Official Title: Optimizing Dementia Care through Collaborative Recovery Interventions

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4. **Sponsor of the study of funding agency (if applicable):** VA Rehabilitation Research & Development Service (Rehab R&D) (D1824-W; Application Number: 1IK2RX001824-01A1)

5. **Research setting:**

This is a community-based study. All in-person study procedures will occur in a convenient community-based setting of the participant's choosing (e.g., their home, a local library, a community center, TVAMC campus, etc.). Most interactions (intervention & assessment) will occur over the telephone.

6. **Purpose of the study (including hypothesis to be tested):**

The purpose of this randomized controlled pilot study is to examine the preliminary effectiveness, feasibility, and potential treatment moderators (e.g., behavioral symptoms and spousal relationship status) of a newly developed intervention that combines elements of the established care consultation (CC) approach with additional counseling modules (CC+C).

Our specific aims and hypotheses follow:

Aim 1: Manualize the integration of care consultation and counseling components. The study team will begin this five-year study by refining and operationalizing the CC+C intervention. The CC+C intervention is guided by a rehabilitation and recovery-based conceptual model to address the most common high distress situations (e.g., relationship distress, veteran or caregiver depression, anxiety, or pain).

Aim 2: Evaluate preliminary effectiveness and feasibility of the CC+C Intervention. A randomized controlled pilot study of distressed dyads will be completed to compare: 1) the established CC intervention, to 2) the CC+C intervention on veteran and caregiver outcomes at 6 months.

Aim 3: Conduct exploratory analyses of the CC+C intervention on veteran long-term care placement at 6 and 12 months and examine two key treatment moderators

(behavioral symptoms and spousal relationship status) that may impact intervention engagement and response to treatment.

Hypotheses for Aims 2 and 3:

Participants assigned to both groups will have: 1) reduced unmet needs, 2) reduced depressive symptoms, and 3) higher levels of satisfaction with care at 6 months than their baseline assessment values.

Caregivers assigned to CC+C will have greater reductions in caregiver burden at 6 months than those assigned to CC alone. Indicators of relationship strain (e.g., marital distress and/or mutuality) will show greater improvement in CC+C than CC at 6 months. 6 month gains in shared pleasant events, social engagement, and quality of life will also be greater in CC+C than in CC alone. 6-month desire to institutionalize will be lower in the CC+C group than those randomized to CC. Treatment engagement (e.g. action plan completion, attendance) is also predicted to be higher in the CC+C group than in CC.

For Aim 3, we anticipate that individuals who receive the CC+C intervention will have lower rates of placement in long-term care facilities at 6 and 12 months than those who receive CC alone. We also expect that behavioral problems will impact treatment outcomes such that those dyads with higher levels of behavioral disturbance at baseline will have greater change scores at 6 months. Spousal relationship to the veteran is also expected to moderate treatment outcome such that spousal caregivers are anticipated to have lower change scores compared to non-spousal caregivers across time; however, we expect this effect to be attenuated in the CC+C condition.

7. **Background, including results of relevant research, gaps in the current knowledge.**

Scope of the Problem

Over five million Americans are diagnosed with Alzheimer's disease or a related disorder (ADRD) and rates are expected to triple by 2050[1]. It is the 6th leading cause of death in the United States and one in three older adults will have dementia when they die[2]. Veterans have high rates of known risk factors that place them at increased risk of developing dementia including: PTSD,[3] diabetes[4,5], substance use disorders,[6] and cardiovascular disorders.[7] Over 7% of veterans 65 and over receiving care through the Veteran's Health Administration (VHA) are currently diagnosed with dementia.[8] In a study of dementia prevalence among VHA system users, Snow, Kunik, and colleagues found that diagnosis by VISN varied between 5.8% to 9.4%.[8] VISN 7, where the current work is proposed, had the highest dementia rates of any VISN in the country and was in the region with the greatest rates overall (i.e., the southeast) perhaps reflecting differences by race,[9] educational achievement,[10] rurality,[11] and/or cardiovascular morbidities.

Spouses comprise the largest group of caregivers for individuals with ADRD. This is particularly true for veterans with dementia, most of whom are men cared for by their

wives.[12] Decades of research suggests that spousal caregivers are uniquely vulnerable due to increased isolation, older age, and cohabitation status which reduce opportunities for respite.[13] Couples in which one individual is diagnosed with dementia often experience substantial depression and frustration adjusting to functional changes and losses in roles, relationship, and independence of the declining loved one.[14-16] Changes in shared intimacy, emotional support, companionship, and reciprocity are consequences of memory loss[17] and associated cognitive changes resulting in grief reactions in up to 71% of caregivers.[18] Some research has cited loss of the relationship with the person as the most distressing element of the disease for caregivers and directly predictive of depression above other aspects of the caregiving context.[14,17] The unique functional and behavioral impairments associated with ADRD contribute substantially to psychological and physical morbidity of family caregivers and high rates of nursing home placement, with 60% of ADRD caregivers rating the emotional stress of caregiving as "high or very high," and over one third reporting depressive symptoms.

Gaps in Current Knowledge

Numerous interventions have been developed by researchers and private organizations to reduce caregiver burden and target mental health and functional outcomes, often trying to simultaneously delay institutionalization.[19,20] With few exceptions, interventions take an either/or approach - focusing on the needs of either the individual with dementia or the family member who is providing care in the home.[21] Yet, the social, physical, medical, and mental health needs of these individuals are often intimately linked – particularly for those who live together – and maintaining or restoring the relationship is essential for optimizing outcomes and maintaining care in the home for as long as possible.[14] In a 2009 review article assessing the frequency that a dyadic perspective was taken in spousal caregiving research, Braun and colleagues[22] noted that only five of 270 articles directly included the perspectives of both individuals. This reflects an urgent need to consider the reality of dementia caregiving – that it occurs between two individuals who often share a long pre-illness relationship history that directly impacts the social, functional, emotional, and ultimately physical health of both individuals impacted by the disease.

A recent systematic review noted almost none of the evidence-based interventions developed to reduce caregiver burden and improve mental health and functional outcomes of the person with dementia "make it off of the shelf" to be readily available in clinical settings. Care Consultation (CC) has emerged as a rare exception.

CC is an evidence-based telephone intervention delivering psychoeducation, care coordination, and resource referrals in diverse areas such as safety and mental and behavioral health support. Exclusive telephone delivery drastically improves access and translatability. A critical barrier to accessing needed services for individuals with dementia and their caregivers is the challenge associated with leaving the home to attend appointments in medical center settings. Limited mobility, rural residence, challenges with orientation and transportation, and other burdens make attending consistent, in-person sessions nearly impossible. Many research interventions have worked around this limitation by sending research staff into the home of those with dementia to provide brief (4-10 session) interventions.[23,24,25] Unfortunately, due to the

progressive nature of dementia, the caregiving context and level of distress changes across the course of the disease making sustained support necessary. Long-term, home-based care is difficult and expensive to sustain in clinical settings and is therefore unrealistic for the large number of individuals that could benefit from services. Providing care over the telephone is responsive to the needs of patients and families and provides care in a low-cost, sustainable format.

CC may be limited in its effectiveness for dyads suffering from high levels of distress. Dr. Bass, developer of CC and consultant on this study, has estimated 20% or more of families in care consultation studies were referred for mental health services for issues that were beyond the scope of care consultation alone. Estimates are even higher among veteran populations impacted by dementia. Though some benefits were observed for all caregivers enrolled in CC (e.g., reduced depressive symptoms, increased satisfaction, reduced unmet needs), care consultation has not consistently had an impact on relationship strain in spousal caregivers.[22] Caregivers who utilize care consultation in combination with other supports (e.g., support groups) have greater reductions in health deterioration and perceived role captivity. Complex mental and physical health comorbidities common in veteran populations (PTSD, substance use, chronic pain), long-standing patterns of marital interactions, and grief as roles shift are intensified by dementia onset and have direct implications for functional outcomes and the ability to maintain a loved one at home.
Dyads in high distress cannot fully benefit from CC unless their high distress condition is also addressed. By layering counseling modules in when needed (CC+C), the current work will establish a manualized framework for integrating distress treatment targets (e.g., relationship distress, depression, pain) for those too distressed to fully engage in CC alone. A stepped intervention approach would address the VA's efficiency needs while allowing the flexibility for more resource-intensive counseling beyond the established CC framework when warranted by high dyad distress.

Next Steps
The goal of this project is to develop a manual for integrating CC and counseling, which is necessary to ensure standardization across clinicians. Preliminary clinical pilot work has been completed in the TVAMC Telephone Assisted Dementia Outreach (TADO) program. However, the TADO clinical program was not established with the resources or scientific rigor necessary to contribute meaningfully to the scientific literature. Therefore the current protocol is a funded research study that will collect preliminary outcome data to examine the potential efficacy of CC+C.

The impact of this work will be fully realized when an efficacious and highly-accessible collaborative-recovery intervention, such as the one being explored, promotes improved quality of living for community-dwelling veterans and their families rather than resorting to more expensive and undesirable intensive care settings.

8. **Potential benefits to the research subject and the knowledge to be gained**

The intervention may provide some psychological relief to the participants and their caregivers. Since all participants will be receiving active treatments, this is more likely in this study than in other designs.

Though veterans with dementia who are in the early stages of the disease may be more able to engage in the dyadic intervention, family caregivers of loved ones in the later stages of the disease are equally likely to be distressed and benefit from counseling targets.[32] Care consultation interventions and counseling interventions have both been used successfully with heterogeneous dementia diagnoses and severity samples.[9,12] The primary benefit of a telephone-delivered intervention is increasing access to services for those with limitations on transportation or their ability to attend in-person sessions.

The participants and caregivers may also benefit by gaining a general sense of well-being and satisfaction from the attention that is paid to them during the course of the study. For example, many individuals enjoy discussing their experiences in assessment interviews and through intervention contacts in similar studies.

9. **Definition of population to which study is directed and justification**
This study involves two groups of participants: 1) the Veteran and 2) their caregiver, selected because they are impacted by a dementia-related disorder. See scope of the problem section above for the justification for conducting an intervention study with this population.

10. **Number of the subjects that will be recruited for study**
At least seventy dyads (i.e. 70 veterans and 70 caregivers) will be recruited to achieve a final sample. However, caregivers can participate independently if the veteran is too impaired to participate meaningfully in the study.

11. **Subject inclusion/selection criteria**

Veterans:
a. Must be age 19 or older
b. Must have a diagnosis of dementia or a related disorder
c. Must live in the community (i.e. not in a VA Community Living Center, nursing home, or other facility)
d. Must cohabitate with a caregiver;
e. Must have reliable access to a telephone
f. Must be willing to consent to participate or provide assent in conjunction with proxy consent if their decision-making capacity is compromised.

Caregivers:
a. Must be age 19 or older
b. Must self-identify as assisting with care for at least 8 hours/week
c. Must be willing to consent to participate.

The study will include women and minorities and aim to represent the percentage reflected in Tuscaloosa VAMC medical care system (12% women, 44% minorities, and 1% Hispanic origin; though numbers of minorities might be slightly lower in the older cohorts targeted for this study as indicated above). No specific inclusion/exclusion criteria related to race/ethnicity are required.

12. **Subject exclusion criteria**

In addition to meeting the inclusion criteria outlined above, participants will be excluded in the following cases.

Veterans:
a. Currently incarcerated
b. Currently pregnant
c. Dyads experiencing low levels of distress (as defined by a score of 0 or 1 on the Dementia Services Mini-Screen[32], see below)

Note. Baseline or post-assessment interviews will be discontinued for Veterans experiencing severe cognitive impairment that would impair their ability to communicate during an interview, consistent with good clinical practices. However, they will not be excluded from participating in intervention sessions as appropriate and their available data (self-report or proxy report) will be retained for analyses.

Caregivers:
a. Currently incarcerated
b. Currently pregnant
c. Experiencing severe cognitive impairment that would impair their ability to communicate during an interview
d. Dyads experiencing low levels of distress (as defined by a score of 0 or 1 on the Dementia Services Mini-Screen[32], see below)

13. **Subject exit criteria**
a. Subjects will exit the study once one of the following conditions are met:
b. Completion of the study protocol
c. Serious or life threatening adverse effects (including death)
d. Withdrawal of consent by the Veteran or the Veteran's caregiver

14. **Justification for use of special subject populations who may present informed consent issues (for example, incompetent patients, children, elderly, etc.) and reason for inclusion.**

The study will not enroll prisoners, children, those who are terminally ill, or pregnant women. The study sample will include participants with varying degrees of cognitive impairment (from intact to severely impaired) and other mental health diagnoses (e.g., serious mental illness) that would classify them as vulnerable populations. In the event that these participants have impaired decision-making capacity, appropriate surrogate

consent will be obtained as described below. This vulnerable population is necessary to include in the current feasibility study to examine whether the intervention will ultimately be beneficial for this principal group. It is also possible that veterans over the age of 89 will be included in this research. However, veterans over the age of 89 will not be specifically targeted for enrollment.

15. **Scientific and ethical justification for excluding classes (gender, race, etc.) of persons who might benefit from the research**

No participant will be excluded from participation in the study on the basis of gender, race, ethnicity, socio-economic status, or physical disability.

16. **Appropriateness of Impact of Study design on risk.**

The risk of this study is low to minimal since it does not involve study medication or invasive procedures. Furthermore, all participants will receive an active treatment / intervention.

Minimal risks for veterans and their family members include:

a. they may feel coerced to participate in interviews,
b. they may feel uncomfortable, tired, or become bored during interviews,
c. raw data from interviews may contain sensitive information that could cause embarrassment if it was obtained by others in an identifiable form.

It is unlikely that any discomfort or negative emotions will exceed those encountered as part of daily life. Interviews will be conducted separately for the veteran and their family member unless the veteran requests otherwise to increase privacy and minimize risk of embarrassment or discomfort. Given the benefits possible and minimal risks involved, the risk-benefit ratio for this study is favorable.

17. **Description of procedures to be performed.**

The assessment schedule is summarized in Table 1 for screening (phone), baseline (in-person), 6-month assessment visit (in-person), and 12-month (phone) assessments. However, if a dyad prefers to complete the telephone assessments in person (e.g., while they are on station for another appointment), arrangements will be made to accommodate that request.

Table 1. Assessment Schedule

Measure (completed by Veteran or caregiver)	Admin. Time	S	B	6 mo	12 mo
Eligibility Screening (CG)	5m	X			
Dem Serv Mini-Screen (CG)	< 2m	X			
Subjective Stress/ Subjective Health (V, CG)	1m		X	X	X
Demographics (CG, CG*)	< 10m		X		
Health Literacy Screener (CG)	< 2m		X		
MoCA (V)	10m		X		

PSM IADL/ADL (CG*)	10-12m		X		
RMBPC (CG*)	5-10m		X	X	
CSDD (V, CG*)	10-20m		X	X	
Veteran QOL-AD (V, CG*)	5-10m		X	X	X
EuroQoL-5 Domain (V, CG*)	<5m		X	X	
Social Engagement (V, CG*)	<5m		X	X	
Dyadic Adj. Scale (V, CG)	5-10m		X	X	
Mutuality Scale (V, CG)	5m		X	X	X
Zarit Burden (CG)	< 5m		X	X	X
GAD-7 (CG)	< 5m		X	X	X
CES-D (CG)	5m		X	X	X
WHO-QOL-OLD (CG)	3m		X	X	
FFMQ (V, CG)	10m		X	X	X
Desire to Inst. (DTI) (CG)	<5m		X	X	X
NH Placement (EHR, CG)	<1m			X	X
Care Consultation Satisfaction Survey (CG)	<5m			X	
Caregiver Time Burden (min)			*<130*	*<105*	*<50*
Veteran Time Burden (min)			*<80*	*<75*	*<30*

Note. V = measures completed by veteran; CG = completed by caregiver; EHR = extracted from the electronic health record.

Screening

A HIPAA waiver for screening purposes will be obtained. Eligibility screening for interested dyads will typically occur over the telephone. If the Veteran and/or caregiver meets the inclusion criteria and do not meet exclusion criteria, a baseline assessment appointment will be scheduled. Informed consent procedures will be performed at baseline in accordance with the consensus recommendations for research with cognitively impaired populations developed by the Alzheimer's Association[33] and described in detail below. Proxy consent and participant assent will be collected when the participant is willing to assent for the study but is determined by the capacity assessment at the time of consent to be lacking capacity. Caregivers will also complete an informed consent. Veterans and their family caregivers will complete separate consent forms.

The Dementia Services Mini-Screen[32] will be used to identify dyads who are in distress and most likely to benefit from enhanced dementia services. This brief assessment tool was developed for use in primary care settings and has established cut-off points with strong sensitivity and specificity data that categorize individuals with dementia and their caregivers into low, moderate, or high stress groups based on the presence of behavioral disturbances and service needs (psychosocial and medical). Using this tool, dyads that endorse only low-moderate stress and few behavioral problems (0 or 1) will be excluded from the study. Excluded dyads will be offered a referral for clinical services. There will be no restrictions on gender or race for veterans with dementia or their caregivers.

Baseline, 6-month, and 12-month Assessments

Baseline and 6-month assessments will occur in the participant's homes or another convenient location of their choice (e.g., local public library). Informed consent will be the first thing addressed during the baseline assessment. Patient data will be collected interview-style by a trained assessor (research assistant) for the veteran with dementia, while the caregiver measures will be completed independently (paper and pencil). The brief 12-month assessment will occur over the telephone to reduce participant burden.

Measures
See assessment schedule described in Table 1 above. All measures are peer-reviewed and frequently used in the research literature with the proposed population. One measure that is likely less familiar to the IRB (i.e., Dyadic Adjustment Scale) has been uploaded with the submission package on IRBNet.

a. **Subjective Health** will be measured using the sum of three items, with higher scores indicating better health.[34] **Subjective Stress** will be measured using two items, with higher ratings indicating increasing levels of stress.

b. **Demographics** including: sex, age, primary racial or ethnic group, education, living arrangement, time since diagnosis, years married, number of marriages, number of children, and income adequacy will be collected for the veteran and their caregiver. Income adequacy will be assessed with a single item asking about difficulty paying for the basics, (1 = very difficult to 5 = not very difficult). Individuals will be asked if they have had any previous counseling experience, are taking any antidepressants, anxiolytics, or memory enhancers and whether doses have been stable for the past 3 months.

c. **Health Literacy** will be measured using a 4-item screener to identify individuals with health literacy issues that could impact their ability to complete self-report measures.[57,58]

d. The **Montreal Cognitive Assessment (MoCA)**[35] a 30-point cognitive screening instrument with excellent discriminative power to detect mild cognitive deficits will be used to measure cognitive status.

e. The **Physical Self-Maintenance (PSM)** and **Instrumental Activities of Daily Living (IADL) Scale**[36] will be used to assess functional status or independence in daily care needs across six physical care domains (i.e., activities of daily living, ADL) and eight IADL domains.

f. The **Revised Memory and Behavior Problems Checklist (RMBPC**[37]**)** which provides an estimate of the frequency of problems and the impact that these problems have on the caregiver will be used to rate behavioral symptoms of dementia.

g. The **Cornell Scale for Depression in Dementia (CSDD**[38]**)** which relies on an interview with the individual and the caregiver will be used to assess depressive and anxiety symptoms.

h. The **Quality of Life in Alzheimer's Disease scale (QOL-AD)** will be used to assess quality of life.[39] Patients and caregivers rate thirteen domains: physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self and life as a whole, using a Likert-type scale.

i. The **Euro-QoL-5 Domain (EQ-5D)** mobility, selfcare, and usual activities subscales will be used to assess autonomy and functional dependence.[40] Health-related quality of life is assessed for five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Caregivers also complete this measure, as has been done in previous studies with individuals with mild to moderate dementia.[40,41,42]

j. **Social engagement** and isolation will be assessed using items modified from the Minimum Data Set questionnaire.[43] This six-item measure includes the ability to take advantage of social interactions and to initiate meaningful social contacts (e.g., ease interacting with others, establishment of own goals).

k. The **11-item Dyadic Adjustment Scale**,[44] a widely used measure of marital satisfaction/distress will be used to assess relationship quality in spousal dyads.

l. The **Mutuality Scale**[45] is a 15-item instrument measuring positive qualities of the relationship on a 5-point scale (0=never to 4=a great deal). Four domains are calculated: shared values, affective closeness, shared pleasurable activities, and reciprocity.

m. The **Zarit Caregiver Burden Interview**[46] a caregiver self-report measure will be used to assess caregiver burden. Each item is rated on a 5-point scale (0 = never to 4 = nearly always).

n. A 7-item **Generalized Anxiety Disorder Screener (GAD-7)**[56] will be used to assess caregiver symptoms of anxiety on a 4-point scale (0-3).

o. An 11-item abbreviated version of the **Center for Epidemiologic Studies of Depression Scale (CES-D)** will be used to measure depressive symptoms.[47] Caregivers will rate the frequency with which they experience depressive symptoms within the past week on a 3-point scale (0 = hardly ever or never, 2 = much or most of the time). Anxiety symptoms will be assessed using the 20-item **Geriatric Anxiety Inventory**.[48] Items on this measure are rated as either "agree" or "disagree."

p. An abbreviated 6-item version of the **World Health Organization Quality of Life measure (WHO-QOL)**[50, 49] designed to assess domains that are specific for older adults will be used to measure quality of life. Items are rated for the past 2 weeks on a 5-point scale (indicating either frequency or valence).

q. The short form, 15-item version of the **Five-Facet Mindfulness Questionnaire (FFMQ)**[59] will be used to measure facets of mindfulness. The five facets are observing,

describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience. The 15-item FFMQ includes three items for each facet.

r. The 6-item **Desire to Institutionalize (DTI)** Scale[51], which assesses the caregivers planning, thoughts, and actions about long-term care (LTC) placement over the past 6 months will be used to assess intentions to institutionalize their loved one. Six yes/no items (e.g., taken steps toward placement) are summed for a score of 0-6. Long-term care placement and/or hospitalization of the veteran (institutionalization) will be assessed using a single item rated either by the caregiver or via electronic health record review if the dyad is no longer enrolled in the study (e.g., due to attrition).

s. The 21-item **Care Consultation Satisfaction Survey** will be used to measure the participants' satisfaction with the Care Consultant and the Care Consultation services provided.

Once baseline data are collected, dyads will be randomly assigned to a condition (see interventions delivered below).

Randomization
Blocked randomization stratified by race and gender will be used to assign participants to either the: (a) CC group, or the (b) CC+C group. This two-group experimental design was chosen over other approaches (e.g., no comparison group designs, three-group design, cross-over design, etc.) because it most closely approximates the next level of clinical research (e.g., an efficacy study), which allows for the most directly applicable conclusions.

Interventions Delivered
1. Care Consultation (CC): is an established telephone-based, empowerment intervention that uses coaching and emotional support to mobilize family caregivers and individuals with dementia through psychoeducation, resource referral, psychosocial support, and encouragement of informal and formal service use utilization. A computerized clinical tool utilizing a password-protected VA-hosted website (i.e., operated within the VA server system) called the Care Consultation Information System (CCIS) guides the care consultant through a standardized delivery of protocol components, replacing a paper-based clinicians manual. Rather than a strong focus on assessment, this intervention is designed to quickly identify areas of unmet need through brief trigger questions called the "initial assessment" – much like an interview guide – which then immediately shapes development of concreate action plans.

The CCIS has been successfully used by the TADO team clinically at the TVAMC. Fidelity reviews, technical support, and problem-solving are available on an ongoing basis through a nominal annual renewal fee. Care consultation has demonstrated robust outcomes across community and VA settings (e.g., Partners in Dementia Care, PIs Kunik & Bass both on the study team) and has been translated successfully beyond research protocols into clinic settings.

2. Care Consultation + Counseling (CC+C): is consistent with the original CC protocol and a collaborative recovery model in that the therapist partners with each dyad in a patient-centered way to prioritize unmet needs as identified during the CC initial assessment. Once this phase has been completed, typically within the first 2 sessions, the CC+C therapist will determine when to initiate counseling (Table 2, below). The counseling component of the recovery-informed CC+C intervention incorporates elements of existing manualized interventions that follow a cognitive behavioral therapy framework (i.e., active engagement, assigning in-session and out-of-session exercises, reframing or restructuring cognitions, interpreting, and educating). The therapist has the flexibility to individualize care such that immediate needs identified by the dyad at the beginning of the care consultation partnership will take priority. For many families this will mean that concrete action plans related to CC domains of care (e.g., arranging benefits, questions about medication) will be implemented before the counseling protocol is initiated. Based on preliminary clinical work in the TADO clinic, it is expected that the course for most cases will follow three phases:

1. Phase 1: Care Consultation (initial assessment and addressing immediate practical needs);

2. Phase 2: Counseling (to address distress and mental health needs beyond the scope of CC alone);

3. Phase 3: Care Consultation (to maintain progress, provide ongoing support, and continue to address lingering needs or those that surface for the first time after core distress elements have been addressed).

Including the individual with dementia is encouraged in CC and CC+C, though many of the original resource materials available focus on the skill development for the caregiver. To continue movement toward a dyad-focused approach in CC+C, phone sessions with the veteran with dementia will be completed whenever possible either before or after the caregiver phone session. Though shared sessions may be possible for some dyads, and more readily available in the future with videoconferencing technology, sequential interactions will be the focus of CC+C.

Table 2. CC+C Session Content

Telephone Session Content (approximately 6-8 Sessions)
1. Introduction to Stress Management (required): Impact of dementia on relationships, impact of stress on caregiving, and introduction to stress management/skills.
2. Mindfulness (required): What is mindfulness, types of mindfulness, and mindfulness in everyday activities.
3. Increasing Pleasant Activities (required): Introduce how discomfort and mood are related to activity level, explore current activity, and discuss ways to modify activities for greater comfort and enjoyment.
4. Grief & Loss (required): ambiguous loss, identifying grief-related emotions, shifting roles & needs fulfillment; disconnect between expectations and current course.

5. Preserving Identity (required): Values/goals; maintaining individual identity of the caregiver and person with dementia, documenting memories, and creating shared meaningful/pleasant activities.
6. Physical Affection & Sexual Intimacy (elective): Touch as nonverbal communication and social connection, building intimacy through shared rituals/routines.
7. Managing Chronic Pain and Distress (elective): Pain education and distress behaviors as indicators of pain.
8. Resentment, Hostility, & Conflict Resolution (elective): Lean about arguments you cannot win; hurtful lapses in memory, accusations & paranoia, and impact of previous patterns of relating on current relationship; commitment to relationship, etc.
9. Alcohol, Substances, and Medications Misuse (elective): Safety planning and management of alcohol/substance of abuse, the impact of memory problems on management of medications and an introduction to resources for sustained support.

Treatment Implementation, Fidelity, and Process Variables:

Treatment delivery: The MSW-level interventionist will be trained to criterion and will be certified before administering the intervention. Accuracy of treatment delivery will be monitored. The interventionist will also complete a fidelity checklist to ensure that all treatment components are delivered during each session. As one measure of potential bias, the treatment fidelity checklist will include a self-reported item assessing the interventionists' desire/pressure to alter the randomly assigned condition for each dyad (i.e., agreement with the following statement will be assessed: "I believe the other arm of the study would have been a better fit for this dyad than the one they were randomly assigned"). Sessions will be audiotaped and 30% of sessions will be randomly selected and reviewed to ensure treatment fidelity to the CC and CC+C protocols. Treatment receipt: will be assessed by documenting the length of all intervention sessions (i.e., direct time spent with the dyads) and indirect time (e.g., documentation, case management, etc.). Participant knowledge of interventions components, which is sometimes included in measures of treatment receipt, is not appropriate for this study.[110] Treatment enactment: will be monitored by: 1) the number of completed Action Plans and homework assignments in each group CC & CC+C, and 2) attendance/adherence to scheduled appointments. Other treatment implementation notes that do not directly impact human subjects protections include interventionists notes about "Process Considerations and Interventionist Pressures" including the interventionists' opinions about the two interventions (CC and CC+C).

18. **Differentiation of "usual (standard) care" from research activities.**

All procedures listed are voluntary in nature and unrelated to current clinical care. Participation in a similar clinical pilot program may be available to some families (e.g., those who live in rural areas may qualify for the Telephone Assisted Dementia Outreach Program, pending sustainment and availability which is unknown at the time this protocol is being submitted). However, no permanent services or "usual" treatment options similar to the one being studied are available at the Tuscaloosa VAMC.

19. **Enlisting clinical expertise.**

The study team has extensive clinical expertise in the delivery of interventions for individuals with dementia and their caregivers. See CVs and Bios uploaded and attached to this protocol for sample publications by the study team.

20. **Description of the anticipated data and how the data will be analyzed to test the specific hypotheses results.**

Study Design, Power, & Target Sample Size
We plan to recruit at least 70 dyads across the 3-5 year study period to ensure 50 completers at 6 months. This rate of 2 dyads per month is feasible given that there are 421 veterans with dementia currently receiving services from the TVAMC outpatient clinics (FY2013 clinical data). If 50% of them are in moderate to high distress (a conservative estimate based on our preliminary work), there would be over 200 individuals eligible. Power analyses were conducted to support this sample size (see attached grant text for more details).

Data Management and Analysis

Data Entry:
Data will be entered using Remark Office Optical Mark Recognition software and analyzed using Statistical Package for the Social Sciences (SPSS). Data analysis will be conducted using the VA Informatics and Computing Infrastructure (VINCI) server behind the VA firewall, as has been done for other TVAMC IRB approved studies. The research assistant will review all data for accuracy and will complete data tracking forms. A descriptive analysis of all assessment data will be conducted in order to examine distributional properties and correlations between the measures and the assumptions of statistical tests will be examined. Where necessary and sensible, data transformations, including the elimination of outliers, will be considered for variables with problematic properties.

Treatment of Missing Values:
Missing values are unavoidable in applied clinical intervention research. Where possible, variables to index the number and reasons for missing values will be documented. Based on the distribution of these missing value indices we may choose to eliminate some participants from the analyses ("list-wise deletion"). The extent that missing values are related to the independent (treatment group) or outcome variables will be assessed and if necessary controlled for statistically. Individuals who complete at least four sessions of the intervention (CC or CC+C) will be included in final analyses when time 2 data are available. Strict intention-to-treat methodologies are too conservative for this relatively small initial pilot study.

Data Analysis:
A series of one-way between subjects analyses of covariance (ANCOVAs) will be used to examine the main effect of "group" on 6 month variables of interest while controlling for values at baseline. The dependent variable in these analyses will be change scores with pre-treatment scores as the covariate. This analysis is statistically equivalent to ANCOVA with pre-treatment scores as the covariate and 6-month scores as the dependent variable, but it has an interpretational advantage in that the change scores represent an individual treatment effect (change during treatment). The change scores also represent the interaction term of a 2 (Group) X 2 (Time) repeated measures ANOVA. Consequently, when other covariates are added to the ANCOVAs to address treatment moderation effects, those covariate effects will be directly interpretable as moderator effects. That is, the added terms will assess the effects of the covariates on changes during treatment irrespective of Group (essentially a Time by Covariate interaction). When the interaction (multiplicative product) of covariate and Group is also added as another term in the ANCOVA, that interaction term will supply the moderating effect of the covariate on change during treatment as function of Group (i.e., differential effect of treatment as a function of the covariate).

Outcome measures for caregivers will be run in separate analyses from those of the veterans with dementia, such that a series of ANCOVAs are anticipated for 1) self-report measures for the caregiver; 2) self-report measures for the veteran with dementia; and 3) proxy-reported measures for the veteran with dementia (as rated by their caregiver). Partial eta squared statistics of effect will be used as the primary indicator of likely treatment effects in this small sample. A large effect is indicated by a partial eta squared (hp2) greater than or equal to 0.14, a medium effect is determined by a value greater than or equal to 0.06, and small effects are determined by values greater than or equal to 0.01. For the purposes of the current study, between groups effect sizes greater than or equal to .01 (a small effect) will be interpreted as potentially clinically meaningful in the interpretation of results since two active treatments are being compared. Cohen's d statistics will also be calculated for the purposes of the current feasibility study because they are one of the most common methods of estimating effect sizes and are more easily interpreted than the partial eta squared effects. In order to calculate Cohen's d statistics, standard error terms will be converted into standard deviations and used with the estimated marginal means from the post-treatment ANCOVAs. Both types of effect sizes will be calculated. Finally, logistic regression analyses will be conducted to determine if NH placement at 6 and 12 months is differentially related to treatment condition (i.e., group assignment) for individuals with dementia. NH placement (or not) will be the dependent variable in these analyses, and independent variables will include Group and relevant covariates.

21. **Risks (physical, psychological, social, and economic) and steps taken to minimize these risks.**

Physical Risks: There are no anticipated physical risks with this study. All activities in the study will be within the normal limits of participants' everyday physical demands. Increased veteran activity and/or range of motion could potentially result in exacerbation

of pre-existing pain conditions (e.g., arthritis, etc.); however, potential benefits in strength/decreased disability exceed potential risks.

Psychological Risks: The risks to participants are minimal because this study utilizes a strengths-based intervention that has been evaluated and supported by other studies without negative psychological effects. Participants may feel that the interview process and completion of the self-report forms are an invasion of privacy. While answering questions about their life experiences or their physical and psychological symptoms, participants may experience transient anxiety, discomfort or embarrassment, or distressing memories may be triggered. To minimize any further discomfort, participants will be allowed to take breaks during the intervention sessions and when completing assessments. If necessary, the appointment may be rescheduled or ended early. Furthermore, the content of self-report data through one-on-one interviews will not exceed self-report information that is requested for clinical purposes as part of routine daily care. Furthermore, intervention exercises (e.g., relaxation training, engagement in pleasant events, practicing communication strategies, etc.) are unlikely to cause distress beyond what would be experienced in a typical day. Home-based data collection may make some participants uncomfortable or embarrassed; however this has not materialized as a measurable risk in other studies using this procedure. There is also a slight chance that despite privacy procedures confidential clinical information could be accessible by individuals not related to the study or the facility. Steps will be followed to protect against this research-related risk.

Risks to caregiver participants could include boredom with the study procedures; frustration, or distress related to discussing their situation in the role of caregiver. They may experience transient anxiety, discomfort, or embarrassment related to their feelings about their role as caregiver or the impact of dementia on their relationships. Study procedures are not anticipated to exceed frustrations or distress encountered in their daily experiences. Any observations or reports of acute distress that could compromise safety (e.g., risk of harm or neglect to self or others) will be handled in compliance with standard operating procedures and within VA ethical guidelines. Acute risk to non-VA patients (i.e., caregivers) will be handled through community mental health networks, emergency rooms, and involvement of local law enforcement if necessary. Specific protocols for staff safety and risk management during home assessment visits were developed during the CDA1 in collaboration with VA experts and the mentoring team. As with other telehealth delivery modalities, the physical addresses of the participants will be identified on or before the first telephone appointment should emergency personnel involvement become indicated during a telephone interaction. Procedures will be implemented to minimize risks. Members of the investigative team have extensive experience in remote risk assessment (e.g., telehealth interventions within the VA) and have published articles on suicide assessment (see Letters of Support) including a recent online article that I developed on this topic.

Legal and Social Risks: An unlikely legal or social risk that must be acknowledged in research is the risk associated with compromised privacy in the unlikely event of a breach of confidentiality for data considered VA sensitive information. These risks are

not unique to this study and are not associated with the intervention or staff training in this proposal. TVAMC has strict and detailed standard operating procedures in place to guard against these risks including policies on the use and storage of data containing PHI. Data collected in the field will remain behind two locks during transport from home interviews to the VA Medical Center where data will be stored (e.g., in a locked HIPAA-compliant secure bag in a locked trunk as is done for home based primary care services and research during the CDA1 period).

Economic Risks: Although most participants are unlikely to be employed, it is possible that some participants may have to miss work in order to attend an assessment visit or a VA health care visit. Every effort will be made to avoid economic risk due to a participant having to miss work during an appointment time. Since assessments occur in the veteran's community and the intervention and some assessments are delivered over the phone, travel-related expenses for study participants are estimated to be minimal. A government car will be used for home visits by project staff.

22. **Describe in detail the provisions for managing adverse reactions and for monitoring data to ensure the safety of subjects. Describe any plans for Data and Safety Monitoring Board (DSMB).**

As described above, serious adverse reactions are not expected. The following details and re-iterates plans for managing adverse reactions:

Medical and Psychiatric Safety Contingency Plan: While in the home, the research team member may call 911 from their government issued cell phone for emergency services at any time if they judge any immediate risk to self or others. Prior to going into the community setting, research team members are trained in the Prevention and Management of Disruptive Behaviors, and home-safety protocols (e.g., like the one used by the TVAMC Home Based Primary Care Team) which involves identification of early warning signs of threat and early means to de-escalate the situation, as well as more advanced escape techniques. For signs of threat to personal safety, the research team member is instructed to leave the premises and contact the PI for addition instructions. During a visit, the research team member may consult directly with the PI for advice and input regarding these situations. The consultation can take place either during or immediately following the assessment visit. If medically or psychiatrically indicated, the Veteran may be seen immediately at the nearest emergency room or VA clinic.

Emergency Response for Unanticipated Adverse Events during HBPC Visit: The research team members will be trained in recognizing medical or psychiatric emergencies. In the unlikely event that a research team member encounters such an unanticipated adverse event during the visit, the research team member will either call 911 (if immediate medical attention is needed) or call the PI. Usual TVAMC procedures will be followed in the event of a serious adverse event or emergency. All serious adverse events (SAEs) related to the study procedures and unanticipated

adverse events will be reported to the IRB and Data Safety Monitoring Board (see below).

In the unlikely event of a level of psychological distress that requires professional intervention for the subject, same day or next business day psychology support and/or counseling will be offered.

The PI will audit case report forms and informed consent forms for compliance with procedures for data safety and human subject protection. Training of the study staff will include steps to assure accuracy and integrity of the data through all stages of the study including accuracy with log entries, case report file entries, and data base entries from case report files. Study staff will be trained with regards to adverse events and unforeseen problems that may occur, and the required procedures for communicating about these events, including IRB report forms. The PI will promptly review all adverse events and unforeseen problems. These will be reviewed and reported per TVAMC IRB guidelines.

A **Data Safety Monitoring Board [DSMB]** will be formed within 30 days of enrolling the first participant. On a biannual basis, the DSMB will convene a meeting, review the progress of the study and evaluate the ongoing safety of participants. At the initial meeting, the DSMB will review the protocol in detail. If at any time during the course of the study, the DSMB judges that risk to participants outweighs the potential benefits, the DSMB has the discretion and responsibility to recommend that the study be terminated. Study stopping rules will be established at the initial meeting. All unanticipated AEs, deaths, and SAEs due to the study procedures will be reported to the DSMB chair within 72 hours. Reports for unanticipated events determined by either the investigator or DSMB to be possibly or definitely related to participation and reports of events resulting in death will be promptly forwarded to all regulatory agencies. In addition to safety monitoring, the DSMB will monitor data quality. At least annually during the study, The DSMB will receive a report on data quality and completeness. At a minimum, this will include an overview of the progress of participants' screened, summary reports describing participant demographics, and summary of data entry progress and query resolution. These reports will be used by the DSMB to evaluate the capacity of the data capture and processing to support scientifically valid findings.

23. **Planned procedure for obtaining informed consent including the circumstances surrounding consent procedures**

Prior to resident enrollment, the potential participant or legally authorized representative (LAR) will be provided with detailed information regarding the study's purpose, procedures, potential risks and benefits, alternatives to participating in the study, and other required elements of informed consent approved by the TVAMC IRB. Potential participants will be given ample time to consider enrollment into the study and can involve family members, significant others and his/her primary treatment providers in their decision. Participants are informed that refusal to participate in this research protocol will not penalize them or change their eligibility for VA services, treatment, or

disability payments. When persons with impaired decision-making capacity are included, surrogate consent will be obtained (described below). Including persons with impaired decision-making capacity as participants is essential in this study and will allow us to gain an understanding of quality of care needs for this population of veterans. In the case of compromised capacity, legally authorized representatives will be able to complete proxy consent procedures. Specifically, the participants' legally authorized representatives (LAR) will receive details about the research study. Participant assent (i.e., patient's willingness to take part in the study) will also be required for their involvement and noted in the source documentation. Note, however, that caregivers can participate without the veteran when that is consistent with the wishes of a given family or the veteran is too impaired to participate meaningfully. Subsequently, the participant's original informed consent documents will be maintained with other essential documents.

Location of the consent process: A private setting, such as TVAMC office or in the participants' home or private room in a community setting (library or veteran service office).

Who will conduct consent: A qualified IRB-approved member of the research team will be responsible for explaining the study, answering questions, and obtaining informed consent. All individuals completing the consent procedure for the research team will have extensive training on the informed consent process and their training will be approved by the PI prior to any procedures being performed.

Decision-making Capacity of the Potential Volunteer: Participants who provide their own consent must have decision-making capacity at the time of the consent discussion and assessment visit. Members of the investigative team have prior experience conducting research with individuals with impaired decision-making capacity; the person obtaining consent will be thoroughly trained using IRB-approved procedures to ensure decision-making capacity before consenting participants. Under all circumstances, the participant's autonomy will be respected. Specifically, the following protocol has been used in the PI's prior research with individuals with dementia:

Capacity Protocol
Individuals with probable dementia are considered to be a vulnerable population so extra cautionary steps will be taken to ensure that participants have capacity to consent to the research study. However, diminished cognitive functioning alone is not considered to be synonymous with capacity to consent to research, which is situation-specific.[29] Moye and Marson's[30] article on assessment of decision making capacity in older adults points out that consenting to research is a fairly specific, "narrow cognitive task" (p. P4). Furthermore, capacity to consent to any given study is based on the complexity of the task and the level of risk involved. Applebaum & Grisso[53] suggest that complex medical or clinical trials may be more difficult for individuals with mild levels of impairment than psychosocial research.

Informed consent procedures will be conducted in accordance with the consensus recommendations for research with cognitively impaired populations,[54] described in

detail below. Proxy consent and participant assent will be collected when the participant is willing to assent for the study but is determined to have diminished capacity at the time of consent. Family caregivers will also complete informed consent for the use of their information in the study. Although many of the outcomes of the intervention are about the individual with dementia, family caregivers will provided their perspective of the individual with dementia's functioning as well as information about their own feelings and opinions and therefore will have to complete a separate informed consent procedure. Informed consent will be completed at the beginning of the baseline assessment visit.

Researchers who conducted the baseline assessment will be trained to assess capacity to consent prior to the first assessment. Consent procedures will be supervised by the PI who has experience conducting capacity assessments within the VHA and in community settings (e.g., The University of Alabama's Elder Law Clinic).

In order to determine capacity to consent, the participant's ability to do the following will be assessed: (a) understand the nature of the research and of his/her participation (e.g., by asking the participant to repeat back in their own words what the study is about); (b) appreciate the consequences of the participation, including personal consequences (e.g., is the participant able to spontaneously provide both negative and positive potential consequences of participating in the study); (c) understand alternatives, including the option not to participate (e.g., do they understand that participation is voluntary); and (d) to make a reasoned and consistent choice (e.g., are they providing logical reasons for wanting to participate and are they consistent over time in their expressed desire to do so).

Investigators will use both orally and visually presented information and the participant will be offered a copy of the informed consent for their records.[55] The researcher will also stop several times during the consent procedure to test for understanding and requested that the participant "put it into their own words," before moving forward. A capacity to consent checklist has been developed to aid in assessment and documentation of capacity procedures in accordance with the TVAMC IRB. If participants are unable to complete the steps outlined above and express interest in participating, participant assent and proxy consent will be completed.

In accordance with VA Handbook 1200.5 requirement that there be documentation of impaired decision-making capacity by a clinician in the electronic record before surrogate consent can be obtained, when evidence of lack of decision-making capacity is identified, the person obtaining consent will confer with a clinician co-investigator (i.e., the PI) from the study and if indicated that clinician will enter a note in the electronic record. The Veteran and caregiver will receive a copy of the informed consents and HIPAA or Notice of Privacy Practices. The informed consent and HIPPA will not be scanned into the Veteran's medical record. Whether consent or assent is given, a participant's decision to withdraw at any time (whether expressed verbally or by resistance to participation) will be honored.

Surrogate Consent Procedures: VHA Handbook 1200.5 describes the conditions under which consent from authorized representatives (i.e. surrogate consent) can be obtained in lieu of consent from the veteran. Similarly, a procedure for informed consent for patients who lack decision-making capacity is spelled out in the TVAMC Center Memorandum and Standard Operating Procedures. Surrogate consent is allowed when a participant is deemed to lack decision-making capacity and the surrogate is provided the same information that would be given the potential participant if competent. Surrogates must have intact decision-making capacity. Whenever possible, surrogates should make decisions based on "substituted judgment", using views the individual expressed while fully capable; if the values of the participant are not known, "best interest" standards may be used. The surrogate signs the informed consent on the appropriate signature line and the process of the surrogate consent is documented in the patient's medical record. Consistent with these policies, the investigators will recognize the following, in descending order of priority, as authorized representatives for research informed consent when potential research participants lack decision-making capacity:

1) Persons appointed as health care agents under a Durable Powers of Attorney for Health Care or a similar document (Legally Authorized Representative for Surrogate Consent);
2) Court-appointed guardian (Legally Authorized Representative for Surrogate Consent);
3) Next-of-kin willing to participate in surrogate informed consent, in the following order of priority as dictated by the state of Alabama (unless otherwise specified in the VAMC medical record for designated next of kin): spouse, adult child (age 19 or older), parent, adult sibling (age 19 or older), grandparent, or adult grandchild (age 19 or older).

If needed, the PI may consult with the TVAMC Privacy Officer, IRB, TVAMC Integrated Ethics Council, or VA Regional Counsel if there are uncertainties about who should serve as a surrogate for an individual patient. When needed, the PI, Privacy Officer, IRB, or other staff on behalf of the TVAMC Human Research Protections Program can consult with VA Regional Council for assistance in applying laws involving authorized representative surrogate consent.

24. **Compensation for participation, if offered, and amount**
No compensation will be provided for study participants.

25. **Plans for protection of patient privacy and confidentiality**
Efforts to maintain privacy of veterans and families enrolled will be a top priority. Safeguards to protect privacy include conducting all interviews in a private and secure area. Whenever possible, the research team will encourage the veteran and caregiver to be in different rooms during the assessment visits (e.g., the researcher will be interviewing the veteran in one room while the caregiver fills out paper and pencil self-report measures independently in another room). This will add to privacy by allowing each member of the dyad to be engaged with the project simultaneously yet separately.

Considerations of privacy during the intervention sessions (conducted over the phone) may be outside the research team's control, in that it will be difficult to know the level of privacy on the other end of the phone (i.e., in the participant's home). As has been done with other studies, the interventionist will thoroughly discuss privacy considerations on initial calls and will be available to answer any questions or problem-solve privacy issues in the home. Before intervention calls, the researcher will also prompt the caregiver or veteran about privacy issues that may arise during the call and will encourage them to move to a private location in the home if possible.

Privacy will also be protected within the VA research space. All study documents will be kept in a locked office or on a computer located in a secure area that is password protected. Electronic information including audio recordings of the intervention sessions will also be password protected. Telephone sessions will be taped in one of two ways: 1) by directly connecting the VA office telephone to the PC through an adapter so that the session can be recorded directly onto the secured VA Network Server (preferred); or 2) using a VA-approved, encrypted digital recorder that is FIPS 140-2 validated (Phillips model as is used on other currently approved IRB studies). Furthermore, fidelity audits of a subset of the interviews will be completed within the VA firewall. All phone interactions with participants will occur in private, secure locations (e.g., private offices); and therefore, the mobile recording device also remains within the VA research space (Building 3, 1st floor, Rooms 127, 130, 131) at all times. Original electronic VA research data stored on a mobile device will be backed up regularly (approximately weekly) and stored securely within VA's protected environment, as described elsewhere.

Additionally, participant PHI will be de-identified in the data analyses, publications, and presentations of research results. Lastly, a Health Insurance Portability and Accountability Act (HIPAA) authorization will be given with the ICF to notify the participant or LAR in what capacity their identifiable personal health information will be used. Both documents provide a detailed outline of the provisions utilized to protect the confidentiality of research data.

26. **Plans for information security.**

Upon enrollment, each study participant will be assigned a unique study identification number (study ID). Personal identifiers (name, SSN, date of birth) will be collected on source documentation only and protected with strict confidentiality in a secure environment. The study ID will identify each individual case report form (CRF) so that data entered into the database will be de-identified. All personally identifying information (PII) will be maintained in a separate secure location from the database. Additionally, information connecting the study ID with the participant is accessible only to study personnel. Access to research study data will be removed for study personnel when they are no longer part of the research team.

Data Management and Access Plan: Paper documents will be stored behind two locks under the PI's supervision (TVAMC Building 3, Room 127, 130, or 131). Electronic study files, including the de-identified databases, will be maintained on the VA secured

network (SNOW/HIGEMAN/MAHANEY or Research Drive/Investigator Files/Hilgeman's Studies) with restricted access and only accessible through a password-protected encrypted computer at TVAMC.

The web-based version of the CCIS (described in the intervention section above) is placed on the SQL 2012 R2 consolidation server. Only trained, verified users with a current username and password (established with confirmation of the PI) can access the CCIS research application.

Data collected in the field will remain behind two locks during transport from home interviews to the VA Medical Center where data will be stored (e.g., in a locked HIPAA-compliant secure bag in a locked trunk as is done for home based primary care services and research during the CDA1 period). Only co-investigators who are listed on the current approved IRB protocol and have up to date VA trainings on HIPAA and data security will transport the data from the community back to the VA.

Data Use Agreement for Analysis of Deidentified Data: A data use agreement(s) will be used to establish the terms and conditions under which Michelle Hilgeman, Principal Investigator (for the ODeC study of the Research Service at the Tuscaloosa VA Medical Center (TVAMC), a component of the U.S. Department of Veterans Affairs) will provide a de-identified dataset to a University Consultant assisting with the analyses. This data use agreement (DUA) covers the transfer of this dataset **from** the Tuscaloosa VA where it currently resides (only members of the ODeC VA investigator team as described in the ODeC protocol) have access; **to** the ODeC study Consultant located at the University (e.g., The University of West Florida or The University of Alabama) regarding the study specified in the agreement. The DUA will be uploaded to IRBNet when completed. The PI, Dr. Michelle Hilgeman will ensure data is de-identified and that all 18 PHI criteria have been removed. The Privacy Officer will be provided with a copy of the data for his review to confirm it has been appropriately de-identified. A copy of the password protected de-identified data file (Excel file) will be emailed. As specified in the IRB protocol, no private health information (PHI) will be transported outside of VA.

Data Access and Accounting: See Appendix A ODeC Data Use Agreement (DUA) for a list of those with access to a copy of the deidentified ODeC data outside of the VA network.

The investigator's research records for this study will be maintained according to the disposition instructions by the National Archives and Records Administration and are published in VHA' s Records Control Schedule (RCS) 10-1, in accordance with the new VHA' s Records Control Schedule 10-1 (RCS) policies for the Office of Research and Development; section 7.6. At study closure or at the PI's expiration of VA appointment, research records will be retained by the research office for storage at the completion of the research study. Documents with private health information data that are not part of the research will be placed in the Shred-it boxes located in the Research suite at TVAMC. For a study such as this one (i.e. not FDA-regulated), the PI may destroy

research records 6 years after the end of the fiscal year after completion of the research project, but the investigator may retain longer if needed.

Public access to publications resulting from the research: The proposed research is to be funded by VA. Publications resulting from the research will be made available to the public through the National Library of Medicine (NLM) PubMed Central website within one year after the date of publication. [Submission procedures are provided on the Office of Research and Development (ORD) website at http://www.research.va.gov/resources/policies/public_access.cfm.]

Public access to final data sets underlying publications resulting from the research: Final data sets underlying publications resulting from the proposed research will not be shared outside VA, except as required under the Freedom of Information Act (FOIA) as this study team does not have access to the necessary infrastructure (e.g., a data repository) to make data publicly available, at this time.

Mechanisms for public access to final data sets underlying publications resulting from the research: Final data sets underlying publications resulting from the proposed research will not be shared outside VA.

Planned Procedure for Misuse, Loss or Theft of VA Sensitive Information: The investigators will comply with VHA policies on prompt reporting of loss, theft, or actual or suspected breaches involving sensitive information, along with any other privacy or security incident or complaint. The ISO will promptly determine whether an incident warrants further reporting and actions. At a minimum, the following should occur as soon as it is discovered that there has been a loss:

1) Report the loss or theft to the VA security/police officers immediately
2) During travel or at another institution, notify the security/police officers at the institution such as hotel security, university security, etc. as well as the police in the jurisdiction where the event occurred
3) Obtain the case number and the name and badge number of the investigating officer(s). If possible, obtain a copy of the case report
4) Immediately (within 1 hour of discovery) call, and email a description describing the event to the following regarding the incident:
    - The PI (if investigators other than the PI are reporting the loss, theft, or actual or suspected breach)
    - The person's immediate supervisor
    - The local Information Security Officer (ISO)
    - The Chief of Staff
    - The Medical Center Director
    - The Associate Chief of Staff for Research and Development
    - The Privacy Officer must be notified when there is any unauthorized use, loss, or disclosure of individually-identifiable patient information.

Any such event must also be reported to the IRB as an unexpected adverse event.

27. **Methods used to identify and recruit patients**.

Recruitment will occur in one of four ways.

a) Through a Clinical Partner: Participants receiving clinical services for dementia or a related disorder at the TVAMC will be offered the opportunity to learn more about this study by a member of their clinical team. Veterans or their caregivers who express interest in learning more to their clinical team, will be contacted by telephone by a member of the study to provide additional information and determine interest and screening for eligibility.

b) Self-Referral: Recruitment materials will also be distributed in clinical areas so that self-referrals can be made.

c) Research Outreach / Introductory Letter & Opt-Out Card:
When a referral is made by a clinical partner or administrative staff without speaking to the veteran or family first, initial contact will be made by mail using an introductory letter. No "cold calls" will be conducted. Introductory invitation letters and IRB approved brochures will be mailed to potential veterans with dementia or a related disorder and their family caregivers with an addressed, postage paid reply card, which will allow participants to express interest in being contacted by the study team. Materials will be created with sensitivity to ensure that receiving a letter invitation to a study is not perceived as distressing. Once consent to be contacted is obtained (either through the health care provider or by returning a reply card), the study team will call the potential participants to give them more information about the study, conduct a brief screening over the telephone, and schedule a home visit if they are interested. A HIPAA waiver for screening and recruitment is requested for this purpose.

d) VINCI Data Pull:
The study would like to contact potential, appropriate, participants for this study through the use of a referral list extracted from the VINCI. We will use VINCI to obtain a listing of potential participants based on study inclusion and exclusion criteria. VINCI is collaboration between the VHA Office of R&D and the VA Office of Information Technology to provide a secure and central analytic platform for research activities. It facilitates access to CDW and provides a secure storage location for all data acquired as well as analytic tools used to manage and analyze the data. All data will be stored within the secure VINCI project folders. VINCI grants access on an as-needed basis to IRB-approved study personnel. Our research team has experience accessing and using VINCI in order to reduce potential problems in data collection, as well as in controlling the quality of the data collected. The research coordinator or Health Science Specialist for the study will request data for this study and a VINCI-identified data manager will assist in identifying and pulling the appropriate data to recruit an adequate number of appropriate subjects more rapidly. Targeting our recruitment efforts also means that non-eligible subjects will not receive extraneous paper or flyers. Study data will be kept in accordance with the Department of Veterans Affairs record control schedule 10-1 (RCS 10-1). The study team will keep all sensitive patient data on VINCI project servers maintained by VINCI OI&T personnel. Any PHI data to be downloaded from VINCI to local storage media must have VINCI data steward permission. Research staff will use

an audited VINCI download utility to move summarized data from VINCI servers to local storage media. The VINCI download utility provides an audit path including a copy of the downloaded material.

28. **Safeguards to prevent coercion or undue influence for study subjects.**

Subjects will be given ample time to read and consider the informed consent. Subjects may have as much time as needed (no time limit) to read and consider the risks and benefits of the study participation. Subjects may involve family members, or significant others in the decision on whether or not to participate in the study. Subjects are informed that refusal to participate in research projects will not change their eligibility for VA services, treatment, or disability payments. No guarantees are made for benefit during the research study. Given this study population, it is anticipated that the consent process will take longer than most participant groups.

29. **Resources.**

All named investigators and research assistants are currently qualified and are trained and experienced in clinical research. They all have adequate offices and space and adequate access to patient's needed for the study.

30. **Safeguards to protect the rights and welfare of mentally disabled and/or decisionally impaired subjects (vulnerable patient populations).**

This study sample will include participants with varying degrees of cognitive impairment (from intact to severely impaired) and other mental health diagnoses (e.g., serious mental illness) that would classify them as vulnerable populations. In the event that these participants have impaired decision-making capacity, appropriate surrogate consent will be obtained as described above. All members of the investigative team have previous experience conducting research with individuals with impaired decision-making capacity. In addition, the Data Safety Monitoring Board (DSMB) will convene on a biannual basis to review the progress of the study and evaluate the ongoing safety of participants. If at any time during the course of the study, the DSMB judges that risk to participants outweighs the potential benefits, the DSMB has the discretion and responsibility to recommend that the study be terminated.

31. **Plans for Adherence to VA Policies and Regulations Regarding Research Involving Controlled Drugs** N:\HRPP POLICIES\Use of Controlled Substance in Research 102706.TIF**:**

Not applicable - Controlled drugs will not be used in this research study.

32. **Reuse of data**

The data collected for this study will be used to write one or more manuscripts for publication. If results of this study are reported in medical journals or at meetings, the veterans will not be identified by name, by recognizable photograph, or by any other means without their specific consent. Audio recordings collected during data collection will

not be used during presentations. Information gathered from this study will also be used as pilot data to write future grant proposals.

33. **Research at external sites and multi-site research in which the investigator is lead investigator.**

Not applicable

34. **References**

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35. **Appendix A ODeC DUA – (for analysis of a copy of the deidentified dataset)**

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