COPE IN PACE STUDY PROTOCOL

Protocol # 831688

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Study Name: The Case for COPE in PACE service settings

Specific Aims

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Protocol Title: A Training and Fidelity Model to Move and Scale Evidence-based Dementia Care and Caregiver Support Programs into Practice: The Case for COPE in PACE service settings

Short Title: The Case for COPE in PACE service settings

Protocol Description: The aims of the study are to determine whether an online training program is the same or better in improving interventionist fidelity to an evidence-based dementia program (COPE) when compared to a high intensity face-to-face traditional form of training. We will develop an online, principle-driven approach using state-of-the science simulation and best practices and a scalable approach to assess fidelity to COPE by applying computational linguistics techniques.

Abstract: This NIA Stage I study is designed to address two leading barriers to implementation of evidence-based dementia care and caregiver support programs into long-term care settings: (1) lack of streamlined, user-friendly, and tested training modalities, and (2) lack of scalable, practical processes to accurately measure fidelity in real world settings. The aims of the study are to determine whether an online training program is the same or better in improving interventionist fidelity to an evidence-based dementia program (COPE) and dementia patient outcomes when compared to a high intensity face-to-face traditional form of training. To accomplish these aims we will develop an online, principle-driven approach using state-of-the science simulation and best practices and a scalable approach to assess fidelity to COPE by applying computational linguistics techniques. We will then conduct a noninferiority trial in Programs for All Inclusive Care for Elders (PACE) organizations randomly assigned to the training conditions. PACE staff will be evaluated post training on their fidelity outcomes. The findings from this project will lay the essential groundwork for a large scale, Stage III-IV, pragmatic trial of COPE in PACE settings throughout the US. Findings will also serve as a model for guiding the development of practical, scalable processes for training and fidelity monitoring in other long-term care settings and for other evidence-based support programs.

Background: Dementia is a devastating neurodegenerative disease and leading cause of disease burden. Many interventions for caregivers and persons with dementia are efficacious but have not been integrated in long-term service and support and consequently are not available to families. Two leading barriers to implementation are the lack of methods to ensure real-world fidelity to delivery, and the need for scalable and reliable training procedures for clinicians. The scientific premise of this project is that by addressing the two leading barriers to the implementation of evidence-based dementia supportive services in service contexts, namely scalable training and fidelity monitoring approaches, we will enhance the impact of dementia by extending it as a person-centered model to being a family-centered program with potential positive outcomes for persons living with dementia and their caregivers.

Specific Aims

Aim 1: In a non-inferiority randomized trial, determine whether an online training program is the same or better in improving interventionist uptake of COPE principles and protocols compared to a high intensity face-to-face traditional form of training. To accomplish this aim we will develop an online, principle-driven approach using state-of-the-science simulation and best practices to train long-term care providers in the evidence-based, dementia care COPE program in 10 PACE organizations. We will compare OTs and RNs trained in the online program to those trained via online in: level of confidence in delivering COPE, level of competency achieved, and training satisfaction following training exposure. We hypothesize that the online program will yield the same or better outcomes as the

traditional training approach.

Aim 2. Compare fidelity of implementing COPE based on receiving the online training versus the traditional face-to-face COPE training program. To accomplish this aim, we will develop a scalable approach to assess fidelity to COPE in PACE programs by applying computational linguistics techniques (e.g. natural language processing) to audio recorded COPE sessions between trained OTs or RNs and PACE participants with dementia. We hypothesize that that the online program will yield the same or better fidelity outcomes as the traditional training approach.

Aim 3: Compare the efficacy of COPE on participant outcomes (persons with dementia physical function, quality of life and caregiver overall wellbeing) by type of COPE training (online vs. traditional face-to-face). To accomplish this aim, we will enroll 50 dyads (25 from sites in online training and 25 from sites with face-to-face training) and provide the COPE program. We hypothesize that dyads will show similar positive gains regardless of how interventionists were trained. The findings from this project will lay the essential groundwork for a large scale, Stage III-IV, pragmatic trial of COPE in PACE settings throughout the US. Findings will also serve as a model for guiding the development of practical, scalable processes for training and fidelity monitoring in other long-term care settings and for other evidence-based support program.

Significance

Dementia, a devastating neurodegenerative disease and leading cause of disease burden, results in substantial health-related costs for persons with dementia, their caregivers (CGs), and society. Over 5 million Americans currently live with Alzheimer's disease or related dementias (1). Although recent research suggests a decline in incidence over the past 12 years, with no cure in sight, providing effective care remains a public priority. More than 15 million unpaid CGs in the US, mostly family CGs, provide daily care over the disease trajectory (2). Caregiving tasks accumulate with disease progression, resulting in significant and well- documented physical, emotional, and financial consequences for families (3-4). Among community-dwelling persons with dementia, functional ability and family CG well-being are the strongest predictors of the increased need for time spent caregiving, hospital use and nursing home placement (5, 6). Dementia adds considerably to Medicare and Medicaid costs due primarily to excess hospitalization and nursing home use (7). As families provide more than 80% of long-term care to older adults (8), and our health care system is dependent upon family involvement, a comprehensive and family-centered approach to managing dementia is required (9).

Many interventions for caregivers and persons with dementia are efficacious but have not been integrated in long-term service and support (LTSS) and consequently are not available to families. Through a synthesis of meta-analyses and systematic reviews of randomized trials, we have identified over 200 dementia caregiving interventions found to be efficacious in improving CG well-being in community dwelling persons with dementia (10-13). There is overwhelmingly strong evidence for the role of CG interventions in reducing family distress (10), and for persons with dementia, delaying institutionalization (11), reducing behavioral symptoms (12), and improving QOL (13). Similarly, we recently conducted systematic reviews of home-based interventions to address needs of persons with dementia. In a review of 24 randomized trials focusing specifically on improving the daily physical function of persons with dementia living at home, most interventions resulted in clinically meaningful improvements (14). However, few proven interventions have been translated for delivery and sustained in real world practice settings with fidelity.

Two leading barriers to implementation are the lack of methods to ensure real-world fidelity to delivery, and the need for scalable and reliable training procedures for clinicians. Most evidence-based dementia interventions lack quality control measures to ensure consistent training in their core

principles that reflect the mechanisms of action or pathways for treatment effects (15). Also, interventions typically lack a scalable approach to assuring treatment fidelity or that the intervention is delivered consistently and as intended. In addition, training and fidelity approaches typically rely on humans, and specifically are over reliant on the original developers, as the sole method for disseminating proven programs -further inhibiting the likelihood of large-scale implementation (16). To address the training barrier, we propose to develop an online program that integrates simulation training. Simulation involves use of standardized patients who are individuals trained to act as a real client/patient in order to simulate a set of symptoms or problems (17,18). The standardized patient is a person carefully coached to simulate an actual patient so accurately that the simulation cannot be detected by a skilled clinician. The simulation, utilizing the simulated/standardized patient (SP) actor enables the maintenance and advancement of professional and safe competencies in interpersonal communication, assessment, targeted techniques, teaching, handling of ethical dilemmas and crisis situations. Simulation has a long history in medical and nursing and other health professional training and has been shown to be highly effective in providing knowledge and skills of complex medical cases (19,20). However, it has not been applied to instructing in evidence-based programs for dementia care. We also propose to use computer language methodologies to develop an automated approach to measure clinician fidelity (21,22). Thus, technology-based solutions to training and fidelity that are easy to use and designed for efficient integration into everyday clinical practice can have a powerful impact on the field of dementia care. To date, such approaches have not been applied to advance evidence-based dementia care and caregiver support programs.

Most participants in Programs of All- Inclusive Care of the Elderly (PACE) have dementia, yet to date, evidence-based programs have not been integrated into their service mix (23,24). PACE provides comprehensive long-term care services and supports to nursing home eligible Medicaid and Medicare enrollees in the community so that elders can remain in their homes (24). Dementia is an independent risk factor for nursing home admission in numerous studies of community-dwelling older adults, even when controlling for numerous comorbidities (25). Among PACE participants with dementia, functional disability and family caregiver physical and emotional strain, are the most important predictors of nursing home admission pointing to the need to keep older adults with dementia at the highest levels of functioning as possible to remain living at home (26). Physical and emotional burdens of providing help with activities of daily living, as well as the challenges of managing disruptive behaviors such as wandering and resistance to care, place CGs at risk for depression, physical health problems, and admitting their relative to a nursing home (25). Thus, PACE is an important test bed for integrating evidence-based programs that can delay or avoid nursing home admissions. Nonetheless, the gap between the dementia care evidence-base and community-based dementia care has long been noted in the literature (26). Despite tremendous strides in developing and testing community-based programs for persons with dementia, they have been tested outside of existing service and funding streams. Also, there has been little study of strategies for effective dissemination of evidence-based interventions and impact on adoption by community-based long-term care settings such as PACE (27,28).

The Care of Persons in their Environment (COPE) Program applies to dementia populations of any etiology and caregivers across dementia care settings- including those participating in publicly funded long-term care programs (29). COPE is a 4-month, family-centered, non-pharmacologic program using occupational therapists (OT) and registered nurses (RN) to optimize functional independence in persons with dementia, and to improve CG dementia management skills. In the original COPE randomized controlled trial (RCT) tested as a Phase Ill (NIA–Stage 11) clinical trial, persons with dementia receiving COPE experienced less functional decline and more activity engagement designed to keep them independent, compared to an attention control group (30). CGs receiving COPE, compared to controls, reported improved well-being, increased confidence in using

behavioral strategies to address dementia symptoms, and greater ability to keep their family member at home (30). Thus, COPE, with its dual focus on functional independence and CG well-being is congruent with the programmatic goals of PACE.

COPE's Core Principles are mechanism focused and compatible with the NIH Common Fund's Science of Behavior Change Program (31). COPE draws upon the Competence-Environmental Press framework (32), Personal Control Theory (33), and Transtheoretical Model of Behavior Change (34). The competence-environmental press framework suggests that competency declines in persons with dementia as a result of an unchanging physical and social environment with substantial demands (or press) on an individual that may result in negative behavioral and functional outcomes (32). With the progression of dementia, the person becomes unable to navigate the environment and may ignore or misinterpret cues and environmental information that would otherwise support adaptive behavior. Therefore, modifying and simplifying aspects of the environment to match reduced competency may minimize excess disability in persons with dementia (35). As such, COPE involves OTs and RNs who work with CGs to learn new strategies (e.g., communication, environmental simplification, stress reduction, use of activity) to maximize functional abilities, improve QOL, and reduce difficulties managing day-to-day care challenges and associated distress. Home sessions over 4 months include: (1) CG education and skills training, (2) environmental modifications, and (3) clinical and laboratory assessments designed to detect undiagnosed medical conditions that increase risk for adverse outcomes such as functional decline, falls, hospitalization and institutionalization.

Personal control theory provides an additional rationale for why an environmental approach may also benefit persons with dementia and their caregivers. According to this theory, maintaining control is a universal imperative achieved by using primary mechanisms such as changing the immediate environment (e.g., objects), secondary mechanisms such as changing cognition/thoughts or emotions or a combination of both (33). Therefore, the unsuccessful application of these mechanisms to achieve control may result in negative affective consequences such as emotional distress and lowered self-efficacy (36). In the process of providing verbal instruction and training to dementia caregivers, the COPE program uses cognitive restructuring and validation to instill greater perceived control and confidence in the caregivers' own abilities to manage the problem and to develop more realistic appraisals of the caregiving situation, dementia-related behaviors, and expectations. Helping caregivers reframe attributions and explain events is important to enable behavioral change and the use of environmental strategies. COPE is designed to reduce excess disability at the mild to moderate stage of dementia to optimize quality of life (38) (Figure 1). COPE also draws upon the Transtheoretical Model of Behavior Change (34, 37) which suggests that changing one's behavior can be challenging and occurs incrementally through stages of readiness. We have suggested that when applied to dementia care, caregivers with little knowledge of dementia and acceptance of using nonpharmacologic strategies are at pre-action stages of readiness (e.g., precontemplation, contemplation or preparation). Alternately, those willing to try new strategies are at action stage. Using these classifications we have shown that caregivers widely vary in readiness, readiness is associated with different caregiver and patient-related baseline factors and that caregivers who either begin or move to high readiness by conclusion ofan intervention are more likely to be therapeutically engaged (p=.030) and report greater intervention benefits (p=.003) (39).

Significance and Scientific Premise: The scientific premise of this project is that by addressing the two leading barriers to the implementation of evidence-based dementia supportive services in service contexts, namely scalable training and fidelity monitoring approaches, we will enhance the impact of PACE by extending it as a person-centered model to being a family-centered program with potential positive outcomes for persons with dementia, familyCGs, and PACE providers. The study addresses recommendations made at the 2017 NIA Workshop, "Innovating the Next

Generation of Dementia and Alzheimer's Disease Care Interventions," which underscored the need for essential groundwork for successful pragmatic trials and ultimate implementation (40). The proposed research reflects the NIA model of behavioral intervention development and specifically, Stage 1. While COPE is an efficacious program (proven in a Stage II randomized clinical trial), we now need to engage in advancing its training and fidelity features (Stage 1) to move towards a pragmatic trial (Stage IV) for large scale testing and dissemination. As such, our proposal is timely and significant for its potential to provide scalable solutions for training and monitoring the fidelity of an evidence- based approach for family centered dementia care. The potential impact of the study is enhanced by strong stakeholder commitment and involvement, and rigorous approaches to the development and testing of the training and fidelity monitoring strategies. The findings will provide essential stepping-stones towards ultimate implementation. Finally, achieving the aims of this proposal has potential to positively impact clinical practice.

Innovation: Our NIA Stage I study is innovative in five important ways:

1. This is the first study to systematically translate an evidence-based program into a PACE setting.
2. The COPE program's shifts the current "person centered" models of dementia care to a "family centered" model by integrating an evidence-based practice that focuses on the dyad (person living with dementia and caregiver) in an existing service and payment model that has potential to produce resulting benefits for both persons with dementia, their CGs and staff.
3. Advances in asynchronous online simulation training points us towards novel solutions to developing and testing a streamlined, user-friendly, approach to training long-term care providers on the implementation of an evidence-based program that is not dependent upon labor-intensive face-to-face training and intensive involvement of the developers of the original program. Thus, this study will have great impact in guiding future efforts to scale evidence into practice by providing a model for scalable approaches to training providers in evidence-based approaches.
4. We will capitalize on recent technological advances by developing an automated process for fidelity monitoring based in natural language processing methods, and advances in statistical test text analysis and behavioral science expertise to produce a computational tool to support and extend the capacity for large-scale fidelity monitoring. Historically, the research gold standard for evaluating fidelity has been human coding applying a theory driven rubric to identify relevant activities. This type of coding requires the training of human readers, establishing inter-rater reliability, and then performing the time-consuming task of coding. This reliance on human judgment for fidelity has been labor intensive, expensive, and has impeded the ability to study widespread dissemination efforts. As a result, it has been impossible to evaluate fidelity in large-scale pragmatic trials in any systematic ongoing manner. The proposed study examines a novel methodology for automating evaluation of clinician fidelity to an evidence-based program that could be used by clinical settings as a systematic approach for quality assurance.
5. Partnering with Trinity PACE, the largest PACE provider in the US, will provide robust, generalizable data. The development of this proposal reflects extensive collaboration among study team members and Trinity Health. Trinity Health PACE is a member of Trinity Health, one of the largest multi-institutional Catholic health care delivery systems in the US. Trinity Health PACE is one of the leading providers of PACE in the county based on the number of available programs. In preparation for this application, during meetings with Trinity Health and Trinity PACE leadership, leaders, administrators and staff all demonstrated clear engagement, and expressed keen interest in improving dementia care practices, and a readiness and capacity for change. In preparation for this RFA 10 Trinity Health PACE organizations expressed willingness to participate (see Letter of Support). PACE Organizations for participation in this trial fit these criteria: a) have a minimum of 90 enrolled participants: b) have OT and RN staff; and c) express willingness to participate and accept random assignment. The lessons learned in this study concerning training and fidelity methodologies will enable us to move rapidly forward with a large, multi-site pragmatic trial to test embedding COPE within existing Trinity PACE. As Trinity PACE Organizations will be highly generalizable to all PACE programs nationally as they all have similar financial and clinical

structures regardless of their management organization nationally.

Approach

Responsiveness to RFA-AG-18-030. Our proposal is directly responsive to this FOA by laying the groundwork for a future effectiveness/pragmatic trial and real world implementation of dementia caregiving interventions. We will create user-friendly, easily delivered online modules to train PACE care providers (Nurses and occupational therapists) in COPE– a proven program that reduces caregiver challenges and enhances daily quality of life of persons living with dementia. The novel online training program will be compared to a usual training condition (high intensity face-to-face) using a non-inferiority randomized trial design **(NIH** Stage I). Secondly, we will develop a scalable approach to monitoring and ensuring "real world" fidelity of delivery in the community using computer linguistic technology. The two training conditions will be evaluated in terms of provider level outcomes (confidence in program delivery and mastery of COPE principles), fidelity adherence using the computationally derived methodology, and outcomes related to persons with dementia and family caregivers.

Interdisciplinary investigative team and relevant experience: This proposal brings together a nationally and internationally recognized strong multi-disciplinary group of investigators from the University of Pennsylvania (PENN), Drexel University (Drexel), Thomas Jefferson University (TJU), and Trinity Health. Each brings expertise in the development and testing of dementia care interventions, training of long term care providers, PACE programming, implementation of evidence-based dementia practice, instructional design, computational linguistics, technology transfer, evidence-based practice translation, clinical and research ethics, and fidelity monitoring.

The study will be Co-led by Nancy Hodgson, PhD, RN, FAAN (PENN Contact Pl: dementia caregiving, implementation science), and Laura N. Gitlin, PhD, FAAN (Drexel Co Pl: COPE program designer, dementia caregiving, RCT expert, applied gerontology, implementation science). The proposal capitalizes on Drs. Hodgson's and Gitlin's 15+ year collaborative relationship including the R01 that tested the COPE program (23). The investigative team includes: 1) Dr. Catherine Verrier Piersol (TJU) a dementia care specialist with expertise in training and fidelity monitoring in intervention protocols including COPE; 2) Dr. Karen Hirschman (PENN), an expert in evidence based practice translation, dementia caregiver interventions and qualitative content analysis; 3) Dr. Susan Rentz (PENN) an expert in geriatric evidence based practice implementation, and qualitative analysis of narrative text in long term care settings; 4) Dr. Ani Nenkova (PENN, computational linguistics) is an expert in natural language processing via automatic summarization; 5) Dr. Melanie Wright (Trinity Health) with expertise in simulation training, technology transfer, and clinical decision aids to support dissemination of evidence in health care systems; 6) Ms. Caroline (Carrie) M. Hays McElroy (Trinity Health). Director of Trinity Health PACE; 7) Dr. Di'Maria Ghalili (Drexel) a nurse scientist with expertise in developing online training and dementia care; 8) Dr. Linda Wilson (Drexel) an expert in the design of simulation for health care providers; and 9) Dr. Susan Aldridge (Drexel), an expert in the design of online education for health care providers.

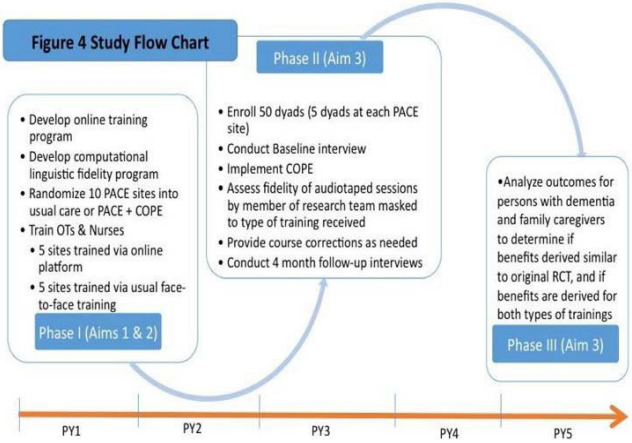
To guide the scientific conduct of this study, and to help position the results to have maximal impact on future pragmatic trials, we have assembled a multidisciplinary Translational Advisory Board (TAB) composed of individuals with clinical expertise in long-term care, dementia care and staff training, and research expertise in speech technology, software development, and implementation of evidence-based practice (Letters of Support and Biosketches). They include Dr. Scott Trudeau of the American Occupational Therapy Association; Mia Pfifer of the National PACE Association; Patricia Pokradt, the Trinity Health PACE Director of Education and Professional

Development; Anna Marshalick, Director of Education, Home Health and PACE for Mercy Health System of Southeastern Pennsylvania; and Dr. Mari Ostendorf an expert in speech recognition and prosody. The TAB will meet in person once yearly with the Leadership Team and Pis. Before meetings, they will receive a study update, other study related materials of relevance to the proposed agenda, and an agenda that will be oriented to updating study progress and asking for feedback on discrete issues relevant to where we are at in terms of trial implementation. Select members of the TAB will also be consulted on a more regular basis during focused study activities. For example, Marshalick and Pokradt will be engaged in Years 1-2 during the development of the training platform, and Ostendorf will be engaged in Years 2-3 during the testing and refinement of the automated fidelity monitoring program (see Budget Justification).

Previous Studies - COPE efficacy trial: The original COPE trial was designed to test the efficacy of the program in a sample of community dwelling persons with dementia requiring seven or more hours of care from a family caregiver in the home setting. Results showed that at the end of the 4-month intervention period, COPE study participants with dementia had greater functional independence in activities of daily living as measured by the Caregiver Assessment of Function and Upset (CAFU) and were more engaged in daily activities compared to controls. Also at the 4-month point, COPE CGs, compared to controls, reported improved well-being and increased confidence in using environmental modifications and dementia management strategies learned from COPE interventionists (all $p < 0.05$) (30). At 9 months post randomization, COPE CGs were twice as likely as controls (40% vs. 20%, $p = 0.02$) to report that the intervention helped "a great deal" in keeping their relative at home (30). These results demonstrated the efficacy of COPE in the community dwelling population with dementia. COPE builds on several previous trials by the investigators (42-43), and demonstrates that a combination of training CGs in problem solving, environmental modification, and task simplification can address CG distress and minimize behavioral disturbances and functional difficulties. We also found that 36% of persons with dementia in the COPE group had one or more undetected or mismanaged medical issue that was resolved through the nurse component of the COPE program. As this was an efficacy trial, the next step in the research pipeline is to prepare for a pragmatic trial to evaluate its translational potential in the "real world" PACE service setting. To date, training in COPE is dependent upon face-to-face intensives led by Ors. Gitlin and Piersol– an unsustainable approach. Also, fidelity is limited to providing a certification of completion of the training and does not extend to ongoing evaluation of its implementation in a practice setting.

Research Plan

Study Design Overview: The project is organized into three Phases: Phase I-development of online training program and fidelity monitoring program (Aims 1 and 2); Phase 11- evaluation of training and fidelity (Aim 3); Phase Ill analytics (Aim 3). (Figure 4)



PHASE 1 of this study involves the first series of activities designed to address Aim 1 (*to determine whether an online training program is the same or better in improving interventionist uptake of COPE principles and protocols compared to a high intensity face-to-face traditional form of training*); and Aim 2 (*to compare fidelity of implementing COPE based on receiving the online training versus the traditional face-to-face COPE training program*). First, we will develop an online asynchronous training program for OTs and RNs to learn the COPE program for its delivery in the PACE setting. We will use state-of-the science simulation and best online learning practices to instruct in the three phases of the program (assessment, implementation, generalizability) and specific techniques. Second, we will develop a model for fidelity monitoring using computational linguistics (automatic classification programs).

PHASE 1a - The Online Training Program: We will develop ten self-paced online learning modules. These modules will enable OTs and RNs to participant to have anytime/anywhere access to content and activities to aid their learning. The modules will include rich multimedia content and interactive assessments to keep the learner engaged. The modules will allow for easy packaging of the content into the latest interoperability standards for such content including the latest Shareable Content Object Reference Model (SCORM) specifications, which will allow for repurposing and sharing with other institutions.

To accommodate diversity of learning needs, the modules will be designed using a hyperlearning model with four dimensions. The general principles will begin with the module learning objectives and follow with a review of core concepts and required and/or self-directed learning activities. The mini-lecture component of the modules will include information on the major concepts of the module. Since the modules will be self-paced, the learner can take his/her time going through them and perform in the embedded interactive learning activities. The clinical reasoning dimension will provide the learner with an opportunity for problem-solving and clinical decision-making. This dimension will contain vignettes and case studies with questions requiring analysis and synthesis. The final dimension will be evaluation/assessment of learning outcomes. This dimension will use teacher-made and standardized pre-and post-tests to assess attainment of specified learning outcomes. The self-paced modules will be highly interactive featuring integrated multimedia content, assessments, and learner evaluations to allow PACE staff to engage with the content at a high level and practice application in simulated scenarios. Each module will require approximately 45-60 minutes/module for the learner to complete. Participants can use the modules separately at different times throughout a training curriculum or they can be assigned at the beginning of a training time by having this information front-loaded.

To develop the modules, we will work intensely in year 01 with an instructional design team at Drexel University along with specialists in dementia care, the COPE program and experts in simulation, use of standardized patients, and training of nurses and other health professionals from Penn, Trinity Health and Jefferson. We anticipate the modules to contain the following content: module 1– introduction to COPE program, research evidence, and core principles underlying the program; module 2 - overview of delivery characteristics, role of RN and OT, three phases (assessment, implementation, generalizability) of the COPE program, permissible adaptations; module 3 and 4- assessment phase, introduction to clinical interview and all assessments and forms; module 5 and 6- implementation phase including helping caregiver identify 3 problem areas, engaging in problem solving and brainstorming, developing and providing an assessment report and offering prescriptions (strategies) for each identified problem area; module ?and 8, generalizability phase or helping caregivers use strategies for one problem area to address another and planning for the future; module 9- developing rapport and working with family caregivers from different backgrounds, cultures, living environments and relationships and helping families balance caregiving with other life roles, adjusting approach by level of readiness; module 10– challenging cases, motivational interviewing, how to explain the program, how to meet caregivers where they are at and provide validation and support.

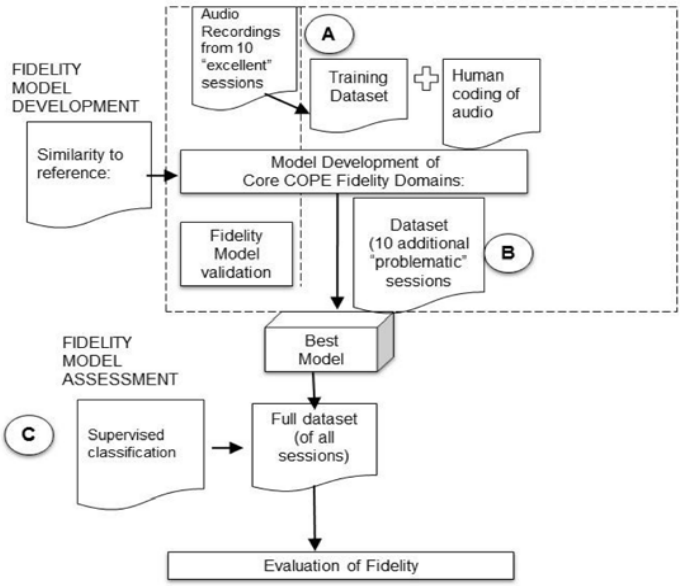
Scripts for each module will be developed and shared with OTs/RNs who are not part of the study but work within Trinity PACE programs. This will allow for continuous feedback loops to assure that the scenarios meet the needs of PACE staff. We will compare the online program to our traditional 3-day face-to-face training currently used with COPE. The 3-day training program will be conducted by Dr. Piersol using a slide deck and case presentations as we have previously done. The comparison of the two training programs is described in section C.5.1.d below.

PHASE 1b - The Fidelity Monitoring Program: We seek to develop a scalable approach to assess fidelity to the COPE Program when it is implemented in a real-world setting such as PACE using computational linguistics techniques (e.g. natural language processing). The essence of fidelity to the Core Principles of COPE program will be captured via the examples provided in Table 1 (see C.4 above) by using automatic classification programs that evaluate both the content that should be included in COPE sessions, and the style of delivery. While automatic classification programs have been applied to measure quality metrics of transcribed narratives in the field of psychotherapy (21), it has not been used to measure other aspects of quality- namely fidelity to evidence-based practices or dementia care and caregiver supportive programs. The development of the automated Fidelity Monitoring Program will occur in three steps (Figure 5), and will be carried out by a technical team consisting of an expert in content analysis, Dr. Ani Nenkova, and a consultant expert in speech recognition and prosody, Dr Mari Ostendorf. Co- I Nenkova has worked extensively on automatic summarization, evaluation of automatic summarization and readability and linguistic style. The ultimate goal of our efforts is to develop a system that- given a recording of a COPE delivery session (e.g. in real time immediately after interaction between the clinician and the caregiver)- produces a three-tiered score, indicating if the fidelity was 'excellent', 'acceptable' or 'problematic'. Special emphasis will be given to the accuracy of identifying 'problematic' COPE fidelity which is not fateful to training and may not produce the same desired outcomes as intervention delivered with higher fidelity.

First, we will obtain n-best list speech recognition of the COPE interaction (46). This will help mitigate recognition errors in the next stage. Until recently, audio recording transcription was fraught with challenges particularly in sessions involving two or more speakers. Advances in audio signaling and speech recognition have brought technology for automating language analysis within reach. Recent research has suggested that text-based features may be more effective than using audio features alone when classifying fidelity in behavioral research (47). Automatic speech recognition software will be used to transcribe sessions, and the resulting words will be used in a text-based model of fidelity. Once transcripts are obtained, two approaches will be developed and contrasted: (1) comparison with a reference delivery and (2) a supervised classification approach. The first has the advantage of needing only a small number of excellent deliveries and several acceptable deliveries, for each of the seven dimensions, while the other needs a larger set of labeled data nut would potentially lead to a higher accuracy of prediction.

Comparison or similarity to reference (Steps A and B): Our approach will leverage techniques widely used in the evaluation of automatically produced content, such as machine translation and automatic text summarization. In these applications, it is not feasible to track system improvement with human judgements of quality. Instead, most of the progress is measured by computing similarity between a set of sample reference text (i.e. what a "good" translation or a good summary would be) and the system output. Such automatic evaluation approached are widely used for machine translation (48) and summarization (49). While there have been some concerns that the automatic measures are not fine enough to distinguish between levels of very good context, these measures show strong ability to distinguish "very bad" content (50, 51) (or poor fidelity) aligns with the needs of our project.

FIGURE 5: Development and validation of Fidelity Monitoring Program



PHASE 2 - Evaluation of Online Training Program in Interventionist Uptake and Fidelity: Phase 2 of this study involves a series of activities designed to evaluate the whether an online training program is the same or better in improving interventionist uptake of- and fidelity to-COPE principles and protocols compared to a high intensity face-to-face traditional form of training.

Eligibility and enrollment: Ten participating Trinity PACE Organizations will participate via webinar in a brief orientation/training to the study and project logistics. Next, Trinity Health PACE organizations will be randomized into two groups using the re-randomization procedures described in the paragraph below; 5 PACE organizations will serve as the "control" site in which training will be provided via the traditional high intensity face-to-face.; 5 PACE organizations will serve as the comparison and be trained through the online training site. Prior to randomization, we will carefully examine PACE organizations on important variables such as size, location (urban; rural) percent of persons with dementia, and staff: participant ratio. In each site, one occupational therapist (OT) and one nurse (RN) will be trained (e.g., 5 OTs and 5 RNs in traditional sites; 5 OTS and 5 RNS in online training sites for a total of 10 OTs and 10 RNs or 20 healthproviders).

Re-randomization procedures. Because COPE will be delivered by PACE staff to multiple participants with dementia within each organization, randomization at the individual participant level could lead to significant contamination between treatment and control conditions within an organization. Prior to randomization, we will collect organization-level data and have measures of organization size (or capacity), location (urban, suburban, rural), and summary characteristics of the participant population at each organization (e.g., percentage with dementia diagnosis, percentage minority). Because we will randomize ten organizations to five face to face and five online training organizations, notable and problematic imbalances on at least a few organization-level characteristics could easily occur by chance in a single randomization. Methodological innovations are needed to achieve balance on these multiple organization-level characteristics while still maintaining the experimental rigor and inferential value of true random assignment. Dr. Hanlon will implement a re-randomization approach to achieve these important methodological goals. The balance match weighted (BMW) design is an innovative re-randomization procedure that is particularly well suited to our goals (54). Using the BMW approach, we will:

1) finalize the list of important covariates for which we desire matching or balancing across intervention and control organizations, 2) generate 20 lists of random assignments for these 10 organizations into intervention and control conditions, 3) calculate propensity scores of intervention assignment as a function of the covariates, and 4) select the random assignment list that minimizes the propensity score differences between intervention and control organizations. The BMW approach provides a random assignment distribution that has an optimal balance on multiple organization-level characteristics. This will result in even greater control over potential covariate influences, and provide somewhat greater power to detect a COPE program effect.

Treatment Conditions:

COPE Online Training: Trinity PACE Organizations assigned to the COPE Online Training will receive the 10- Module training program described above. Designated OTs and RNs at the assigned PACE Organization will be emailed unique log-in details and instructions for completing the online training within the 3 day training window (to align with control group training) but at their own pace. Log-in details including date, time and duration in training sessions will be tracked.

COPE Face-to-Face Training: We will train one OT and one RN at each of the five PACE organizations randomly assigned to the Face-to-Face training. Dr. Piersol will conduct trainings. Our training program will involve up to 3 days which include about 4 hours of initial readings, PowerPoint presentations, and case presentations. Trainings will either be in person or web conference (via GoToMeeting.com) sessions. We will offer three of these training sessions to accommodate COPE staff members' schedules and assure an interactive process. Further, interventionists will participate initially in monthly tele-conference or web conference sessions and then 6 times a year over the duration of intervention delivery. Sessions will involve case presentations, troubleshooting, and adherence monitoring. We have used this approach in multi- organization endeavors with up to 15 interventionists actively participating by telephone. Using a structured agenda and assigning case presentations a priori facilitates productive discussions. We have allocated funds for COPE staff members' time to participate in training and follow-up bimonthly calls to troubleshoot cases.

Both groups will participate in monthly debriefing sessions which will be recorded and used to understand type of questions asked, problems encountered etc. to compare the two training groups on. We have a specific agenda and methodology for interventionists to provide case reports (55). We will also establish a password secure and encrypted email list serve for interventionists to post challenges and receive feedback from Pis and other interventionists.

Analysis of Aim 1: To compare the training programs on Interventionist uptake. We will conduct pre and post surveys to assess changes in knowledge and assess satisfaction with the training. COPE interventionists will need to demonstrate Knowledge and Competency in treatment delivery to be certified by Pis and Dr. Piersol in COPE delivery, a measurement approach we use effectively in our trials (56). We will conduct a noninferiority analysis to determine if online training compared to high intensity face-to-face training results in same or better in Knowledge and Competency scores. Independent-samples t test, 2 test, and Fisher's exact test will used to compare the groups.

Analysis of Aim 2: The fidelity model will be used to compare sessions delivered by interventionists under the two different conditions (online versus traditional face-to-face training conditions).The accuracy of the computationally derived "best model" automatic summarization fidelity ratings("excellent", "acceptable", "problematic") will be evaluated against human ratings for all recorded session (N=600). The comparison of the automated fidelity relative to human fidelity rating will be evaluated through a comparison of agreement (Kappa coefficient). Human ratings will

be conducted by Ors Hirshman and Renz using the COPE Adherence Scale (1= excellent, .5 = acceptable, 0=problematic).

PHASE 3 - Efficacy of COPE on PACE *participant outcomes* by type of COPE training: This aim will be accomplished by evaluating dyad outcomes of the COPE program under the two different training approaches. Following training, each of the PACE organizations will enroll 5 persons with dementia and their caregivers in the study. This will yield 50 family dyads (25 dyads in traditional training sites and 25 dyads in online training sites). At 4 months, all dyad study outcomes will be assessed (Table 2).

Study Procedures

PHASE I of this study involves the first series of activities designed to address Aim 1: (to determine whether an online training program is the same or better in improving interventionist uptake of COPE principles and protocols compared to a virtual/remote training lead by a trained OT); and Aim 2: (to compare fidelity of implementing COPE based on receiving the online training versus the virtual/ remote COPE training program). First, we will develop an online asynchronous training program for OTs and RNs to learn the COPE program for its delivery in the PACE setting. We will use state-of-the science simulation and best online learning practices to instruct in the three phases of the program (assessment, implementation, generalizability) and specific techniques. Second, we will develop a model for fidelity monitoring using computational linguistics (automatic classification programs).

PHASE 1a -The Online Training Program: We will develop ten self-paced online learning modules. These modules will enable OTs and RNs to participant to have anytime/anywhere access to content and activities to aid their learning. The modules will include rich multimedia content and interactive assessments to keep the learner engaged. The modules will allow for easy packaging of the content into the latest interoperability standards for such content including the latest Shareable Content Object Reference Model (SCORM) specifications, which will allow for repurposing and sharing with other institutions. To accommodate diversity of learning needs, the modules will be designed using a hyper learning model with four dimensions. The general principles will begin with the module learning objectives and follow with a review of core concepts and required and/or self-directed learning activities. The mini-lecture component of the modules will include information on the major concepts of the module. Since the modules will be self-paced, the learner can take his/her time going through them and perform in the embedded interactive learning activities. The clinical reasoning dimension will provide the learner with an opportunity for problem-solving and clinical decision-making. This dimension will contain vignettes and case studies with questions requiring analysis and synthesis. The final dimension will be evaluation/assessment of learning outcomes. This dimension will use teacher-made and standardized pre- and post-tests to assess attainment of specified learning outcomes. The self-paced modules will be highly interactive featuring integrated multimedia content, assessments, and learner evaluations to allow PACE staff to engage with the content at a high level and practice application in simulated scenarios. Each module will require approximately 45-60 minutes/module for the learner to complete. Participants can use the modules separately at different times throughout a training curriculum or they can be assigned at the beginning of a training time by having this information front-loaded. To develop the modules, we will work intensely in year 01 with an instructional design team at Drexel University along with specialists in dementia care, the COPE program and experts in simulation, use of standardized patients, and training of nurses and other health professionals from Penn, Trinity Health, and Jefferson. We anticipate the modules to contain the following content: module 1 introduction to COPE program, research evidence, and core principles underlying the program; module 2 - overview of delivery characteristics, role of RN and OT, three phases (assessment, implementation, generalizability) of the COPE program, permissible adaptations; module 3 and 4- assessment phase, introduction to clinical interview and all assessments and forms; module 5 and 6- implementation phase including helping caregiver identify 3 problem areas, engaging

in problem solving and brainstorming, developing and providing an assessment report and offering prescriptions (strategies) for each identified problem area; module 7 and 8, generalizability phase or helping caregivers use strategies for one problem area to address another and planning for the future; module 9- developing rapport and working with family caregivers from different backgrounds, cultures, living environments and relationships and helping families balance caregiving with other life roles, adjusting approach by level of readiness; module 10 challenging cases, motivational interviewing, how to explain the program, how to meet caregivers where they are at and provide validation and support. Scripts for each module will be developed and shared with OTs/RNs who are not part of the study but work within Trinity PACE programs. This will allow for continuous feedback loops to assure that the scenarios meet the needs of PACE staff. Secondary analysis will be performed on audio recordings obtained for fidelity monitoring from the Tailored Activity Program (TAP) study (Gitlin, Hodgson, Piersol-Co-Is), in order to identify typical care challenges to include in the online learning modules. We will compare the online program to our 3-day virtual/remote training lead by an trained OT currently used with COPE. The 3-day virtual/remote training program will be conducted by Dr. Piersol using a slide deck and case presentations as we have previously done.

PHASE 1b -The Fidelity Monitoring Program: We seek to develop a scalable approach to assess fidelity to the COPE Program when it is implemented in a real-world setting such as PACE using computational linguistics techniques (e.g. natural language processing). The essence of fidelity to the Core Principles of COPE program will be captured via the examples provided in Table 1 (see C.4 above) by using automatic classification programs that evaluate both the content that should be included in COPE sessions and the style of delivery. While automatic classification programs have been applied to measure quality metrics of transcribed narratives in the field of psychotherapy (21), it has not been used to measure other aspects of quality- namely fidelity to evidence-based practices or dementia care and caregiver support programs. The development of the automated Fidelity Monitoring Program will occur in three steps (Figure 5) and will be carried out by a technical team consisting of an expert in content analysis, Dr. Ani Nenkova, and a consultant expert in speech recognition and prosody, Dr. Mari Ostendorf. Co-I- I Nenkova has worked extensively on automatic summarization, evaluation of automatic summarization, and readability and linguistic style. The ultimate goal of our efforts is to develop a system that- given a recording of a COPE delivery session (e.g. in real-time immediately after interaction between the clinician and the caregiver)- produces a three-tiered score, indicating if the fidelity was excellent, acceptable, or problematic. Special emphasis will be given to the accuracy of identifying problematic COPE fidelity which is not fateful to training and may not produce the same desired outcomes as intervention delivered with higher fidelity. Before recruitment begins and COPE sessions can be recorded, secondary analysis will be performed on audio recordings obtained for fidelity monitoring from the TAP study. As a precursor to the COPE program, the TAP audio recordings will be examined for fidelity linguistic purposes. Exploratory analysis will also be performed on audio recordings of baseline interviews of consenting research participants. After obtaining caregiver consent, baseline interviews and COPE interventionist sessions will be recorded and automatically transcribed via a HIPAA-compliant, Penn-approved third party. Transcriptions will be kept on a secure password-protected Penn Nursing laptop and PHI will be removed. The resulting anonymous transcripts will be saved on a secure password-protected server and original transcripts that include PHI will be destroyed immediately.

PHASE 2 - Evaluation of Online Training Program in Interventionist Uptake and Fidelity Phase 2 of this study involves a series of activities designed to evaluate whether an online training program is the same or better in improving interventionist uptake of- and fidelity to- COPE principles and protocols compared to the virtual/remote training lead by a trained OT. Eligibility and enrollment: Ten participating Trinity PACE Organizations will participate via webinar in a brief orientation/training to the study and project logistics. Next, Trinity Health PACE organizations will be randomized into two groups using the re-randomization procedures described in the paragraph below; 5 PACE organizations will

serve as the control site in which training will be provided via the virtual/remote training lead by a trained OT; 5 PACE organizations will serve as the comparison and be trained through the online training site. Prior to randomization, we will carefully examine PACE organizations on important variables such as size, location (urban; rural) percent of persons with dementia, and staff: participant ratio. In each site, one occupational therapist (OT) and one nurse (RN) will be trained (e.g., 5 OTs and 5 RNs in virtual/remote training sites; 5 OTS and 5 RNS in online training sites for a total of 10 OTs and 10 RNs or 20 health providers) Re-randomization procedures. Because COPE will be delivered by PACE staff to multiple participants with dementia within each organization, randomization at the individual participant level could lead to significant contamination between treatment and control conditions within an organization. Prior to randomization, we will collect organization-level data and have measures of organization size (or capacity), location (urban, suburban, rural), and summary characteristics of the participant population at each organization (e.g., percentage with dementia diagnosis, percentage minority). Because we will randomize ten organizations to five virtual/remote and five online training organizations, notable and problematic imbalances on at least a few organization-level characteristics could easily occur by chance in a single randomization. Methodological innovations are needed to achieve balance on these multiple organization-level characteristics while still maintaining the experimental rigor and inferential value of true random assignment. Dr. Hanlon will implement a re-randomization approach to achieve these important methodological goals. The balance match weighted (BMW) design is an innovative re-randomization procedure that is particularly well suited to our goals (54). Using the BMW approach, we will: 1) finalize the list of important covariates for which we desire matching or balancing across intervention and control organizations, 2) generate 20 lists of random assignments for these 10 organizations into intervention and control conditions, 3) calculate propensity scores of intervention assignment as a function of the covariates, and 4) select the random assignment list that minimizes the propensity score differences between intervention and control organizations. The BMW approach provides a random assignment distribution that has an optimal balance on multiple organization-level characteristics. This will result in even greater control over potential covariate influences and provide somewhat greater power to detect a COPE program effect. Treatment Conditions: COPE Online Training: Trinity PACE Organizations assigned to the COPE Online Training will receive the 10- Module training program described above. Designated OT/ RNs at the assigned PACE Organization will be emailed unique log-in details and instructions for completing the online training within the 3-day training window (to align with control group training) but at their own pace. Log-in details including date, time and duration in training sessions will be tracked. COPE Virtual/Remote Training: We will train one OT and one RN at each of the five PACE organizations randomly assigned to the virtual/remote training. Dr. Piersol will conduct trainings. Our training program will involve up to 3 days which include about 4 hours of initial readings, PowerPoint presentations, and case presentations. Training will take place via web conference (via GoToMeeting.com or other platform) sessions. We will offer three of these training sessions to accommodate COPE staff members' schedules and assure an interactive process. Further, interventionists will participate initially in monthly tele-conference or web conference sessions and then 6 times a year over the duration of intervention delivery. Sessions will involve case presentations, troubleshooting, and adherence monitoring. We have used this approach in multi-organization endeavors with up to 15 interventionists actively participating by telephone. Using a structured agenda and assigning case presentations a priori facilitates productive discussions. We have allocated funds for COPE staff members time to participate in training and follow-up bimonthly calls to troubleshoot cases. Both groups will participate in monthly debriefing sessions which will be recorded and used to understand type of questions asked, problems encountered etc., to compare the two training groups. We have a specific agenda and methodology for interventionists to provide case reports (55). We will also establish a password secure and encrypted email list serve for interventionists to post challenges and receive feedback from Pis and other interventionists.

PHASE 3 (Aim 3): Efficacy of COPE on PACE participant outcomes by type of COPE training. This aim will be accomplished by evaluating dyad outcomes of the COPE program under the two different training approaches. Following training, each of the PACE organizations will enroll 5 persons with dementia and their caregivers in the study. This will yield 50 family dyads (25 dyads in traditional training sites and 25 dyads in online training sites). At 4 months, all dyad study outcomes will be assessed

Administration of Surveys

To compare the training programs on Interventionist uptake, we will conduct pre and post surveys to assess changes in knowledge and assess satisfaction with the training. Survey interviews will be conducted by key personnel via phone or video chat. After obtaining verbal consent from caregivers, caregivers will self-administer a 30-minute REDCap survey. A link will be sent via email to the caregivers. If caregivers prefer to complete the survey on paper, the research team will collect the caregiver mailing address and send via mail along with stamped envelope to be returned to the study team. After the caregiver has completed the self-administered survey, researchers will interview caregivers for up to one hour video chat. The interview will be recorded for quality assurance and research purposes. Data Management Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data. We will set up all surveys and tracking forms in REDCap. Interviewers will use an iPad or computer programmed with the survey questions in REDCap to facilitate direct capture of data in real time. We will build in checks to minimize missing and out of range values, which are essential features of REDCap. De-identified data files are entered and stored on the hard drive of the PC of the project statistician if necessary for offsite work, and the DU server. In this way a copy of the data always remain secure in the rare event of fire or computer damage at the central research office. Any identifiable data is only stored on the server and is password protected. This assures that identifiable data cannot be stolen from a laptop or computer. After obtaining caregiver verbal consent, baseline interviews and COPE interventionist sessions will be recorded and saved on the password protect server. Audio recordings will be sent to a HIPAA-compliant Penn-approved third party strictly for the purposes of automatic transcription. After transcription, any identifying information will be removed from documents resulting in anonymous transcripts to be kept on the research office server.

Data Management

We will set up all surveys and tracking forms in REDCap. Interviewers will use an iPad or computer programmed with the survey questions in REDCap to facilitate direct capture of data in real time. We will build in checks to minimize missing and out of range values, which are essential features of REDCap. De-identified data files are entered and stored on the hard drive of the PC of the project statistician if necessary for offsite work, and the DU server. In this way a copy of the data always remain secure in the rare event of fire or computer damage at the central research office. Any identifiable data is only stored on the server and is password protected. This assures that identifiable data cannot be stolen from a laptop or computer. After obtaining caregiver verbal consent, baseline interviews and COPE interventionist sessions will be recorded and saved on the password protect server. Audio recordings will be sent to a HIPAA-compliant Penn-approved third party strictly for the purposes of automatic transcription. After transcription, any identifying information will be removed from documents resulting in anonymous transcripts to be kept on the research office server.

Analysis Plan

Analysis of Aim 1: To compare the training programs on Interventionist uptake. We will conduct pre and

post surveys to assess changes in knowledge and assess satisfaction with the training. COPE interventionists will need to demonstrate Knowledge and Competency in treatment delivery to be certified by Pis and Dr. Piersol in COPE delivery, a measurement approach we use effectively in our trials (56). We will conduct a noninferiority analysis to determine if online training compared to virtual/ remote training results in same or better in Knowledge and Competency scores. Independent-samples t-test, 2 test, and Fishers exact test will used to compare the groups.

Analysis of Aim 2: The fidelity model will be used to compare sessions delivered by interventionists under the two different conditions (online versus virtual/remote training conditions). The accuracy of the computationally derived best model automatic summarization fidelity ratings (excellent, acceptable, problematic) will be evaluated against human ratings for all recorded session (N=600). The comparison of the automated fidelity relative to human fidelity rating will be evaluated through a comparison of agreement (Kappa coefficient). Human ratings will be conducted by Drs Hirshman and Renz using the COPE Adherence Scale (1= excellent, .5 = acceptable, 0=problematic).

Analysis of Aim 3: To compare the efficacy of COPE on participant outcomes. One-sided to-sample t-tests will be used to examine non-inferiority at 4-months. Upper and lower 95% confidence intervals will be presented for means and medians. Assumptions of normality and equality of variance between groups will be evaluated using Shapiro□Wilk and modified Levene's texts, respectively. Should the variances be unequal, the Aspin-Welch unequal variance t-test will be used to examine non-inferiority; should the normality assumption be violated, the non-parametric Mann-Whitney U test will be used to examine non-inferiority. Descriptive statistics including measures of central tendency (mean, median, mode) and variation (standard deviation, interquartile range, range) for continuous measures as well as frequencies and percentages for dichotomous and categorical variables will be run for all measures at each timepoint. Outliers will be assessed by visual inspection of distributions and checked for accuracy. Histograms and Q-Q plots will be used to evaluate assumptions visually. Two-sample t-tests (or non-parametric Wilcoxon tests, as necessary) and Fisher's exact tests will be used to examine differences in demographic and treatment variables between intervention groups at each timepoint. To demonstrate that the online COPE training intervention is the same or better than the virtual/remote training intervention with regards to participant outcomes, one-sided two-sample t-tests will be used to examine non-inferiority at 4 months. Upper and lower 95% confidence intervals will be presented for means and medians. Assumptions of normality and equality of variance between groups will be evaluated using Shapiro-Wilk and modified Levene's tests, respectively. Should the variances be unequal, the Aspin-Welch unequal variance t-test will be used to examine non-inferiority; should the normality assumption be violated, the non-parametric Mann-Whitney U test will be used to examine non-inferiority.

Consent Process: All informed consent guidelines of the University of Pennsylvania Institutional Review Board (IRB) will be followed. We will use a multi-stepped approach to gaining consent from Trinity Health PACE occupational therapists and nurses (OT/RNs) using email, DocuSign, PennBox, or mail to obtain consent signatures. The Penn site will obtain consent from OT/RNs who agree to complete the training program. Discussions about consent will take place between the study team and OT/RN participants via phone and video conferencing programs (Skype, FaceTime, Blue Jeans, Zoom, etc.). Two Trinity Health PACE sites will participate in a pilot test of all study procedures. OTs and RNs from these sites will sign the "OT and RN ICF Pilot Test" document. This version of the ICF notes that these participants will participate in the pilot test or beta test. Then, recruitment of caregivers will be done by Trinity research liaisons who will read a Penn-approved recruitment script to caregivers or share flyers with study team contact information to use. Interested caregivers will contact study team members (if received flyer) or be contacted via telephone by Penn study team members (if consented to have their contact shared) who will provide more detail about the study, answer questions, and read the caregiver verbal consent script. Within the script is language that informs the caregiver that 1) the

OT and research team will record and transcribe COPE sessions and interviews with dyads for quality and assurance purposes, and 2) the research team will collect patient data from the Trinity Health PACE medical record for research purposes. The objectives, procedures, and a clear statement explaining risks and benefits of this study will be presented via the consent script. Caregivers who consent verbally will be emailed or mailed a copy of the consent script which has been signed by the Penn researcher obtaining consent. If caregivers consent to participant, caregivers will be screened for eligibility. Caregivers will be informed that the screen is confidential and completely voluntary. All call notes, consent forms and telephone screens will be performed and housed in REDCap or on a Penn-approved secure server. Penn will house all recruitment and consent forms and assume responsibility for any and all modification of ICFs. For those initially eligible based on the telephone screen and who consent to participate, a full baseline telephone interview will be conducted either following the screen or at a time more convenient for the caregiver but within one week of completing the screen. Regardless of when the baseline interview is conducted, the interviewer will again obtain verbal consent from the family caregiver for their participation. Participants who currently active or in the follow-up stage will need to re-consent to participate. Caregivers who originally consented prior to September 18th, 2022, will be called and read the additional information added to the consent form and asked if they have any questions. Once all questions have been answered, caregivers will be asked to verbally consent. Once confirmation of consent is received over the phone, caregivers will receive an updated copy of the written statement of research. Staff participants (occupational therapists and registered nurses) who have signed consent forms prior to September 16th, 2022 will need to be re-consented. These participants will receive an email with the new consent language listed and a blank copy of the updated consent form attached. Staff participants will be asked to follow up with any questions they have. If participants do not have questions or all questions have been answered, participants will be asked to sign the form and send back to Penn researchers.

Study duration: Caregivers The study will take place over a period of 4 months. This means that COPE dyads (persons with memory problems and their caregivers) will receive up to 10 1-hour sessions over the course of 4 months by an occupational therapist; and up to two face-to-face or virtual visits and 1 telephone session by a registered nurse. We anticipate enrolling 50 participants from 10 Trinity Health PACE organizations. RNs/OTs: The educational portion of the study will be 16 hours in length. For OTs, the implementation portion of the study will consist of up to 10 one-hour home visits over a 4-month period during the year in which the dyads are recruited and participate in the COPE intervention. For RNs, the implementation portion will consist of up to 2 two-hour clinical evaluation in-home or virtual visits with each PACE dyad soon after they are enrolled in the COPE program.

Risk / Benefit Assessment: There are only minimal risks associated with this study. It is anticipated that caregivers will experience more benefits than risks from their participation in this study. Caregivers in the intervention group will potentially benefit by receiving on-going support, learning specific techniques for managing their own stress, disease education and by having unmet needs identified and managed. Older adult clients of caregivers in the COPE Program may benefit indirectly from the techniques and understandings their caregivers obtain. All families receive the COPE Program; one group will receive the COPE Program from OT/RNs trained via an online simulation approach; another group will receive the COPE Program from OT/RNs trained via video conference training conducted by a trained OT.

Data and Safety Monitoring: Although this is a minimal risk study and a Phase IV effectiveness trial (NIA Stage I), we propose to develop an independent Data and Safety Monitoring Committee (DSMC) to assure participant safety and adherence to human subject protection policies. We plan to identify a 3 to 5-member DSMC of individuals with different types of expertise covering practical trial methodologies, mixed method designs, long-term care services, and dementia care. Here we outline our proposed plan for data and safety monitoring, key responsibilities of members, time of meetings, and schedule for and content of major reports

to be provided to the DSMC for this proposed trial. Primary responsibilities: The DSMC will be responsible for reviewing the safety of study participants during the conduct of this study and provide recommendations to the research team on specific aspects of the research protocol as it pertains to safety, potential study alerts and adverse events. Specific responsibilities of the DSMC will be to: a) provide an independent periodic review of recruitment and enrollment progress; b) review adverse events (AEs) including serious events and offer recommendations regarding the trial based on such observed events; c) serve in a consultative capacity to the research team regarding study procedures to address ethical dilemmas (e.g., reporting of abuse), safety of subjects in the trial, and appropriateness of all study procedures. Composition of the DSMC: The DSMC will be an independent multi-disciplinary group consisting of biostatistical, applied research and clinical experts who collectively have experience in practical trial designs, multi-site trials and mixed methods. The 3 to 5 member board will have no apparent conflict of interest with the investigative team or study including financial, scientific or regulatory in nature. DSMC members will be responsible for advising the Pis of any changes in their relationship and/or financial interests that occur during the course of the trial. The DSMC and Pis will be responsible for deciding whether these changes create a conflict of interest. Any DSMC member who develops a conflict of interest during the course of the trial will be asked to resign from the DSMC and another person with similar areas of expertise will be sought. Otherwise, DSMC membership is to be for the duration of the trial. DSMC Meetings, Documentation: We propose that the DSMC have one face-to-face meeting prior to entering into the field for the trial and one teleconference call each subsequent year unless the DSMC decides and votes otherwise at its first organizational meeting. More frequent meetings or teleconferences may be held in the rare need to review serious adverse events from the trial at the discretion of the DSMC. At the initial meeting in year 01 (anticipated to occur in month 5 prior to entry into the field), the DSMC will review all study procedures including data collection forms, intervention protocol and oversight plan. At this meeting, the DSMC will agree on whether there should be interim analyses, and if so, the stopping rules and interim analysis plan that avoids potentially biasing the investigative team. Modifications to protocols based on the DSMC review will be made prior to entering the field. At subsequent conference calls, the DSMC will review the progress of the study (accrual rate, protocol deviations and interim study analyses if recommended) and make recommendations. A representative of the research team will keep minutes of these meetings. A copy of the minutes approved by the DSMC will be shared with the IRB of UPENN. The minutes will include recommendations of the DSMC and be provided to the NIH after each meeting. Meetings of the DSMC will be open unless the DSMC requests otherwise. A closed meeting of the DSMC may be requested if it is deemed necessary to review outcomes data. The DSMC chair or their designate will take meeting notes of closed sessions. Provision of Data for DSMC Review. Interim Analyses: We elect not to consider interim analyses in this study due to the extended time for recruitment and the low likelihood of a sufficiently large effect that would make it possible to stop early. This study is designed as a non-inferiority trial in which two different training methodologies are being evaluated, Outcomes of the COPE program for people with dementia and caregivers are secondary and serve to confirm (or not) whether the online training approach is as good or better than traditional face-to-face intensive training. However, we will revisit this decision with the DSMC at its first organizational meeting. Adverse Event (AE) Reporting: The DSMC will be notified by the Pl of any serious AE within 48 hours of initial notification to the project team that is attributed to the intervention (low or high probability). All members of the DSMC will receive copies of all safety reports at the time of their submission to the IRB. Safety Monitoring Plan: We do not anticipate any adverse reactions to the training approaches or implementation of the COPE program. Based on our previous work and studies in this area by others, there is only a small risk that family caregivers or persons with dementia will become increasingly anxious to the point that it becomes an adverse event (e.g., harmful to self or others) as a consequence of the COPE program. However, interviewers/ interventionists will be well trained to manage this reaction or make an effective referral if necessary and documentation of all such events will occur. Recruitment and AE Reports: Reports presented to the DSMC will include data on enrollment (study accrual by month; comparison of expected to actual enrollment; number of individuals screened, number eligible and number ineligible, number randomized by gender, and AEs. Also, the DSMC will receive reports of the number of study participants who discontinue from each study arm (those receiving COPE from interventionists trained via face-to-face/virtual versus those receiving COPE from interventionists trained via online program) and/or the study and reasons for discontinuation. We propose that reports be provided to the DSMC twice yearly. However, the DSMC will decide upon the schedule of

reports at their first organizational meeting. Also, the DSMC may request reports as needed as well as the unblinding of the data should they deem this necessary. If unblinded outcome data is required, the biostatistian for this study (Dr. Hanlon) will serve as a liaison for the PIs, database and the DSMC in order to assure that the Pl and the investigative team remains blinded. For the first meeting of the DSMC, members will receive and review the following materials: a) Grant proposal, relevant appendices, reviewers comments; b) our quality control procedures c) IRB approved verbal assent scripts; d) Telephone screen, baseline and follow-up batteries; e) Shell of Access data base for management of interview schedules and enrollment information; f) Subject tracking forms; g) Adverse event procedures and forms; h) Intervention treatment documentation forms; i) Shell for reporting recruitment and enrollment; j) Data shells for reporting tracking information and baseline characteristics; k) Decision rules for intervention termination (e.g., death, extended hospitalization, relocation, nursing home placement); I) Protocols, data collection kits, participant information for salivary biomarker data collection.

Study Instruments

Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission. All enrolled Trinity PACE trainees will complete baseline pre and post training surveys to assess changes in knowledge and assess satisfaction with the training including the NOMAD framework measure which has been adapted with COPE-specific language. Demographics (age, gender, race, ethnicity, education and years employed by Trinity) will be collected at baseline for all trainees as well. At baseline, one representative from each site will complete a baseline questionnaire about their site's staff-participant ratio and location characteristics (urban rural, suburban). At baseline, study team members will collect demographics (age, gender, race, ethnicity, education, address, age, living arrangement, employment status, neighborhood characteristics, relationship status and duration of care) of caregivers and persons with dementia and self-reported data on incomes and feelings of financial strain. The following study instruments will be administered to all caregivers at baseline and four months. The Caregiver Relationship Scale will assess the relationship of person with dementia and their caregiver. The LSNS-R: Caregiver Social Support measure with gather self-reported data about the quality of support received from family and friends. The health-related quality of life and functional ability of the person with dementia will be collected using the Short-Form 36 (SF-36). Caregivers will report the dependence level and functional ability of the person with dementia via the CAFU. Caregivers will report on the presence of a set of behaviors exhibited by the person with dementia, the severity and frequency of those behaviors and level of distress felt by the caregiver via an adapted version of the NPI-Q (Neuropsychiatric Inventory). Caregivers will self-report the sense of capability and confidence in providing support to person with dementia via the Short Sense of Competence Questionnaire (SSCQ): 7 items. Caregivers will self-report feelings of depression via the PHQ-9. Caregivers will self-report their perceptions of caregiving skills via the Caregiver Mastery. Caregivers will self-report their perception of change in wellbeing via Perceived Change for Better Index (13 items). Caregivers will report the quality of life of the person with dementia via QOL-AD CG. Caregivers will self-report their confidence level taking care of PLWD via the CG Confidence in Using Activities and Caregiver Confidence in Medical Sign/Symptom Management. Caregivers will self-report perceived burden as a caregiver of person with dementia via Caregiver Burden. Caregivers intervention progress will be tracked and collected via an intervention instrument called the summary of problem areas and caregiver progress.