Protocol
Title: A Non-pharmacological Intervention for Patients With Alzheimer's Disease and Family Caregivers (Care Partners Program)
NCT#: NCT03333252
Date: December 10, 2020

1) Protocol Title

Care Partners Program – CP Program

2) Objectives*

This study protocol describes the study that is sponsored by Florida Department of Health and by the National Institutes of Health/National Institute on Aging. Both entities provide support for the design, conduct, and data analysis of the study.

This study will evaluate the efficacy and feasibility of an innovative dyadic non-pharmacological intervention (DT) that is delivered through an interactive state-of-the-art technology that includes an evidenced-based **caregiver component** modeled after REACH II (Belle et al., 2006) **augmented** by an evidenced-based cognitive and functional training component for the **individual with AD (care recipient)** (Acevedo & Loewenstein, 2007; Loewenstein et al., 2004, 2006). The program is designed to: be synergistic; emphasize issues important to caregivers in the earlier stages of caregiving; help the caregiver prepare for caregiving transitions; and engage the caregiver as a therapy extender. The program will be tailored for the CG using a risk appraisal approach (Czaja et. al., 2009) and for the CR. It will also be culturally tailored and based on a community-based and stage-model approach to intervention development. The DT intervention will be compared to a control condition (CC) that includes non-specific mental stimulation for the CR and a nutrition intervention for the CG (we chose this for equivalent contact time). Two hundred and forty dyads will be randomly assigned to the DT or CC conditions. The proposed DT intervention builds on: the findings of our group that specific cognitive training techniques can result in improvement and maintenance of gains in cognitive and functional performance in mild stage AD patients (e.g., Acevedo & Loewenstein, 2007); our evidenced caregiver interventions (e.g., Belle et al., 2006); our technology-based interventions (e.g. Eisdorfer, Czaja et al., 2003; Czaja et al., 2013) and our on-going technology-based caregiver intervention program (Caring for the Caregiver Network). **The specific aims** of this project are to:
1) Evaluate the efficacy of the DT intervention on CG outcomes.
Hypothesis 1.1: CGs assigned to the DT condition will demonstrate decreased distress and burden relative to CGs assigned to the CC condition.
Hypothesis 1.2: CGs assigned to the DT condition will experience greater improvements in quality of life, mutuality (quality of the caregiver-patient relationship), and caregiving efficacy relative to CGs in the CC condition.
2) Evaluate the efficacy the DT condition on outcomes for individuals with mild stage AD (CRs).
Hypothesis 2.1: CRs assigned to the DT condition will demonstrate greater improvements in cognitive and functional performance and quality of life and less distress than CRs assigned to the CC condition.

Given our access to diverse populations, we will gather preliminary information on ethnic differences in response to the intervention and the cost and sustainability of the DT intervention. The study will provide critical information for a future larger scale multi-site effectiveness trial. Our goal is to develop a program that is flexible, easily accessible for diverse populations of CGs/CRs and improves outcomes for both members of the dyad, which could ultimately yield significant savings for families and society.

3) Background*

The number of individuals with AD and related dementias is expected to increase significantly in the United States and worldwide in the coming decades with a related increase in burden on the patient, family members and society. Currently, an estimated 5.4 million individuals in the United States are living with AD and estimates suggest that this number will increase to 16 million by 2050. In the state of Florida alone there are 500,000 individuals living with AD and it is anticipated that this number with increase to 720,000 by 2025 (Florida Department of Elder Affairs, 2015; Alzheimer's Association, 2015). Florida has more patients with AD than any other state except California. Alzheimer's Disease 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. AD is also a principal cause of physical disability and institutionalization among older adults. In the U.S. Medicare and Medicaid paid about $170 billion for care of AD patients in 2014, and by 2050, experts estimate these costs will rise to $800 billion a year (Alzheimer's Association, 2015).

There is a pressing need to identify interventions that decrease the cognitive/ functional and behavioral manifestations of the disease in the patient, and the distress and health-related consequences experienced by family caregivers. In this regard, vast resources have been directed towards interventions to prevent or cure AD. To date, most of these approaches have been pharmacological and to date most have limited efficacy. While it is imperative to continue these efforts it is also important to explore the efficacy of non-pharmacological approaches to help mitigate the symptoms of the illness. There is an emerging body of research indicating that secondary prevention intervention methods such as cognitive training interventions are effective in patients with mild AD (e.g., Loewenstein et al., 2004; Acevedo & Loewenstein, 2007). To date, most cognitive training programs have focused solely on component cognitive abilities (e.g., processing speed), which shows limited transfer to everyday activities. Interventions such as these can be broadened to include functional training (e.g. how to training); procedural memory is generally in tact in the early stages of the disease (e.g., Hirono, Mori, Ikejiri, Imamura, Shimomura, Ikeda, et al., 1997). For example, it is feasible to reinforce previously learned procedural tasks or teach new ones such as how to maintain and check a memory notebook. Evidence also indicates that early stage patients can benefit from receiving information regarding their illness and available resources as it enables them to participate in decision-making regarding care choices, which alleviates distress for both themselves and their caregiver. Thus intervening in the early stages of the disease represents "a window of opportunity" for the individual with AD. There have also been a broad range of intervention studies aimed at the caregiver that have shown significant effects in reducing burden, lowering depression, and delaying the placement of patients (Brodaty, Green & Koschera, 2003; Schulz, Martire & Klinger, 2005).

However, there are limitations with current intervention programs for both AD patients and caregivers. For example, existing cognitive training interventions for patients a) typically require multiple sessions of facility- based training, creating logistic barriers for patients and families, b) involve considerable interventionist cost, and c) do not provide the optimal intensity and dosage of treatment. Proven caregiver intervention programs also typically involve home-based therapist visits (e.g., Belle et al., 2006) and many have been evaluated on caregivers of patients in the moderate or severe stages of the disease. Our work and that of others (e.g., Acevedo & Loewenstein, 2007; Blieszner & Roberto, 2010) has shown that caregivers of patients with mild cognitive impairments also experience distress, have limited knowledge about dementia and memory impairments, and caregiving. Further, caregiver preparedness in managing the patient's condition is linked to caregiver distress (e.g., Schumacher, Stewart, & Archbold, 2007).

The vast majority of intervention efforts have also targeted only one member of the dyad. We believe that there are important synergies to be gained by treating the caregiver and patient

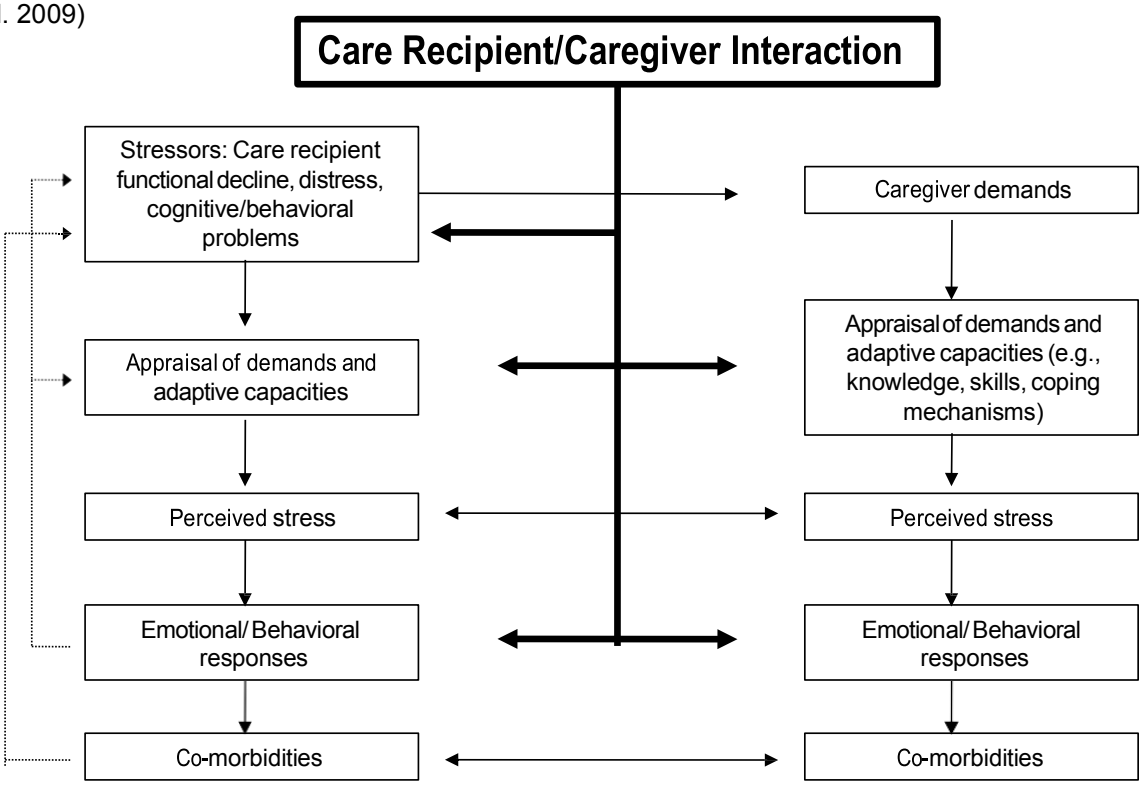
simultaneously in an integrated and an interactive manner. Several studies have shown that there is a reciprocal interaction between the well-being of the care recipient and that of the caregiver (e.g., Lyketsos et al., 2003; Schulz et al., 2008; Terri et al., 1997; Schumacher et al., 2007), and studies have shown that reducing patient distress can reduce caregiver burden (Lyketsos et al., 2003; Terri et al., 1997). In addition, recent data indicates that degree of mutuality (quality of the patient-caregiver relationship) and shared involvement in illness-related care by both the caregiver and patient influence caregiver outcomes (Schumacher et al., 2006, 2007; Berg & Upchurch, 2007). We recently found (Schulz, Czaja, Lustig, Zdaniuk, Martire, & Perdomo, 2009) that an intervention that focused on both Spinal Cord Injured patients and their caregivers resulted in significant improvements in caregivers outcomes when compared to a caregiver only condition and a control condition. To our knowledge, there has been a paucity of research in the dementia caregiver literature that uses an integrated intervention approach.

In the proposed study, we attempt to address limitations of previous research by developing and evaluating the efficacy for both members of the dyad (caregiver and AD patient), of a dyadic integrated innovative technology-based intervention (DT) designed to improve the cognitive and functional status and quality of life of the patient and to reduce burden and distress in the caregiver and improve their quality of life and caregiving self-efficacy. The intervention is also designed to improve the mutuality between the caregiver and patient. The overall paradigm is grounded in theory (e.g, Pearlin et al., 1990; Given, Collins, & Given, 1988, Schumacher et al., 2007), and modeled after a Dual Target intervention developed and implemented by Schulz and Czaja (Schulz, Czaja et al., 2009) for older spinal cord injured patients and their family caregivers (SCI Connect) and our previous research with caregivers and AD patients. Our intervention approach is also consistent with theoretical views that among couples, coping with chronic illness is a dyadic process (e.g., Berg & Upchurch, 2007) and findings that among couples dealing with illnesses, greater collaborative involvement in dealing with problems is related to greater well-being for both members of the dyad (Meegan & Goedderis, 2006). Specifically, the dyadic intervention (DT) represents an integrated dementia management program in which the AD patient will receive cognitive/functional training that is based on an empirically-derived program developed by the team at the University of Miami (UM) and the caregiver will receive a comprehensive intervention package based on the evidenced-based intervention modeled after the REACH II program and modified and implemented in the VideoCare project (Czaja, Loewenstein, Schulz, Nair, & Perdomo, 2013) and the on-going Caring for the Caregiver Network study (See Preliminary Studies). The paradigm will also actively engage the caregiver as a therapy extender (deliver the cognitive/functional training) and is designed to promote a collaborative care pattern where the patient and the caregiver work together on strategies to manage the symptoms of the illness (e.g., Schumacher et al., 2007).

The program is synergistic and will be designed so that the caregiver and patient components are mutually reinforcing. We believe that for individuals with an illness or disability and their caregivers, it is important to consider the reciprocal impact that providers and care recipients have on each other in terms of the perception and the emotional and behavioral response to stress and the reciprocal effects of illness (Bookwala & Schulz, 1996; Schulz et al., 2008) (Figure 1). Thus we believe that an intervention that simultaneously targets the caregiver and the care recipient will result in positive outcomes for both members of the dyad. We also believe that the active involvement of the caregiver as a therapy extender for the patient will increase their knowledge of the disease and of the patient's experiences. This will help reinforce information they receive in the caregiver component of the intervention regarding the symptoms of the illness. Further, the knowledge the caregiver gains in the caregiver component of the intervention relating to communication skills will enable them to deliver the therapy more effectively and allow the patient to feel more supported. This should facilitate the patient's involvement in the

cognitive training sessions and encourages practice of the exercises between sessions, which enhances the likelihood of a positive cognitive outcome. The caregiver's active involvement in the intervention will also increase the caregiver's perception that they are engaging in activities, which can actually benefit the patient as opposed to just engaging in symptom management. The interaction between the caregiver and patient in the cognitive therapy process will also enhance feelings of mutuality, which has an influence on perceived burden and caregiver distress (e.g., Schumacher et al., 2007). Improving the skills of the patient may also lessen care demands which will have a positive influence on both caregiver and patient outcomes. A further benefit of the integrated approach is that having the caregiver trained in the provision of the therapy allows for regular and continuous treatment without the need of an outside therapist. This is cost effective, increases adherence, and maximizes dosage effects. Finally, we believe the caregiver's active involvement in therapy will increase the caregiver's perceptions of positive aspects of care provision which is turn linked to level of caregiver distress and patient placement (Schulz et al., 2004).

Figure 1. Conceptual model of stress-health process applied to the care-recipient/patient (left panel) and caregiver (right panel) showing interactive nature of care recipient and caregiver outcome (Adapted from Schulz et al. 2009)



The cognitive component of the intervention (Loewenstein, Acevedo, Czaja, & Dura, 2004) will employ a multi-modal approach to train both cognitive and functional skills in mild-stage AD patients. The model focuses on bypassing and compensation for episodic memory deficits mediated by the hippocampus and other medial temporal lobe structures and includes empirically validated techniques such as spaced retrieval (Camp 1989; Camp & Stevens, 1990), dual cognitive support at acquisition and retrieval (Bird & Kinsella, 1996; Lipinska & Backman, 1997), implicit memory/motor learning (Acevedo & Loewenstein, 2007; Farina et al., 2002), and employs compensatory techniques such as a memory-notebook system. An unique aspect is a focus on training on procedural and functional skills that have real world relevance (Loewenstein & Acevedo, 2006; Loewenstein & Mogosky, 1999).

The caregiver component of the intervention is guided by the Stress Process Model (SPM) of caregiving (Pearlin et al.,1990), which views the consequences of caregiving as resulting from the interrelationships among several factors including the socio-economic characteristics (e.g., relationship, race/ethnicity) and resources (e.g., social support) of the caregiver, primary (e.g., level of patient impairment) and secondary stressors (e.g., job and relationship difficulties) to which they are exposed, and the caregiver's appraisal of these stressors. It is also guided by transactional models of caregiving (e.g., Schumacher et al., 2006), which include a focus on caregivers and patients as individuals as well as the transactional nature of the relationship between the patient and caregiver. The intervention is also based on a multi-component approach to caregiver interventions and a structured but tailored intervention approach whereby the intervention is tailored to meet the specific needs of the caregiver (Belle et al., 2006; Czaja et al., 2009, Czaja et al., 2013). The intervention is designed to enhance the caregiver's skills and preparedness for the caregiver role, resources available to the caregiver (e.g., social support; knowledge of community resources) and reduce known areas of caregiver risk (e.g., burden, emotional distress).

The integrated intervention approach will also incorporate innovative technology and use state-of-the-art computer tablets as a mechanism for intervention delivery. Use of technology in the context of caregiving with older adults has been found to be feasible, acceptable, and cost-effective across heterogeneous patient and caregiver populations including White Caucasians, African-Americans and individuals of Latino background (Czaja & Rubert, 2002; Eisdorfer, Czaja et al., 2003; Bank et al., 2006; Nichols et al., 2008; Czaja et al., 2013). Technology offers several advantages over traditional intervention approaches. For example, the use of technology allows a "without walls" approach and increases access to information and support. Further, the use of technology offers unparalleled flexibility in the presentation of information. Healthcare professionals can also use technology to monitor the status of the caregiver or the care recipient and deliver an intervention in a cost-effective fashion (Czaja, Eisdorfer & Schulz, 2000; Czaja et al., 2013).

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4) Inclusion and Exclusion Criteria*

Care Recipient (Patient) Inclusion Criteria:

- MMSE 17 – 25 (with Mungus age and education correction)* ;
    - If the CR scores 16 – consult PI to determine eligibility
- Needs help with higher level of IADLs (e.g., managing finances, helping remember appointments, handling medications)

- Shows memory problems (e.g., repetitive questioning, forgetting what day it is, losing or misplacing things)

* Care recipients who score high on the MMSE will also be given the Clinical Dementia Rating Scale (CDR). The criteria for inclusion of these participants is having a CDR of 0.5 or 1.0; for subjects unable to participate in in-person visits, a telehealth version of the MMSE will be given using the same age and education corrected cutoffs.

Caregiver Inclusion Criteria:

- MMSE ≥ 26 (with Mungus age and education correction)*
- Providing care for a friend or relative with AD for a *minimum of eight hours* per week for at least the past six months
- Being over the age of 21 years
- Living with or nearby the patient
- Having a telephone
- Planning to stay in the study geographic area for the duration of the study

* For subjects unable to participate in in-person visits, a telehealth version of the MMSE will be given using the same age and education corrected cutoffs.

Exclusion Criteria for Caregiver and Care Recipient Dyads
Exclusion criteria for the dyads include: 1) Presence of significant sensory or motor deficits (e.g., visual or hearing loss, paralysis) in the patient or caregiver that are judged to preclude completion of the study measures; 2) Patient or caregiver is in active treatment for cancer; 3) Patient or caregiver has a terminal illness with a life expectancy of 6 months or less; 4) Patient is in the late stage of the disease, is bed-bound, or nursing home admission planned within 4 months;

5) Procedures Involved*

The study population will include White non-Hispanic, Black/African American and Hispanic caregivers and their loved ones. We anticipate to screen a maximum of 350 caregiver participants. We expect 240 participants (caregiver and care recipient) to complete the study.

The study will be conducted in English or Spanish. We will recruit and randomly assign participants; following a baseline assessment, 240 participants will be enrolled and randomly assigned to one of two groups: 1) Caregiving Condition or 2) Health Promotion (Nutrition) Condition. 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 in the beginning of the study, 6 months, and 12 months (after completion of the intervention).

Interested participants (caregivers) can contact us via telephone or email. One of our research associates (RA) will provide more information about the study to potential participants. An approved script including verbal consent obtained from the potential participant in order to ask them questions to determine their eligibility criteria. If the participant is eligible for the study, an appointment will be provided, and one of our interventionists will visit the participant and conduct the baseline assessment at the participants' homes in their preferred language (Spanish or English). This assessment with the caregiver will last between 2 and 3 hours. And

the assessment with the care recipient will be about 1.5 hour. In instances where assessments cannot occur in-person we will use a modified battery to conduct the assessment using a telehealth platform. These virtual visits can be broken up into two or more visits if requested by the participants. We will use paper-based forms and/or REDCap to administer the assessments.

The baseline assessment with the caregiver consists of a series of questionnaires assessing the help provided by the CG to the care recipient (e.g., ADLs/AIDLs), the level of burden, stress, and depression perceived by the CG while providing the care, the amount of social support available to the CG, and the preparedness of the CG to provide continuing care to their loved ones. The assessment with the care recipient consists of measures of depression, executive functioning (Trails A & B), working memory (Letters and Number set, digit span), processing speed (digit symbol), and verbal fluency (category fluency). In instances where the assessment is conducted virtually, certain measures may be excluded (e.g., Trails A & B, Digit Symbol). The assessment with the caregiver and care recipient might not be completed in the same visit. The study protocol allows multiple visits to complete the assessments.

During the baseline home visit, the interventionist will go over the written informed consent with the participants (caregiver and care recipient). For virtual visits, participants will review an electronic consent form; if participats do not have a device to provide e-consent, a copy of the consent form will be mailed to the participant for signature.The assessment will not begin unless the participant has a full understanding of the informed consent form and has signed the form. In the event the care recipient can't comprehend or give consent to the assessment, the interventionist will get the assent from the caregiver. Some assessments (randomly) will be recorded for quality assurance purposes.

Upon the completion of the baseline, participants will be notified by the Project Coordinator or designee about their randomization condition: Caregiving or Health Promotion condition. During first intervention session, all participants will receive a computer tablet equipped with WiFi access. The interventionist will provide a brief tutorial on the usage of the computer tablet before starting the activities of the intervention. It is one computer tablet per dyad.

The **Caregiving condition** will have a component for the caregiver and a component for their loved ones (the care recipient). The care recipient component will have a series of cognitive training tasks. The care recipient will meet with the interventionist on a weekly basis. The interventionist will train the care recipients on how to access these training tasks and complete homework/practice sessions. The caregiver has a total of 12 one-on-one sessions throughout the 6 months of the intervention period. Some of these sessions will be joint sessions with the care recipient. The 12 sessions will cover topics such as depression and emotional well-being; self-care and healthy behaviors; strategies for communication; strategies for mood and stress management; and strategies for management of behavioral /cognitive problems. The first, the third, and the last sessions will be at the participant's home when possible. The other sessions will be conducted via the computer tablet using videoconference program. The caregivers will also be part of 5 support group sessions where the facilitator will review the material covered in the individual sessions. For most of the part, the caregivers don't have sessions with the interventionist while the care recipients are present. Although, there will be sessions that will be conducted with both of them together because of the nature of the topic/conversation.

The **Health Promotion condition** will also have a component for the caregiver and one for the care recipient. The care recipient component will consist of mental stimulation exercises such as computer games. And the caregiver component will consist of nutrition and health promotion topics. They will have access to basic educational information from Alzheimer's Association on tips for dealing with the cognitive loss and available community resources.

Similar to participants of the caregiving condition, the caregivers of the Health Promotion condition will also have 12 one-on-one sessions with the interventionist. The first, the third, and the last sessions will be in-person when possible and the others will be via the computer-tablet using video conference program. The care recipient will have weekly sessions with the interventionist and weekly assignments as well. Caregivers and care recipients of this condition will also have some joint sessions throughout the intervention period of 6 months.

In certain cases, we may be unable to visit in the participant's home. In these cases, we will conduct any sessions, trainings or assessments needed over the telephone and/or secure videoconferencing. Care recipient participants may request to reduce the number of sessions with the interventionist.

We will obtain participant written consent for audio/video recording when we go over the Informed Consent Form during the baseline assessment visit. Since participants can withdraw their consent anytime during the study, we will verbally obtain the consent to audio/video record before the actually recording. Participant's agreement to be recorded will become part of the recording.

We will be administering 2 IRB-approved follow-up assessments one 6-months post session 1, and one 12-months post session 1 (regardless of when the 6-month visit occurs).

Participants can choose to keep the computer tablet at the end of the study – 12 months if they complete participation.

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 and the Center on Aging and Behavioral Research. 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 and the Center on Aging and Behavioral Research. The Data Manager of the Center or designee monitors the logs. Upon 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*

Preliminary Analyses

Prior to any statistical tests, descriptive statistics, *including* histograms, box plots or scatter diagrams, will be used to assess distribution of variables and their inter-relationships, as well as to detect missing data and outliers for outliers that are deemed to be legitimate values, two types of analyses will be performed and the results compared and reported: the first analysis will include the outliers, and the second will exclude them. Transformations, such as logarithmic or square root transformations will be used for variables with skewed distributions, prior to their inclusion in any analyses that require normality or approximate normality. If normality cannot be achieved through transformations, then non-parametric techniques will be used. Bivariate analyses (e.g., chi-square tests, t tests) will be used to assess patterns of association of factors potentially associated with outcome measures. Appropriate correlational analyses will be performed for each of the independent variables as well as with the outcome variables to identify factors related to outcomes or that are likely to be confounders. Factors that will be considered as potential confounders are those observed to have moderate associations (using a liberal size for preliminary tests of association such as a=0.25) with appointment adherence as well as with independent variables specified in the hypotheses. These variables will be controlled for in analyses for specific hypotheses, as appropriate.

Primary Analytic Strategy

Our plan for the main analyses is to use the General Mixed Model (Ware, 1985), which is an analytic strategy that can be employed for the hypotheses under each specific aim. 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-sectional analyses (comparing outcomes by condition), which we will perform at baseline, and at the post intervention follow-up. In addition, to the cross-sectional analyses comparing the main effect of treatment we will also examine main effects for race/ethnicity and treatment by race interactions. We have specified primary outcome variables for both the caregiver (e.g., CESD) and patient (e.g., HVLT-R). However, as the intervention targets a number of different areas related to patient and caregiver outcomes there are a number of secondary measures. When possible, we will examine and employ a multivariate approach. Using a set of measures that are included in our outcome battery, Schulz et al (2009) created a multivariate outcome and we will employ a similar approach. For the cognitive variables, composite measures will be created using principal axis factoring approaches or selecting measures that load most highly on derived factors representative of a particular domain (e.g., memory).

For each hypothesis, we will consider models that incorporate covariates and interactions in order to examine the effects of potential mediator and moderator variables on outcomes. For example, a potential mediator of caregiver outcomes is improvement in both cognitive and functional status of the patient, which will be incorporated in longitudinal models of change. Similarly, training dosage and adherence to homework assignments captured in real time on the tablet will be examined in relation to 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.

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 and the Center on Aging and Behavioral Research. 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 Weill Cornell's secure file transfer.

8) Risks to Subjects*

The main objective of the study is to develop and test the efficacy and feasibility of an integrated, dyadic-based intervention program (Caregiving Condition), delivered through technology that will include cognitive/ functional training for the AD patient and engage the caregiver (CG) as a therapy extender. The participants will be answering a series questions and working with an interventionist 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 experience 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 practice the skills learned in the study in their caregiving activities. Their participation in the study can help investigators in refining future technology-based caregiving intervention program(s) to help diverse caregivers of individuals with 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 are regular 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 an 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 Weill Cornell Medicine Center on Aging and Behavioral Research and in the participants' homes. The intervention is technology-based, thus facilitating the communication and interaction between RAs and participants. Only study assessments (baseline, 6th month, and 12th month) and select sessions may take place at the participant's home.

In cases where a participant is unable to complete a follow-up assessment in-person, a subset of the assessments will be done by phone in order to obtain outcome measures at the proper timepoint.

12) Resources Available

All the study personnel have their CITI certificate. The PI holds regular meetings 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 Center on Aging and the Weill Cornell Medicine Center on Aging and Behavioral Research lead by Dr. Sara J. Czaja 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 contains 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 WCM PR department will be informed and notified of the ongoing research. The PR department will be provided with the promotional materials for the study. WCM 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 members within the project plan 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 WCM approved ad will also be posted in non-WCM newsletters and advertisement sections. Promotional material used in this study are: flyer, radio ad and advertisement blurb.

IRB-approved letters may be sent to designated patients from WCM/NYPH clinics with IRB approval.

Once potential participants learn of the study, they will phone the recruitment phone line. A brief telephone interview will be 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 caregiver participants will receive $30 for each completed assessment, for a total of $90 ($30 at baseline, 6-month,12-month visits). Eligible care recipient participants will receive $20 for each completed assessment, for a total of $60 ($20 at baseline, 6-month and 12-month visits). $10 will be provided to those that do need meet eligibility.

15) Local Number of Subjects

We anticipate to screen a maximum of 350 participants. We expect 240 participants (120 dyads) to complete the study. 80 participants will be from University of Miami and 160 will be from the Weill Cornell Medicine Center on Aging and Behavioral Research.

16) Confidentiality

This study does not collect specimens. The data are questionnaire based and participants will be completing them on paper or online using a secure and unique log. All the data will be stored and secured using the procedure implemented by the Data Manager of Center on Aging and the Weill Cornell Medicine Center on Aging and Behavioral Research. 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 on Aging and the Weill Cornell Medicine Center on Aging and Behavioral Research in the Mental Health building. The electronic and audio recorded data/interview will be kept in server computer at the Center on Aging and the Weill Cornell Medicine Center on Aging and Behavioral Research as well. The data will be backed-up on a regular basis by the Data Manager and the copies will be kept in a double locked office at the Center on Aging and the Weill Cornell Medicine Center on Aging and Behavioral Research. Only study-related staff (listed in the IRB protocol) will have access to the data.

The online data will be collected on REDCap (WCM has approved this survey/data collection service and has a subscription to it). Connections to the server are 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 are regular meetings 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 an 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 and HIPAA authorization. Questions will be answered and addressed accordingly. Therefore no additional process will be used to obtain consent from them. Care Recipients are required to successfully respond to the Informed Consent Feedback Tool in order to be eligible for participation in the research study.

When a person (caregiver), 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. Then they will ask the participant's permission to proceed with the telephone screening questionnaire that would lead us to make a decision as to whether or not he or she 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 obtain 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 is 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 or virtual visit by one of the research team members (CITI certified) will be scheduled. A written informed consent form will be obtained by the CITI-certified and protocol trained RA during the first visit. Before any additional study-specific information is obtained, participants will be asked to read the IRB-approved consent form. The potential participant is asked to read the consent form and, if agreeable to participate, sign it in the presence of an assessor. If consenting virtually, the participant will follow the IRB-approved method.

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 for a baseline assessment.

19) **Process to Document Consent in Writing**

The RA (CITI certified) will obtain a written Informed Consent Form or electronic informed consent from the caregiver and the care-recipient during the first visit. For visits that cannot take place in person and where the participants do not have access to an electronic device, a consent form will be mailed to the participant for signature and returned to complete the process. The same process to document consent in writing is implemented for both, the caregiver and the care recipient. Additionally, care recipients are required to successfully respond to the Informed Consent Feedback Tool in order to be eligible for participation in the research study. Upon the arrival the participant’s home or at the start of the virtual visit and prior to engaging in any study-related activities, the RA must obtain the signed ICFs and complete Feedback Tool.

The Informed Consent Process can be done in English or Spanish depending on the language of preference of the participant. The participant is asked to read the ICF and ask questions. If the RA detects the participant is having difficulty 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.

We have provided the Informed Consent Form for the caregiver and that of the care recipient.

20) **External Co-Investigators**

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Last Name:	Loewenstein
Degree:	PhD
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Responsibilities:	Dr. Loewenstein acts as the site PI for the University of Miami.

All data is shared in it's de-identified state.

* DUA/MTA language between the University of Miami and WCM is embedded in the subcontract language

Appendix A:

CP Program Telephone Follow-Up Assessment

Measure	# of Items
Caregiver	
ADL/IADL Modified	11
Caregiving Medical Nursing Tasks	15
*Burden Interview	12
Positive Aspects of Caregiving	11
*CESD	11
Social Support	12
Use of Formal Care and Services	Only items: 1,2, 5-8
Quality of Life	1
Caregiver Preparedness	6
Caregiving Self-efficacy	9
Caregiver Self Health Rating	Only items: 1,2
Loneliness	20
CP/Nutrition Evaluation	21
*Cognitive Decline of CR Scale	Change stem as compared to the **last six months and ask items: 1 -6**
Care Recipient	
Quality of Life AD	
CESD	

Before asking the scale items on the Cognitive Decline of CR Scale (items 1 – 6) Please ask the CG the following question:

-

"Compared to six months ago has your partner's (Care recipient) cognition:

Gotten Much Worse, (2) Gotten Slightly Worse, (3) Stayed the Same, (4) Gotten Slightly Better (5) Gotten Much Better?

At the end of the Evaluation for CP ask the CG in the CP condition the following questions:

To what extent did your partner use the organizational tool?

(1) Very frequently (2) Frequently (3) Occasionally (4) Rarely (5) Never

How often did your partner do the computer exercises?

(1) Very frequently (2) Frequently (3) Occasionally (4) Rarely (5) Never

I found the organizational tool valuable?

(1) Strongly agree (2) Agree (3) Neither agree or disagree (4) Disagree (5) Strongly Disagree

The computer exercises were beneficial for my partner
(1) Strongly agree (2) Agree (3) Neither agree or disagree (4) Disagree (5) Strongly
(2) Disagree

At the end of the Evaluation for CP ask the CG in the Nutrition condition the following questions:

How often did your partner do the computer exercises?

(2) Very frequently (2) Frequently (3) Occasionally (4) Rarely (5) Never

The computer exercises were beneficial for my partner
(3) Strongly agree (2) Agree (3) Neither agree or disagree (4) Disagree (5) Strongly Disagree