Title: **Family Telemental Health Intervention for People with Dementia and their Caregivers**
Protocol # **1567**
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Abstract:

The increase in prevalence of dementia over the last 50 years has resulted in a concomitant rise in the number of families facing the physical, emotional, and psychological stress associated with caregiving. Behavioral symptoms that occur in persons with dementia (PWD) lead to negative mental and physical health outcomes for caregivers and predict caregiver decisions to institutionalize PWD. Resources to Enhance Alzheimer's Caregiver Health - VA (REACH VA), has demonstrated its ability to improve caregiver burden, emotional and physical well-being, social support and management of behavioral symptoms. Although REACH VA represents one of the best available approaches to help caregivers, treatment non-response and modest treatment effects remain significant issues. A variety of factors may be associated with non-response to behavioral intervention — one particularly robust predictor of non-response is interpersonal skill.

The goal of this research project is the first step toward systematically identifying and addressing caregiver interpersonal challenges using telehealth technology. Observation via telehealth provides the physical and emotional distance for better identification of interpersonal behaviors that may be more difficult to achieve when in person in addition to providing the opportunity for recording interactions. This project involves three interrelated activities: (1) refinement and pilot testing of a video based observational coding manual (OCM) to evaluate interpersonal skills of family caregivers interacting with PWD (2) development of a treatment manual integrally linked to the OCM and (3) assessment of the feasibility of delivering the treatment.

Methods:

Participants: We anticipate that approximately a total of 20 caregivers will be recruited into the study. No participants will be excluded because of gender, race, health status, or marital status.

Although care recipients will have dementia, for those with mild to moderate dementia, evidence from prior studies demonstrate that such individuals often have decision-making capacity and are able to recognize the risk-benefit profiles of various research study scenarios. Care-recipients who refuse to participate in the study will not be approached again.

We will use the standard procedures for addressing capacity that are employed by many institutions' human subjects review boards. The following questions will be employed:

I just went over what participating in this study entails. I am going to ask you a few questions just to make sure you understand the study before we begin.

1. What would you be doing if you agree to participate in this study?
(Examples of acceptable answers: "Answer questions," or "Talk to my family member.")
*☐ Person is able to answer this ☐ Person is **not** able to answer this*

2. What can you do or ask me to do if you are uncomfortable with a particular question?
(Examples of acceptable answers: "Ask to skip the question." "Ask you to ask something else.")
*☐ Person is able to answer this ☐ Person is **not** able to answer this*

3. What can you do if you decide after we start that you do not want to participate in the study?
(Examples of acceptable answers: "Tell you that I do not want to do this anymore.")
*☐ Person is able to answer this ☐ Person is **not** able to answer this*

Eligibility: Either the caregiver or the care-recipient must be a Veteran.

The caregiver must:

1. Be at least 18 years old
2. Be the primary family or friend who helps or supports an individual with dementia
3. Be involved in the care of the person with dementia (at least 4 hours of care per day).
4. Report that the care-recipient exhibits behavioral problems that are distressing.
5. Not be currently receiving the REACH VA protocol.

Additionally, the care-recipient must:

1. Must have a documented diagnosis of dementia
2. Have cognitive impairment (MMSE<23 or SLUMS<20 or diagnosis of dementia based on chart review)
3. Be out of bed and able to respond to a caregiver's instructions or interventions

Although we will accept caregivers without significant mood symptoms or burden into the pilot, we will strive for a minimum of 50% of the sample with either PHQ-9>5 or Zarit Burden Scale >9 to ensure sufficient data on distressed caregivers.

Should worrisome conditions such as depression, suicidality, or other concerning clinical conditions be apparent during a research interview or observation, treatment interviewers and therapists will follow a scripted protocol to notify the appropriate medical personnel and the PI so that appropriate notification and clinical follow-up is ensured. All research staff will also be trained to provide appropriate referrals to non-VA resources for caregivers who experience distressing symptoms during the study, as caregivers may be ineligible for VA care.

Recruitment: We will utilize a multimodal recruitment approach consisting of: targeted direct mail, provider referral, and advertisements. Subject recruitment will occur via referral from VA providers in Primary Care, the Geriatric Clinic, Family Caregiver Program, Memory Disorders

Clinic, Neuropsychological Testing Service, Home Based Primary Care, Psychology Service, and the Social Work Service of the three campuses participating in the study. We will meet with key providers caring for large numbers of Veterans with dementia, provide study details, and weekly follow up until recruitment numbers are achieved. All providers will have easy access to handouts describing the project to facilitate provider-patient discussions about possible referral.

Additionally, to recruit Veterans who serve as caregivers to family or friends we will advertise: (1) in Primary Care and Mental Health Clinics on all three campuses of VA NYHHCS, (2) on websites (e.g. the Alzheimer's Association, NY State Division of Veteran's Affairs, social networking sites), (3) with community organizations who serve Veterans (e.g. Vietnam Veterans of America -NY Chapter).

Procedure: This project involves two interrelated activities: (1) refinement and pilot testing of a video based observational coding manual (OCM) to evaluate the interpersonal skills of family caregivers interacting with PWD, (2) development and pilot testing of a treatment manual integrally linked to the OCM that is designed to improve caregiver interpersonal skills.

(1) Refining and pilot testing the OCM: We will convene an Expert Advisory Panel (EAP) with expertise in interpersonal and family caregiving processes and family psychotherapy to provide feedback on the OCM. The OCM represents an adaptation of previously established and reliable coding manuals developed for assessing interaction patterns in couples, families, and dementia caregiver research. Using an iterative process of refinement based on EAP feedback, pilot coding of video from five initial dyads, and feedback from those dyads we will use coding schemes originally developed for research and adapt them for clinical use. We will then recruit 15 additional dyads and videotape their interactions. Five Psychology Trainees will be trained on the OCM. The PI and pairs of Psychology Trainees will independently code each video to assess validity (face, concurrent, convergent, discriminant, content, and criterion), reliability (alternate form, inter-rater, and internal consistency) and analyze qualitative data from semi-structured interviews of caregivers, care-recipients, and clinicians to assess acceptability and utility of the OCM.

(2) Development and pilot testing of the Family Intervention: As the OCM is being created, we will draft a treatment manual for a family intervention informed by established empirically supported interventions for couples and families. The treatment manual will specifically target the identified interpersonal skills deficits in the OCM. A draft of the Treatment Manual will be presented to the EAP, eliciting feedback for further refinement. We will pilot test the family intervention via telehealth with the dyads who received the OCM and assess feasibility of delivery, dyad benefit from dyad and therapist report, and descriptive analyses of changes in interpersonal conflict, caregiver depression, anxiety, and burden.

Study Visits and Measures:

Visits:

Dyads will be recruited in 2 waves.

In wave 1, 5 dyads (or more dyads until sufficient data is collected for the development of the intervention, estimated 5-10 dyads total) will be recruited and complete

1. First Contact,
2. *Assessment Session*
3. Recording Task
4. Feedback session, Caregiver Intervention is Offered

In wave 2, the remaining dyads will be recruited and complete

1. First Contact,

1a. Assessment Session,

2. Recording Task,
3. Family Therapy, and

3a. Exit Measures.

3b.Therapist Exit Measures (Participants will not be present for this)

1. First Contact (15 minutes, wave 1 only): Initial contact with the caregiver will consist of brief contact to both share information about the study with the caregiver, as well as get basic screening information from the caregiver. Caregiver will be asked their care recipient's current diagnosis and whether the care recipient is currently bed bound, this information will be used as screening for inclusion/exclusion criteria only in order to reduce participant burden of travel to the VA for screening visits, and will not be stored as research data. At this time, the participant dyads will also be screened for potential participation in another caregiver intervention that focuses on dementia caregiver support (including but not limited to the Dementia Caregiver Intervention) which will be offered in lieu of the Family Therapy intervention that is only offered for wave 2 participants. The Assessment Session will be scheduled. This screening can be completed via phone or in person, based on the patient's preference.

2. First Contact (15 minutes, wave 2): Initial contact with the caregiver will consist of brief contact to both share information about the study with the caregiver, as well as get basic screening information from the caregiver. Caregiver will be asked their care recipient's current diagnosis and whether the care recipient is currently bed bound, this information will be used as screening for inclusion/exclusion criteria only in order to reduce participant burden of travel to the VA for screening visits, and will not be stored as research data. At this time, the Assessment Session will be scheduled. This screening can be completed via phone or in person, based on the patient's preference.

1a. *Assessment Session (2 hours, Waves 1 & 2*): The Assessment Session will be done in person with study staff. All participants (care recipient and care giver) will sign required study informed consent documents prior to the collection of any data. Participants found to be

eligible will proceed with the Telehealth Assessment, participants found ineligible will not be enrolled in the Telehealth Assessment or Family Treatment. Additional VA and community resources will be offered. Eligibility will be determined based on the administration of the following items:

a. Demographics
b. HABC Monitor
c. KCMS
d. PHQ-9
e. GAD-7
f. Zarit

3. Recording Task (1 hour, all waves): We will use existing telehealth facilities and equipment to record dyads as they engage in the two OCM tasks. Research staff will bring participants to designated telehealth rooms and ensure the equipment is operating appropriately. They will then leave the room and a research staff will present the rationale and instruction for each task via the telehealth video monitors. The first task will be recorded for 10 minutes. After 10 minutes, research staff will provide instructions for a second 10-minute task via the telehealth video monitors. The second task will be recorded for 10 minutes.
    a. Task 1: Dyads will collaboratively plan a hypothetical pleasant event. This task will allow clinicians to observe the caregiver's ability to involve the care-recipient in eliciting preferences, validating feelings and desires, demonstrating emotional engagement and connection, and providing appropriate structure and guidance around planning this hypothetical event.
    b. Task 2: Dyads will work together to complete a puzzle. We will instruct caregivers to not solve the puzzle themselves but to assist care-recipients in the completion of the task. The task will allow clinicians to observe the caregiver's ability to reduce complex tasks into simple instructions, observe and modify the approach based on care-recipient reactions, regulate care-recipient frustration, and simultaneously attend to the care-recipient's feelings and the successful completion of the task.

2a. *Feedback Session (30 minutes, Wave 1 only),* Research staff will conduct semi-structured interviews separately with each member of the dyad to assess reactions to participating in the tasks, perceived benefit, ways to make the tasks more relevant, and willingness to participate in additional treatment following the tasks. Research staff will tailor the care-recipient interview to fit care-recipients' needs and verbal abilities.

4. The Dementia Caregiver Intervention (~4-6 weeks, Wave 1 only) The intervention offers short-term therapy for caregivers of persons with dementia to assist in communication, problem-solving, and caregiver stress management. Some Dementia Caregiver Intervention intake measures overlap with the current study's intake battery, including the demographics forms, PHQ-9, GAD-7, and Zarit Burden Scale. Based on the First Contact eligibility results, the participant will be offered the opportunity to enroll and participate in both the current study and a separate caregiver intervention. Once consented, the participants will complete the additional caregiver intervention specified intake measures (the Adult Attachment Scale,

URICA Readiness for Mental Health Treatment, Dementia Severity Rating Scale, the Multidimensional Scale of Perceived Social Support, the Structured Clinical Interview for DSM-IV Axis II Personality Disorders, the Personality Assessment Inventory, and the Secure Base Script Assessment – Older Adult Version) in addition to the current study measures. This will only be offered to the first five participant dyads to enroll in the current study. Participants have the option to come in on a separate day to consent to and complete measures for the Dementia Caregiver Intervention.

5. Family Therapy (~12-16 weeks, Wave 2 only): Performed by Family Therapist Dr. Cory Chen. Our development of the treatment manual will be informed by the specific interpersonal skills deficits identified in the process of refining the OCM. We anticipate that the treatment manual will be approximately 12-16 sessions and will include the following specific strategies, the implementation of which will be tailored by clinicians to the specific interpersonal deficits identified in the OCM: (1) psychoeducation on dementia, (2) communication and problem solving skills, (3) safety building skills, (4) relationship satisfaction enhancement skills, (5) "meaning making" (i.e. collaboratively identifying the personal significance of events), (6) identification of core patterns from dyad relationship history, (7) techniques to shift emotional responses, (8) techniques to increase emotional attunement, and (9) techniques to increase attunement to care-recipient needs

3a. Exit Measures (2 hours, Wave 2 only): The Exit Measures will be done in person with study staff. Tasks will include

a. KCMS
b. PHQ-9
c. GAD-7
d. Zarit
e. Semi-Structured Interview (Separate for Caregiver and Care Recipient, when possible)

3b. Therapist Exit Measures (30 minutes, Wave 2 only; Participant not present): Research staff will conduct semi-structured interviews with Family Therapist to gather data on their experience providing the treatment and potential modifications to both the treatment and the OCM based on therapist experience providing the family intervention.

Measures:

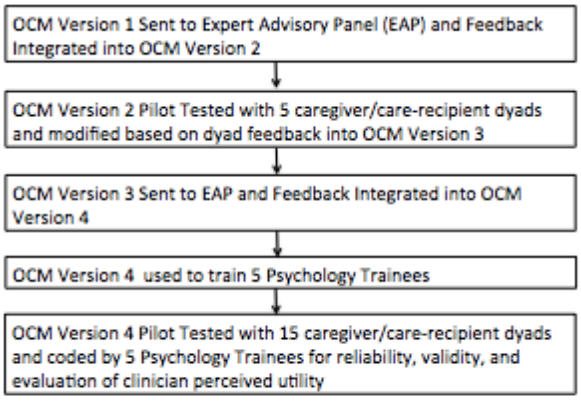
1. Healthy Aging Brain Center Monitor (HABC Monitor): A 31-item caregiver assessment of dementia severity, caregiver stress, and mood. Contains three patient symptom domains (Cognitive, functional, behavioral/psychological) and a caregiver quality of life domain. Shown to have good internal consistency (0.73-0.92) and construct validity.
2. The Kansas Marital Conflict Scale (KMCS): A 37-item self-report scale consisting of three subscales of how well partners are able to: (1) listen and understand each other's

perspectives, (2) express his or her point of view , and (3) come to a mutually satisfactory compromise. It has been shown to have high internal consistency (α = .87 to .90) and test-retest reliability (r = .62 to .92). *Although developed for marital relationships, all items are applicable or easily modified for a variety of interpersonal relationships.*

3. Patient Health Questionnaire – 9 (PHQ): A 9-item self-report scale based on DSM-IV criteria for Major Depressive Disorder, has been shown to have good sensitivity and specificity and is predictive of health outcomes such as sick days, clinic visits, and symptom related difficulty. Internal reliability of the PHQ-9 is excellent (α = 0.89).
4. Generalized Anxiety Disorder Screener (GAD-7): A 7-item self-report scale used to assess anxiety symptoms. It has demonstrated good reliability, sensitivity (0.89) and specificity (0.82). Originally designed to assess Generalized Anxiety Disorder, it has been used as a screening and symptoms severity measure for a range of common anxiety disorders.
5. Zarit Burden Scale: A 12-item self-report scale shown to have acceptable indices of internal consistency for the two distinct factors of the scale – personal strain and role strain (α =0.88 and α =0.78) and a good predictor of caregiver mental health outcomes.
6. Feedback Session Interview: We will conduct semi-structured interviews with the initial five dyads following the two interaction tasks of OCM V-2 for additional refinement in developing OCM V-3. Research staff will conduct semi-structured interviews separately with each member of the dyad to assess reactions to participating in the tasks, perceived benefit, ways to make the tasks more relevant, and willingness to participate in additional treatment following the tasks. Research staff will tailor the care-recipient interview to fit care-recipients' needs and verbal abilities. We will incorporate dyad feedback into OCM V-3.
7. Exit Measures Semi-Structured Interview: Similar to the Feedback Session Interview, yet modified for based on information gathered from that interview. This will be given to the 15 dyads in Wave 2.
8. Therapist Exit Measures: Research staff will conduct semi-structured interviews with Family Therapist to gather data on their experience providing the treatment and potential modifications to both the treatment and the OCM based on therapist experience providing the family intervention.

OCM Development:

OCM Versions: OCM Version-1 (V-1) is adapted from established and reliable coding manuals designed to assess interaction patterns in couples, families, and dementia caregiver research. We will create OCM V-2 based on EAP guidance and feedback. OCM V-3 will be created based on pilot testing on 5 dyads and dyad feedback. OCM V-4 will be developed based on a second round of EAP feedback. We will use OMC V-4 to train interventionists, who will pilot test it with 15 dyads for reliability, validity, and utility.



Expert Advisory Panel: We will use two rounds of feedback from an Expert Advisory Panel (EAP) with expertise in family caregiving processes and two rounds of pilot testing with dyads to refine and test the OCM. EAP members will not be exposed to PHI.

Expert Advisory Panel Members	**Institution**	**Expertise**
Steffany Fredman, PhD	Penn State University, Dept. of Human Dev. and Family Studies	Co-Creator of Cognitive Behavioral Conjoint Therapy for PTSD and developer of observational coding protocol for family emotional involvement
David Miklowitz, PhD	University of California – Los Angeles, Semel Institute	Creator of Family Focused Therapy for Bipolar Disorder and expert in family observational coding
Zoya Simakhodskaya, PhD	New York University, New York Center for Emotionally Focused Therapy	Expert in Emotion Focused Therapy for couples
Theodore Waters, PhD	New York University, Dept. of Psychology	Expert in coding of attachment processes in family and couples interactions.
Sarah Yarry, PhD	VA New York Harbor Healthcare System	Co-Creator of ANSWERS Family Intervention for Caregivers of Individuals with Dementia
Steven Zarit, PhD	Penn State University, Dept. of Human Dev. and Family Studies	Expert in Dementia Caregiving

Treatment:

Based on Stage I treatment manual development guidelines, an outline of the treatment and description of the major contents of sessions will be developed and include: (1) overview, description, and rationale, (2) formulation of the problem, (3) treatment goals, (4) similarities and distinctions from other approaches, (5) specifications of defining interventions (unique and not unique essential elements, recommended elements, proscribed elements), (6) session content,

and (7) description of format for delivery. Treatment will be adapted from empirically supported family and couples protocols designed in other contexts where significant caregiving is provided to an identified patient (i.e. when one member of the couple or family has a physical or mental illness or in the context of parenting skills training).

Our development of the treatment manual will also be informed by the specific interpersonal skills deficits identified in the process of refining the OCM. We anticipate that the treatment manual will be approximately 12-16 sessions and will include the following specific strategies, the implementation of which will be tailored by clinicians to the specific interpersonal deficits identified in the OCM: (1) psychoeducation on dementia, (2) communication and problem solving skills, (3) safety building skills, (4) relationship satisfaction enhancement skills, (5) "meaning making" (i.e. collaboratively identifying the personal significance of events), (6) identification of core patterns from dyad relationship history, (7) techniques to shift emotional responses, (8) techniques to increase emotional attunement, and (9) techniques to increase attunement to care-recipient needs.

A draft of the Treatment Manual will be presented to the EAP with a series of questions to obtain feedback and identify additional modifications necessary for successful implementation given the unique characteristics of: 1) clinicians in the VA providing treatment and 2) VHA medical centers where the treatment will be delivered. The draft will be sent to the EAP for feedback at month 5 (with OCM V-3). EAP members will provide written feedback on the treatment manual with proposed modifications. The PI will use panel feedback to revise the treatment manual. A summary of the EAP feedback will be created and sent to EAP members with the revised treatment manual. EAP members will review other EAP members' feedback, their own prior ratings, and the revised treatment manual. We will convene the EAP over telephone or CVT to discuss the new draft of the treatment manual and obtain additional feedback to complete the final version of the treatment manual.

Training:

Psychology Trainees will be participants in the VA NYHHS Externship Program. Training will include presentation of literature on dementia, caregiving, and other topics relevant to the OCM. Examples of prototypical interactions will be shown to illustrate behavioral anchors for scoring. The infrastructure for the psychology training program has been in operation for the last four and a half years. We will train psychology trainees on the OCM V-4 including a 2-hour didactic and practice/explanation of coding procedures illustrated by video recorded interactions of the five dyads used to Pilot Test OCM V-2.

Following completion of training, psychology trainees will watch the dyad interaction videos of the 15 dyad pairs and code the interactions based on the procedure learned in OCM V-4 training. Two psychology trainees will watch and code each video to evaluate interrater reliability. The PI will also rate each video as a criterion coder. Research staff will conduct semi-

structured interviews with psychology trainees to gather data on their experience learning the coding, coding the interactions, and perception of the clinical utility of the coding procedure.

Data Analysis:

Assessment of Validity of OCM V-4

1. Face Validity will be established based on interpretation of qualitative interview data of caregiver, care-recipient, OCM rater, and EAP panel member responses regarding the relevance of the tasks and coding method. We will use Grounded Theory, a systematic and rigorous set of principles for text interpretation developed by Strauss and Corbin (1998) to interpret qualitative data. During an "open coding" phase, meaningful statements that convey discrete concepts and ideas will be identified and allocated a code that maintains the meaning of the original expression as closely as possible. The constant comparative method of analysis will be used to continually refine the interview and coding procedure. This method involves an iterative process of making comparisons at each level of analysis (data with data, data with codes, codes with categories, etc.) throughout data collection and analysis. This process allows investigators to continuously modify and refine coding and create categories as data is being collected and analyzed. After the initial round of coding, all interviews will be recoded to ensure that the final codes are applied equally to all interviews. The codes will be grouped together into higher-level categories and ultimately distilled into the main themes of the research. Over the course of the process, a record of the process of idea generation, analyses, questions and hypothesized theoretical understandings will be maintained. Our initial hypothesized understanding is based on literature from CBT couples and family therapy, Expressed Emotion, Emotion Focused Therapy, and Attachment Theory ,
2. Concurrent Validity will be established by examining the correlation between the OCM V-4 summary scores and the Kansas Marital Conflict Scale (KMCS), a self-report measure designed to assess interpersonal difficulties. Due to the small sample size, we will use Spearman's correlation coefficient. We anticipate OCM V-4 scores to be moderately to highly correlated with the KMCS.
3. Convergent Validity will be established by examining the correlation between the OCM V-4 summary scores and constructs that are anticipated to be different but related to interpersonal difficulties. We anticipate OCM V-4 scores to be moderately correlated with HABC Monitor behavioral/psychological and caregiver quality of life subscales, Zarit Burden, PHQ-9 rated depression, and GAD-7 rated anxiety.
4. Discriminant Validity will be established by examining the correlation between the OCM V-4 summary score and variables anticipated to be unrelated or less related to interpersonal difficulties (e.g. HABC Monitor cognitive and functional subscales, education, SES, religion). We anticipate OCM V-4 scores to show no or small correlations with these variables. We will also compare the mean OCM V-4 summary scores of caregivers who experience significant caregiver burden or depression (PHQ-9>5 or Zarit Burden Scale >9) to those who do not report significant burden and depression to determine whether the

identified interpersonal variables differentiate caregivers who are experiencing significant distress from those who are not.

5. Criterion Validity will be established by examining inter-rater reliability of the trainee's coding with those of the PI as the Criterion Coder. We anticipate that the trainees will show good reliability with the Criterion Coder.
6. Content Validity will be established by calculating a content validity ratio to analyze the EAP's evaluation of each item in the OCM as "essential," "useful, but not essential," or "not necessary."

Dyad Perceived Feasibility and Utility of Treatment: Following treatment, research staff will assess caregivers with the KMCS, PHQ-9, GAD-7, Zarit burden scales and conduct semi-structured interviews with caregivers (and care-recipients, when possible) to assess reactions to the treatment, perceived benefit, feedback how to make the treatment more relevant, and willingness to refer others to the treatment. We will summarize retention rates and conduct descriptive analyses of the primary outcomes (mean with SD, median with IQR, boxplot, and frequency table) at baseline and post treatment. Within group effect sizes (Cohen's d) will be calculated. The constant comparative method of analysis will be used to analyze qualitative interview data.

Clinician Perceived Feasibility and Utility of Treatment: Research staff will conduct semi-structured interviews with family therapists to gather data on their experience providing the treatment and potential modifications to both the treatment and the OCM based on therapist experience providing the family intervention. Research staff will record and transcribe all interviews for qualitative analysis. The constant comparative method of analysis will be used to analyze qualitative interview data.