinued battery: for caregivers who refuse and/or can't spend the time to complete the regular battery. This battery will be used so we can collect data from those who refuse or terminate their participation prematurely.

During the initial assessment (baseline), if the RA learnt of information that could disqualify the participant, the RA will still complete the entire assessment. The sequence of questionnaires in the assessments (baselines and follow-ups) could vary from participant to participant. It will be determined by the PI or designee and occasionally upon the request of the participant.

Upon the request of the participant, the location of assessments and sessions might take place in an alternate location outside of their homes. However, in such instances, we will maintain the same level of privacy and confidentiality as they are originally intended for.

Also, due to the diversity of Spanish speaking participants, the RA will reword/paraphrase the battery whenever and wherever is necessary to make sure the participants understand the question.

6) Data and Specimen Banking*

The study does not collect specimens.

All the data will be stored and secured using the procedure implemented by the Data Manager of Center on Aging. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

Study data request goes through a web-based check-in and check-out procedure implemented by the Center on Aging. The Data Manager of the Center or designee monitors the logs. Upon de granting of the approval, the requester will either get the hard copy of the data or link to access the electronic data. All the data will not contain any identifying information.

7) **Data Management***

Our study design is a 3x2x3 mixed model design with 2 between subject factors (ethnicity and condition) and one within subject factor (measurement time).
Data will be double entered to insure completeness and accuracy. Initially, we will evaluate appropriate range checks, scatter plots, tests of normality and heterogeneity of variance. If there are difficulties with parametric assumptions after appropriate data transformations, non-parametric procedures will be employed. Given the goals of this study, there are a number of measures required to address specific aspects of specific aims. We have attempted to define primary caregiver outcome measures as well as secondary measures that are important in any study examining acceptability and comparative efficacy across and within racial/ethnic groups. These measures will also enable us to conduct moderation and mediation analyses and will provide important data regarding racial/ethnic differences in the caregiving experience and data to inform future refinements of the intervention. Such measures are also essential in evaluating comparative effect sizes and for the development of future clinical trials.

Our study design allows for comparisons across the three-racial/ethnic groups between the two conditions across the three time points. Our primary outcomes will be measures of caregiver depression and burden. We will also be examining social support, caregiver self-efficacy, self-care and physical health symptoms, and problem behaviors and caregiving skills will combine these measures using multivariate methods developed in the REACH II trial in which differences in 6-month and 12-month follow-up values among each group or comparisons across groups can be compared to baseline.

Our plan for the main analyses is to use the General Mixed Model. This model is suitable for analysis of unbalanced data, does not require the assumption of normality of the dependent variable (in fact it can be used when the response of interest is a binary variable or a count variable), can incorporate account for missing data in statistical models and is implemented in different analytical software packages such as the Proc MIXED in SAS. In addition to the longitudinal analysis, the model also permits cross-group analyses, which we will perform at baseline, 6 and 12 months post intervention follow-ups. We will consider models that incorporate covariates and interactions in order to examine the effects of potential mediator and moderator variables on outcomes. We are aware that given the relatively modest sample size available for some of the analyses, careful consideration must be given to potential problems such as over parameterization; thus, only a limited number of covariates will be included in each model. Post-hoc tests of means for any statistically significant main effect will be accomplished using the paired t-tests procedure. Given that there are multiple dependent measures, there is an increased possibility of spurious Type 1 family-wise alpha error. To minimize the possibility of Type 1 errors but to reduce the likelihood of a Type II error, the test-wise alpha for each F contrast will be set at $p < .01$. Post hoc tests for interactions will be

conducted using methods developed by Aiken and West.

Structure equation modeling (SEM) procedures will be used to examine if additional caregiving characteristics (e.g., age; gender) moderate the effects of the intervention on the primary outcomes and if the effects of the outcomes are mediated by variables such as familism, social support and religious coping mediate the intervention's effect of outcomes. We will develop overall models and separate models for each racial/ethnic group.

We will also examine clinically significant outcomes using methods developed in REACH-II in which a .5 SD improvement is considered clinically significant at a particular follow-up period.

All the study personnel who handle the data completed the CITI course. All the identifying information is removed from the rest of the data as soon as it reaches the Center on Aging. Only the study coordinator or designee has access to the password protected identifying information of the participant. The signed informed consent forms are stored in a separate double locked room. E-mail encryption is required when emailing any sensitive data. During transmission of large data files, we will use the "securesend".

8) Risks to Subjects*

The main objective of the study is to evaluate the feasibility and effectiveness of a culturally tailored technology-based intervention to help caregivers who are caring for their loved ones with Alzheimer' disease or dementia. The participants will be answering a series questions and working with a RA in learning skills in helping them in coping with their caregiver demands and taking care of themselves.

This intervention is a psycho-behavioral based program and the material that are derived from successful caregiving studies. Participants will not be exposed to any kind of risk. Based on our previous experience, participants might feel tired and boredom while completing the assessments. They are not exposed to any other risk while participating in this study.

We believe this is a not greater than minimal risk study.

9) Potential Benefits to Subjects*

Participants can put on practice the skills learn in the study in their caregiving activities. Their participation in the study can help with investigators in refining future technology-based caregiving intervention program to help diverse caregivers of Alzheimer's disease or memory problems.

10) Vulnerable Populations*

The study involves Normal, healthy volunteers who are capable of providing consent to participate in the study.

The research team will not use undue influence or manipulation in order to recruit study participants. Our team has extensive experience in recruiting this population and is aware of the ethical conduct necessary to protect human subjects in research. There is weekly meeting to monitor recruitment activities to discuss and review our recruitment

practices and efforts. During recruitment activities and presentations in community events, the research team provides and explains the content of the flyer to potential participants, and answers and clarifies any questions/ concerns that potential participant may have. Interested participants are instructed and directed to call the phone number or send email to the address display in the flyer.

11) Setting

The study takes place at the University of Miami Miller School of Medicine Center on Aging and the participants' homes. The intervention is technology-based, thus facilitating the communication and interaction between RA and participants. Only study assessments (baseline, 6th month, and 12th month) take place at the participant's home.

12) Resources Available

All the study personnel have their CITI certificate. The PI holds a weekly meeting with the study coordinator and data manager to review the progress of the study. At the same time, there are weekly meetings on data management and recruitment of participants. There is also a weekly clinical team meeting of assessors who are working one-on-one with the participants to monitor and review the progress of the participants.

The PI has extensive experience conducting research studies. Most of the members of this study are involved in other on-going studies at the Center. The Center has a computer dedicated to store and process the data. It also has secure room and cabinets to store study-related documentation. In addition, the study team is composes of assessors who are fully bi-lingual. They are fluent in both English and Spanish, thus capable of implementing the study in either language.

13) Prior Approvals

NA

14) Recruitment Methods

After IRB approval the research team will contact potential recruitment sites and inform them about the study. These sites will be provided with IRB approved promotional materials (flyer) for recruitment. At the same time, the UM PR department will be informed and notified of the ongoing research. The PR department will be provided with the promotional materials for the study. UM sites such as those that make regular postings and newsletters will also be contacted and provided with an approved ad or communication regarding the project. The CITI certified staff member within the project plans to also attend health fairs and /or senior centers and events and have flyers available at various community centers so that potential participants can learn of the study. The UM approved ad will also be posted in non-UM newsletters and advertisement sections. Promotional material use in this study are: flyer and advertisement blurb.

Once potential participants learn of the study, they will phone the recruitment phone line. A brief telephone interview will conducted. If these participants are eligible for the study, they will then be scheduled for the baseline assessment.

Participants will not have any financial liabilities for participating in the study. The study provides financial compensation for their time/effort in completing the

assessment. Eligible participants will receive $30 for each completed assessment, for a total of $90 ($30 at baseline, $30 at 6th month, and $30 at 12th month). Participants who quit or complete partial assessment will receive $10.

15) Local Number of Subjects

We anticipate to screen a maximum of 350 participants and to study about 280 participants. We expect 240 participants to complete the study. The participants will be from University of Miami.

16) Confidentiality

This study does not collect specimens. The data are questionnaire based and participants will be completing them online using a secure and unique log. All the data will be stored and secured using the procedure implemented by the Center for Cognitive Neuroscience and Aging. The access to records and participants data will be allowed only to the study personnel. The data will not contain any identifying information.

The hard copy data will be stored in a double locked office at the Center in the Mental Health building. The electronic and audio recorded data/interview will be kept in server computer at the Center as well. The data will be backed-up on a regular basis and the copies will be kept in a double locked office at the Center. Only study-related staff (listed in the IRB protocol) will have access to the data.

The online data will be collected on Qualtrics (the University has approved this survey/data collection service and has a subscription to it). Connections to the server are 128-bit SSL encrypted. Minimum levels of password complexity will be enforced. The Tablet will be locked down, requiring a 4-digit PIN.

17) Provisions to Protect the Privacy Interests of Subjects

During the informed consent process, participants are made aware of who will have access to the study data (see section of Confidentiality). The participants are instructed to sign the Informed Consent Form only when he/she is completely satisfied with the information in the ICF, and all his/her questions are answered fully. We will not release participant information to anybody who is not listed in the Confidentiality section of the ICF.

18) Consent Process

The research team will not use undue influence or manipulation in order to recruit study participants. Our team has extensive experience in recruiting this population and is aware of the ethical conduct necessary to protect human subjects in research. They are all CITI certified. There is weekly meeting to monitor recruitment activities to discuss and review our recruitment practices and efforts. Most of the members of the research team who have an active role in the conduct of the study (screening, assessment, and conducting the study) will also be involved in the recruitment and consent process.

During recruitment activities and presentations in community events, the research team provides and explains the content of the flyer to potential participants, and answers and clarifies any questions/ concerns that potential participant may have. Interested

participants are instructed and directed to call the phone number or send email to the address displayed in the flyer.

The study involves adults who have the capacity to consent. These potential participants are able to read and comprehend the information written in the Informed Consent Form. Questions will be answered and addressed accordingly. Therefore not additional process will be used to obtain consent from them.

When a person who is interested in the study contacts us via telephone or email to request information, a trained and certified screener/assessor will call the participant back and explain the basics of the study, and then ask for participant's permission to ask questions that would lead us to make a decision as to whether or not him or her might be an appropriate candidate for the study or basically would qualify for the study. This process is a preliminary screening done over the telephone, which is not feasible to do by having a written consent. If and only when a person 1) has agreed to be screened over the phone; 2) understands that this study represents research; and 3) understands their participation is voluntary and that they can withdraw their consent at any time, will the screening process proceed. We will not obtained a written consent form for the phone screening process as this research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent if normally required outside of the research context (45 CFR 46.117 (c) (2). It is not possible to have written consent from each potential participant for practical as well as cost reasons.

Upon the completion of the telephone screening and if the participant appears eligible for the study, a home visit by one of the research team members (CITI certified) to participant's home will be scheduled. A written informed consent form will be obtained by the CITI-certified and protocol trained RA during the first visit to the potential participant's home. Before any additional study-specific information is obtained, participants will be asked to read the IRB-approved consent form as well as the UM consent for audio/visual recording. The potential participant is asked to read the consent form and, if agreeable to participate, sign it in the presence of an assessor.

During the phone screening process and other screening steps and after the potential participant verbally consents to participating in the study, they will be scheduled for an appointment at their home.

19) Process to Document Consent in Writing

The RA (CITI certified) will obtain a writing Informed Consent Form from the participant and the care-receiver during the first home visit. Upon the arrival the participant’s home and prior to engage in any study-related activities, the RA must obtain the signed ICFs.

The Informed Consent Process can be done in English or Spanish depending on the language of preference from the participant. The participant is asked to read the ICF and ask questions. If the RA detects the participant is having difficult reading the ICF, the RA will read with the participant alternating paragraphs. In order to assess whether the participant comprehends the ICF, the RA will ask the participant to paraphrase the content of the ICF.

Participant will sign and date the ICF in the presence of the RA once all his/her questions and concerns have been answered. The ICF will be stored in a separate location from the rest of the study data.

The RA will follow the same consenting process with the care-receiver If the RA detects the care-receiver can't comprehend due to the memory impairment, the RA will review it with the participant and proceed with the assenting process.

We have provided the Informed Consent Forms for your approval: English and Spanish, and Participant (Caregiver) and Care-Receiver (Care-Recipient).