STUDY PROTOCOL:
Testing Tele-Savvy, an On-line Psychoeducation Program for Dementia Family Caregivers
Short Title: Testing Tele-Savvy
Dual PI: Kenneth Hepburn
School of Nursing
Dual PI: Patricia Griffiths
School of Medicine
Co-I: Melinda Higgins
Co-I: Glenna Brewster
Co-I: Joe Nocera

National Institute of Aging (NIA)
NCT03033875
Protocol version date: December 9, 2019

AIMS. The backdrop for this application is our well-understood national reliance on family members to provide virtually all community-based care for 5.3 million persons living with Alzheimer's disease and other dementias, a population that will likely triple in the next 35 years.[1] Unless we soon find a way to prevent and cure dementing illnesses like Alzheimer's, the country will continue to face an urgent need to find ways to sustain and bolster the capacity of these family caregivers to manage the multiple daily care challenges they face and to preserve their well-being while doing so. Without family caregivers, the burden of care could well overwhelm the formal components of our care system. This application seeks support for a randomized trial to test a program designed to meet this critical need. We seek to test Tele-Savvy, an internet-based program based on the widely disseminated, in-person Savvy Caregiver psychoeducation program,[2] one of the effective, evidence-based programs identified in PAR -15-348 (Research on Informal and Formal Caregiving for Alzheimer's Disease) to which this application is addressed. Delivered in scheduled videoconferences and independently viewed on-line video lessons, Tele-Savvy aims to develop/enhance caregivers' skills and caregiving mastery, reduce adverse effects of caregiving, and improve the quality of the lives of caregivers and care recipients. Our pilot results support the fidelity of Tele-Savvy to its evidence-based platform, demonstrate benefits for caregivers, illustrate the program's national reach, and support our readiness for the proposed larger trial.

A number of psychoeducation programs for caregivers, including our own Savvy Caregiver program, have been effective in relieving distress, increasing self-efficacy, managing caregiving challenges, and enabling caregivers to sustain care over longer periods of time.[3-6] However, many Alzheimer's caregivers cannot take part in these programs because virtually all such programs require caregivers to arrange care for the care recipient while the caregivers travel to and attend the programs. These are obstacles in rural or remote areas where transportation issues further restrict caregivers' already limited access to caregiver programs, but they are no less a problem in inner cities and suburbs. These obstacles highlight a substantial challenge to our ability to rely on caregivers as a continuing care resource for persons living with Alzheimer's disease: we need theory-driven psychoeducation programs that can be made readily available to caregivers who may not be able to attend in-person programs.

Tele-Savvy extends the growing use of distance means for program delivery. Over the past 15 years, telephone, videophone, and internet/web-based platforms have been used to deliver prevention, patient education, disease self-management, and caregiver education programs through a variety of methods for a variety of conditions.[7-14] Distance methods for dementia caregiver education include: stand-alone, individually accessed material designed for self-study with no peer or expert contact;[15-17] individually studied material with web-mediated expert contact;[18-23] web-based one-on-one client-expert interaction, with or without ancillary asynchronous teaching/ learning material; and combinations of these modalities coupled with a variety of group interactions. The evidence for the positive effect of such programs on Alzheimer's caregiver well-being is beginning to accumulate.[24] Tele-Savvy represents a unique advance. Over six weeks, through weekly scheduled group videoconferences and daily email-delivered asynchronously viewed video lessons, it simulates the intense, interactive in-person six-week group experience of the Savvy Caregiver program. It is, virtually, an in-person psychoeducation program at a distance.

We seek to make an effective psychoeducation program widely available to family caregivers of persons living with Alzheimer's disease and related disorders. Taking advantage of the growing use of and familiarity with the internet by persons of caregiving age, the project will advance us toward that goal. We will test the program in an established context of collaboration among the Outreach, Recruitment, and Education Cores of four NIA-supported Alzheimer's Disease Centers (ADC). We will employ a wait-list randomized design in which 18 blocks of 15 caregivers each will be assigned either to immediate Tele-Savvy participation groups or to attention control or usual care groups that are invited to participate in Tele-Savvy six months after baseline data collection (total n=270). We will pursue 3 aims::

Aim 1. Establish the effectiveness of Tele-Savvy in reducing or retarding the affective impact (burden, depression, anxiety) on caregivers associated with dementia family caregiving
Aim 2. Establish the effectiveness of Tele-Savvy in promoting the quality of life of persons with Alzheimer's (agitation; Quality of Life; affect) whose caregivers are trained by Tele-Savvy
Aim 3. (a) Establish the effectiveness of Tele-Savvy in enhancing caregiver mastery and (b) test the mediating effect of mastery and enactment on Aim 1 & 2 outcomes

We also propose, as an Exploratory Aim, to examine the comparability of the program's efficacy across three racial/ethnic groups (African Americans, Caucasians, and Latino/Hispanics).

Significance and Innovation.
The Landscape. Dementing conditions, including the most prevalent of these, Alzheimer's disease, pose a large and growing problem nationally and worldwide. Unless dramatic breakthroughs occur, the current population of 5.3 million persons living with these conditions will swell to at least 14 million by 2050.[1] These persons are distributed across the landscape, in inner cities, in suburban areas, and in rural America; there is even some evidence that the current and future prevalence of Alzheimer's in rural areas is disproportionate to the rural population's share of the overall population.[2-4] Care for these persons is costly. Total estimated cost of care in 2015 will be $216 Billion; by 2050, it could exceed $1 Trillion.[1]

Alzheimer's Family Caregivers. Persons living with Alzheimer's disease and related illnesses spend most of the course of their illness in the community and receive most of their care from informal – usually family – caregivers.[5] Currently, about 15 million adults annually provide 17.9 billion hours of family care for community-dwelling persons living with Alzheimer's and other illnesses (PLWA); this represents approximately 85% of the care they receive and it is estimated to be the equivalent of $218 Billion in paid care.[1,30] As well as the more "domestic" work of maintaining a household and attending to the safety of the person, Alzheimer's family caregiving entails chronic care management, a role typically filled by persons with clinical or professional training. Alzheimer's family caregivers are responsible, for example, for medication management; behavior guidance and management; medical, legal and financial case management; treatment monitoring and provision; activity design and delivery; ADL assistance. Moreover, since most PLWA are ≥ 65 years, most live with at least one other chronic illness; this adds to the caregiving role. <u>Few caregivers are trained for this work</u>.

The condition of family caregivers is well documented. Despite possibly deriving satisfaction and reward from their work, caregivers pay a toll for the services they render. The chronic stress of their role places them at greater risk for morbidity and mortality than peers who are not caregivers.[31-33] The adverse effects on their psychological and physical well-being are extensive; there is well-established compromise to their immune systems.[6] Economic strains (from loss of job productivity and out-of-pocket expenses), social isolation, and family conflicts and tensions further raise the toll of caregiving.[35-37] Furthermore, in the face of these assaults, it appears that caregivers neglect their own care, increasing their own risk of morbidity, co-morbidity, and early mortality.[38] Behavioral and psychological symptoms of dementia (BPSD) are the strongest predictors of negative caregiver outcomes and are consistently linked to negative outcomes for the person living with dementia (PLWA).[39-43] Deployment of effective caregiving strategies appears to buffer caregivers' stress.[11]

Caregiver Intervention Programs. The condition of caregivers has drawn considerable attention over the past 2-3 decades, and many programs, usually in-person and often of a group nature, have demonstrated some positive benefit for caregivers' overall well-being.[4-6,45,46] While it is clear that not all needs have been met,[47] a number of systematic reviews have identified the characteristics of interventions that appear to contribute to their success.[4-6,45] Group programs focused on skill- and mastery-building and/or on improving enacted coping behaviors that respond to caregiving stress (e.g., managing BPSD)[5,48] and that are interactive or adult-learner-focused appear to be especially beneficial.[49] Several psychoeducational programs have been

singled out as particularly effective (like REACH,[50] the NYU model,[51] and the Savvy Caregiver[2]), and these have been designated as evidence-based by the US Administration for Community Living.[52] Programs like these have spread, and the evidence-based designation facilitates federal support for their wider use.

Challenges and Solutions. Access to beneficial programs is problematic. Although rural caregiving has been singled out as presenting particular problems for access,[53-60] the issue of access is endemic. Whether caregivers live in rural areas far distant from program sites or in inner cities – or in suburbs – they all face the same issues.[61] They have to travel to programs, so transportation is an issue. Distance in miles can be a barrier in rural areas, but distance in time on public transportation can be a barrier in urban areas – even if the program site is only a few miles away. Time is a problem in other ways. Most in-person programs involve 90-180 minute sessions; add in travel time, and it may mean the caregiver has to commit a half day to participating. Finally, and perhaps most importantly: what is the caregiver to do about the person for whom s/he provides care? Arranging – and often paying for – care is a real and substantial barrier to participation.

Technology – in particular, the internet – offers a possible solution to the problem of caregivers' restricted access to beneficial programs. The internet is no longer a scarce, rarely-available or difficult-to-use technology, and its use among middle-aged and older persons – the typical age range of caregivers – continues to rise. In 2009 internet use in this group was 59%; most recently, it is 79-89%.[62,62] While there is not, as yet, universal access, this trend of increasing availability and use is especially true for Alzheimer's caregivers.[63,63] The internet is a major source of information for Alzheimer's caregivers; moreover, there appears to be an association between internet use and enhanced caregiving self-efficacy.[65]

A variety of increasingly sophisticated, technologically-assisted delivery strategies have been employed to provide information and education to dementia family caregivers, but reviews lament the dearth of randomized trials (RCT).[24] Early telephone-based programs, provided in group or one-on-one formats, sought to provide support and instruction. A key feature of these programs was their ability to link caregivers to professionals at a distance.[7-10,66,67] Stand-alone DVD and internet-based instructional and educational programs allowed caregivers to learn asynchronously about dementing conditions and caregiving strategies. Some programs were augmented by or linked with in-person contact with experts, generally through messaging or email.[15-17] Others linked on-line line asynchronous video educational material with one-on-one interaction (PRN or scheduled) with a coach/counselor through messaging or email.[18-23] Recent technologically-assisted programs employ a group format, enabling professionally-led synchronous interaction among caregivers. Some program have been linked to home visits, have included asynchronous educational materials, and have involved chat functions, enabling off-line communication among caregivers and with experts.[68-71]

Innovation. To our knowledge, there have been no efforts to date to simulate, through distance means, the dynamic and temporal intensity of an in-person evidence-based psychoeducation program for Alzheimer's family caregivers. Tele-Savvy is such a program. It combines asynchronous self-instruction and synchronous group coaching, teaching and interaction and does so over the same (six week) time period occupied by its evidence-based platform, the Savvy Caregiver program. Tele-Savvy has the capacity to add a new dimension to telemedicine; it can enable newly emerging Alzheimer's care delivery models embedded, for instance, in accountable care organizations or medical homes, to promote practice change by more fully and more effectively (and accessibly) partnering with caregivers to enhance the performance of these delivery models, to improve home-provided care, and to preserve the well-being of patients and caregivers.

Preliminary Work. The work we propose rests on the solid foundation of the project team's experience with Alzheimer's caregivers and the demonstrated performance of the program's evidence-based platform, the Savvy Caregiver Program (SCP). Our prior work testifies to our ability to succeed at a project of this scope. Our pilot work with Tele-Savvy at the Atlanta VA and Emory's Alzheimer's Disease Research Center provides promising preliminary results to support further testing of Tele-Savvy.

The Savvy Caregiver Program (SCP). As depicted below, SCP is a 12-hour structured program offered in-person by trained facilitators, over six weeks in 2-hour group sessions. The SCP curriculum envisions the caregiving role as one demanding skill and knowledge, an outlook that could be considered clinical in nature. Alzheimer's caregivers

Week	Topics and Content	Self-Management Behaviors
1	Introduction to dementing illnesses Cognitive losses and caregiving strategies	Improved knowledge and understanding of
2	Stages of dementia The role of confusion in dementia Caregivers' feelings and self-care	

daily assist the PLWA with routine tasks. Choosing and carrying out an effective guidance strategy is a sophisticated task, and it is repeated multiple times each day. This involves understanding the person's capacities and gauging the degree and kind of assistance that will be effective while also attending to the person's emotional well-being, maintaining a

3	Tailoring tasks and activities to fit with stages of dementia	dementia and caregiving role
4	Debriefing and further practice with tailoring tasks and activities	Acquisition, development, and enactment of effective caregiving strategies
5	Further debriefing and practice with tailoring caregiving strategies Family roles in caregiving	
6	Community resources for caregiving Summary of content and skills	Engagement in self-care activities
All	Self-Care exercises	

reasonable level of behavioral calm, and helping the care recipient to have days that are relatively pleasant. Such guidance combines the acumen of a number of disciplines (e.g., nursing and occupational therapy). SCP uses strategies and techniques from nursing,[72-76] psychology,[43,77-79] and occupational therapy[80-83] to provide insight into Alzheimer's and its effects and to suggest ways of succeeding in the work of caregiving. Guided imagery helps participants appreciate the way in which dementing disorders produce confusion and how confusion prompts eruptive responses. Group exercises elicit participants' feelings about caregiving and about strategies they have deployed to guide everyday tasks.

SCP seeks to promote caregivers' appreciation for the scope of their own work; increase their skills and knowledge for caregiving; strengthen and appreciate their growing mastery in the role; adopt a more strategic ("clinical") outlook about their caregiving; develop more effective strategies for caregiving; and improve their skills for self-care. SCP draws on a broad chronic condition management framework[84,85] that is aligned with social cognitive theory[86,87] and the stress process model.[44,88-90] Within this framework (see Figure, right), caregiving stress constitutes a basic threat to the well-being of the dyad. To affect primary appraisal, the SCP curriculum provides information about the progressive dementia-produced losses in thinking, emotional and behavioral control, and the ability to perform everyday tasks and about the impact of caregiving on caregivers. Instruction, practice, and coaching allow for the application of Bandura's principles (successful demonstration of a desired behavior; observation of the performance of a desired behavior by a peer; and

Tele-Savvy Theoretical Framework

advocacy of a desired behavior by a respected authority[86]) to strengthen caregiving mastery (secondary appraisal), and promote development and enactment of a repertoire of self-derived successful caregiving and self-care/self-management coping behaviors. Debriefing offers the opportunity to report successful enactment of these behaviors. Gains in knowledge and skill, improvements in mastery, and deployment of effective caregiving strategies contribute to caregiver and care-recipient well-being (less distress; better quality of life for both; reduced BPSD). In sum: How the threats of caregiving are managed has an effect on the outcomes of the overall process (caregiver affect and PLWA quality of life), as mediated by mastery.
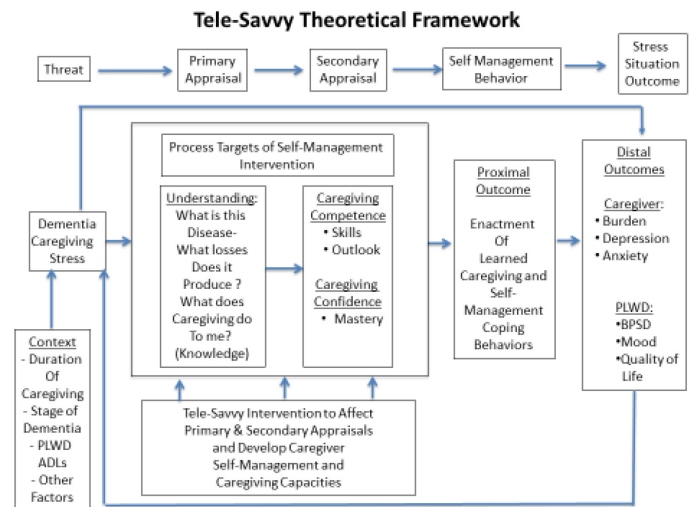
Savvy Caregiver Program (SCP) Development and Testing. SCP is a fully manualized version of two NINR-supported wait-list control trials of group psychoeducation programs provided in-person to family caregivers of PLWA (Minnesota Family Workshop (MFW: NR002971; PI: Ostwald; co-I: Hepburn) and Partners in Caregiving (PIC: NR04517; PI: Hepburn)). Both trials reported statistically significant improvements (with moderate effects) in caregiver burden, depression and anxiety and caregiver mastery.[91-92] SCP was developed to enable community organizations to provide this psychoeducation program to caregivers. We tested SCP efficacy in an Alzheimer's Association-supported wait-list control trial (IIRG-023946). At baseline and 5 months after enrollment, intervention subjects showed significant improvements on measures of distress (p=0.022), mastery (p=0.018), and caregiving competency (p=0.000) while control participants did not. When compared with each other over time, the intervention group differed significantly (and in positive ways) from the control caregivers on the measures of distress (p=0.030), mastery (p=0.019), and loss of self to the caregiving role (p=0.042). Formative evaluation data confirmed the utility and usability of program materials.[2,93]

Savvy as a Widely Disseminated Program. Savvy has been adopted by a wide variety of local, regional and statewide agencies in more than a dozen states (some through the federally-supported Alzheimer's Disease Supportive Services Program). State-based evaluation results mirror those of the SCP trial. Maine's SCP participants showed improved competence, mastery, and personal gain (*p* < 0.05) and a reduction in depressive symptoms and negative reactions to their person's behavior (*p* < 0.05) at 5 and 12 months.[94] California reports similar improvements in caregiver well-being in a racially/ethnically diverse caregiver population.[95] Program materials (trainer's and caregiver's manuals, the train-the-trainer programs, program fidelity monitoring capacity) support its continued implementation.

Many sponsors have found ways to support the program's Maintenance. SCP now has "defined status" in Michigan, making its provision eligible for federal reimbursement – a major step for SCP sustainability that can serve as a model for other states.

Total Tele-Savvy Program Duration: 43 Days

● Weekly Group Videoconferences   — Six Daily Video Lessons per Week

Tele-Savvy. Tele-Savvy engages groups of (on average) six dementia family caregivers in a program that extends over 43 days (see figure below). The program begins with a scheduled 75-minute group videoconference led by one or two facilitators; similar group videoconferences then take place each of the next six weeks (i.e., seven video-conferences). In between the video-conferences, caregivers receive daily emails with links to 5-20 minute on-line video lessons that they can watch <u>on their own schedule and as often as they wish</u> (there are 36 unique video lessons; the Tele-Savvy story board (Appendix A) delineates the content of these video lessons). The curriculum includes all of the elements of SCP plus material from an advanced program (SCP-II)[96] and from Co-PI Griffiths' caregiver self-care projects (see below). The videoconferences incorporate the coaching/debriefing feature of SCP to allow caregivers to report enactment of learned and self-developed management strategy behaviors into their own caregiving. The videoconferences include talks and exercises and also allow caregivers to raise questions. Each daily video presents a teaching point linked to the overall curriculum. All follow the same format: experts provide instruction about a topic, and the lesson is carried forward by brief, scripted talks by other experts or is enacted in brief vignettes in which a fictional family caring for a father living with Alzheimer's demonstrates – at various stages of the illness – effective caregiving techniques linked to the day's teaching points.
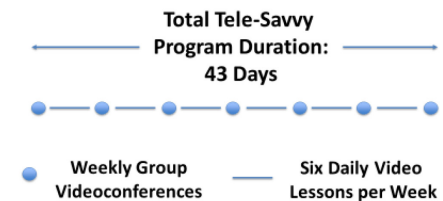
Tele-Savvy Fidelity with Savvy Caregiver. We asked six SCP experts (two of the original authors and four master trainers) to assess the extent to which Tele-Savvy accurately and faithfully embodied SCP. Materials detailing the curriculum and delivery strategy and links to several of the daily video lessons familiarized the experts with the program. We asked the experts to compare Tele-Savvy with SCP across ten dimensions (fidelity to theory; curriculum; time; concept development; teaching images; group interaction; caregiver interaction; design; use of homework; materials) and to rate the extent to which Tele-Savvy was equivalent to, improved on, or fell short of the original on each dimension. Reviewers saw Tele-Savvy as equal to or an improvement on SCP on all but one of the individual dimensions; these "improved" ratings appear to derive from the additions we made. Several reviewers questioned whether a distance format could enable meaningful "connectedness" or interaction among the participants. We paid special attention to the issue of connectedness in the formative evaluation we conducted in the pilot studies.

Preliminary Effectiveness. Caregivers participating in pilot tests sponsored by the VA and the Emory ADRC were asked to complete questionnaires prior to and within two weeks of completing the Tele-Savvy program. The battery included the 12-item Zarit Burden Inventory-Short Form,[97] the Center for Epidemiological Studies depression scale short form (CES-D 10),[98] the State-Trait Anxiety Inventory (STA-I),[99] several sub-scales from Pearlin's Mastery scale,[100] and the Revised Memory and Behavior Problem Checklist (RMBPC).[101] Following the program, we also asked them to respond to evaluative statements such as "I believe I am more knowledgeable as a caregiver." Other items elicited caregivers' perceptions of the quality (0-low to 10-high) of the overall program and its individual components (manual, videos, group classes, self-care sessions). We also sought suggestions for program improvements.

In all, 58 caregivers completed both the VA pilot (22) and the ADRC pilot (36). Combined results indicate significant reductions in BPSD and caregiver upset with symptoms (p=0.012), reduced caregiver burden (p=0.003) and depression (p=0.007) and increased caregiver competence (Mastery) (p=0.001). Significant effects sizes were medium (low of .40 for burden and high of .55 for BPSD upset). Participants who used their

own computers and home internet (as in the proposed trial) encountered no technical difficulties, and only 2 experienced bandwidth problems that interfered with video participation in the videoconferences (audio was fine). Most caregivers (all but one "neutral") 'agreed' or 'strongly agreed' that the program provided useful strategies and the content was personally meaningful to them and their situation. There were no ratings of 'disagree' or 'strongly disagree' with statements about feeling more knowledgeable, confident and skillful. Caregivers gave high ratings to the quality of each program component, including a high of 9.7$\pm$.7 for the daily video class modules. Over 90% gave a rating of 9 or 10 to the program overall, manual, group classes and daily video classes. The median viewing of daily modules was ~80%.

Formative interviews with 19 ADRC trial participants sought their assessments of the program, including their experiences of "connectedness" (the expert reviewers' concern) and of the delivery technology. All provided positive assessments for the overall program (all indicated they would recommend it to others). Almost all reported clear benefits: improved caregiver skills (strategies, assessment abilities, patience) and/or an enhanced self-care focus (methods and permission to engage in self-care). Almost all felt connected both to the other caregiver participants and to the facilitators. More than 3/4ths indicated a preference for the on-line format and would chose it over an in-person format. They recommended improvements in the materials, and some whose PLWA were late in their illnesses or in the MCI stage recommended targeting the program to caregivers whose care recipients were in the early and middle stage of the illness. These recommendations are reflected in our proposed materials refinements and subject targeting criteria.

VA Tele-Rehabilitation and Caregiving. Co-PI Griffiths has engaged in VA-supported studies using distance means to assess, prescribe and train caregiving dyads on the use of assistive technology for activities of daily living within the home environment *(CG ASSIST-D7873-R (Hepburn, Co-I))* and to decrease stress in care dyads engaged in self-managing the stress of one or more chronic conditions (*SLEEP-E Dyads study E7249W* (Hepburn Co-I/Mentor)). The studies have produced a library of video assets (i.e., guided meditations (GM), therapeutic breathing exercises) used to promote caregiver healthy behavior and well-being. Viewers (N=41) provided very positive ratings of four guided meditation videos (emotion recycling; inner sanctuary; breathing; and Metta meditation). Over 92% enjoyed the sessions and more than 83% agreed they felt more relaxed after each.[102-103] Some of these materials developed by Dr. Griffiths are incorporated into Tele-Savvy.

The Study Team and Collaboration Among Centers. The co-PIs, Drs. Hepburn and Griffiths, and the site co-Is, Drs. Boise, Morhardt, and Shah, lead or are members of the Outreach, Recruitment, and Education Cores of the participating ADCs, and all have collaborated previously through the Core network or other research work. Each ADC site provides access to populations of interest. The Emory ADRC research registry (~500) is composed of ~30% African American participants. The Oregon Health Science University ADC clinic last year served 648 unique patients, 47% of whom lived in rural areas. The OHSU ADC collaborates with its medical system's telemedicine and rural primary care practice-based research network. Co-I Boise's work related to dementia and caregiving has explored barriers to assessment, caregiver attitudes to care, implementation of psychoeducation programs, and the use of distance technology in care.[104-107] The Rush Alzheimer's Disease Center (RADC) offers patient care services at the Rush Memory Clinic, including neurological and psychological evaluations and consultation with Alzheimer's specialists. Through support as a State of Illinois Alzheimer's Disease Assistance Center, the RADC manages the Rush Memory Clinic Data and Specimen Repository to link patients and their families to research opportunities. Approximately 1/3 of pre-consented Alzheimer's-diagnosed patients with MMSE ≥ 13 and with family caregivers are African American and 2/3 are Caucasian. The Rush ADC Latino Core builds on established community links to promote research engagement by persons of Latino/Hispanic heritage who are living with Alzheimer's disease and their family caregivers. The Cognitive Neurology and Alzheimer's Disease Center at Northwestern University specializes in the care and scientific study of neurological diseases that interfere with cognition and behavior. The clinical core has a registry of over 300 patients and the Northwestern Neurobehavior and Memory Clinic's multidisciplinary team sees over 500 new patients each year with a heterogeneity of dementia disorders, as well as Alzheimer's disease and dementia with Lewy bodies. The patient population is local to the Chicago area but a significant number, particularly those with a primary progressive aphasia, come from across the country. The majority (88%) of patients with caregivers are Caucasian.

Monthly team videoconferences will be conducted to discuss project progress, recruitment, data collection and analysis, and other issues. The Emory coordinating team will meet weekly. The site co-

investigators and Dr. Hepburn will also meet annually at the ADC Directors' meeting. Additional Data Safety Monitoring Board committee meetings will be held mid-year in years 2 and 3.

Scientific Approach

Design. We aim to enroll 375 subjects in 25 cohorts of 15 subjects each, starting in project month 9 (see project timeline). We expect to enroll, on average, four cohorts per quarter through project year 2 1/2. Recruitment of every 2 cohorts (30 participants total) is scheduled to take place every 6 weeks.   We will use a three-arm design with participants randomly assigned on a 2:2:1 ratio to immediate participation in the Tele-Savvy intervention (N=108), immediate participation in an attention control condition (Healthy Living) (N=108), and a usual care condition (N-54). There will be five data-collection points evenly spaced across 12 months. Those in each cohort's intervention condition will take part in Tele-Savvy immediately following baseline data collection. Those in the attention control and usual care conditions will take part in Tele-Savvy after a delay of 6 months (following the 6-month data collection point. Below, we describe the preparation activities in which we will engage (facilitator training and material revisions) and then describe the trial itself. Four NIA-supported Alzheimer's Disease (Research) Centers will collaborate in recruitment, and Emory University will serve as the coordinating center. Emory will be responsible for randomization of subjects (recruits from all sites will be pooled together for randomization), for delivery and fidelity monitoring of the intervention and attention control condition, and for all data gathering and analysis.

Please see the added document for Amendment 8.

Project Timeline, by Quarters

Main Project Activities	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Staffing; Training; Finalizing																
DSMB scheduled meetings		X			X				X				X			X
Enroll 18 cohorts (15 each) + Acquisition			30	60	90	120	150	180	210	240	270					
Data Collection																
Data Cleaning and Analysis																
Dissemination																

Preparation.

Attention Control Condition Materials Preparation. The attention control condition (see below) will involve the distribution of video and text materials on exercise and nutrition. These are largely be materials from the NIA Go4Life program. Dr. Nocera has led the effort of selecting and sequencing the materials and has worked with Drs. Griffiths and Hepburn and the Project Director to format them into an internet-delivered program. Finalization of these materials (curriculum development and mapping content for group, individual, and asynchronous elements) has occurred during the preparatory phase of this study. Go4Life content is well-developed and is pertinent to caregivers, however, it does not address caregiving issues the way Tele-Savvy Program does. Go4Life provides a motivational framework for a healthier lifestyle, methods to track commitment and improvement, and more than 60 tip sheets on activities, nutrition, health benefits and safety around which daily video modules will be built. Additionally, videoconferences will be developed to incorporate on-line group interaction for attention-control participants to match the time in videoconferences (but not the content) among Tele-Savvy participants.

Facilitator Training. Persons from a variety of backgrounds (nursing, social work, education, etc.) who have experience leading the in-person Savvy Caregiver program will facilitate the synchronous group components of the Tele-Savvy program. We will compile a facilitator's manual, based on the material from the Savvy Caregiver's trainer's manual (see Appendix B) used in the Tele-Savvy pilot and the Tele-Savvy syllabus that delineates the content of the synchronous group videoconferences (Appendix A). The manual will provide clear educational objectives, a time-linked agenda, and descriptions of (and supporting material for) the talks and exercises conducted in each session. A training program (Dr. Hepburn's Savvy Caregiver train-the-trainer program modified for Tele-Savvy) will be used. The training will engage facilitators in practicing the methods and material covered in the videoconferences, and will help facilitators to tailor to the videoconference format the coaching skills essential to facilitating the development of caregiver self-efficacy. It will also focus on the development and maintenance of "connectedness;" in this on-line environment, the facilitator can rely less on

non-verbal cues and has to employ a more directive style to manage group dynamics, such as "calling on" individuals to report on their home activities or to determine if they have questions. One or more facilitators will be trained to conduct the videoconference component of the "Healthy Living" attention control condition. Drs. Nocera and Griffiths will develop and conduct the training program for the attention control facilitator(s). As part of training, each facilitator will lead, as appropriate, a dry run of Tele-Savvy and the Healthy Living programs. The lead investigators will observe these dry runs, providing coaching and additional training, as needed. Former participants of the in-person Savvy Caregiver program will be invited to participate.

Facilitators will be assigned to lead cohort-based Tele-Savvy groups based on their time availability; the leader will be consistent across the seven sessions of the cohort's participation. No facilitator will ever lead more than two groups at a time. Over the course of the project, the investigators and the Project Coordinator will monitor Tele-Savvy and Healthy Living fidelity by observing and evaluating ≥ 3 individual group sessions per facilitator per cohort using a fidelity checklist. Fidelity will evidenced by ≥ 80% adherence to a group session compliance checklist. (Appendix D) Compliance ratings < 80% and median caregiver ratings for session quality of < 8 will signal Hepburn and Griffiths to discuss with facilitators, conduct PRN remedial training and observe/participate in the next two sessions or until ratings adherence is achieved and maintained.

Facilitators will be hired part-time or as consultants as a way to demonstrate that fidelity to the Tele-Savvy Program curriculum can be maintained across interventionists. Additionally, working with part-time facilitators in this study will provide evidence on the feasibility of similar employment of facilitators in other settings, such that Tele-Savvy may be administered by employees of existing organizations (e.g., social workers) as a part of their preexistent job description rather than their sole responsibility. Such incorporation of Tele-Savvy administration into the whole job description is more likely to make Tele-Savvy adoptable in a variety of settings rather than reliance on full-time facilitators.

Materials Finalization. Tele-Savvy is ready for testing. Our preliminary work has established the 43-day structure of the program and its delivery mechanisms. We have updated introductions and select content in the daily videos to include minority experts and actors for case examples. A course syllabus will be provided to participants to allow them to see the course as a whole and to link specific parts of the curriculum to the Caregiver Manual (Appendix C). Note page copies of the Powerpoint slides used in the videoconferences and daily lessons will be provided. The guides to the use of the interactive communication technology used in the program will be upgraded, based on our pilot experiences. Materials from the NIA website for Go4Life has been adapted for use in the attention control condition (see below). We will be placing the Tele-Savvy and attention control material on two commercially available platforms (Vidyo and Canvas) for which Emory has licenses and provides technical assistance. Both require little technical know-how by users; both are accessed by links provided via emails that we will send to participants.

Randomized Trial.
Subjects. Participants will be informal caregivers (family/friends) of persons living with Alzheimer's disease or another dementia. Participants must be providing at least 4 hours per day unpaid assistance, on average, for a person in the early-middle stage of illness (Clinical Dementia Rating of $\geq$ 1 by home ADC) who is community-dwelling and for whom there is no established plan for institutionalization in the next six months. Caregiver may or may not reside with their care recipient, but care recipients must live in the community and not in an assisted living facility, nursing home, or another institutional setting. The participant must not be involved in another caregiver training study and must not have participated in in-person Savvy Caregiver Program or Tele-Savvy previously. Each participant must have access to a computer or a mobile device with adequate internet connection, microphone, and speakers (to be able to participate in teleconferences) and be able to use email (this was not a serious barrier in the pilot studies). Participants must be able to read, speak and understand English and have no uncorrectable vision or hearing deficits that might impede participation. Questions posed after explaining the project during eligibility determination and the consent process will be used to gauge caregivers' cognitive ability to take part in the project. Webcams will be mailed to those caregivers who do not have them for the duration of the entire program and caregivers will be asked to mail webcams back after participation in Tele-Savvy.

Power Analysis and Sample Size Determination Several considerations enter into sample size determination: (1) our wish to accommodate as many caregivers as feasible given time/resources; (2) our experience and prior results from SCP trials; (3) sample and effect sizes/attrition rates in recent dementia CG

meta-analyses. With a final expected sample size of 215 (86, 86, 54 in Tele-Savvy (TS), attention control (AC), and usual care (UC) groups respectively), for the primary intervention test (group-by-time effect) comparing the outcomes of the three group changes from T1 to T2 to T3 (3-by-3 repeated measures design of three groups measured at three time points), at 80% power and 5% significance level, small-to-moderate effect sizes, *Cohen's f = 0.21-0.24* may be detected for the main effects for group, time and group-by-time interaction effects (given moderate correlation between measurement pairs of r=0.3-0.5) (power analysis using PASS 14 Power Analysis and Sample Size Software (2015). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass). After adjusting for any potential group differences, the overall intervention effect of the Tele-Savvy program for the combined T1-to-T3 pre-post effects for the immediate Tele-Savvy group plus the T3-to-T5 pre-post effects from the AC and UC groups will yield a total estimated 215 subjects to perform a pre-post test to detect a small effect size of d=0.19 at 80% power and 5% significance level. With the pooled sample, we will be able to also test the mediating effects of mastery and self-efficacy on the Tele-Savvy program for the caregiver outcomes. As shown by Fritz and MacKinnon (2007), sample sizes of 148-196 were adequate to achieve 80% power to detect small-to-moderate effect sizes for the indirect effect of the independent variable on the dependent variable through the mediating variable considering both the Sobel test as well as percentile and bias-corrected bootstrapped approaches.[108] Although our analytic strategy is robust to missing data we will enroll 270 CGs (108 for TS and AC groups and 54 for UC group) per consideration 1 above (maximize accommodation) allowing for an expected 20% attrition. For the exploratory aim comparing the program's efficacy across the 3 ethnicity groups, with an expected final sample size of 215 subjects and proportions of approximately 65% Caucasian, 20% African American, 15% Hispanic, at 80% and 5% level of significance, we will be able to detect moderate effect sizes Cohen's f=0.19-0.23 (for 3-group by 2-time point RM-ANOVA for group, time and group-by-time effects).

Recruitment and Consent. To the extent possible, all sites will use existing research registries of PLWD and established community partnerships (e.g., with local Alzheimer's Association chapters or other community agencies) to identify caregivers who might be interested in the study. All study sites have robust recruiting networks and strong recruiting track records; we expect a diverse participant group with 25-40% minority (African American and Latino/Hispanic) participation. All of the ADCs have extensive outreach capacity, so we expect candidates will be identified at a distance from, as well as close to the Centers; this was the case in the Tele-Savvy pilots which drew participants from the Atlanta area but also from as far away as California, Minnesota, and Maine. We will employ the same enrollment and consent procedures as in the pilots. Caregivers will be informed about the study by the local coordinator or PI or, through referral, by Emory study staff. If interested, the person will be screened for eligibility by Emory staff (by asking potential subjects to repeat information provided about the study).   Those eligible and still interested will be engaged in the consent process by Emory staff; the process will occur through a documented phone or video consent process.

Computer Set-up and Research Interviews. Cohorts will be composed of consented individuals from the study sites (i.e., the cohorts are not site-specific). Once a consented caregiver cohort has been identified, an Emory research specialist (termed a "navigator") will establish a time for a phone call to take him/her through the relatively straightforward steps of using email to follow URL links that open Vidyo, the videoconferencing application to be used in the project. Following this and while the navigator and participant are still on the phone, the navigator will send a test email to initiate a Vidyo conference with the person. [If we have had to send a webcam, the navigator will help the participant to install it.]   During the videoconference, the navigator will guide the participant through practice in the use of the basic videoconference operations: accepting an incoming conference invitation; muting and unmuting the microphone; muting and unmuting the video camera; using the chat function; and ending the conference. At the end of this call, the navigator will schedule a time for a data collection call (done in person on Vidyo). These procedures were effective in the pilot.

A second Emory research specialist will make the data collection call, providing another opportunity to practice using Vidyo. All data collection will be done by a project research specialist at Emory, trained and supervised by the Emory Co-PIs. This specialist will have no other contact with the subjects and will be blinded to and will ask subjects not to discuss their study condition. For each instrument (or portion of each instrument), the interviewer will show the response options for the particular scale on the screen, so that the respondent does not have to keep those in mind (slides can be projected on the Vidyo platform). We used this procedure in the ADRC pilot project; it worked well and sped up the time of the interviews. Based on experience with the Tele-Savvy pilots, the research interview conference takes 40-60 minutes; it can extend over two calls, if necessary.

All patient records will be kept in a locked file cabinet in the research office at the School of Nursing (i.e. Wesley Woods) and will be accessible only to the PI and the research team.

       Subject Randomization, Coordination, and Retention. Once a cohort of 15 consented subjects has been consented and interviewed, the study statistician (Higgins) will use a block randomization scheme to assign equal numbers of members of the cohort to immediate Tele-Savvy or attention control or usual care wait-list participation. As the figure to the right illustrates, the three groups will each, over 12 months, get the Tele-Savvy program. Attention control program will be administered solely to participants who have been randomized to be in attention-control condition initially. Thus, participants who have been randomized to be in Tele-Savvy condition initially or to usual care will not receive attention-control intervention at 6 months post-baseline Navigators will inform subjects of group assignment and will establish a schedule for participation. For immediate Tele-Savvy participants, start time and time of day for the videoconferences will be set. For those in attention control, start time and time of

Timeline for Each Participating Cohort

day for the videoconferences will be set likewise. For those in the usual care condition, an individual schedule of "empathic calls" will be established. Videoconferences for both Tele-Savvy and attention control will be offered on weekdays (during business hours and evenings) and on weekends to facilitate participation for caregivers who may not be able to join videoconferences on weekdays. Caregivers who might be best served by a Saturday or an evening program will be placed into a block and randomly assigned to Tele-Savvy or attention control conditions. Caregivers for whom weekday participation is non-problematic will be allocated to conditions as described above.

       After navigators inform caregivers about their condition assignment and establish a schedule for participation for those in immediate Tele-Savvy and attention control groups, navigators will conduct individual videoconferences to introduce them to Canvas, a widely used course management platform that will house the daily video lessons. Canvas allows participants to view video lessons at their own convenience and as often as they wish, but it does not allow them to disseminate them. It allows us to track individual use, so we can monitor the "dose" of each participant's viewing. Navigators will teach caregivers how to login and access materials in Canvas and will provide navigators' contact information, reinforcing that caregivers should contact navigators for technical assistance at any time. Canvas also allows us to post evaluation questionnaires. The videoconference will provide participants with another opportunity to practice with Vidyo and to practice opening the lessons (during their participation in Tele-Savvy, navigators will send emails to remind them to access the lessons). The procedure for orienting participants to Canvas will be provided to usual care group participants following the 6-month data collection point and prior to their entry to the Tele-Savvy program. In an effort to keep them engaged in the study, regardless of group assignment, all subjects will receive a monthly study newsletter that will provide information about practices to promote healthy living drawn from NIA's Go4Life program. The e-newsletters will be sent by local site coordinators.

Immediate Participation Group Procedures. Prior to the first group videoconference, Tele-Savvy hard materials (caregiver manual; workbook; journal; resource list) will be mailed to participants. Two days prior to the initial group videoconference (welcoming call), an email will be sent to participants asking them to view the orientation video lesson – the first lesson in the Canvas site. The initial group videoconference will begin a 43-day, six-week sequence of contact in which the daily video lessons are available to participants for asynchronous viewing in between the group videoconferences. The group videoconferences will be led by one or two trained facilitators, last approximately 75 minutes, and follow a fixed agenda and syllabus (see Appendix A). Vidyo allows all of the participants to see one another (they are also identified on the screen only by their first names); whoever is speaking is seen in the full-screen. Vidyo allows participants to ask questions directly or through a chat function. As with Savvy, an important function of the group meetings – following the introductory session – is to allow participants to demonstrate (or witness) successful implementation of effective caregiving strategies and to ask questions about the material presented during the week's daily videos or during the conference itself. The course syllabus and standardized slide decks structure each class in 15-20 minute increments: (1) Facilitators greet and check in with each of the CGs; (2) coaching and debriefing (e.g., hearing how (after the first week) CGs did with the homework, answering questions and/or
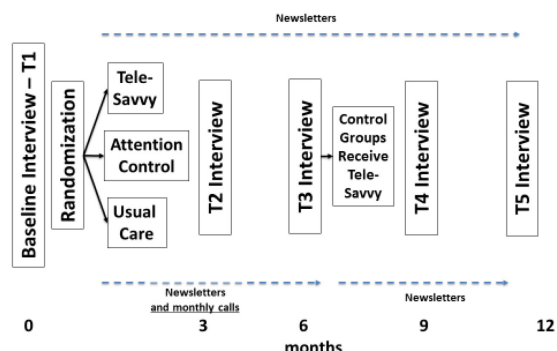
responding to feedback about the week's material; (3) review of key points and concepts from the week's video sessions and introduction of new material (lecture, video vignettes and/or exercise; (4) reports of self-care activities (5) provision of homework assignments and adjournment. A project navigator will initiate and monitor each videoconference. The navigator will keep attendance records and troubleshoot the conferences, providing real-time assistance, should any participant need it; assistance is also logged.

All daily video lessons will be posted on the Canvas site, and participants will receive weekly email reminders to view them, at their convenience. Specifically, videos will be posted, by week, in the order they are listed in the syllabus (e.g., video 1 on day 1, then video 2 on day 2). Caregivers are not under pressure to "keep up" with daily viewing; the program allows participants to view the videos when they are able and as often as they wish. Each daily lesson follows the same pattern: (1) Greeting by hosts (2) Slide presentation of educational content (3) caregiving vignettes (a telenovela-type portrayal of a wife and daughter helping to guide the days of a husband living with dementia; the vignettes were written and directed by the Co-Is and played by amateur actors whom we coached) or guest lecture (4) Recap of key points. The video lessons are 6-20 minutes in length, and they will remain available to participants for two weeks after program's end.

Wait List Attention Control Group Condition and Participation. The attention control condition consists of video and text materials on exercise, diet, and healthy living drawn from the NIA Go4Life program. While these materials provide important and beneficial information, we believe they will not affect our postulated key mediators (mood, mastery and care recipient quality of life). They will provide equal attention, but should not confound the trial. The same number of brief modules as employed in Tele-Savvy (36) will be provided over the course of six weeks; videos will emerge on Canvas site weekly in a manner similar to the Tele-Savvy condition described above. Likewise, navigator will send attention control participants weekly reminder e-mails to log into Canvas and view daily videos. All attention-control participants will convene weekly for a videoconference that will mirror Tele-Savvy videoconference in format and length but will differ in content. Specifically, attention control videoconferences will not contain any information on caregiving strategies, but rather will center on the application of healthy living strategies. A standard structure of each videoconference will be employed by attention-control facilitators: (1) Facilitators greet and check in with each of the caregivers; (2) coaching and debriefing (e.g., hearing how (after the first week) caregivers did with the homework, answering questions and/or responding to feedback about the week's material; (3) review of key points and concepts from the week's video sessions and introduction of new material; (4) reports on any activities that caregivers may have implemented based on the Go4Life materials; (5) provision of homework assignments and adjournment.

Usual Care. Those randomized to this group will be encouraged to continue to receive care for the person living with dementia through whatever arrangement had been in place. Since this group will represent a sort of natural history of caregiving, we will not, with one exception, ask them to restrict any activity they might undertake to seek care for the person or information for themselves. The exception we will request is that, during the 6-month period, they not enroll in an extended caregiver education program. If, in the course of these 6 months, they participate in support groups, visit education web sites, attend informational seminars and/or consult with their health care providers, that will be fine. These are all part of the natural history.

Approximately four months after initial data collection, attention-control and usual care participants will be contacted to schedule their participation in Tele-Savvy which will begin 6 months after their baseline assessment. Their Tele-Savvy experience will be exactly the same as that described above (***Immediate Participation Group Procedures***). These participants will be offered the opportunity of another practice session with Vidyo and Canvas prior to the beginning of Tele-Savvy.

Category	Instrument	Instrument Description	Psychometrics
Baseline Only PLWA Cognitive Status	Informant Questionnaire on Cognitive Decline in the Elderly (*IQCODE*),	A 16-item rating scale (can be informant completed) not contaminated by education	Correlates well with dementia diagnosis; predicts dementia dx as well or better than the MMSE. [109-110]
Demographic Information	Demographic sheet Caregiving History	SES, PLWA information, length of caregiving, co-residence with recipient.	Study-developed form (Baseline only)
PLWA ADLs	Lawton ADL/IADL scale	13-item scale elicits caregiver assessment of PLWA ADL and IADL functioning	Interrater reliability between .87-.91[111]
[Caregiver Vars] Appraisal: Stress	Perceived Stress Scale	14-item Likert-type questionnaire; higher scores reflect higher perceived stress	Internal consistency ranges reported at 0.84 or higher.[112]

Depression	Center for Epidemiological Studies-Depression	A 20 item Likert scale scored 0-3 with somatic and psychological subscales	Alpha=.85 for general population; validity well-established[98]
Anxiety	State-Trait Anxiety Inventory	A 20-item 4-point Likert scale is sensitive to changes in transitory anxiety	STAI state sensitive reliability reported at .94[99]
Burden	the Zarit Burden Inventory (ZBI),	A 22-item 4-point Likert scale, widely used in caregiving studies	Used in multiple studies with well-established validity[113]
Dyadic Relationship	Dyadic Relationship Scale	11-item scale assesses dyadic strain and dyadic interaction perceived by caregiver	Caregiver alphas = .84 and .85[114]
Coping	Ways of Coping Scale	A 42-item scale with 4-point Likert responses identifies emotion- and problem-focused coping responses	Used in multiple studies with well-established validity[115]
Caregiver Mastery	Pearlin Mastery, Loss, and Competence	6 brief (3-6 item) Likert scales assessing mastery and loss dimensions	Alpha coefficients from .71-.92.[100]
Caregiver Skill	Caregiver Assessment of Behavioral Skill	17-item self-report assessment of behavioral management skills	Chronbach alphas from 0.75-0.94 with good validity[116]
Caregiver Reward	Positive Appraisal of Care Scale: Consequential Gain	6-item subscale providing caregiver self-rating of benefits and positive experiences of caregiving	Cronbach's alpha 0.84 for the Consequential gain sub-scale. Established validity. Test-retest reliability 0.86 (p<0.01).[117]
Caregiver Self-Care	Mindful Self-Care Scale Sub-scales	Sub-scales related to supportive relationships (5 items); self-compassion and purpose (6); mindful relaxation (6); clinical (6); and general (3) [26 items total]	Cronbach's alpha 0.89 for the total 33-item scale (excluding sub-scales Clinical and General); 0.83 for Self-Compassion and Purpose sub-scale; 0.77 for Mindful Relaxation sub-scale. Construct validity established preliminarily.[118]
Caregiver Health	Self-rated Health	1-item questionnaire	Test-retest reliability 0.92[119]
[PLWA Variables] Quality of Life	Quality of Life Scale in Alzheimer's Disease	Assesses QOL in 13 domains on a 1-4 point Likert scale. Used as a self-report and surrogate-report instrument	Good internal consistency (Cohen's α=.86) and inter-rater reliability (Cohen's *K*>.70).[120]
Behavioral and Psychological Symptoms in Dementia	Revised Memory and Behavior Problem Checklist	A 22-item Likert scale instrument that assesses patient behaviors and caregiver responses to them	Reliabilities of .84-.90 are reported for behavior and reaction.[101]
Care Recipient Mood	Neuropsychological Inventory Questionnaire	12 item inventory assessing severity of mood states or behaviors reflecting mood	Test-retest correlations between total symptom and distress scores in15 subjects were 0.80 and 0.94, respectively (P< 0.0001 for both.[121]

Data Collection. Data will be collected at baseline and at four subsequent points (months 3, 6, 9, and 12). Each data collection event will follow the same procedure used with the baseline interviews. The Navigator will establish the appointment for the Vidyo interview, and the research specialist, blinded to condition, will conduct the interview. The data collection schedule allows for a direct comparison of outcome measures between groups (at 3 and 9 months); it allows for an examination of prolonged effects (at 9 and 12 months) in the immediate participation group; and it allows for pooling of data across both groups to examine the mediating effects of mastery on distal outcomes in caregivers and PLWD and to compare effects across racial/ethnic groups. Qualitative evaluation interviews will occur at T2 and T3 for a sub-sample of immediate and T4 and T5 for a sub-sample of attention control subjects.

III. G. Variables and Measures. The table above delineates the battery of standardized instruments we will employ; these have well-established psychometric properties (reliability, validity), are used extensively with dementia caregivers, and have been used previously in the *Savvy Caregiver* trials.

As depicted in the figure below, there is a link between our theoretical model and the measures used to test it. Most data will be gathered through the regular interviews, some data will be obtained from self-reported evaluations that caregivers will complete through forms posted on the Canvas site (for example, through logs on the Canvas site in which caregivers report caregiving behaviors they have enacted). After each program, caregivers will be asked, in phone or Vidyo interviews conducted by project investigators, to evaluate the program, indicating what they did/did not like, what did/did not work, how the intervention was helpful or not, and how they would change it. Blackboard will allow us to monitor adherence, dosage and intensity of the

intervention. We will be able to track, for each participant, which daily videos were viewed, when they were viewed and in what pattern (e.g., daily or in a batch), and how often. Attendance in the videoconferences will be recorded. We will also document any indications – through participant complaints or the Navigator's log – of participant burden (e.g., complaints voiced during interviews or need to split interviews over multiple sessions) and reports of barriers to participation (e.g., CGs unable to join call, quality of audio/video).

Data Management and Analysis Plan   Data will be entered at the time of each interview directly into the dedicated project tablet computer and saved on Emory's secure REDCAP platform. All data entry screens are set up in REDCAP and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported into SPSS weekly and syntax run for cleaning, further data verification and file concatenation.

Data integrity checks. After each cohort data-gathering point, all data will be merged in SPSS for scale computation, aggregation, and inferential analysis. In preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of merged files. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). Formal test-retest/inter-rater reliability coefficients will be computed as data are concatenated.

Tele-Savvy Measures Linked to Theoretical Framework

Analytic approach. Preliminary analyses will examine baseline differences among completers and non-completers and by study arm (immediate/attention control/usual care) as a randomization check using means/SDs/Inter-quartile range and t-tests for continuous variables and counts/percentages and N-Par/Chi-Square tests for categorical variables. The association of predisposing factors (demographics, CG history, relationship and care recipient status at baseline) with baseline data as well as change in outcomes over time will be examined using goodness of fit, variance analysis, or correlational techniques depending upon measurement characteristics of variables involved. Where significant baseline associations are detected, these potential confounders will be controlled in subsequent tests of major hypotheses through use of covariates/model adjustments.

Aims 1, 2 and 3 (a). Our primary aims are concerned with assessing the effect of the Tele-Savvy program for reducing or retarding the burden, depression, and anxiety of Alzheimer's family caregiving, promoting the quality of life of persons with Alzheimer's (BPSD, agitation; Quality of Life; affect), and enhancing caregiver mastery. We will employ multi-level mixed effects models (MLM) with random (participant) and fixed (cohort) effects to test linear (and non-linear) trajectories of change for the intervention groups and model group X time and group*time interactions. To compare the Tele-Savvy intervention to the attention control and usual care groups, the first 3 time points will be used to test for differences between the 3 group longitudinal trajectories. Additionally, we will combine the intervention effects for the three groups across the main 3 time points from just before receipt of the intervention to immediately after the intervention to the 1st follow-up time point (T1-to-T2-toT3 for the immediate group and T3-to-T4-to-T5 for the attention control and usual care groups respectively). These combined time points will be referred to as cT1, cT2, cT3. If there are significant differences between or among the 3 groups at the time point immediately prior to receipt of the intervention (cT1), these "baseline" effects will be included and adjusted for in the final model. Overall time effects will be assessed as well as planned post hoc comparisons for immediate effects (cT1 to cT2), longer term effect (cT1 to cT3) and sustained effects (cT2 to cT3). Sidak Type-I error rate adjustment (which has higher power than Bonferroni) will be applied for the multiple pairwise time point comparisons.[122] Additionally, longer term sustained effects will be captured for the immediate Tele-Savvy group using the additional follow-up times at T4 and T5 for this group. The proposed study design has the advantage of capturing 3 "baseline" time points for the wait-list attention control and usual care groups which will provide an excellent opportunity to evaluate what if any potential "placebo" effects there may be from being enrolled in this type of study.[123] These initial
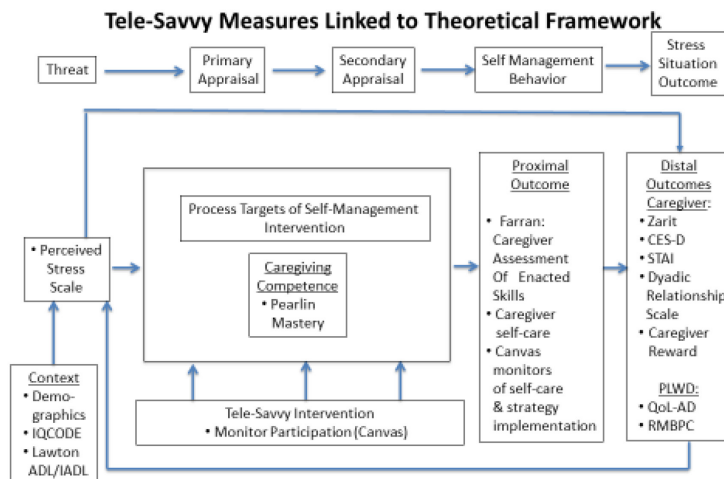
data captured at T1-T2-T3 for the delay group will also be used to evaluate any potential decline occurring during this time period. All model assumptions will be tested; grand mean centering used to help combat multi-collinearity between variables; and standard diagnostic tests and influence statistics used to test the distributions of the residuals. MLM models utilize all available data for all participants at each time point and have the advantage of adjusting for the missing data over time, where repeated measures ANOVAs do not. Further covariate predictors of missingness over time will be included to additionally adjust for these confounders[124] To aid in final interpretation we will include the 95% confidence intervals around means by intervention group and time period. SPSS v.22 will be used for all analyses at the 5% significance level.[122]

Aim 3(b). To test the mediating effect of mastery on Aim 1 & 2 outcomes, we will employ the PROCESS add-on module for SPSS[125] which includes performing the combined approaches of Baron and Kenney, the Sobel test, as well as semi-parametric estimation and testing of the Sobel test through bootstrapping. The focus will be on both the immediate (T2 for immediate Tele-Savvy group and T4 for attention control and usual care groups pooled together) and sustained (T3 for immediate Tele-Savvy group and T5 for attention control and usual care groups pooled together) effects of Tele-Savvy on the mediating measure of mastery on the Aim 1 and Aim 2 outcomes of caregiver burden, depression, anxiety, and dyadic relationship and PLWD BPSD, agitation, mood, and quality of life. These indirect/mediation effects will also be tested and evaluated using structural equation modeling via AMOS v.22.[126]

Exploratory Aim. All subjects will eventually participate in Tele-Savvy, and we will be able to assess program impact on the key caregiver and care recipient measures to test whether the program had similar or different effects across racial/ethnic groups (African American, Caucasian, and Latino/Hispanic). We plan to use the ANCOVA technique to conduct this analysis, using race/ethnicity as the covariate of interest. We expect to conduct a similar analysis to examine differences in impact on rural versus urban caregivers. As our enrollment table indicates, we expect a 20:65:15 African American:Caucasian:Latino subject distribution. The qualitative interviews of participants will enable us to explore the extent to which Tele-Savvy meets caregivers' needs, regardless of race/ethnicity and whether, and, if so, how, it might need to be adjusted to better address the caregiving situations of particular groups.

We will use the technique of constant comparison[127] to analyze the qualitative evaluation data gathered from Tele-Savvy participants (at a point four-months after participation). Co-PI Hepburn and the project coordinator will independently read the transcripts from the first few cohorts, identifying codes that indicate unique observations expressed by participants as well as topics and broader themes around which various codes might cluster. They will compare codes and themes to arrive at mutually agreed upon revisions/refinements in the developing coding scheme (Dr. Griffiths will adjudicate any unresolvable disagreements) and then apply the scheme to transcripts over the course of the project. As significant new themes are identified, previously coded transcripts will be re-read, applying the revised scheme.

Limitations and Challenges. Our decision to limit participation to caregivers with computers and internet access is based on our pilot experience. In the ADRC pilot, we required participants to have their own computers and internet connection; we encountered very few problems. Access is not universal among caregivers, so results will not generalize to all caregivers, but, as noted, internet use in the target age groups (middle-aged and older) continues to rise.[128] We will employ easy-to-use platforms (Vidyo and Canvas) for Tele-Savvy and attention control conditions; both platforms are accessed by a simple click on an email-supplied link. Navigators can train caregivers to use Canvas and technical assistance of navigators will be provided (via phone and e-mail). A navigator will monitor all Tele-Savvy videoconferences to address any technical problems that might arise. We plan to conduct the videoconferences during weekday working hours; this may be a barrier for some eligible caregivers. To address this, we will schedule an occasional program on a weekend or in the evening. While recruitment is always a reasonable concern, our experience with the pilots provides confidence; operating with very little support, we were easily able to recruit 58 caregivers who completed the studies in the course of approximately 18 months. All of the collaborating sites were chosen because their recruitment bases are at least as strong as that at Emory. There were very few dropouts in the pilots among those who actually began the program (<10%); we have used a 25% attrition rate to be conservative in our estimates for our recruitment target.

References

1. Alzheimer's A. 2016 Alzheimer's disease facts and figures. *Alzheimers Dement.* 2016;12(4):459-509.
2. Hepburn K, Lewis M, Tornatore J, Sherman CW, Bremer KL. The Savvy Caregiver program: the demonstrated effectiveness of a transportable dementia caregiver psychoeducation program. *J Gerontol Nurs.* 2007;33(3):30-36.
3. Gallagher-Thompson D, Coon DW. Evidence-based psychological treatments for distress in family caregivers of older adults. *Psychol Aging.* 2007;22(1):37-51.
4. Martin-Carrasco M, Ballesteros-Rodriguez J, Dominguez-Panchon AI, Munoz-Hermoso P, Gonzalez-Fraile E. Interventions for caregivers of patients with dementia. *Actas Esp Psiquiatr.* 2014;42(6):300-314.
5. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist.* 2002;42(3):356-372.
6. Pinquart M, Sorensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects? *Int Psychogeriatr.* 2006;18(4):577-595.
7. Czaja SJ, Loewenstein D, Schulz R, Nair SN, Perdomo D. A videophone psychosocial intervention for dementia caregivers. *Am J Geriatr Psychiatry.* 2013;21(11):1071-1081.
8. Finkel S, Czaja SJ, Schulz R, Martinovich Z, Harris C, Pezzuto D. E-care: a telecommunications technology intervention for family caregivers of dementia patients. *Am J Geriatr Psychiatry.* 2007;15(5):443-448.
9. Glueckauf RL, Davis WS, Willis F, et al. Telephone-based, cognitive-behavioral therapy for African American dementia caregivers with depression: initial findings. *Rehabil Psychol.* 2012;57(2):124-139.
10. Winter L, Gitlin LN. Evaluation of a telephone-based support group intervention for female caregivers of community-dwelling individuals with dementia. *Am J Alzheimers Dis Other Demen.* 2006;21(6):391-397.
11. Griffiths L, Blignault I, Yellowlees P. Telemedicine as a means of delivering cognitive-behavioural therapy to rural and remote mental health clients. *J Telemed Telecare.* 2006;12(3):136-140.
12. Kroenke K, Theobald D, Wu J, et al. Effect of telecare management on pain and depression in patients with cancer: a randomized trial. *JAMA.* 2010;304(2):163-171.
13. Luptak M, Dailey N, Juretic M, et al. The Care Coordination Home Telehealth (CCHT) rural demonstration project: a symptom-based approach for serving older veterans in remote geographical settings. *Rural Remote Health.* 2010;10(2):1375.
14. Taylor DM, Cameron JI, Walsh L, et al. Exploring the feasibility of videoconference delivery of a self-management program to rural participants with stroke. *Telemed J E Health.* 2009;15(7):646-654.
15. Beauchamp N, Irvine AB, Seeley J, Johnson B. Worksite-based internet multimedia program for family caregivers of persons with dementia. *Gerontologist.* 2005;45(6):793-801.
16. Kajiyama B, Thompson LW, Eto-Iwase T, et al. Exploring the effectiveness of an internet-based program for reducing caregiver distress using the iCare Stress Management e-Training Program. *Aging Ment Health.* 2013;17(5):544-554.
17. Lewis ML, Hobday JV, Hepburn KW. Internet-based program for dementia caregivers. *Am J Alzheimers Dis Other Demen.* 2010;25(8):674-679.
18. Cristancho-Lacroix V, Wrobel J, Cantegreil-Kallen I, Dub T, Rouquette A, Rigaud AS. A web-based psychoeducational program for informal caregivers of patients with Alzheimer's disease: a pilot randomized controlled trial. *J Med Internet Res.* 2015;17(5):e117.
19. Ducharme FC, Levesque LL, Lachance LM, et al. "Learning to become a family caregiver" efficacy of an intervention program for caregivers following diagnosis of dementia in a relative. *Gerontologist.* 2011;51(4):484-494.
20. Hayden LJ, Glynn SM, Hahn TJ, Randall F, Randolph E. The use of Internet technology for psychoeducation and support with dementia caregivers. *Psychol Serv.* 2012;9(2):215-218.
21. Lai CK, Wong LF, Liu KH, Lui W, Chan MF, Yap LS. Online and onsite training for family caregivers of people with dementia: results from a pilot study. *Int J Geriatr Psychiatry.* 2013;28(1):107-108.
22. Liddle J, Smith-Conway ER, Baker R, et al. Memory and communication support strategies in dementia: effect of a training program for informal caregivers. *Int Psychogeriatr.* 2012;24(12):1927-1942.

23. Williams VP, Bishop-Fitzpatrick L, Lane JD, et al. Video-based coping skills to reduce health risk and improve psychological and physical well-being in Alzheimer's disease family caregivers. *Psychosom Med.* 2010;72(9):897-904.
24. Boots LM, de Vugt ME, van Knippenberg RJ, Kempen GI, Verhey FR. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. *Int J Geriatr Psychiatry.* 2014;29(4):331-344.
25. Abner EL, Jicha GA, Christian WJ, Schreurs BG. Rural-Urban Differences in Alzheimer's Disease and Related Disorders Diagnostic Prevalence in Kentucky and West Virginia. *J Rural Health.* 2016;32(3):314-320.
26. Morgan DG, Semchuk KM, Stewart NJ, D'Arcy C. Rural families caring for a relative with dementia: barriers to use of formal services. *Soc Sci Med.* 2002;55(7):1129-1142.
27. Morgan DG, Stewart NJ, Crossley M, et al. Dementia care in rural and remote areas: the first year of a CIHR new emerging team. *Can J Nurs Res.* 2005;37(1):177-182.
28. Singh GK, Siahpush M. Widening rural-urban disparities in life expectancy, U.S., 1969-2009. *Am J Prev Med.* 2014;46(2):e19-29.
29. Zhu CW, Scarmeas N, Torgan R, et al. Clinical characteristics and longitudinal changes of informal cost of Alzheimer's disease in the community. *J Am Geriatr Soc.* 2006;54(10):1596-1602.
30. Hurd MD, Martorell P, Delavande A, Mullen KJ, Langa KM. Monetary costs of dementia in the United States. *N Engl J Med.* 2013;368(14):1326-1334.
31. Pinquart M, Sorensen S. Associations of stressors and uplifts of caregiving with caregiver burden and depressive mood: a meta-analysis. *J Gerontol B Psychol Sci Soc Sci.* 2003;58(2):P112-128.
32. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *JAMA.* 1999;282(23):2215-2219.
33. Schulz R, Sherwood PR. Physical and mental health effects of family caregiving. *Am J Nurs.* 2008;108(9 Suppl):23-27; quiz 27.
34. Kiecolt-Glaser JK, Dura JR, Speicher CE, Trask OJ, Glaser R. Spousal caregivers of dementia victims: longitudinal changes in immunity and health. *Psychosom Med.* 1991;53(4):345-362.
35. Covinsky KE, Eng C, Lui LY, et al. Reduced employment in caregivers of frail elders: impact of ethnicity, patient clinical characteristics, and caregiver characteristics. *J Gerontol A Biol Sci Med Sci.* 2001;56(11):M707-713.
36. Gaugler JE, Zarit SH, Pearlin LI. Caregiving and institutionalization: perceptions of family conflict and socioemotional support. *Int J Aging Hum Dev.* 1999;49(1):1-25.
37. Tremont G, Davis JD, Bishop DS. Unique contribution of family functioning in caregivers of patients with mild to moderate dementia. *Dement Geriatr Cogn Disord.* 2006;21(3):170-174.
38. Foley KL, Tung HJ, Mutran EJ. Self-gain and self-loss among African American and white caregivers. *J Gerontol B Psychol Sci Soc Sci.* 2002;57(1):S14-22.
39. Bass DM, Judge KS, Snow AL, et al. Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. *J Am Geriatr Soc.* 2013;61(8):1377-1386.
40. Hebert R, Dubois MF, Wolfson C, Chambers L, Cohen C. Factors associated with long-term institutionalization of older people with dementia: data from the Canadian Study of Health and Aging. *J Gerontol A Biol Sci Med Sci.* 2001;56(11):M693-699.
41. Molloy DW, Bedard M, Pedlar D, Lever JA. Institutionalization in cognitively-impaired inviduals. *Clinical Gerontologist.* 1999;20(2):3-22.
42. Noelker LS. Incontinence in elderly cared for by family. *Gerontologist.* 1987;27(2):194-200.
43. Teri L, Logsdon RG, Uomoto J, McCurry SM. Behavioral treatment of depression in dementia patients: a controlled clinical trial. *J Gerontol B Psychol Sci Soc Sci.* 1997;52(4):P159-166.
44. Folkman S, Lazarus RS. Coping as a mediator of emotion. *J Pers Soc Psychol.* 1988;54(3):466-475.
45. Gallagher-Thompson D, Steffen AM. Comparative effects of cognitive-behavioral and brief psychodynamic psychotherapies for depressed family caregivers. *J Consult Clin Psychol.* 1994;62(3):543-549.
46. Cooper C, Balamurali TB, Selwood A, Livingston G. A systematic review of intervention studies about anxiety in caregivers of people with dementia. *Int J Geriatr Psychiatry.* 2007;22(3):181-188.
47. Zarit SH, Femia EE. A future for family care and dementia intervention research? Challenges and strategies. *Aging Ment Health.* 2008;12(1):5-13.

48. Parker D, Mills S, Abbey J. Effectiveness of interventions that assist caregivers to support people with dementia living in the community: a systematic review. *Int J Evid Based Healthc.* 2008;6(2):137-172.

49. Gitlin LN, Hodgson N. Caregivers as therapeutic agents in dementia care: The evidence-base for interventions supporting their role. In: Gaugler JE, Kane RL, eds. *Family caregiving in the new normal.* Philadelphia, PA: Elsevier, Inc.; 2015:305-356.

50. Belle SH, Burgio L, Burns R, et al. Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: a randomized, controlled trial. *Ann Intern Med.* 2006;145(10):727-738.

51. Mittelman MS, Roth DL, Haley WE, Zarit SH. Effects of a caregiver intervention on negative caregiver appraisals of behavior problems in patients with Alzheimer's disease: results of a randomized trial. *J Gerontol B Psychol Sci Soc Sci.* 2004;59(1):P27-34.

52. Department of Health and Human Services. *Justification of estimates for appropriations committees.* Washington, DC2015.

53. Bedard M, Koivuranta A, Stuckey A. Health impact on caregivers of providing informal care to a cognitively impaired older adult: rural versus urban settings. *Can J Rural Med.* 2004;9(1):15-23.

54. Chwalisz K, Clancy Dollinger SM, O'Neil Zerth E, Tamkin VL. Education, training, and support for rural caregivers. In: Talley RC, Chwalisz K, Buckwalter KC, eds. *Rural caregiving in the United States: Research, practice, policy.* New York, NY: Springer; 2011.

55. Davis LL, Gilliss CL, Harper MS. Family caregiving: implications for rural practice, policy, education, and research. In: Talley RC, Chwalisz K, Buckwalter KC, eds. *Rural caregiving in the United States: Research, Practice, Policy.* New York, NY: Springer; 2011.

56. Glymour MM, Kosheleva A, Wadley VG, Weiss C, Manly JJ. Geographic distribution of dementia mortality: elevated mortality rates for black and white Americans by place of birth. *Alzheimer Dis Assoc Disord.* 2011;25(3):196-202.

57. Innes A, Morgan D, Kosteniuk J. Dementia care in rural and remote settings: a systematic review of informal/family caregiving. *Maturitas.* 2011;68(1):34-46.

58. The National Advisory Committee on Rural Health and Human Services. *The 2008 report to the Secretary: rural health and human services issues.* 2008.

59. Rocca WA, Petersen RC, Knopman DS, et al. Trends in the incidence and prevalence of Alzheimer's disease, dementia, and cognitive impairment in the United States. *Alzheimers Dement.* 2011;7(1):80-93.

60. Russ TC, Batty GD, Hearnshaw GF, Fenton C, Starr JM. Geographical variation in dementia: systematic review with meta-analysis. *Int J Epidemiol.* 2012;41(4):1012-1032.

61. Black BS, Johnston D, Rabins PV, Morrison A, Lyketsos C, Samus QM. Unmet needs of community-residing persons with dementia and their informal caregivers: findings from the maximizing independence at home study. *J Am Geriatr Soc.* 2013;61(12):2087-2095.

62. Fox S, Brenner J. *Family caregivers online.* 2012.

63. Kim H. Understanding Internet Use Among Dementia Caregivers: Results of Secondary Data Analysis Using the US Caregiver Survey Data. *Interact J Med Res.* 2015;4(1):e1.

64. Stellefson M, Chaney B, Barry AE, et al. Web 2.0 chronic disease self-management for older adults: a systematic review. *J Med Internet Res.* 2013;15(2):e35.

65. Erickson J, Johnson GM. Internet use and psychological wellness during late adulthood. *Can J Aging.* 2011;30(2):197-209.

66. Glueckauf RL, Ketterson TU, Loomis JS, Dages P. Online support and education for dementia caregivers: overview, utilization, and initial program evaluation. *Telemed J E Health.* 2004;10(2):223-232.

67. Mahoney DF, Tarlow BJ, Jones RN. Effects of an automated telephone support system on caregiver burden and anxiety: findings from the REACH for TLC intervention study. *Gerontologist.* 2003;43(4):556-567.

68. Blom MM, Zarit SH, Groot Zwaaftink RB, Cuijpers P, Pot AM. Effectiveness of an Internet intervention for family caregivers of people with dementia: results of a randomized controlled trial. *PLoS One.* 2015;10(2):e0116622.

69. Kwok T, Au A, Wong B, Ip I, Mak V, Ho F. Effectiveness of online cognitive behavioral therapy on family caregivers of people with dementia. *Clin Interv Aging.* 2014;9:631-636.

70. Marziali E, Garcia LJ. Dementia caregivers' responses to 2 Internet-based intervention programs. *Am J Alzheimers Dis Other Demen.* 2011;26(1):36-43.

71. Torp S, Hanson E, Hauge S, Ulstein I, Magnusson L. A pilot study of how information and communication technology may contribute to health promotion among elderly spousal carers in Norway. *Health Soc Care Community.* 2008;16(1):75-85.

72. Algase DL, Beattie ER, Antonakos C, Beel-Bates CA, Yao L. Wandering and the physical environment. *Am J Alzheimers Dis Other Demen.* 2010;25(4):340-346.

73. Beck CK, Vogelpohl TS, Rasin JH, et al. Effects of behavioral interventions on disruptive behavior and affect in demented nursing home residents. *Nurs Res.* 2002;51(4):219-228.

74. Buckwalter KC, Gerdner L, Kohout F, et al. A nursing intervention to decrease depression in family caregivers of persons with dementia. *Arch Psychiatr Nurs.* 1999;13(2):80-88.

75. Harvath TA, Patsdaughter CA, Bumbalo JA, McCann MK. Dementia-related behaviors in Alzheimer's disease and AIDS. *J Psychosoc Nurs Ment Health Serv.* 1995;33(1):35-39.

76. Kovach CR, Noonan PE, Schlidt AM, Wells T. A model of consequences of need-driven, dementia-compromised behavior. *J Nurs Scholarsh.* 2005;37(2):134-140; discussion 140.

77. Burgio L, Stevens A, Guy D, Roth DL, Haley WE. Impact of two psychosocial interventions on white and African American family caregivers of individuals with dementia. *Gerontologist.* 2003;43(4):568-579.

78. Coon DW, Thompson L, Steffen A, Sorocco K, Gallagher-Thompson D. Anger and depression management: psychoeducational skill training interventions for women caregivers of a relative with dementia. *Gerontologist.* 2003;43(5):678-689.

79. Gallagher-Thompson D, DeVries HM. "Coping with frustration" classes: development and preliminary outcomes with women who care for relatives with dementia. *Gerontologist.* 1994;34(4):548-552.

80. Allen CK. Occupational therapy: functional assessment of the severity of mental disorders. *Hosp Community Psychiatry.* 1988;39(2):140-142.

81. Gitlin LN, Kales HC, Lyketsos CG. Nonpharmacologic management of behavioral symptoms in dementia. *JAMA.* 2012;308(19):2020-2029.

82. Gitlin LN, Winter L, Burke J, Chernett N, Dennis MP, Hauck WW. Tailored activities to manage neuropsychiatric behaviors in persons with dementia and reduce caregiver burden: a randomized pilot study. *Am J Geriatr Psychiatry.* 2008;16(3):229-239.

83. Gitlin LN, Winter L, Corcoran M, Dennis MP, Schinfeld S, Hauck WW. Effects of the home environmental skill-building program on the caregiver-care recipient dyad: 6-month outcomes from the Philadelphia REACH Initiative. *Gerontologist.* 2003;43(4):532-546.

84. Anderson RA, Bailey DE, Jr., Wu B, et al. Adaptive leadership framework for chronic illness: framing a research agenda for transforming care delivery. *ANS Adv Nurs Sci.* 2015;38(2):83-95.

85. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. *Nurs Outlook.* 2009;57(4):217-225 e216.

86. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. *Psychol Rev.* 1977;84(2):191-215.

87. Bandura A. Human agency in social cognitive theory. *Am Psychol.* 1989;44(9):1175-1184.

88. Folkman S, Lazarus RS, Gruen RJ, DeLongis A. Appraisal, coping, health status, and psychological symptoms. *J Pers Soc Psychol.* 1986;50(3):571-579.

89. Folkman S. Personal control and stress and coping processes: a theoretical analysis. *J Pers Soc Psychol.* 1984;46(4):839-852.

90. Pearlin LI, Schooler C. The structure of coping. *J Health Soc Behav.* 1978;19(1):2-21.

91. Hepburn KW, Lewis M, Nelson Kirk L, et al. Partners in caregiving. *Clinical Gerontologist.* 2006;29(1):53-69.

92. Ostwald SK, Hepburn KW, Caron W, Burns T, Mantell R. Reducing caregiver burden: a randomized psychoeducational intervention for caregivers of persons with dementia. *Gerontologist.* 1999;39(3):299-309.

93. Hepburn KW, Lewis M, Sherman CW, Tornatore J. The savvy caregiver program: developing and testing a transportable dementia family caregiver training program. *Gerontologist.* 2003;43(6):908-915.

94. Samia LW, Aboueissa AM, Halloran J, Hepburn K. The Maine Savvy Caregiver Project: translating an evidence-based dementia family caregiver program within the RE-AIM Framework. *J Gerontol Soc Work.* 2014;57(6-7):640-661.

95. Kally Z, Cote SD, Gonzalez J, et al. The Savvy Caregiver Program: impact of an evidence-based intervention on the well-being of ethnically diverse caregivers. *J Gerontol Soc Work.* 2014;57(6-7):681-693.

96. Samia LW, Hepburn K, Nichols L. "Flying by the seat of our pants": what dementia family caregivers want in an advanced caregiver training program. *Res Nurs Health.* 2012;35(6):598-609.

97. Bedard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: a new short version and screening version. *Gerontologist.* 2001;41(5):652-657.

98. Radloff S. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement.* 1977(1):385-401.

99. Spielberger CD, Vagg PR. Psychometric properties of the STAI: a reply to Ramanaiah, Franzen, and Schill. *J Pers Assess.* 1984;48(1):95-97.

100. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist.* 1990;30(5):583-594.

101. Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: the revised memory and behavior problems checklist. *Psychol Aging.* 1992;7(4):622-631.

102. Griffiths PC, Sanford JA. ADL task performance in mobility impaired older dyads: preliminary data from the CG ASSIST pilot. *Assistive Technology: From Research to Practice: AATE.* 2013;33:446.

103. Sanford JA, Griffiths PC. Using remote tele-video technology to provide in-home AT assessment and training to mobility-impaired elders and their caregivers. *Assistive Technology: From Research to Practice.* 2013;33:741-747.

104. Boise L, Eckstrom E, Fagnan L, et al. The rural older adult memory (ROAM) study: a practice-based intervention to improve dementia screening and diagnosis. *J Am Board Fam Med.* 2010;23(4):486-498.

105. Boise L, Neal MB, Kaye J. Dementia assessment in primary care: results from a study in three managed care systems. *J Gerontol A Biol Sci Med Sci.* 2004;59(6):M621-626.

106. Connell CM, Boise L, Stuckey JC, Holmes SB, Hudson ML. Attitudes toward the diagnosis and disclosure of dementia among family caregivers and primary care physicians. *Gerontologist.* 2004;44(4):500-507.

107. Galvin JE, Meuser TM, Morris JC. Improving physician awareness of Alzheimer disease and enhancing recruitment: the Clinician Partners Program. *Alzheimer Dis Assoc Disord.* 2012;26(1):61-67.

108. Fritz MS, Mackinnon DP. Required sample size to detect the mediated effect. *Psychol Sci.* 2007;18(3):233-239.

109. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol Med.* 1989;19(4):1015-1022.

110. Jorm AF, Scott R, Cullen JS, MacKinnon AJ. Performance of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) as a screening test for dementia. *Psychol Med.* 1991;21(3):785-790.

111. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist.* 1969;9(3):179-186.

112. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* 1983;24(4):385-396.

113. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist.* 1980;20(6):649-655.

114. Sebern MD, Whitlatch CJ. Dyadic relationship scale: a measure of the impact of the provision and receipt of family care. *Gerontologist.* 2007;47(6):741-751.

115. Vitaliano PP, Russo J, Carr JE, Maiuro RD, Becker J. The Ways of Coping Checklist: Revision and Psychometric Properties. *Multivariate Behav Res.* 1985;20(1):3-26.

116. Farran CJ, Fogg LG, McCann JJ, Etkin C, Dong X, Barnes LL. Assessing family caregiver skill in managing behavioral symptoms of Alzheimer's disease. *Aging Ment Health.* 2011;15(4):510-521.

117. Yamamoto-Mitani N, Sugishita C, Ishigaki K, et al. Development of instruments to measure appraisal of care among Japanese family caregivers of the elderly. *Sch Inq Nurs Pract.* 2001;15(2):113-135; discussion 137-141.

118. Cook-Cottone CP, Guyker W. The Mindful Self-Care Scale: mindful self-care as a tool to promote physical, emotional, and cognitive well-being. 2016, manuscript in preparation.

119. Lorig K, Stewart A, Ritter P, Gonzalez V, Laurent D, Lynch J. *Outcome measures for health education and other health care interventions.* Thousand Oaks, CA: Sage Publications; 1996.

120. Thorgrimsen L, Selwood A, Spector A, et al. Whose quality of life is it anyway? The validity and reliability of the Quality of Life-Alzheimer's Disease (QoL-AD) scale. *Alzheimer Dis Assoc Disord.* 2003;17(4):201-208.

121. Kaufer DI, Cummings JL, Ketchel P, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin Neurosci.* 2000;12(2):233-239.

122. *IBM SPSS Statistics for Windows* [computer program]. Version 22.0. Armonk, NY: IBM Corp; 2013.

123. Benedetti F. *Placebo effects: understanding the mechanisms in health and disease.* Oxford: Oxford University Press; 2014.

124. Hedeker D, Gibbons RD. *Longitudinal data analysis.* John Wiley & Sons; 2006.

125. Hayes AF. *Introduction to mediation, moderation, and conditional process analysis: A regression-based approach.* New York, NY: Guilford Press; 2013.

126. Arbuckle J. AMOS. New York, NY: IBM Corporation; 2013.

127. Lincoln YS, Guba EG. *Naturalistic inquiry.* Sage; 1985.

128. Smith A. Older adults and technology use. 2014; http://www.pewinternet.org/2014/04/03/older-adults-and-technology-use/.