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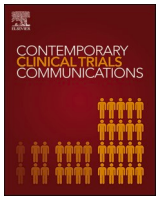

Training to Move an Evidence-based Dementia Caregiver Support Program into Practice: A pragmatic, randomized, non-inferiority trial protocol☆,☆☆

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ABSTRACT

Background: Despite over 200 evidence-based dementia caregiver programs, we know little about the best approaches for optimally scaling these programs in daily service contexts, nor do we fully understand the most effective approaches of ensuring successful implementation. As a result, a small fraction of the many individuals living with dementia and their caregivers within in the US have access to evidence-based programs. A leading barrier to implementation of evidence-based dementia caregiver support programs into long-term care settings is the lack of streamlined, scalable, user-friendly, and tested training modalities.

Objective: To describe the protocol for a study evaluating the implementation of the Care of Persons in their Environment (COPE) in Programs of All-Inclusive Care for the Elderly (PACE) setting. The COPE in PACE study aims to determine if self-paced, online training in the evidence-based dementia care program COPE is non-inferior to the traditional, in-person, instructor-led training for improving clinician knowledge and competence, patient symptoms, function, caregiver confidence and burden, and therapeutic alliance between clinicians and caregivers.

Methods/Design: Pragmatic, multisite randomized controlled non-inferiority trial is being used to assess the implementation of COPE into PACE. The study utilizes a type III hybrid effectiveness design with a primary focus on measuring implementation factors and a secondary focus on measuring COPE effectiveness through caregiver and patient outcomes and therapeutic alliance. The 'COPE in PACE' study is an ongoing trial being conducted in 10 PACE settings throughout the US (NCT04165213).

Discussion: This study design has potential to guide future translational efforts by providing program adaptation, fidelity monitoring and implementation details to enhance scalability of evidence-based programs.

Clinical trial registration: NCT04165213.

1. Introduction

Recent systematic reviews and meta-analyses consistently demonstrate overwhelmingly compelling evidence for clinically meaningful improvements from supportive dementia care interventions [1]. Yet, despite over 200 promising dementia care programs tested in RCTs and with proven benefits along a range of important psychosocial and health outcomes, only a small fraction has been translated or sustained in real world practice settings [2–5]. As a result, the 16+ million dementia caregivers as well as individual living with dementia do not have access to supportive evidence-based programs [6–8]. Furthermore, despite all the tremendous investments in dementia caregiving research, we still know little about the best optimal implementation strategies for successful scaling of dementia caregiver programs in long-term service contexts. The field of implementation science specifically focused on dementia care interventions is still relatively young, with limited

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pragmatic trials explicitly measuring implementation outcomes. Most studies have focused more on clinical outcomes rather than implementation-specific measures [9].

While face-to face training and individual online training have been shown to be effective training approaches for clinicians [10], there remains a lack of evidence on the comparative efficacy of newer, self-paced, online training compared to well-established, in-person training led by a skilled instructor. This study will directly compare a self-paced online training with an established in-person training for occupational therapists and nurses on the implementation of an evidence-based dementia caregiver program in a long-term care setting and analyze the two conditions on clinician outcomes and outcomes of persons living with dementia (PLWD) and their caregivers (CG).

The purpose of this paper is to describe the study protocol for a non-inferiority trial with the primary aim of determining if online training is non-inferior to in-person training in eliciting changes in dementia clinician (occupational therapists and nurses) outcomes. The secondary aim is to monitor and compare fidelity to the COPE program by clinicians trained in both methods by measuring therapeutic alliance throughout COPE delivery. Finally, the third aim is to compare changes in dementia CGs who received support from clinicians trained in either of the two conditions. The primary hypothesis is that online training is not inferior (e.g., just as effective) to in-person training (gold standard) for enhancing clinician knowledge and competence (aim 1) and fostering therapeutic engagement between clinician and caregiver (aim 2). A second hypothesis is that dyads consisting of persons living with dementia (PLWD) and caregivers (CGs) who receive the evidence-based dementia caregiver program (COPE) from online trained clinicians will improve similarly in clinical outcomes to dyads receiving COPE from instructor-trained clinicians including patient symptoms and function, and CG confidence and burdens (aim 3).

1.1. The COPE program and study setting

The Care of Persons with Dementia in their Environment (COPE) program is an evidence-based intervention designed to support both PLWD and their family CG [11,12]. The program brings healthcare professionals directly into the family home, where occupational therapists (OT) and registered nurses (RN) work with CG over a 4-month period. During 1-h sessions, CG are coached in strategies to maximize the functional abilities of PLWD while also improving their quality of life and reducing the challenges and stress associated with daily care.

The intervention is delivered primarily by OTs, who conduct up to 10 sessions guiding CGs through assessment, implementation, and generalization phases. RNs complement this care with up to 3 additional sessions. To ensure CG receive an effective dose of the intervention, a minimum of 4 OTs sessions must be completed. Multiple randomized trials have demonstrated the benefits of this bio-behavioral approach for both people with dementia and their caregivers [10–12]. By conducting sessions in the family home, COPE creates a comfortable environment for learning and implementing new care strategies. This personalized approach helps CGs develop practical solutions for their specific caregiving challenges while reducing the distress often experienced.

Although efficacious, COPE's uptake and integration into the real world of dementia care has not fully occurred. Therefore, developing and testing replicable, accessible, and sustainable processes for training and monitoring evidence-based programs such as COPE is critical to enable scaling up and widespread implementation. In this study, COPE is being implemented in Programs of All-Inclusive Care for the Elderly (PACE) settings. PACE provides comprehensive long-term care services and supports to nursing home eligible Medicaid and Medicare enrollees in the community so that older adults can remain in their homes [13]. Most PACE participants (enrollees) have dementia, yet to date, evidence-based programs have not been integrated into the PACE service mix [13,14]. Among PACE participants with dementia, functional disability and family caregiver physical and emotional strain are the most important predictors of nursing home admission [14,15]. 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 [15]. These factors highlight the importance of maintaining the highest levels of functioning in PLWD to enable them to continue living at home [15]. Thus, PACE is an important test bed for integrating evidence-based programs that can delay or avoid nursing home admissions. This pragmatic trial is designed to address the leading barrier to implementation of evidence-based dementia care and CG support programs into long-term care settings, namely the lack of streamlined, user-friendly, and tested training modalities [16].

Online training has emerged as a powerful solution for addressing traditional barriers to implementing evidence-based care by providing flexible and accessible educational opportunities for healthcare professionals. Research by Zhang and colleagues (2006) demonstrated that online learning platforms significantly improve knowledge retention and clinical practice behaviors compared to traditional methods [17]. A 2020 systematic review by Valenstein-Mah and colleagues found that online training programs can reduce implementation costs while maintaining equivalent or superior learning outcomes [18]. Furthermore, Khalil et al. showed that healthcare providers who participated in online evidence-based practice training reported higher rates of guideline adherence and improved patient outcomes [19]. While online training has shown increased short-term provider knowledge and adherence, the evidence is insufficient on client outcomes. Therefore, research is needed on training methods implementation and client outcomes to ensure efforts to train providers are effective and efficient.

1.2. Innovation in study design

The COPE in PACE study design utilizes a type III hybrid effectiveness approach, through which, the primary focus comparing the two training approaches by evaluating implementation outcomes with a secondary focus of capturing effectiveness of the intervention being implemented [20]. While the efficacy of the COPE program has been studied in previous trials, this study is the first of its kind to compare effectiveness of COPE delivered by clinicians who were trained in one of two different modes of training. The effectiveness of COPE will be evaluated on multiple levels including 1) clinician knowledge and competency, 2) clinician ability to implement COPE as trained and finally, 3) the impact on dyad outcomes. If both training modalities can improve clinicians' competence, confidence and knowledge of COPE, this will translate to improved outcomes for both the PLWD and their CG. Finally, data on therapeutic alliance from the point of view of both the clinician and the caregiver will be collected at each COPE session to monitor fidelity of the COPE program by training type. Fig. 1 illustrates the study design.

We are using two conceptual frameworks to inform COPE implementation measures: 1) Normalization Process Theory (NPT) [21] and 2) Promoting Action on Research Implementation in Health Services (PARIHS) [22]. The NPT framework guided our understanding of individual determinants of behavior in PACE settings that may influence our outcomes at multiple levels. PARIHS includes a comprehensive, multi-level taxonomy of factors that influence implementation (e.g., inner and outer settings of the organization, implementation processes). Both models are synergistic in driving implementation success and guided our consideration of what implementation strategies would be important to target and measure.

2. Methods

2.1. Sample

The inclusion criteria are purposively broad to reflect the real-world

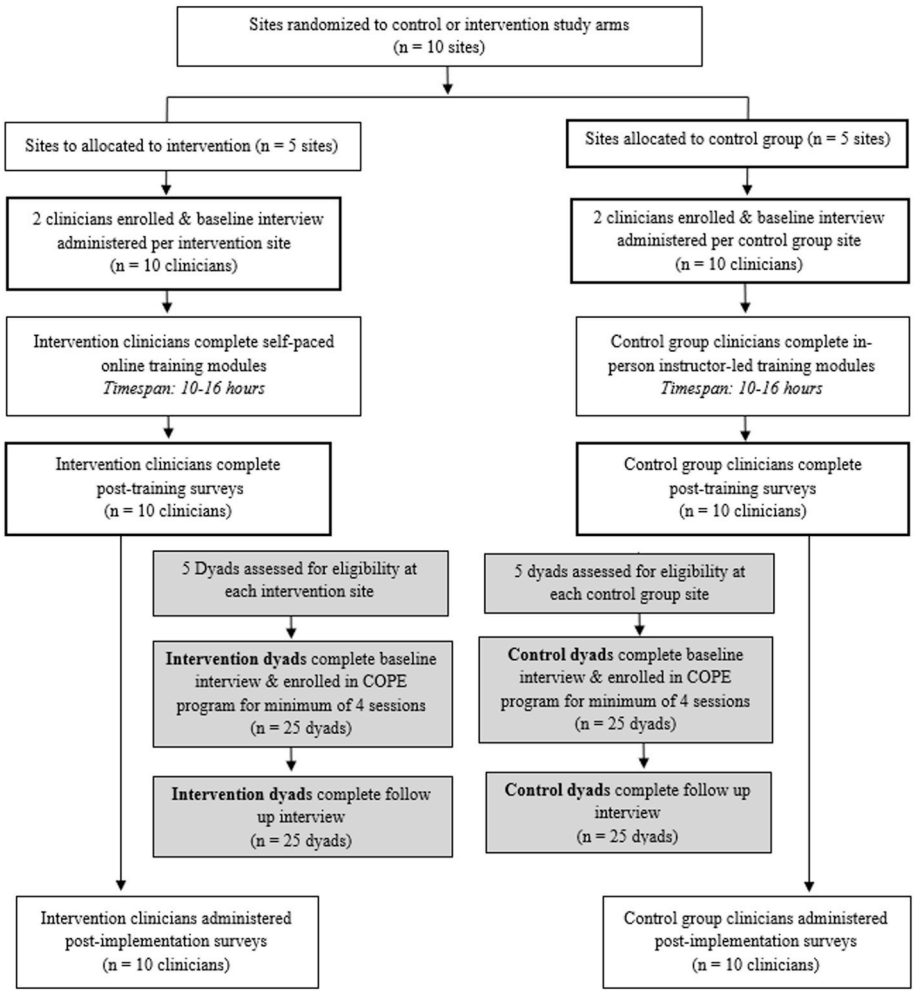

Fig. 1. Consolidated Standards of Reporting Trials diagram
CONSORT illustrates the participant flow starting with randomization at the site level and continuing with enrollment and data collection of clinicians, then dyads.

case heterogeneous mix of PACE staff, PACE participants and their CGs using PACE programs. PACE organization staff are eligible if they are employed full time for more than one year as Occupational Therapists (OTs) or Registered Nurses (RNs) at the enrolled PACE site. PACE participant-family caregiver dyads will be enrolled for this study. PACE participants are eligible to participate if they: a) are enrolled at a participating Trinity Health PACE site; b) have a diagnosis of dementia or have at least four errors on the Mental Status Questionnaire (MSQ) [23], which is updated for each PACE participant every 6 months; (The MSQ threshold of = 4 errors is considered moderate cognitive impairment); and c) speak or understand English. Dementia CGs are eligible to participate if they: a) have primary responsibility for care of the PACE participant (defined as being the responsible party who enrolled the participant in PACE and who provides hands-on or supervisory assistance with one or more instrumental or daily activities of living); b) speak English; c) have a telephone and are willing to participate in 3 telephone interviews (baseline, 4-and 9 month follow-ups); and d) are 21 years of age or older (male or female). While more than one family member may provide care to the PACE participant and participate in the COPE sessions, we will enroll the family member designated as the responsible party for the purpose of evaluating treatment effects. Exclusion Criteria: PACE participants with dementia will be excluded if they: a) have a co-existing diagnosis of schizophrenia or bipolar disorder; b) are bedbound and/or unresponsive; c) have been hospitalized >3 times in past year; d) is in active treatment for a terminal illness or in hospice; or e) are participating in a concurrent experimental drug study designed to treat agitation or aggressive behaviors. Dyads are not eligible if: a) they plan to move from the area within 9 months of enrollment, b) either individual is involved in other support services/trials. These criteria are designed to minimize attrition and exclude CGs of PLWD at high mortality risk who may not benefit from the COPE Program. Recruitment of clinicians and dyads will be tracked and reported using the Consolidated Standards of Reporting Trials (CONSORT) diagram [24].

2.2. Setting and site randomization

Ten Trinity PACE programs in eight states will serve as the study setting. Stakeholders representing Trinity PACE provider, administrators, and caregivers will be engaged throughout the research process from initial study design to implementation and dissemination of findings. Their engagement may take various forms but includes participating in interviews and research team meetings to inform intervention delivery, providing feedback on study materials and outcome measures, helping identify recruitment strategies, and assisting with the interpretation and dissemination of findings.

Prior to study launch, ten PACE Organizations will participate via webinar in a brief orientation/training to the study and project logistics. Next, PACE organizations will be randomized into two groups using re-randomization procedures using the balance match weighted (BMW) design that is particularly well suited to our goals [25]. 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 greater power to detect a COPE program effect.

Twenty clinicians from ten PACE organizations will implement COPE. Five of these PACE organizations will serve as the "control" site in which training will be provided via the traditional in-person, instructor-led method; five PACE organizations will serve as the comparison and be trained through the online asynchronous training site. Prior to randomization, we will carefully examine PACE organizations on important variables such as size, location (urban, rural), percent of PLWD, and staff to participant ratio. In each site, a pair of clinicians (one OT and one RN) will volunteer to be trained after meeting with supervisors to discuss the study. Once trained, each clinician pair at each site will deliver COPE to 5 dyads of PLWD and a designated CG.

2.2.1. Data collection

Outcome measures for clinicians will be collected prior to training, post training and post COPE delivery to 5 dyads. Outcome measures for dyads will be collected prior to COPE and after COPE delivery. Trained research assistants blind to random assignment will collect outcome measures. Assessment of data collector blinding in research studies will involve systematic monitoring and documentation of procedures to ensure data collectors remain unaware of treatment assignments, including maintaining separate teams for data collection and intervention delivery, implementing access controls, and conducting periodic verification checks. The effectiveness of blinding will be evaluated by having data collectors guess participant group assignments, calculating blinding indices, and maintaining detailed logs of any potential unblinding events or protocol deviations.

An overview of the participant flow is provided in Fig. 2 (Consolidated Standards of Reporting Trials diagram). The trial has been prospectively registered with the ClinicalTrials.gov Registry (NCT04165213) with approval provided by the relevant institutional Human Research Ethics Committees at the University of Pennsylvania.

2.3. Training interventionists

COPE Online Training: We developed ten self-paced online learning modules. These modules will enable clinicians to learn asynchronously and have anytime/anywhere access to content and activities. The modules include rich multimedia content and interactive assessments to keep the learner engaged and 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 [26]. To accommodate diversity of learning needs, the modules were 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 are self-paced, the learner can take their time going through them and perform in the embedded interactive learning. 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 clinicians to engage with the content at a high level and practice application in simulated scenarios. Each module will require approximately 45–60 min/module for the learner to complete. Table 1 details the standard training time and content covered in each of the ten modules.

Trinity Health 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 site 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 In-Person Training (Traditional): We will train one OT and one RN at each of the five PACE sites randomly assigned to the instructor-led training. The co-developer of the COPE program (CVP), an expert educator and primary COPE trainer, will conduct training in person using PowerPoint slides that frame the online training and similar case

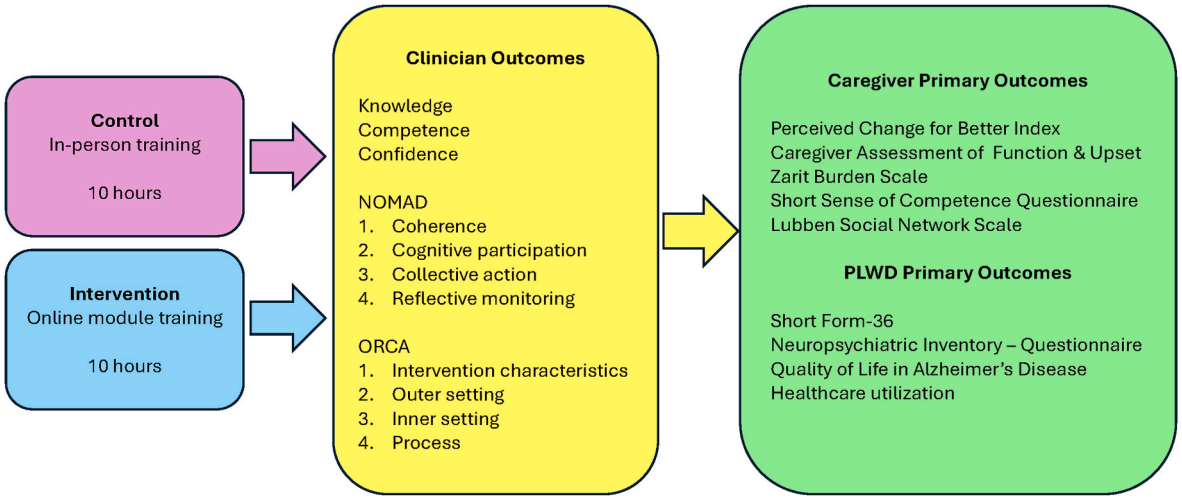

Fig. 2. COPE in PACE Study Flow Chart
Study diagram following two training programs' effect on clinician knowledge competence, confidence and delivery and the subsequent effect on dyad (PLWD and caregiver) outcomes.

Table 1
COPE learning modules & learning objectives.

Module	Learning Objectives
Module 1: Introduction to COPE *12 min*	COPE's Three Phases: • Phase 1: Assessment • Phase 2: Implementation • Phase 3: Generalization
Module 2: Overview of the COPE Program *37 min*	• Explain delivery characteristics of the COPE program • Describe its three phases • Describe distinct roles of the occupational therapist and nurse in the COPE Program
Module 3: Taking Care of Yourself *34 min*	• Understand the importance of helping CGs learn strategies to take care of themselves • Understand the impact of chronic stress on health and wellbeing in both the PLWD and the caregiver • Identify sources of stress (PLWD, Caregiver and Environment) • Demonstrate use of different stress reduction techniques
Module 4: The Role of the COPE Nurse *33 min*	• Describe the unique role of nurse in COPE program as a health coach and collaborator with PLWD and caregiver • Identify potential triggers for behavioral symptoms and functional decline that may require further medical assessment and/or treatment • Understand how to partner and communicate with PLWD and their CGs • Describe how COPE Nurse and OT collaborate
Module 5: The Role of the COPE Occupational Therapist: Phase I – Assessment *48 min*	• Understand assessments conducted by COPE occupational therapist of PLWD, Caregiver, and home environment • Understand how to identify strengths and care challenges
Module 6: The Role of the Occupational Therapists Continued and Implementation Phase *43 min*	• Demonstrate delivery of assessment report • Demonstrate problem solving and brainstorming • Develop COPE prescriptions • Present and teach strategies with CGs using COPE prescriptions • Review caregiver use of strategies in subsequent sessions
Module 7: The Importance of Activity 98 min	• Understand importance of activity • Identify one or more activities of interest and how to grade to a person's abilities • Arrange environments to support engagement • Instruct CGs in using activity as part of daily care routines.
Module 8: Helping Families Use Strategies for Newly Emerging Care Challenges 33 min	• Summarize progress in addressing caregiver-identified care challenges • Practice with CGs use of strategies for newly emerging care challenges • Demonstrate an approach to helping families think about the future
Module 9: Working with Diverse Families 33 min	• Describe key challenges in working with families • Determine strategies for working with families with different styles, preferences, and values • Demonstrate active listening and empathy and how to pivot in a session
Module 10: Wrap Up 50 min	• Brief recap of the COPE program • Prepare for program implementation • How to use COPE binders • Acceptable adaptations • Involve other disciplines • Document and evaluate the program • Next steps

examples. Our training program will take place over 10–16 h, to align with the time of online training and include readings, PowerPoint presentations, and case presentations. We will offer three days of these training sessions per site to accommodate multiple COPE staff members' schedules and assure an interactive process.

We note that while individual learning allows for self-paced, independent study focused on personal comprehension and reflection, group learning facilitates collaborative knowledge sharing and skill development through peer interaction and shared experiences. If differences between the two training groups are noted during analysis, the mechanism explaining these differences will be explored. Both groups will participate in biweekly debriefing and coaching sessions, at which, qualitative notes will be taken to understand the types of questions asked and to discover implementation challenges. 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 videoconferencing using a structured agenda and assigning case presentations a priori facilitates productive discussions [27]. PACE sites will be reimbursed for COPE staff members' time to participate in training and follow-up calls to troubleshoot cases.

2.4. Outcomes

Aim 1 Clinician Outcomes: To compare the training programs on Interventionist uptake, we will conduct surveys to assess changes in knowledge and assess satisfaction with the training. COPE clinicians will need to demonstrate Knowledge and Competency in treatment delivery, a measurement approach we use effectively in our trials [20].

The implementation measure based on Normalization Process Theory (NoMad) captures the ways in which work must be reconfigured both individually and collectively by those involved in the work of implementation [21]. We will administer NoMad prior to COPE implementation and then again post COPE implementation. At each time point, clinicians rate their agreement from 1 (strongly agree) to 5 (strongly disagree) with 20 phrases that capture 4 domains (coherence, cognitive participation, collective action and reflexive monitoring). Clinicians will also rate 0 (not at all) to 10 (completely) items that capture how they think COPE fit into their workload and site. These items include: When you use [COPE], how familiar does it feel? Do you feel that [COPE] is currently a normal part of your work? Do you feel that [COPE] will become a normal part of your work? [21].

The Organization Readiness to Change Assessment (ORCA) derived from the PARIHS model will help track Organizational readiness from clinicians and PACE leadership at the middle and upper management levels. ORCA uses 20 domains to assess the core elements to successful implementation of evidence-based interventions: 1) evidence, 2) context 3) scale and 4) facilitation [22]. Clinicians will be administered the ORCA just prior to training (pre-training baseline), prior to implementation (post training baseline) and post implementation (follow up). Tracking each domain and core element regularly will allow for intervention (additional trainings, coaching sessions) at sites with varying readiness. Similarly, clinicians will complete the Determinants of Implementation Behavior Questionnaire to identify factors that influence implementation behaviors so that adaptations can be made to improve the implementation behaviors of COPE clinicians.

The Determinants of Implementation Behavior Questionnaire (DIBQ) will be administered to clinicians. We will survey clinicians using a modified 36-item questionnaire assessing 14 domains including knowledge, skills, and clinician/site readiness to implement COPE [27]. The Determinants of Implementation Behavior Questionnaire (DIBQ) will be administered prior to implementation and post-implementation to track the change in COPE knowledge, skills, intentions and beliefs that occur after clinicians have the opportunity to deliver COPE. Table 2 lists clinician outcomes.

Aim 2: Therapeutic alliance: In this study, fidelity to COPE will be

Table 2
Clinician outcome measures.

Domain	Measure	Test Occasion
Demographics	Staff Demographics: site, age, gender, race, ethnicity, education, years employed, job category	Pre-training baseline
Clinician knowledge and competence	NoMAD: Normalization Process Theory	Pre-training baseline & follow up
Evidence, context, scale and facilitation factors influencing Clinician/site readiness to implement COPE	ORCA: Organizational Readiness Change assessment	Pre-training baseline, post-training baseline & follow up
COPE training evaluation, satisfaction & confidence	COPE Training Evaluation	Post-training baseline
Clinician knowledge, skills, beliefs, intentions to implement COPE	DIBQ: Determinants of Implementation Behavior Questionnaire	Post-training baseline & follow up

measured through the Therapeutic Engagement Index (TEI) which has been used in previous studies to measure the delivery of clinical instructions by clinicians and the acceptance of those instructions by caregivers [28,29]. Therapeutic alliance is an important aspect of COPE delivery as it is has been shown to promote treatment adherence, participant retention, and validity of outcomes through the development of trust and collaborative relationships between providers and participant [30–32]. COPE is intended to be tailored to the specific needs, abilities and culture of the individual family, sessions content and activities are unique to each family. As such, measuring therapeutic alliance is a more practical way of monitoring fidelity to COPE. As part of COPE training and study procedures, the TEI will be completed by clinicians on paper after each COPE session. In addition, caregivers will be asked to complete a 12-item version of the TEI from their perspective over the phone within a week of each COPE session. TEI responses from caregivers and clinicians will be compared across each session. The mean TEI responses will be compared to dyad outcomes by study arm to test the relationship between therapeutic alliance and COPE training type. Table 3 lists the 12 TEI items chosen to measure therapeutic alliance between clinicians and caregivers.

Table 3
Therapeutic Engagement Index items for clinicians and caregivers.

	Therapeutic Engagement Index (completed by clinician)	**Caregiver Engagement Survey** (completed by caregiver)
	During today's session, did the caregiver …	During today's session, to what extent did you …
1	make provider feel welcomed to return?	feel comfortable with the therapist?
2	[a] appear bored or disinterested?	[a] feel bored?
3	ask questions and demonstrate curiosity.	ask questions about caregiving difficulties?
4	disclose relevant information?	share relevant information about your daily difficulties/concerns?
5	indicate the contact was useful?	tell the therapist that the session was useful?
6	share own knowledge?	share your own knowledge about the topic?
7	offer feedback when a suggestion was made?	offer feedback to the OT/RN?
8	express a need for more information?	ask for more information?
9	[a] indicate strategies had no effect/ made matters worse?	[a] reveal that their strategies did not help/made things worse?
10	reject suggestions?	accept suggestions made by the OT/RN today?
11	demonstrate understanding of strategies?	say that you would follow up with the OT/RN's suggestions?
12	[a] convey the information was not applicable to their situation?	[a] tell the OT/RN the information was not applicable to your situation?

[a] Reverse scored.

Aim 3: Dyad Outcome Measures: To test the efficacy of COPE on PACE participant outcomes by type of COPE training, each of the PACE organizations will enroll 5 PLWDs and their CGs in the study enrolled over a 24-month period. 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 4).

Dyad level outcomes include those identified as clinically meaningful to both PACE participants and PACE organizations such as patient symptoms and function, caregiver confidence and burden, and caregiver connections/therapeutic alliance. All enrolled CGs complete two interviews by telephone, one at enrollment (baseline) and a second at 4-months after enrollment and receipt of the COPE intervention. Research assistants blinded to training group allocation will conduct interviews. Outcome measures summarized in Table 4 were selected based upon the adequacy of their psychometric properties, cultural sensitivity, brevity, and sensitivity to change.

Table 4
Dyad (PLWD and CG) outcome measures.

Domain	Measure	Test Occasion
Demographics	Gender, race, ethnicity, education, zip code of pace site, age, Employment status, Participant site, neighborhood characteristics, relationship status with CR, duration of care of loved one (months)	Baseline (T1)
Mental state	CR mental state via Saint Louis University Mental Status Exam (SLUMS) or Montreal Cognitive Assessment (MoCA) [35]	Baseline (T1)
Medications	CR Medication Log	Baseline (T1)
Health condition	CR health behaviors and health conditions such as skin, incontinence, nutrition, etc.	Baseline (T1) & 4 Months (T2)
Healthcare utilization	Reports of emergencies (hospitalizations), 911 calls and falls	Baseline (T1) & 4 Months (T2)
Social support	Lubben Social Network Scale (LSNS-R): Caregiver social support [36]	Baseline (T1)
QOL & functional ability	Short-Form 36 (SF-36) [37]	Baseline (T1) & 4 Months (T2)
Dependence & functional ability	Caregiver Assessment of Function and Upset (CAFU) [33]	Baseline (T1)
Neuropsychiatric behaviors	Neuropsychiatric Inventory–Questionnaire (NPI-Q) [34]	Baseline (T1)
Neuropsychiatric behaviors and activities selected by CG to target with clinician through COPE	Target Behaviors	Baseline (T1) & 4 Months (T2)
Caregiver competence	Short Sense of Competence Questionnaire (SSCQ) [38]	Baseline (T1) & 4 Months (T2)
Caregiver depression	Patient Health Questionnaire-9 (PHQ-9) [39]	Baseline (T1) & 4 Months (T2)
Perceived change	Perceived Change for Better Index (13 items) [40]	Baseline (T1) & 4 Months (T2)
Quality of life	Quality of Life in Alzheimer's Disease (QOL-AD) [41]	Baseline (T1) and 4 Months (T2)
CG confidence	CG Confidence in Using Activities [40]	Baseline (T1) and 4 Months (T2)
CG burden	Zarit Burden Scale (12-item) [42]	Baseline (T1) and 4 Months (T2)

CGs will take an active role in selecting caregiving skills or PLWD behaviors they would like to focus on in COPE sessions. After Caregiver Assessment of Function and Upset (CAFU) [33] and Neuropsychiatric Inventory–Questionnaire (NPI-Q) completion [34], CGs will be asked to select and rank up to 4 "target behaviors" from the list of activities of daily living, (ADLs) independent activities of daily living (IADLs) discussed in the CAFU and neuropsychiatric behaviors discussed in the NPI-Q. CGs will rank "target behaviors" by how bothersome CGs find them and then share their confidence levels (1-10) and duration of assistance in months for each. At the follow up interview, CGs will review the top "target behaviors" and rate their confidence.

2.5. Data analysis

Power: In our previous work, COPE demonstrated a mean physical function score on the CAFU equal to 5.6 with a standard deviation of 0.66 [12]. Using this information, group sample sizes of 20 dyads each (COPE online vs COPE in-person) achieve 80 % power to detect non-inferiority using a one-sided, two-sample *t*-test. The margin of non-inferiority is −0.3 and the true difference between the group means is assumed to be 0.2. The significance level (alpha) is 0.05 and the assumed population standard deviations are 0.7. Assuming 20 % attrition, we seek to enroll a total of 50 participants, with 25 per group so that the necessary 20 per group is achieved.

Analysis: 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 in-person 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.

Analysis of Aim 1 & 2: We will conduct a non-inferiority analysis to determine if online training compared to high intensity in-person training results is the same or better in Knowledge, Competency and TEI scores. Independent-samples *t*-test, 2 test, and Fisher's exact test will be used to compare the groups.

Analysis of Aim 3: To compare the efficacy of COPE on dyad 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.

Discussion: There is still a great deal of work to do to assure that PLWD and those caring for them receive the resources they need when they need it. The strong evidence supporting the effectiveness of dementia care programs will have limited relevance if these programs are not designed or conducted in a way to support implementation and sustainability in practice. Our protocol is timely and significant for its potential to provide scalable solutions for training in 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 project has potential to positively impact clinical practice. Our hope is that we can help guide future translational efforts by providing program adaptation/fidelity and implementation details to enhance scalability of evidence-based dementia programs.

CRediT authorship contribution statement

Nancy A. Hodgson: Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Miranda V. McPhillips:** Writing – review & editing. **Karen B. Hirschman:** Writing – review & editing, Formal analysis, Data curation. **Emily Summerhayes:** Writing – review & editing, Validation, Supervision, Data curation. **Catherine Verrier Piersol:** Writing – review & editing, Project administration, Methodology. **Laura N. Gitlin:** Writing – review & editing, Validation, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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