Study Protocol

IIR 14-080 – DELIVERY MODELS OF CAREGIVER SUPPORT AND EDUCATION
NCT02368132
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CMCVAMC Specific Protocol Summary Content Requirements for IRB Committee Review	CMCVAMC IRB CMC VA Medical Center Institutional Review Board

A. **Protocol Title**
   1. **Full Protocol Title: Comparative Effectiveness of Delivery Models for Caregiver Support and Education**

   2. **Date of Protocol Summary and Version #: Date 1.17.20 Version # 22**

B. **Principal Investigator's Full Name and Degree: Shahrzad Mavandadi, PhD**

C. **Co-Investigator's Full Name and Degree**: **Laura Wray, PhD**

D. **Financial Sponsor** (Provide the name of the agency, organization, company or person providing funds for the research study.) **HSR&D Merit Review**

E. **Grant** (Provide the name of individual who holds the grant and the grant number, if applicable.) **Mavandadi IIR 14-080**

F. **Protocol Number** (Provide the financial sponsor's protocol number, if applicable.) **n/a**

G. **Institution(s) responsible for the project:**
   1. For single-site studies - CMCVAMC is the only institution involved. Yes ☐ No ☒
   2. For multi-center studies.
      2.1. CMCVAMC is the Coordinating Center in which the PI is the lead investigator. Yes ☒ No ☐ N/A ☐
      2.2. Provide the name of the Coordinating Center. Yes ☐ No ☐ N/A ☒
      2.3. List the name of the other sites involved. **VA Western New York Health System (VAWNYS)**
      2.4. Provide the FWA numbers for each of the other sites involved. **00002279**

THE FOLLOWING INFORMATION MUST BE CMCVAMC-SPECIFIC, THAT IS, SPECIFIC TO WHAT WILL BE DONE WITH CMCVAMC-RECRUITED VETERANS.

A. Background and Significance: (Describe succinctly and clearly the past findings which justify the plan for this project. A summary of the relevant literature in the area of interest and reports of previous studies should be included.)

1. Interventions for Non-Professional Caregivers of Individuals with Dementia

Individuals with dementia are faced with chronic, progressive declines in cognitive, physical, behavioral, and psychosocial functioning. Accordingly, dementia takes a significant toll not only on individuals with the condition, but also on their family and friends. As many as 80% of persons with dementia receive care at home from members of their social network.[13] Informal caregivers (CGs), who provide a wide range of assistance and support for the care recipient (CR), are often referred to as "hidden patients" as they are at increased risk for experiencing chronic stress and fatigue, difficulties in psychosocial functioning, and declining emotional and physical health.[14] Moreover, CG burden and stress, physical functioning, lack of knowledge regarding services, and difficulty coping with patients' behavioral symptoms are associated not only with CGs' quality of life, but also with CR outcomes (e.g., behavioral symptoms, nursing home placement, morbidity, and mortality).[15-17] Recognizing that successful dementia management requires interventions aimed at not only CRs, but also at addressing CG needs, a number of CG-based interventions have been developed. These interventions include

psychosocial interventions (e.g., behavioral management training, individual/group skills training, individual/group supportive counseling, case management), technology-based interventions (e.g., use of GPS location systems to address wandering), and respite care (e.g., institutional/overnight services, in-home respite).[8]

Results from systematic literature reviews suggest that participation in these programs is associated with improved CG well-being and ability to cope with CR symptoms, decreased CR dementia-related behavioral and psychological symptoms, reduced nursing home placement rates, and longer time to nursing home placement.[8, 18, 19] The strongest empirical support, however, appears to exist for multicomponent, individually tailored programs that incorporate a variety of treatment approaches (e.g., skills training, group support, home/environmental modifications, respite care).[20, 21] For example, the Resources for Enhancing Alzheimer's Caregiver Health (REACH and REACH II) trials, which used a combination of 12 individual in-home and telephone sessions and five telephone support group sessions, have been associated with numerous positive outcomes including reduced CR problem behaviors and CG burden and depressive symptoms.[21-23] Notably, a recently completed six-month feasibility and implementation study of the REACH VA program within VA Home Based Primary Care programs found a positive impact on CG burden and CR problem behaviors.[24]

Recent trials have also lent support to collaborative care management interventions for CGs. These programs address the fact that the majority of individuals with dementia receive their care from their primary care providers (PCPs).[9, 10, 25] Collaborative care interventions involve disease management that is coordinated and delivered by an interdisciplinary team comprised of care managers, PCPs, and informal CGs. Two recent collaborative care trials that involved individualized assessment and care management plans, monitoring, skills training, and action plan development, found evidence for reduced CG depression and stress and CR problem behaviors.[3, 10] Within the VA, the Partners in Dementia Care (PDC) trial has shown particularly promising results. PDC, a telephone administered care management program, not only provides education, emotional support, and training for CGs, but also helps CGs access both medical and non-medical, VA, and community services by way of a strong partnership between VAMCs and local Alzheimer's Association Chapters.[26] Finally, as discussed in more detail below, our own group has conducted two pilot projects to evaluate the feasibility and impact of a CG-based, individually tailored, collaborative care program that is an adaptation of the Telehealth Education Program (a telephone administered support and skills training program for groups of CGs of Veterans with dementia).[4] Initial findings from the program suggest positive CG and CR outcomes.[27]

While tailored, multicomponent programs that include care management have a strong evidence base, they tend to be both staff and time intensive (e.g., interventions lasting six months or longer), often lack the benefits derived from structured group participation and support from caregiving peers, and, in most cases, rely in large part on in-person visits. In an effort to improve cost-efficiency, outreach, and access to CGs, more recent efforts within the VA have sought to examine the feasibility and impact of brief, telephone and internet-based CG group programs.[4, 28, 29] This type of program, including our Telehealth Education Program (TEP), which is telephone administered and delivered in group settings for 10 weeks, has been shown to have a positive impact on CG outcomes and to be cost-effective.[4] The program incorporates multiple components, including the provision of emotional support, education, stress management, and skills training. Findings from the program are promising and suggest that brief, telephone administered interventions for groups of CGs that encourage mutual peer support and feedback are an effective and cost efficient form of CG intervention.

Taken together, the findings outlined above lend support to the notion that multicomponent, individually tailored programs that target specific CG-CR needs and include collaborative care management may be particularly effective in improving CG and CR outcomes. Moreover, as discussed in greater detail below, programs that incorporate both individual and group components may have an additive positive effect on the impact of multicomponent care management programs.[1, 16] Nevertheless, numerous methodological, instrumentation, and analytic issues preclude the ability to determine which elements of these various interventions are the most feasible and effective.[8] Past CG intervention studies have tended to use small sample sizes and attrition rates have been typically high. Qualitative and quantitative indicators vary significantly from study to study, making direct comparisons of findings across studies challenging. Similarly, the lack of a clear distinction among specific techniques used in

psychosocial interventions (e.g., skills training vs. behavioral management training) across studies complicates the ability to determine what types of strategies are most effective. Finally, while the majority of past studies have compared the intervention group to usual care, only a few studies have examined the comparative effectiveness of different intervention strategies (e.g., individually-delivered vs. individual + group delivered) in a single study.[11, 30] *Thus, in order to more clearly distinguish the "active ingredients" that make interventions for Veterans and their CGs both feasible and effective, it is important for future intervention work to include adequately powered, comparative effectiveness trials of different delivery and intervention techniques that employ a single, uniform set of assessments, seek to reduce participant attrition rates, and maximize intervention outcomes*.[8]

2. Caregiving in a Social Context: Caregiving Impact on Social Network Structure and Function and The Role of the Caregiver-Care Recipient Relationship Type

As discussed above, although individually-delivered, multicomponent care management programs have a strong evidence base, they may lack the benefits afforded by interventions that incorporate group participation and mutual support from caregiving peers. Nevertheless, few studies have specifically examined the comparative effectiveness of group vs. individual delivery of intervention components and the extent to which these different intervention modalities impact outcomes.[8, 11, 30] This represents a notable gap in the field, as group-delivered interventions are likely to precipitate changes in CGs' social networks, thus ultimately having a positive impact on CG outcomes. It is well accepted that social relationships help to buffer stress, enhance psychological wellbeing, and attenuate and/or delay declines in health, and as such, greater social integration and social support have been shown to predict positive outcomes among CGs.[18, 31, 32] Aspects of one's social relationships with others can be characterized as "structural" or "functional". While structural aspects of social ties include indices of network size and frequency of contact, functional aspects include the various types of support received from others; that is, the nature and quality of the support provided.[33] Due to their caregiving role and demands, CGs may experience significant declines in their ability to interact with members of their social network. Spousal CGs may be especially vulnerable to reductions in social support. Not only do social networks tend to dwindle in size with advanced age, but the chronic, progressive nature of dementia often leads to the loss of the spousal CG's closest social tie (i.e., their spouse).[34, 35]

Thus, the extent to which CG interventions help to improve and strengthen CGs' social network structure and function and compensate for weak ties may help account for the positive impact of group interventions on CG wellbeing. In one of the few studies to compare a CG support intervention provided in either a group or individual format, Toseland and colleagues (1990) found that adult child CGs assigned to both intervention modalities experienced significant improvements in coping and reduced stress.[11] However, the processes, or mechanisms, by which adult child CGs improved differed across the two modalities; while CGs in the individually delivered program spent more time problem solving and discussing highly personal issues (e.g., marital difficulties), CGs in the group intervention were more likely to exchange information, share and compare caregiving experiences, and spend time engaging in social interactions and discussions that were non-caregiving related. Accordingly, CGs in the group intervention reported increases in the size of their social networks and greater positive changes in both formal and informal social support. *Individually-based interventions that are augmented with a group support component may not only lead to reduced CG burden and distress, but also may improve social network function and structure, both of which are essential for wellbeing and resilience in the caregiving role.*

An additional factor that is rarely taken into account in CG intervention trials is the extent to which various individual-level factors moderate the association between intervention group assignment and outcomes. For example, prior work has suggested that factors such as baseline CR symptom severity, CG distress, and ethnicity may impact enrollment, attrition rates and outcomes among CGs participating in CG interventions.[30, 36] While studies typically control for these variables in a post-hoc fashion, few studies specifically sample or stratify results based on these potential moderators. By not accounting for important moderators a priori in the design phase, studies may lack the necessary power to detect moderators of intervention outcomes that can help determine for whom and under what circumstances varying intervention strategies are most effective. Identification of subgroups of patients who may

respond more favorably to different treatment strategies also can further help to tailor programs for maximum impact.

The relationship between the CG and the CR is one potential moderating factor that has been shown to have a significant impact on intervention enrollment rates, participant retention, and outcomes. Only a few studies have specifically examined the moderating role of relationship type on engagement, drop-out, and intervention outcomes.[30, 37, 38] While some studies have examined "atypical" family CGs (e.g. nieces, nephews, siblings, [71] the majority of this work has examined spousal versus adult child CGs due to demographic trends suggesting that spouses and adult children are most likely to assume the role of caregiving. For example, adult child CGs are significantly less likely than spouses to participate in CG-related trials and research studies, and are more likely to drop out once enrolled.[38, 39] Potential explanations that may account for these trends include logistic factors such as continued full time employment despite their caregiving role, having to care for young children of their own, and having other family and personal obligations to fulfill.[38, 40] Moreover, in comparison to spousal CGs, adult children CGs have been reported to perceive their burden as more overwhelming and their CR's quality of life as poor, which may impact both willingness to participate in studies and intervention outcomes.[40-42] Alternatively, despite the fact that spousal CGs often are coping with their own chronic conditions, functional limitations, and the profound grief associated with gradually losing their spouse, they may be more motivated to participate and stay engaged in intervention studies. This motivation may be due to the lack of competing demands and the closeness, commitment, and investment inherent in the marital relationship.[40, 43] It may also be that relationship closeness, particularly among spousal CGs, is associated with attenuated CR cognitive and functional decline.[43] Research comparing "atypical" family CGs (e.g., grandchildren, nieces/nephews, siblings) to "typical" family CGs (i.e., spouses and adult children) is sparse, primarily due to lack of power to run subgroup analyses. In one of the only studies to examine differences among multiple family CG types, Nichols et al. (2011) found that while the various family CG groups differed on multiple factors (e.g., extent to which bothered by dementia symptoms, social support from others, demographics (e.g., age, employment status), the caregiving experience is comparable across "typical" and "atypical" family CGs and hence family CGs of both types are likely to benefit from CG interventions. *It is therefore important that intervention trials be designed and powered to explicitly take the relationship between the CG and CR into account, as more work is needed to determine which treatment modalities and components are most accommodating and effective in not only engaging and retaining spousal, child, and other family CGs, but also in producing the greatest impact on outcomes.*

3. Conclusions and Rationale for the Current Study

Taking this previous work into account, the proposed study seeks to examine the comparative effectiveness of two modalities (*individual* TEP + individual care management vs. *group* TEP + individual care management) of a previously piloted brief, care management and dementia skills training, education, and support intervention for CGs of Veterans with dementia receiving primary care at the VAWNYHS, CMCVAMC and affiliated CBOCs. The intervention is modeled after the VISN 2 Telehealth Education Program (TEP) and the VISN 4 MIRECC Behavioral Health Laboratory (BHL). As alluded to above, the TEP is an existing, manualized program developed and validated with groups of CGs of Veterans with moderate to severe dementia.[4] The program's inclusion of education, emotion/problem focused coping skills and problem solving techniques, and peer support is based on well-established principles of interventions with older adults.[44] The BHL is a multi-component, telephone-based clinical service designed to help identify and manage behavioral health issues. The CMCVAMC and the University of Pennsylvania were the development and founding sites of the BHL. Within the VHA, the BHL has been recognized as a Best Practice for identification and early intervention of MH and substance abuse symptoms in primary care patients. Key features of the BHL collaborative care model include frequent patient contact, ongoing monitoring of treatment adherence and assessment of symptomatic outcomes using a direct data entry computer program, referral to appropriate services, patient and provider feedback, and modification of treatment plans when needed.[45]

Integrating features of both the TEP and BHL, both active intervention arms of the proposed study will incorporate an interdisciplinary team comprised of dementia care managers, PCPs, and CGs, will be patient/CG-centered and individually-tailored to take variability in CR/CG needs, preferences, and

comorbidity into account, and will seek to improve access to and the use of VA and community services and resources. CR-CG interactions will be targeted by working with CGs to help them better manage disease symptoms as well as their own personal affect and well-being. The program will assist PCPs in treatment planning by supporting VA dementia recommendation concordant care and facilitating triage of individuals into the appropriate level of care, ranging from structured symptom monitoring and follow-up assessments to referral to community-based services and specialty care. Finally, although all CGs randomized to the 2 intervention arms will participate in the TEP, half of the randomized CGs will receive TEP via a telephone group format, while the other half will receive the TEP material via individual phones calls.

The proposed project seeks to address knowledge gaps, represents a shift from traditional methods used to evaluate CG interventions, and has the potential to directly inform current clinical practice. Traditional treatment strategies that rely on face-to-face contact do not address practice and patient level logistical issues that are particularly relevant in dementia care. Frequent contact for monitoring and therapeutic intervention are key components in successful treatment of these patients and their informal CGs but may be taxing to the patient and family and difficult for the system to sustain.[25] To overcome logistical challenges we have chosen to adopt a strategy of offering brief, dementia care management, psychoeducation, and support by way of telephone assessment and intervention. Accordingly, the intervention is innovative in a number of ways. Providing CGs with the option of participating in the program over the telephone allows access to education and support without having to manage the difficulties of getting the Veteran out of the house or finding supervision for him/her in order to attend face-to-face sessions and minimizes the strain placed on the Veteran and family to find transportation to the VAMC for care. Telephone-based delivery also will enable us to serve CBOCs and rural areas using a regional, “hub and spoke” model. Both the BHL and TEP programs, which are primarily delivered via telephone, manualized (which enables CGs to work on program material at their leisure) and intended to be brief (i.e., 3 months) in duration, have been quite successful in overcoming logistical issues that might serve as barriers to engagement in interventions for Veterans in smaller clinics or rural settings.[46] These program features have the potential to result in higher CG participation and satisfaction, service utilization, improved health, and, accordingly, sustained CR independent functioning.

Second, our stratified sampling of spousal, adult child CGs, and other family (e.g. siblings, nieces/nephews, grandchildren) will lead to more generalizable findings and help us identify subgroups of CGs for whom different intervention modalities might be most effective. Existing work on CG interventions tends to either include one type of CG (e.g., spouse, adult child) or statistically adjust for relationship type in post-hoc analyses, with few studies specifically sampling based on relationship type. While the use of homogenous CG samples in research reduces variance and potential confounding and helps generate “clean” findings that are more easily interpreted, this is done at the expense of generalizability of the findings. Moreover, the finding that spousal, adult child, and other family CGs represent distinct groups with different caregiving experiences and patterns of enrollment, attrition, and outcomes, highlights the value of examining how different family CGs respond to individual vs. group intervention. Modeling the moderating role of relationship type in the association between different intervention modalities and outcomes can help inform future studies and shed light on ways to tailor CG interventions to ensure participant retention and maximum impact.

H. **Purpose of the Project:** (Clearly provide the purpose of this research project.) **The purpose of the project is to: a) test the comparative effectiveness of 2 delivery models (individual TEP + individual care management vs. group TEP + individual care management) of a telephone-based, collaborative dementia care intervention for caregivers (CGs), and b) explore whether the individual or individual + group intervention is more effective/acceptable among spousal vs. adult children/other family member CGs.**

I. **Describe the Research Questions or Hypotheses** (that is, what questions are you trying to address by conducting the research.**)**

Aim 1: What is the relative impact of usual care (UC) vs. collaborative care and support delivered in either a group or individual format on CG and CR outcomes?
-We hypothesize that both the group and individually delivered interventions will be superior to UC, with the group delivered intervention (which will include both TEP group sessions and individual care management calls with CGs) resulting in the greatest changes in outcomes over time: group > UC (Hyp1A); individual > UC (Hyp1B); group > individual (Hyp1C).

Aim 2: Does the relationship between the CG and CR differentially impact the relative acceptability (Aim 2A) and efficacy (Aim 2B) of the group vs. individually delivered intervention (i.e., moderation model)?
-We anticipate that the group intervention will be associated with higher intervention engagement rates (Hyp2A) and be more effective (Hyp2B) among spousal, relative to adult child/other family, CGs.

J. **Primary Outcome Variable(s):** (Define the primary outcome variable(s) used to support the study objectives (e.g. if the objective is to show that treatment A is superior to treatment B in the treatment of subjects with essential hypertension, the primary outcome variable is blood pressure measurement.) **CG burden and CG distress in response to CR dementia-related symptoms**

K. **Secondary Outcome Variable(s):** (Define the secondary outcome variables. Such measured variables should also include the timing of measurement.) **Overall CG mental health (VR 16)**

L. **Study Design and Methods:**

1. Is this a clinical trial? ☐YES ☒NO
   1.1. If yes, what type? Check all that apply.
   ☐ **Phase I** ☐ **Phase II** ☐ **Phase III** ☐ **Phase IV**
   1.2. If yes, this study must be registered on Clinicaltrials.gov.

2. **Design**
   2.1. What research methods will be used in the project? Check all that apply.

☒ Surveys/Questionnaires	☒ Interviews	☒ Audio Taping
☐ Behavioral Observations	☒ Chart Reviews	☐ Video Taping
☐ Focus Groups	☒ Randomization	☐ Double-Blind
☒ Control Group	☐ Placebo	☐ Withhold/Delay Treatment
☐ Specimen Collection	☐ Deception	☒ Telephone Survey
☐ Other (Describe)		

   2.2. Describe how randomization or other treatment assignment will be made. **Once inclusion/exclusion criteria are met, we will use a random number table that will be generated using the PROC PLAN macro in SAS v9.3 to randomly assign equal numbers of CGs to the individual TEP + individual care management, group TEP + individual care management, or UC arms. The randomization program will take into account stratification by relationship type (spouse/partner, adult child/other family). This will yield 135 CGs per arm (90 spouses/partners, 45 adult children/other family). We will enroll more spousal CGs than adult children/other family CGs because this distribution more closely reflects the demographic composition of CGs providing care for Veterans with dementia found in our preliminary work.**
   2.3. For retrospective research studies, provide the "look-back" period. (e.g., December 1, 1999 through December 31, 2008.) **This is primarily a prospective study. However, for the medical chart review component of the project, data from**

Veterans' medical charts will be extracted for a period of one year prior to the CGs' 3 month research assessment date.

3. **Study Duration**
   - 3.1. Provide the estimated length of time to enroll all subjects and complete the study. **4 years**
   - 3.2. Explain the expected duration of subject participation including any follow-up. **Research assessments will be conducted at baseline and 3, 6, and 12 month followup. If randomized to a treatment arm, CGs will receive up to 3 months of care management services.**
   - 3.3. Specify the projected date of completion of the proposed study. **February 2019**

4. **Drug Information** (If not applicable state, "Not Applicable.") **Not Applicable**
   - 4.1. Specify if the drug or biological agent is:
     - 4.1.1. FDA approved **N/A**
     - 4.1.2. Used for off-label purposes **N/A**
     - 4.1.3. Not yet FDA approved**.** **N/A**
   - 4.2. Include the FDA Investigational New Drug (IND) number for all non-FDA approved and off-label drugs, biological agents or nutritional supplements. If not applicable state, "Not Applicable." **N/A**
   - 4.3. Provide all relevant information about the drug **N/A**
   - 4.4. Explain any wash-out periods, rescue medications permitted and any type of medications not permitted while enrolled in the study. **N/A**
   - 4.5. Describe blinding and un-blinding procedures. **N/A**
   - 4.6. Include the dosage, route of administration, previous use, and the safety and efficacy information on any drug used for research purposes. **N/A**
   - 4.7. Describe rationale for the dosage in this study. **N/A**
   - 4.8. Justify why the risks are reasonable in relation to anticipated benefits and/or knowledge. **N/A**
   - 4.9. Describe where drug preparation will be done. **N/A**
   - 4.10. All drugs for CMCVAMC subjects must be dispensed through the VA investigational pharmacy. **N/A**
   - 4.11. Describe where the study treatment will be administered. **N/A**
   - 4.12. Describe plan for tracking a non-compliant treatment study subject. **N/A**
   - 4.13. Summarize any pre-clinical data. **N/A**
   - 4.14. Describe the process for the storage, security, dispensing and return of an investigational drug. **N/A**

5. **Investigational Device** (If not applicable state, "Not Applicable.") **Not Applicable**
   - 5.1. The Investigational Device Exemption (IDE) number must be submitted for all significant risk devices and if an IDE exists for a non-significant device. **N/A**
   - 5.2. Significant Risk or Non-significant Risk - If a device is not approved by the FDA, specify whether or not the sponsor has determined this device to be a "significant risk" or "non-significant risk" as defined by the FDA. **N/A**
   - 5.3. Provide all relevant information about the device. **N/A**
   - 5.4. Describe blinding and un-blinding procedures. **N/A**
   - 5.5. Specify if device is:
     - 5.5.1. FDA approved **N/A**
     - 5.5.2. Used for off-label purposes **N/A**
     - 5.5.3. Not yet FDA approved. **N/A**
   - 5.6. Explain if the investigational device will be delivered and/or stored by the Principal Investigator or Pharmacy Services. **N/A**

5.7. Describe the process for the storage, security, dispensing and return of an investigational device. **N/A**

5.8. For research involving an investigational device, describe the SOP or plan for device control. **N/A**

5.9. Address how the device will be stored in such a way that only research staff associated with the protocol will have access to the device. **N/A**

5.10. Describe measures that will be put into place to ensure that the device will only be used in participants of this research protocol. **N/A**

M. **Does this project involve international research?** ☐YES ☒NO

1. *For further instructions refer to VHA Directive 2005-050, Requirements for Conducting VA-Approved International Research Involving Human Subjects, Human Biological Specimens, or Human Data*
2. *VHA Handbook 1200.05 definition of international research - VA international research is any VA-approved research conducted at international sites (not within the United States (U.S.), its territories, or Commonwealths); any VA-approved research using either human biological specimens (identified, de-identified, or coded) or human data (identified, de-identified, or coded) originating from international sites; or any VA-approved research sending such specimens or data out of the U.S. (see par. 56).* ***NOTE:*** *For the purposes of this Handbook, research conducted at U.S. military bases, ships, or embassies is not considered international research.*

N. **Study Procedure**

1. **Study Procedures**

1.1. Outline all study procedures - (*If necessary, include a table or flow chart, showing the schedule of the procedures and interactions. Distinguish between interventions that are experimental and carried out for research purposes vs. those that are considered standard of care. Routine procedures that are performed solely for research purposes should also be identified.)*

A. Overview: We will conduct a prospective, longitudinal, randomized control group study. Caregivers (n=405) of Veterans with dementia will be randomly assigned to one of 3 arms (1. UC, 2. individual TEP + individual care management or, 3. group TEP + individual care management) and assessed at baseline and 3, 6, and 12 month follow-up. Each study arm will include 135 CGs. In order to examine the moderating role of CG-CR relationship type, sampling and randomization will be stratified by whether the CG is a spouse/partner or adult child/other family CG. Subjects will include CGs of Veterans with dementia who have had at least one PACT encounter in the past 6 months. The study will employ a combination of self-report survey and chart-review based data collection techniques. All intervention components and research interviews will be administered via telephone, though CGs may choose to complete research assessments using paper and pencil. Clinical patient record data will be extracted using the VA Informatics and Computing Infrastructure (VINCI).

B. Baseline and 3, 6, and 12 month Follow-up Procedures (all participants, regardless of randomization): Once the CG is recruited, screened, and randomized (greater detail on recruitment, screening and randomization provided below), the Research Assistant will contact the CG for the baseline research assessment (please refer to Appendix I for list of assessments and related citations). This assessment will include a battery of standardized, well validated questionnaires regarding CRs'/CGs' sociodemographic characteristics, CRs' dementia-related symptoms and associated CG distress and burden, CGs' mental and physical functioning, CGs' social network structure and function, and CRs' psychiatric symptoms, comorbid medical conditions, and physical functioning. All research assessments will be re-administered at 3, 6, and 12 month follow-up. At the beginning of each research assessment, RAs will remind participants that they are not aware of their group assignment and will ask that participants not disclose which of the study arms they participated in. Data on CRs' medication use and inpatient/outpatient medical service use will be extracted from the CRs' clinical record. Data will be coded and identifiable.

C. Intervention Procedures:

i. *Care Management:* CGs assigned to both active intervention arms will receive care management services. Care management will involve regular contact between CGs, PCPs, and the care manager. The care manager, who will be a nurse or licensed clinical social worker with at least 2 years of experience in clinical/research settings, will monitor CRs' symptoms, provide psychoeducation and support to CGs, influence adherence to VA concordant care guidelines by providing timely and tailored information to PCPs, and collaboratively make appropriate care decisions and service referrals. The care managers will be supervised and meet weekly to review active cases and discuss individual action plans either in person or virtually with a clinical psychologist (Drs. Wray or Klaus) or geriatric psychiatrist (Dr. Streim). This supervision process has been successfully used in our past collaborations.

Following the baseline assessment, the care manager will contact CGs a minimum of 3-4 times over the course of 3 months to complete clinical/needs assessments. *All CGs randomized to the two intervention arms will receive these individual care manager contacts.* The number of visits/calls will be determined based on clinical judgment and perceived CG need. During these visits/calls, the care manager will assess CRs' and CGs' general service use and needs. Questions about CRs' dementia-related behavioral and memory issues and CGs' mood also will be asked. Corresponding care plan(s) will be developed. CGs will be contacted specifically at approximately 2, 5, and 9 weeks after the baseline assessment for brief follow-up phone calls designed to monitor, via CG report, patients' medication adherence, side effects, and symptoms. If appropriate, after the visit/call (including the medication monitoring calls), a report summarizing patient and CG outcomes will be generated and sent to each CG along with educational materials regarding specific reported symptoms. The care manager will help coordinate connection to VA and community programs, if needed. Progress reports also will be generated, where appropriate, for patients' PCPs following interviews/contacts to help in treatment planning and to alert clinicians of special issues. The care manager will personally contact PCPs to discuss cases in which CRs are not improving and/or experiencing significant symptoms or side effects (either via phone, encrypted email, fax, or a research note in CPRS). They also may contact the PCP throughout the study regarding the CG's status, particularly in regards to caregiver distress and burden. Based on the severity of symptoms and medical service needs reported, the care manager also may make recommendations and help coordinate scheduling in primary and specialty care. For tracking and process evaluation purposes, the care manager will keep log sheets and document each contact with CGs, community/VA service agencies, and PCPs/providers.

ii. *Telehealth Education Program (TEP):* The second major component of the intervention is the TEP. The program includes both a CG workbook and care manager manual. All CGs will be sent the entire workbook, which includes education material and summarizes and outlines homework for each of the modules. The delivery of TEP will vary depending on randomization group as follows:

a) Individual Delivered TEP Arm: Based on evaluation of the baseline interview, the CG and care manager will work together to determine which of the modules are most appropriate for the CG. In addition to two mandatory modules that cover the stages of dementia and provide a brief introduction to problem solving techniques, action plan development, and coping skills, CGs can select from a menu of additional modules covering various content areas evaluated during the course of the monthly assessments (e.g., communication skills, behavioral management techniques, stress management and coping skills, long-term planning, etc.). Each individual TEP session will begin with reviewing education related to the selected module. The remainder of each session will involve coaching the CG on emotion-focused and problem-focused coping strategies. The care manager will also discuss problem solving with the CG to reinforce the action plan and the educational component of the intervention. Each session will be delivered over the telephone and will last 40 minutes-1 hour. Sessions will occur approximately every other week, depending upon the availability and preference of the CG. The number of TEP contacts will depend on the number of topics chosen and covered.

b) Group Delivered TEP Arm: CGs assigned to this arm will be asked to participate in all TEP modules in a group format. Each call will take up to 1.5 hours. Each group will be comprised of 5-8 CGs who will call into a VANTS teleconference line at a pre-specified time. The content of the calls will mirror those in the individual TEP delivered program. As with the individual

TEP delivered program, each session will begin with reviewing a different education topic and the remainder of the call will involve reviewing weekly action plans, discussion of emotion and problem focused coping strategies, and skills training. This arm, however, will include the added component of peer group support. CGs will be given the option of sharing their contact information with one another. CGs will be asked to complete their workbooks prior to the next session.

In order to monitor the quality of the individual and group care management/TEP sessions and care managers' fidelity to the model, all individual and group sessions will be audiotaped using a digital recorder. 20% of the sessions will be randomly selected by the PI using a random number generator for fidelity purposes. These digital files will be uploaded onto a shared study folder that will reside on the VISN 4 MIRECC server under password protection and made available only to key personnel at both sites. Audio recordings will be encrypted and password protected and will only be used for supervision purposes.

D. Usual Care Procedures: After the initial baseline research assessment described above, participants randomized to UC will be sent general material about VA and community resources for patients with dementia and their CGs. CGs will receive brochures entitled: Rewards of Caregiving; Caring for the Caregiver; A Checklist for New Caregivers; 5 Tips to Avoid Caregiver Burnout; 50 things Every Caregiver Should Know; Balancing Caregiving, Family, and Work; and, Long Distance Caregiving. With the exception of this material, individuals in this group will receive UC and will be contacted again at 3, 6, and 12 months for follow-up research assessments. CGs in the UC group will be free to seek medical, psychological, social support, and social services that are available through VAMCs or any other non-VA/community source.

1.2. Explain if and how the follow-up of subjects will occur. **Follow-up CG research assessments will be conducted at 3, 6, and 12 months post-baseline. CG assessments will be conducted by phone or, if the CG prefers, packets will be mailed to the CG along with stamped, return envelopes. CRs' medical charts will be reviewed for a period of up to one year following the 3-month CG assessment.**

1.3. Describe where, how and who will be conducting study procedures. **Randomization group will be assigned by the PI, Research Coordinator, or Biostatistician. Screening, research assessments, and chart reviews will be conducted by the Research Assistants. Care management will be provided by Care Managers. Supervision will be provided by Drs. Joel Streim, Johanna Klaus, and Laura Wray. All procedures will be conducted at either the CMCVAMC MIRECC or CHERP or VAWNYHS Center for Integrated Healthcare (except in the case where the CG prefers to have the assessment packets mailed to them).**

1.4. If a survey study, specify the estimated amount of time that subjects will need to complete the questionnaires/tools. **Approximately 40-60 minutes**

1.5. If a blood draw, specify the amount of blood to be drawn in milliliters and in teaspoonfuls or tablespoonfuls and specify how often and where the blood will be drawn. **N/A**

2. **Data Collection** (Include all questionnaires and survey tools with the submission.)

2.1. Provide

2.1.1. the mode of data collection, e.g. telephone, in-person, questionnaire, interviews, **All research assessment, questionnaire data (unless in cases where the CG prefers to complete a follow-up research assessment packet at home) and data collected over the course of care management will be collected via telephone. Medical and pharmaceutical claims data will be collected via VINCI (please see detail below). Data will be coded and identifiable.**

2.1.2. the precise plan for how data is to be collected or acquired

Research Assessment and Care Management Data Collection Procedures: The vast

majority of research assessment and care management data will be collected by telephone and entered electronically on a password-protected website run by the CMCVAMC's Data Management Unit (DMU) or on the Research Electronic Data Capture website (REDCap). The DMU is a closed data entry system that has been designed so that only the responsible data entry person and the DMU supervisor can enter and/or edit data. The PIs or research staff from both sites will be able to access and request the data at any point during the study so that audits of the study's current data input can be conducted and the data's integrity assessed. Data will be stored on the CMCVAMC's Data Management Unit or REDCap for the duration of data collection. REDCap (Research Electronic Data Capture) is a web-based application for managing data acquisition during clinical research. REDCap is supported by the VA Information Resource Center and is maintained within the VA firewall so that it is only accessible on the VA intranet. REDCap will be used in this study for data entry. For participants completing the interview via phone, a blank copy of the assessment will be sent in advance of the scheduled assessment calls to help facilitate the interview. We will ask each respondent whether they are in a safe, private setting and if they are assured that their responses are not being monitored in order to ensure candid responding. Research assessment data also will be collected using hard copy, paper versions of the data forms should the CG prefer to complete the research assessment on their own. The paper versions will be created using Cardiff Teleform software and mailed to CGs along with a stamped return envelope.

Medical and Pharmaceutical Claims Data Collection Procedures: We will work with VINCI in order to expedite chart extraction of clinical data including VA and, where possible, non-VA medical/pharmaceutical, encounter, and fee information, as well as mortality status of the care recipients. When estimating non-VA utilization/cost of care (e.g., community nursing home care, home-based care, etc.), we plan to follow HERC's guidebook which provides detailed documentation and suggestions for extracting and analyzing data on cost and procedures.[6] The database will also include a "time window" variable spanning one year prior to and one year following the 3 month research assessment. Specifically, we will ask for stop codes, ICD-9/DSM-IV codes, CPT codes, and pharmacy fill dates/days supply. We also will separately consider high cost health care utilization (e.g., ER visits, walk-in clinic visits, inpatient stays) and utilization of scheduled primary and specialty care services. Extracting clinical patient record data electronically will greatly improve validity and reduce respondent burden.

2.1.3. exact location where data will be collected, **by phone, either at the CMCVAMC MIRECC and CHERP or VAWNYHS Center for Integrated Healthcare; by hard copy, in the CG's home (completion of self-report assessments)**

2.1.4. exact location where data entry will take place. **CMCVAMC MIRECC, 2nd Floor, Suite B228; CMCVAMC CHERP, Annex, 2nd Floor, Suite 202, VAWNYHS Center for Integrated Healthcare**

2.1.5. the "title" of individual(s) collecting the data and analyzing the data, e.g. principal investigator, research coordinator. **Research Assistant, Project Coordinator, and Care Managers will all collect and enter data. PI and Biostatisticians will manage and analyze the data.**

2.2. Provide a time line for each aspect of the study.

Figure 2. Gantt Chart for Proposed Project Timeline

Project Year	One					Two		Three		Four	
Project Month	*1-2*	*3*	*4-5*	*6*	*7-12*	*1-11*	*12*	*1-11*	*12*	*1-10*	*11-12*
Calendar Year	**2015**					**2016**		**2017**		**2018**	
Calendar Month	*Jan-Feb*	*Mar*	*Ap-May*	*Jun*	*Jul-Dec*	*Jan-Nov*	*Dec*	*Jan-Nov*	*Dec*	*Jan-Oct*	*Nov-Dec*
PREPARATORY PHASE											
Train preexisting BTC/MIRECC RA/CM											
Hire & train Care Managers, Project Coordinator, and RA(s)											
Receive Final IRB/R&D Approval											
Finalize DMU forms and form development; prepare TEP manuals and study material for distribution to participants											
Enroll project with VINCI and specify data to be extracted											
Create randomization and tracking databases (the latter will be managed via VINCI)											
Meet with BHL and BTS staff to review study objectives; distribute study fliers to clinical staff											
Hold virtual team meetings											
SAMPLING, RECRUITMENT, and DATA COLLECTION PHASE											
Extract list of eligible Veterans from VINCI (ongoing, periodic activity)											
Commence recruitment, rolling enrollment, BL assessments, care management calls, and TEP groups (for those randomized to TEP group delivery)											
Begin and continue follow-up research assessments											
[Recruit last wave of caregivers and initiate care management/TEP (3 month duration) for last wave of CGs randomized to active intervention arms]											
Extract VINCI clinical, encounter, utilization & cost data (ongoing, periodic activity)											
DATA ANALYSIS, DISSEMINATION, and IMPLEMENTATION PHASE											
Data entry and cleaning (periodic, ongoing activity)											
Merge randomization assignment, DMU, and VINCI databases (periodic, ongoing activity)											
Begin and continue data analyses (interim and final)											
Begin and continue dissemination efforts											

2.3. Chart/Records/Data Review (retrospective and/or prospective)

2.3.1. Provide the planned or approximate number of charts/records/data to be accessed

2.3.1.1. CMCVAMC **Charts of 235 Veterans**

2.3.1.2. Other site **Charts of 170 Veterans**

2.3.2. Does this protocol employ an Honest Broker? ☐YES ☒NO

2.3.2.1. If yes, provide name of individual.

2.3.2.2. If no, explain who will access the charts/records.

2.3.2.3. Describe from what database charts/records/data will be accessed.

3. **Future Use of Data and Re-Contact**, if applicable.

3.1. If any of the participant's data are going to be retained after the study for future research, the following information must be provided to the participant:

3.1.1. Where will the data be stored? **N/A**

3.1.2. Who will have access to the data? **N/A**

3.2. If the subject is going to be re-contacted in the future about participating in future research, this must be specified. Describe the circumstances under which the participant would be re-contacted whether within the VA or outside the VA. **N/A**

3.2.1. If subjects will receive aggregate study results at the end of the study, the informed consent document must contain this information.

4. **Specimen Collection**
   - 4.1. Give the source of all specimens and whether they were collected for research, treatment or diagnosis. **N/A**
   - 4.2. State where specimens will be stored, secured and when discarded. **N/A**
   - 4.3. Explain how destruction of samples will be substantiated. **N/A**

O. **Genetic Testing, if applicable**

1. Explain if the study is looking for an association between a genetic marker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value.
   Not Applicable
   - 1.1. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve participant counseling.
   - 1.2. Describe if the study is based on the premise that a link between a genetic marker and a specific disease or condition is such that the marker is clinically useful in predicting the development of that specific disease or condition.
   - 1.3. Will the subject be notified of the results and the provision for genetic counseling? ☐ Yes ☐ No ☐ N/A
     - 1.3.1. If yes, explain further.
   - 1.4. If biological specimens are used in this protocol, please respond to the following questions by checking the appropriate box:

	YES	NO	N/A
a. Does the project involve genetic testing?	☐	☐	☐
b. Will specimens be kept for future, unspecified use?	☐	☐	☐
c. Will samples be made anonymous to maintain confidentiality? *(Instructions: Note: If there is a link, it is not anonymous. Coding is not anonymous.*	☐	☐	☐
d. Will specimens be destroyed after the project-specific use is completed?	☐	☐	☐
e. Will specimens be sold in the future?	☐	☐	☐
f. Will subjects be paid for their specimens now or in the future?	☐	☐	☐
g. Will subjects be informed of the results of the specimen testing?	☐	☐	☐
h. Are there any implications for family members based on specimen testing results? (If yes, they may be participants.)	☐	☐	☐
i. Will subjects be informed of results obtained from their DNA?	☐	☐	☐

   - 1.5. Will specimens be de-identified? ☐YES ☐NO ☐ N/A
     - 1.5.1. If yes, please describe the procedures to be used.
     - 1.5.2. Include at what point in the process the specimens will be de-identified.
   - 1.6. Describe what measures will be taken to minimize the following risks from breaches of confidentiality and privacy resulting from participating in **THIS aspect** of the research project:
     - 1.6.1. physical
     - 1.6.2. psychological
     - 1.6.3. financial
     - 1.6.4. social
     - 1.6.5. legal harm

P. **Banking of Collected Specimens**

1. **Will collected specimens be banked**? ☐YES ☐NO ☒N/A
   - 1.1. *IF BANKING SPECIMENS, IT MUST BE AT AN APPROVED VA REPOSITORY*. (*For additional information, refer to VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research - March 9, 2009.)*

1.2. If yes, specify the location where specimens will be banked.
1.2.1. If the location is a non-VA site, has the mandatory approval from the Chief Officer of Research and Development (CRADO) been obtained through submission of a tissue banking application (VA Form 10-0436 - Off-site Application for an Off-site Tissue Banking Waiver)? ☐YES ☐NO ☐N/A
1.2.2. If applicable, attach a copy of the VA Form 10-0436
1.3. Explain how destruction of banked samples will be substantiated.

Q. **Subject Recruitment** (characteristics of the study population)

1. **Provide the planned or targeted enrollment at**:
1.1. CMCVAMC - **235**
1.2. Other sites - **170**
1.3. Not applicable; chart review or use of previously collected data - ☐

2. **Screening and/or Eligibility Requirements**
2.1. Describe and provide justification for:
2.1.1. Inclusion criteria

- **Veteran and CG are 18 years of age or older.**
- **Veteran is community dwelling.**
- **Veteran has had at least one PACT encounter at the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC), VA Western New York Healthcare System (VAWNYHS), or affiliated community-based outpatient clinics in the past six months at the time that data is extracted from VINCI for recruitment.**
- **Veteran meets criteria for dementia that is verified by informant report (AD8[53], score of 2 or above)).**
- **CG endorses that Veteran has a diagnosis of dementia.**
- **CG lives with or provides care for the Veteran for an average of at least 4 hours per day.**
- **Veteran's CG is willing and able to provide informed consent.**
- **CG is either a spouse/partner, adult child, or other family member (e.g. sibling, niece/nephew, grandchild).**
- **CG screens positive for moderate CG burden (per Zarit Burden Interview (4-item) score of 3 or more).[51]**

2.1.2. Exclusion criteria

-
- **CG cognitive, hearing, visual, or other physical impairments leading to difficulty with informed consent process, assessment, or participation in intervention visits.**
- **CG participation in a pre-existing support group or CG intervention at enrollment (however CGs can subsequently enroll in any treatment they choose).**
- **Veteran is deceased (per Vital Status records in VINCI)**

2.2. List all screening and/or eligibility requirements. **Please see inclusion/exclusion criteria above**
2.3. Explain any special test or evaluations potential subjects may have to undergo before they are actually determined to be eligible for the study. **AD8, Zarit Burden Interview**
2.4. Not Applicable; subjects not recruited; chart review. ☐

3. **If applicable, indicate what populations will be targeted for recruitment as participants. Check all that apply.**

Males	☒
Females	☒

Inpatients	☐
Outpatients	☒
VA Employees	☐
Non-English Speaking**	☐
Veteran Family members***	☒
Non-Veterans***	☒
Other (Specify)	☐
Not Applicable, chart review	☐

3.1. **For non-English speaking subjects - If an investigator proposes to use a participant population that does not speak or read English, a copy of the translated document, as well as the English version, needs to be forwarded to the IRB for approval. Translator certification is also required. **N/A**

3.2. ***If non-veterans will be recruited for this study, explain why sufficient veterans are not available to participate in the project [VHA Handbook 1200.5, paragraph 16a]. Veteran's spouses/partners, caregivers, etc. are considered non-veterans for the purposes of this study. **This study is specifically designed to target spousal and adult child caregivers of Veterans with dementia. Thus, these non-Veterans must be recruited for the study.**

3.3. ***Has approval to recruit non-veterans been received from the ACOS/R&D and Medical Center Director?

3.3.1. ☐ Not Applicable

3.3.2. ☒ Pending *(Non-veteran forms should be used. IRB office will obtain approval from ACOS/R&D and Medical Center Director.)*

4. **Does this project target a specific race or ethnic group as participants?** ☐YES ☒ NO
If yes, check all that apply.

Race	
American Indian or Alaskan Native	☐
Asian	☐
Black or African American	☐
Native Hawaiian or other Pacific Islander	☐
Black, not of Hispanic origin	☐
White, not of Hispanic origin	☐
Other	☐

Ethnicity	
Hispanic or Latino	☐
Not Hispanic or Latino	☐
Other	☐

4.1. Provide justification why this/these group(s) was/were chosen. **N/A**

5. **What is the age range of participants?** Check all that apply.

Children (Under 18) Requires Waiver from CRADO (VHA Directive 2001-028, Research Involving Children)	☐
Young Adults (18-21)	☒
Adults (22-65)	☒
Seniors (Over 65)	☒
Over 89	☒
Not Applicable, chart review	☐

6. **Are there specific reasons why certain populations (i.e., age, gender or ethnic groups) are excluded as participants?** ☐YES ☐NO ☒N/A

6.1. If yes, specify reasons.

7. **Does the project require enrollment of the following classes of participants?**

	YES	NO
a. Employees	☐	☒
b. Individuals with impaired decision making capability	☒	☐
c. Pregnant women	☐	☒
d. Economically and/or educationally disadvantaged persons	☐	☒
e. Prisoners	☐	☒
f. Illiterate, limited, or no English language proficiency	☐	☒
g. Terminally ill patients	☐	☒

7.1. If applicable, what is the justification for including any of the above classes of participants in the project? **Although the study is targeted towards non-Veteran, family CGs of Veterans with dementia, we will be collecting medical/pharmacy record data on Veterans using clinical patient records in order to compare utilization and cost across randomization arms. We also need access to Veterans' medical records in order to provide care management for Veterans whose CGs are randomized to the treatment arms.**

7.2. If the project requires enrolling any of the above classes of participants describe any project-specific measures or special considerations, steps, or safeguards to ensure that these individuals are adequately protected. **Due to the fact that the intervention has been designed for CGs of Veterans for dementia, this study requires that Veterans have documentation of a dementia diagnosis in their clinical patient records and/or screen positive for dementia as part of eligibility criteria. We will call the contact number in the Veteran's medical record. Given that the Veterans targeted will have moderate to severe dementia, we do not anticipate that they will be able to communicate effectively over the phone. However, if the Veteran does answer, we will describe the study and ask for the name and contact information of the family caregiver. Thus, in these cases, a verbal assent to contact his/her representative (i.e., CG) will be attained. In addition to verbal assent (or lack of dissent) from the Veteran to contact his/her representative, informed consent will be required from the Veteran's representative who will also qualify as the Veteran's designated CG. Finally, we will ensure the Veterans' confidentiality and privacy by protecting the data collected for this project using the steps outlined below.**

8. **Describe the exact plan how subjects will be identified and recruited for the study.**

8.1. Discuss methods, e.g., referrals from physician offices, clinics, programs, or through advertisements and brochures.

There will be three main recruitment strategies. First, prior to patient recruitment, study staff will meet with clinical staff from primary care (including the geriatric clinic) at both sites, the CMCVAMC Behavioral Health Laboratory (BHL), and VAWNYHS Behavioral Telehealth Center (BTC) and provide a brief overview of the project's aims and procedures. As a reminder, the BHL and BTC are the Primary Care-Mental Health Integration programs at the CMCVAMC and VAWNYHS, respectively. The programs both provide clinical behavioral health assessments for Veterans referred by primary care. Clinical staff from primary care will be asked to refer potentially eligible participants to the Research Coordinator. At the completion of the initial BHL/BTC clinical behavioral health assessment, all patients potentially eligible for the study who also have a dementia diagnosis will be informed of the project and asked if they would be interested in being contacted by a Research Coordinator in order to discuss a study for which they might be eligible in participating. BHL/BTC staff will be asked to document in an electronic database (stored on the shared secure, password-protected MIRECC server that will be made available to both sites) the names and phone numbers of patients who agree to further contact. Second, using data extracted from VINCI, we will prepare a list of

Veterans who have had at least one PACT encounter in the past six months and who are currently being prescribed a cholinesterase inhibitor or memantine medication or who have a diagnosis of dementia in their active problems list. The list will also include each Veteran's respective medical provider. Next, each provider will receive a list of his or her patient names and will be asked to identify any patients who may be eligible for the project, or for whom the provider believes that CG education and support would be a helpful service. Third, we will use data from the Clinical Case Registry to create a list of patients with a diagnosis of dementia and/or are currently being prescribed a cholinesterase inhibitor or memantine medication who have also seen a primary care provider in the last 6 months. As with the list from VINCI, we will contact each provider before contacting the patients. In addition to these three main referral sources, we will also accept referrals from non-VA social workers or other clinicians who are both aware of the project and see Veterans in the community as part of their daily practice. Study staff will not solicit referrals from these clinicians.

Patients referred to study staff through these mechanisms will receive a letter stating that their provider has identified them as someone who might be appropriate for a new program designed to help Veterans with memory problems and their CGs. Within one week of receiving this letter, Veterans and CGs will be called by the Research Coordinator/research assistant to assess interest in participation. We will call the contact number in the Veteran's medical record. If the Veteran answers, we will describe the study and ask for the name and contact information of the family caregiver. The Veterans' identity will be verified by first asking for their full name and the name of their CMCVAMC primary care physician. After telephone discussion of the information in the consent/HIPAA form, and encouraging the asking of questions/concerns, the CG will be asked if s/he gives consent to be enrolled in the study. The Research Coordinator/RA will be using an IRB approved script as well as a checklist to ensure each element of consent is covered. Interested CGs will be mailed a copy of the verbal informed consent form. Non-Veteran caregivers also will receive a Copy of Notice of Privacy Practices, and acknowledgement of its receipt will be noted. Once the consent is fully executed, the Research Coordinator/research assistant will confirm study eligibility by completing the screening assessment. Veteran/CG dyads will be eligible for enrollment if they meet the inclusion/exclusion criteria outlined above. Once eligibility is established, the CG will be randomized to one of the three study arms.

8.2. If using a clinic, be specific about who will identify the potential subject and how that information will be transmitted to the research staff. **As described above, clinical staff from primary care will be asked to refer potentially eligible participants to the Research Coordinator. At the completion of the initial BHL/BTC clinical behavioral health assessment, all patients potentially eligible for the study who also have a dementia diagnosis will be informed of the project and asked if they would be interested in being contacted by a Research Coordinator in order to discuss a study for which they might be eligible in participating. BHL/BTC staff will be asked to document in an electronic database (stored on the shared secure, password-protected MIRECC server that will be made available to both sites) the names and phone numbers of patients who agree to further contact.**

8.3. If snowball method will be used, discuss the process and how the first individuals will be recruited. **N/A**

8.4. Describe how information will be disseminated to subjects, e.g. handouts, brochures, flyers and advertisements *(include all recruitment materials with this submission*). **Patients referred to study staff will receive an introductory letter stating that their provider has identified them as someone who might be appropriate for a new program designed to help Veterans with memory problems and their CGs. The letter is included in the submission.**

9. **Informed Consent**
   - 9.1. Informed Consent will not be sought. ☒
   - 9.2. Written informed consent from participants (VA Form 10-1086 is attached). ☒
   - 9.3. Written informed consent from participants' legally authorized representative (LAR) as required by VA policy and/or applicable state laws (VA Form 10-1086 is attached). ☒
   - 9.4. Request Waiver of Documentation of Informed Consent ☒
   - 9.5. List the **title** of the key personnel involved in the following activities:
     - **9.5.1. Person Obtaining Consent**
       - 9.5.1.1. Provide the title(s) of individual(s) **Research Coordinator, Research Assistant**
       - 9.5.1.2. Type of training received to perform this process **CITI and VA Human Subjects Training; PI will train staff on consent procedures**
     - 9.5.2. **Pre-Recruitment Screening** (the use of medical records and other data bases to determine populations and individuals eligible for the study), **As described above, at the completion of the initial BHL/BTC clinical behavioral health assessment, all patients potentially eligible for the study who also have a dementia diagnosis will be informed of the project and asked if they would be interested in being contacted by a Research Coordinator. Second, using data extracted from VINCI, we will prepare a list of Veterans who have had at least one PACT encounter in the past six months and who are currently being prescribed a cholinesterase inhibitor or memantine medication and/or have a diagnosis of dementia in their active problems list. The list will also include each Veteran's respective medical provider. Each provider will receive a list of his or her patient names and will be asked to identify any patients who may be eligible for the project, or for whom the provider believes that CG education and support would be a helpful service. Third, we will use data from the Clinical Case Registry to create a list of patients with a diagnosis of dementia and/or who are currently being prescribed a cholinesterase inhibitor or memantine medication who have also seen a primary care provider in the last 6 months. As with the list from VINCI, we will contact each provider before contacting the patients.**
     - 9.5.3. **Recruitment Process** (the process in which individuals are contacted and first introduced to the study and to the possibility of participating as subjects), **Patients referred to study staff will receive a letter stating that their provider has identified them as someone who might be appropriate for a new program designed to help Veterans with memory problems and their CGs. Within one week of receiving this letter, Veterans and CGs will be called by the Research Coordinator/research assistant to assess interest in participation.**
     - 9.5.4. **Informed Consent Process** (the process by which recruited subjects are fully informed about participating in the study and then formally give their voluntary consent for participating),

       Because the referred patients will be known to have moderate to severe dementia, and in consideration that this is primarily a telephone-administered, CG-based intervention, we have chosen to pursue verbal informed consent only with the patient representative/CGs. We will call the contact number in the Veteran's medical record. Given that the Veterans targeted will have moderate to severe dementia, we do not anticipate that they will be able to communicate effectively over the

phone. However, if the Veteran does answer, we will describe the study and ask for the name and contact information of the family caregiver. Thus, in these cases, a verbal assent to contact his/her representative (i.e., CG) will be attained.

After telephone discussion of the information in the consent/HIPAA form, and encouraging the asking of questions/concerns,the CG will be asked if s/he gives consent to be enrolled in the study. The Research Coordinator/RA will be using an IRB approved script as well as a checklist to ensure each element of consent is covered. Interested CGs will be mailed a copy of the verbal informed consent script. Non-Veteran CGs also will receive a Copy of Notice of Privacy Practices, and acknowledgement of its receipt will be noted. In all cases, the investigators view the process of informed consent as an ongoing process that continues throughout participation in the study. Digital recordings of consent (which were part of study protocol in the past) will be stored on VA servers behind secure firewalls and maintained in accordance with the medical center policy for records and patient/CG information will be entered onto the study-specific electronic tracking spreadsheet which will be stored on the shared MIRECC secure, password-protected server and made available only to study staff. Paper copies of the consent checklist with only a recruitment ID number will be stored in the CHERP suite in the annex. Both the electronic ICF data will be kept separate from any coded, de-identified data.

9.5.5. **Screening of Recruited Subjects** (those activities in the protocol in which a final determination of eligibility of prospective subjects is made during the early phases of the study, using laboratory data, inclusion and exclusion criteria, and other person-specific information), **Once the consent is fully executed, the Research Coordinator/Research Assistant will confirm study eligibility by completing the screening assessment. Veteran/CG dyads will be eligible for enrollment if they meet the inclusion/exclusion criteria outlined above. Specific screening assessments include: AD8, Zarit Burden Interview.**

9.5.6. Include the breakdown of each individual's responsibilities:

9.5.6.1. Principal Investigator, **Ensure participant privacy and confidentiality; Oversee and ensure quality of all aspects of consent process (including periodic audits); Obtain and document consent when needed**

9.5.6.2. Co-Principal Investigator, **Ensure participant privacy and confidentiality; Oversee and ensure quality of all aspects of consent process (including periodic audits)**

9.5.6.3. Research Coordinator, **Ensure participant privacy and confidentiality; Oversee and ensure quality of all aspects of consent process (including periodic audits); Obtain and document consent; All other consent-related activities (e.g., screening), as described above**

9.5.6.4. Additional research staff by title, **Research Assistant-obtain and document consent, ensure participant privacy/confidentiality; All other consent-related activities (e.g., screening), as described above**

9.6. Will informed consent be obtained from potential subjects prior to determining eligibility?
☒YES ☐NO ☐N/A

9.6.1. If no, provide justification and a HIPAA Waiver of Individual Authorization for Disclosure of Protected Health Information.

9.7. Define when a subject is enrolled into the study, e.g. after the subject signs the informed consent or after randomized to treatment. **Subjects are enrolled in the study after randomization to one of the three treatment arms and completion of the baseline interview**

9.8. Describe:

9.8.1. The process when informed consent will be obtained and protecting patients' privacy. **Digital recordings of consent (which were part of the study protocol in the past) will be stored on VA servers behind secure firewalls and maintained in accordance with the medical center policy for records and patient/CG information will be entered onto the study-specific electronic tracking spreadsheet which will be stored on the shared MIRECC secure, password-protected server and made available only to study staff. The electronic ICF data will be kept separate from any coded, de-identified data. Paper copies of a consent checklist with only a recruitment ID will be kept in a binder in a locked filing cabinent in the CHERP suite in the annex.**

9.8.2. Any waiting period between informing the prospective participant and obtaining consent. **There will be a short period of time between contacting the CG via mail and obtaining verbal informed consent.**

9.8.3. Steps taken to minimize the possibility of coercion or undue influence. **Potential participants/representatives/CGs will be made aware of the fact that they do not have to take part in this study, and their refusal to participate will involve no penalty or loss of rights to which they or the Veteran are entitled.**

9.9. Provide the language

9.9.1. used by those obtaining consent **English**

9.9.2 understood by the prospective participant or the legally authorized representative **English**

9.10. Provide location where informed consent will be obtained. **Research offices of the CMCVAMC CHERP (Annex, Suite 202) or VAWYNS Center for Integrated Healthcare (Bldg 20, 1st floor, Room 128)**

10. **Waiver or Alteration of Informed Consent Requirements/Waiver of Requirement to Obtain Documentation of Informed Consent**

10.1. Are you requesting a waiver or alteration of informed consent? *(Check all that apply)*

10.1.1. No ☐

10.1.2. Yes; provide justification. ☒ **In order to utilize Veterans' medical records for the purpose of identifying potentially eligible participants and recruitment, we will request a waiver of all elements of informed consent, including HIPAA. We also will request a waiver of all elements of informed consent/HIPAA in order to extract Veterans' medical record data for research purposes. Without the waiver, we cannot verify the Veterans' dementia diagnosis or extract and analyze clinical data, as only their representative/CGs are consented and enrolled. Moreover, without access to Veterans' names, phone numbers, and addresses prior to their assent, we cannot contact potentially eligible participants for the initial screening and assent process. We also need access to medical records in order to determine the association between study assignment and medical utilization and cost. Finally, given that the Care Manager will work with the CG and providers to help address any medical/social service needs the Veteran may have, it is necessary to have access to these data. We also are seeking a waiver of documentation of informed consent for CG participants in this study.**

This minimal risk study will be performed completely over the phone. We have learned from experience that requesting that CGs (many of whom are themselves frail and aged) sign and return consent forms causes significant delays in recruitment so that the study cannot be practicably completed within the allotted timeframe. If approved, CGs, will instead participate in a telephone consent process..

10.1.3. Yes; for recruitment purposes only. ☐

10.1.3.1. An IRB may approve a consent procedure which **does not include, or which alters**, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- ☒ 1. The research involves no more than minimal risk to the subjects;
- ☒ 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- ☒ 3. The research could not practicably be carried out without the waiver or alteration; and
- ☒ 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- ☐ 5. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  a. Public benefit or service programs;
  b. Procedures for obtaining benefits or services under those programs;
  c. Possible changes in or alternatives to those programs or procedures; or
  d. Possible changes in methods or levels of payment for benefits or services under those programs.

10.2. **Are you requesting a waiver to obtain documentation of informed consent?**

10.2.1. No ☐

10.2.2. Yes; provide justification. ☒

10.2.2.1. An IRB may **waive the requirement for the investigator to obtain a signed consent** form for some or all subjects if it finds either:

- ☐ 1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- ☒ 2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- *NOTE: In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.*

R. **Compensation** *(The amount of compensation may not constitute an undue inducement to participate in the research.)*

1. Summarize any financial compensation that will be offered to subjects. **Participants will receive up to a total of $50.00 for their participation in the project.**
2. Provide the schedule for compensation. **There are 4 potential periods for compensation.**
   2.1. Per study visit or session. **$20 for baseline assessment, and $10 for each completed follow up research assessment (i.e., 3, 6, and 12 month follow up)**
   2.2. Total amount for entire participation. **Up to $50.00**
3. Explain how compensation will be provided via cash, voucher, gift card, etc. **Compensation will be distributed in the form of a check sent by mail following the schedule outlined above.**
4. If financial compensation will be prorated, explain the process. **N/A**
5. Not Applicable - ☐

S. **Withdrawal/Early Withdrawal**

1. Describe how and when a subject may withdrawal from the study. **Participants will be made aware that they may withdraw from this study at any time during the course of the research/care management assessments/visits without penalty or loss of VA or other benefits to which they are entitled. If a patient chooses to withdraw from the study, a note will be made in their study file.**
2. Provide procedures for the orderly termination of participation by the participant and if any consequences would result from early withdrawal from the study. **N/A**
3. Explain if survival data is required. If so, clarify how data will be obtained. **N/A**
4. Not Applicable; subjects not recruited; chart review. ☐

T. **Risk/Benefit Assessment**

1. **Potential Study Risk**s
   1.1. Describe and assess all of the following risks that may be associated with the research:
      1.1.1. Physical **N/A**
      1.1.2. Psychological **There is a small risk of some inconvenience and/or anxiety due to the time required to complete questionnaires. There also is a small risk that being asked questions about some psychological concerns and/or social interactions with network members may lead to some uncomfortable feelings.**
      1.1.3. Social **N/A**
      1.1.4. Economic **N/A**
      1.1.5. Monetary **N/A**
      1.1.6. Legal **N/A**
      1.1.7. Loss of confidentiality **Given the use of CGs' self-report data and Veterans' clinical patient records, the main risk associated with participating in this study is potential breach of confidentiality.**
      1.1.8. Assess the likelihood and seriousness of such risks. **The proposed research/clinical assessment batteries include standardized, well-validated measures of sociodemographic variables, patient- and caregiver-characteristics, and psychosocial functioning. Thus, in light of the relatively non-invasive nature of the study, we do not foresee any serious risks. Given the procedures set forth to protect participants' confidentiality, we also do not foresee a high likelihood of loss of confidentiality.**
      1.1.9. Other
   1.2. Specify what steps will be taken to minimize these risks. **To minimize any risk, no matter how minimal, participants will be reminded that they do not need to answer any questions that they feel uncomfortable with and that may choose to cease their participation in the research assessment at any time.**

1.3. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used. **N/A**

1.4. If chart review, breach of confidentiality is always a concern. Specify what steps will be taken to minimize these risks. **Procedures for protecting against or minimizing potential risks to participants' privacy or confidentiality over the course of data collection, storage, management, and analysis will be guided by our past work with similar research methods and participants as those proposed here. Procedures include: 1. formal training sessions for all research staff emphasizing the importance of confidentiality; 2. specific procedures developed to protect CRs'/CGs' confidentiality, and 3. formal mechanisms limiting access to information that can link data to individual respondents.**

During collection of research assessment data, care management calls, and TEP group calls, we will ask CGs whether they are in a private, comfortable setting and if they are assured that their responses are not being monitored by another person. The data collection records and any collected PHI will remain confidential. Upon providing informed consent, CGs will be assigned a random Study ID number/code, absent of any personal or identifying information. Hence, all research and clinical data used in analyses will be coded and identifiable. In order to ensure participant privacy and confidentiality, this Study ID number will be used on all electronic research datasets, and in cases where CGs prefer to complete the research assessments at home, on data collection forms. Digital audio files created during the TEP group sessions also will be coded with the Study ID number. Group members involved in the calls will only be referred to by their first names. Only the PI/Co-PI will review the audio files for supervision and feedback purposes. All coded electronic dataset(s) will be located on a shared VA folder created on the MIRECC's secure, password-protected server. Any hard copies of records that contain direct subject identifiers (e.g., name, assessment dates) will be stored in a separate locked filing cabinet in the Care Manager or PI/Co-PI's office at each site. Moreover, forms with identifiable information will be kept separate from de-identified data forms, which will only be labeled with the participants' Study IDs. Only the PI/Co-PI and research staff at each site will have access to these files, except in the case where the VA IRB and other federal regulatory agencies request access for auditing purposes.

To further ensure Veterans' and CGs' privacy, the clinical databases that include Veteran/CG PHI and identifiers (e.g., first, middle, last names; SSN's; addresses and phone numbers; date of birth; age over 90 years; ID numbers/medical record numbers; and dates/procedural codes associated with health service utilization and pharmacy records) extracted from VINCI will remain in the designated study folder on the VINCI secure server. All data retreived from the Clinical Case Registry will be located on the MIRECC secure, password-protected server. At the point of conducting analyses, a separate research database will be created, de-identified of any personal or identifying information (i.e., all fields with PHI or identifiers will be removed), and kept in a separate password protected file on the shared VA folder created on the MIRECC server. We will merge this file with the self-report research and care management assessment data. To protect confidentiality during the course of coding, cleaning, and analyzing data, we will use these coded, merged research databases. The PI and biostatisticians will be primarily responsible for analyzing the data, and all data entry and analysis will take place on the MIRECC server using the coded databases. To facilitate data tracking and monitoring, the PI and her designee will maintain, under a limited password, a lookup database that links the research database to the original clinical databases with PHI in the event that identification of the individual Veteran is necessary. The lookup database linking the study IDs and PHI will be

kept on the designated study folder on the VINCI server and routinely monitored by the PI.

2. **Potential Study Benefits**
   2.1. Assess the potential benefits to be gained by the individual subject, as well as benefits that may accrue to society in general as a result of the planned work. **There are no guaranteed benefits to participating in the proposed study. However, if assigned to one of the intervention arms (e.g., individual TEP + individual care management, group TEP + individual care management), CGs might benefit from the psychoeducation, monitoring, resource connection, and coaching that the Care Manager provides. CGs assigned to the group TEP + individual care management arm might also benefit from receiving mutual support and feedback from peers. CGs of CRs with dementia, as well as society in general, may ultimately benefit from an examination of the comparative effectiveness of the intervention arms as such an analysis will expand what is known about the potential effectiveness of brief, patient/CG centered, telephone-delivered CG interventions.**
   2.2. If the subject does not receive any direct benefit, then it must be stated here and in the consent form. **There are no guaranteed, direct benefits.**

3. **Alternate Procedures**
   3.1 Describe the alternatives available to the subject outside the research context. **The alternative to subjects is to receive usual care made available to Veterans at the two centers.**
   3.2 If none, state that the alternative is not to take part in this research study at all.

U. **Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) (**All Phase III studies are required to have a DSMB. *However, the IRB has the right to require a DSMB with any study.)*

1. **Will an independent DSMB or DMC oversee the project?** ☐YES ☒NO ☐N/A
   2.1. If yes, please provide contact information for the DSMB or DMC or Coordinating Center Representative and attach a copy of the charter.
   Name: Phone Number:
   Title: E-mail**:**

2. **If a DSMB or DMC will not monitor this study, who will monitor this study? Check all that apply.**
   ☒ Principal Investigator
   ☐ Sponsor
   ☐ VA Cooperative Studies Program
   ☐ Safety monitoring committee

V. **Data Monitoring** (*Monitoring plans describe how a monitor, independent of the study team, regularly inspects study records to ensure the study is adhering to the study protocol and applicable research regulations and CMCVAMC requirements. Monitoring plans do not necessarily require the use of an independent Data and Safety Monitoring Board (DSMB). Such independent boards are usually reserved for high-risk phase I studies, or large, multi-center phase III trials. Federally funded studies may require the use of an independent DSMB.)*

1. **Describe the data monitoring plan.** (All protocols must have a data monitoring plan appropriate for the potential risks and the complexity of the study.) **Given the primarily survey- and clinical record-based nature of this project and the minimal risks associated with participation, the PI, Co-PI, and project Medical Director, Dr. Streim (Co-I), will be the primary sources for data quality monitoring. Other clinician Co-Investigators as well**

as members of faculty at both sites will be asked to provide on an *ad hoc* basis consultation regarding: 1) consent/assent procedures, 2) data collection issues, 3) risks associated with disclosure of confidential information, and 4) ongoing monitoring of participant progress, especially regarding potential adverse events. The PI/Co-PI and the research team will meet in-person/virtually every week (and more frequenty, if needed) to discuss recruitment, retention, breaches in confidentiality, adverse events and any issues with data collection. A random subset of interviews will be reviewed for accuracy and completeness. Any occurrence of distress or difficulty or any breach of subject confidentiality at any point during the study will be recorded in the subject's file.

2. **Describe how protocol deviations, adverse events, serious adverse events, breaches of confidentiality, unanticipated adverse device effect (UADE), and unanticipated or unexpected problems will be reported to the CMCVAMC IRB and sponsor**. *(Refer to the CMCVAMC IRB Standard Operating Procedure (SOP) Manual for reporting guidelines.)* **All protocol deviations, breaches of confidentiality, adverse events or other problems will be identified and reported to the local site's IRB, Privacy Officer, and/or Information Security Officer after discovery, as stipulated by regulations. Non-serious adverse events and anticipated adverse events and problems will be logged and discussed with the Medical Director in the routine clinical supervision of clinical staff. The Medical Director will initiate review of concerns arising from the ongoing review of non-serious and anticipated adverse events that appear to impact the study/risk ratio on an ad hoc basis. The PI/Co-PI will formally assess the impact of the aggregate of events(s) and comment on the implications for future participants and the need for changing the risk to benefit ratio of participating in the study. All serious adverse events and non-serious unexpected events will be reported to the PI/Co-PI and IRB in accordance with Good Clinical Practice Guidelines and IRB Regulations. Severe adverse events (SAEs) (e.g., hospitalization, death), will be reported to the PI/Co-PI within 24 hours and to the IRB within 48 hours. Unexpected adverse events will be reported to the IRB within 72 hours. Minor and anticipated adverse events and problems will be logged and reported in the annual/continuing review to the IRB.**
   2.1.
      2.1.1. Describe the management of information obtain that might be relevant to participant protections such as:
         2.1.1.1. Unanticipated problems involving risks to subjects or others
         2.1.1.2. Interim results
         2.1.1.3. Protocol modifications

3. **If applicable, define the plan for subjects if research shows results such as:**
   3.1. Depression **CGs experiencing depressed mood or other distress will be encouraged to discuss these feelings with their primary care provider. Additionally, CGs will be given information about potential available resources that can help them identify a licensed psychologist or community mental health center in their area. In cases where CGs report significant depressive symptoms, we will follow the procedures outlined below for suicide and abuse.**
   3.2. Suicide **For any positive response (presence of depression, suicidal ideation, possible safety issues or abuse), the Care Managers/Medical Director/clinically responsible designee will follow procedures for initiating a referral for individualized mental health support, starting with (1) acknowledgement of the distress or safety issue; (2) education about the importance of getting help/not approaching the issue alone; (3) engagement of the CG by the Care Manager or Medical Director/clinically responsible designee to determine if they are willing to accept additional help, and (4) exploring options for help such as referral to a local mental health provider or other appropriate resource. If the Care Manager or**

Medical Director/clinically responsible designee determines that a life-threatening emergency exists, appropriate action may include calling 911 on behalf of the CG. If not an imminent emergency, the CG will be asked if they prefer to contact their own primary care provider for a referral, or if they want the Care Manager or Medical Director/clinically responsible designee to provide guidance in finding a local mental health provider.

3.3. Abuse **In addition to the procedures outlined above, if the Care Manager or Medical Director/clinically responsible designee suspects possible abuse, they will follow local policies and state reporting laws, including reporting the incident to Adult Protective Services when appropriate.**

4. **Statistical Analysis**

4.1. Include statistical power calculations and the assumptions made in making these calculations. **Power calculations were computed for Aims 1 and 2. We assumed the availability of 405 participants that are eligible and agree to participate in the study. For the purposes of the power analysis, we considered 3 outcome measures (CG distress in response to dementia symptoms (RMBPC), CG burden (ZBI), and overall CG mental wellbeing (MCS subscale of VR16)). The power analysis, conducted using PASS v12, was based on the linear mixed effects model that considers the correlation among 4 repeated measures per CG and interactions between intervention group, time and CG type. The power analysis also took into consideration the following additional factors: 1) 10% drop-out; 2) adjusted 2-sided significance level of 0.017 due to multiple outcome measures which is a conservative approach; and 3) 80% power. In Aim 1, the primary interest is the interaction effects between time and intervention group. Assuming a 0.2 standardized decline in outcome within individuals over time, a correlation of 0.75 between repeated measures within an individual, and a total sample size of 360 after 10% drop-out, the study has 80% power to detect a 0.4 effect size {or larger} between the largest and smallest effects associated with intervention groups. In Aim 2, the primary interest is to examine the impact of the CG and CR relationship on outcomes which will be modeled as a three-way interaction between time, intervention group and CG/CR relationship. The power for Aim 2 is estimated using the same assumptions as in Aim 1, but with a sample size of 180. The study has 80% power to detect an effect of 0.66 between intervention groups within one type of CG/CR relationship. From a clinical significance standpoint, an effect of 0.4 equates to a mean of 4.6 (VR16), 3.6 (NPI), and 5.2 (RMBPC) points using data (i.e., SDs) from our pilot work. Of note, prior meta-analytic work suggests that improvements of 0.4-0.5 standard deviations on measures of CG outcomes are considered *clinically meaningful* effects and indicative of "study success", regardless of statistical significance.[1-3] Thus, we are confident that we will have power sufficient to detect clinically meaningful effects.**

4.2. Define plans for data and statistical analysis, including key elements of the statistical plan, stopping rules and endpoints. **Preliminary Analyses: Preliminary descriptive, univariate analyses (e.g., means/standard deviations and frequencies/percentages for continuous and categorical variables, respectively) will be used to examine ranges, distributions, proportions, and potential outliers for all study variables. We will apply appropriate transformations to highly skewed continuous variables (e.g., cost data). One-way analysis of variance (ANOVA) and chi-square analyses will be used to examine the effectiveness of the randomization in balancing the sociodemographic and background variables across study arms. Covariates that are not balanced will**

be treated as confounders and included in final models. All preliminary analyses will be conducted using SAS version 9.3 (SAS Institute, Cary, NC).

Specific Aim 1-Assessing Randomization Group Differences in CG Outcomes: In order to analyze the degree to which randomization group is associated with changes in our three primary outcomes (i.e., CG distress in response to CR dementia-related symptoms, CG burden, and CG mental functioning) over time (Hyp 1A-1C), we will run three separate intent-to-treat, mixed effects linear regression models (using SAS PROC MIXED). Mixed models account for multiple observations and make use of all available data for each CG (regardless of drop-out or missing assessment periods), account for subject-level clustering, and accommodate modeling of contemporaneous and lagged effects and time variant and invariant variables. Specifications for the mixed models will include random effect estimates for intercept and slope (i.e., time) to account for within-individual variability. We will specifically test for group by time interactions. All models will control for baseline scores for the respective outcome and covariates identified during the preliminary analysis phase. It is important note that while these three variables are our primary outcomes, we also will run post-hoc mixed models (including mixed effects logistic models for binary outcomes; SAS PROC NLMIXED) to examine the relative impact of the intervention on other outcomes including CR frequency of NPI and RMBPC symptoms, CR IADL/ADLs, CG engagement in VA and non-VA services, and inpatient/outpatient costs (cost data will be analyzed using a Gamma distribution). Corrections will be made for multiple comparison effects.

Specific Aim 2-Evaluating the Moderating Role of CG-CR Relationship Type: In order to examine the moderating role of CG-CR relationship type on study/intervention engagement (Hyp 2A) and our 3 primary outcomes (Hyp 2B), we will again run the linear and logistic mixed effects models outlined above, and include estimation of random effects for both intercepts and slopes, as well as all main effects, relationship type*time interactions, and relationship type*randomization group*time interactions (i.e., all 2- and 3-way interactions). We also will run logistic regression models examining whether consent and engagement in each of the study arms for eligible CGs varies as a function of relationship type.

Although not a primary aim, we also will run post-hoc analyses examining other potential moderating effects (e.g., ethnicity, employment status, urban vs. rural dwelling). We acknowledge the challenge in employing these more complex, 3-way interaction models, particularly given the anticipated heterogeneity (both in terms of clinical and sociodemographic characteristics) of our sample. While we could have chosen to make our inclusion/exclusion criteria more stringent to minimize these analytic challenges, we feel that the knowledge to be gained from potentially being able to address secondary objectives outweighs any challenges. We will, however, carefully consider these issues and take clinical significance into account when interpreting our results.

W. **Privacy and Confidentiality** *(Privacy refers to persons and to their interest in controlling the access of others to themselves.) (Confidentiality refers to protecting information from unauthorized disclosure or intelligible interception.) (Investigator should contact the Privacy Officer for additional details.)*

1. **Indicate the type of data that will be received by the Principal Investigator. Check all that apply.**
   1.1. ☐ De-identified – Without any identifiers that could link the data to a specific participant. (Contact Privacy Officer for assistance. *If data is coded, it is not considered de-identified.)*

1.2. ☐ Identified – Linked to a specific participant by identifiers sufficient to identify participants. (See HIPAA and Common Rule Criteria for list of identifiers.)

1.3. ☒ Coded – Linked to a specific subject by a code rather than a direct identifier. If coded is checked, specify:

1.3.1 Explain who will maintain the link or code. **The lookup database linking the study IDs and PHI will be kept on the designated study folder on the VINCI server and routinely monitored by the PI and Research Coordinator.**

1.3.2 Describe who will have access to the link or code. **The PI, Co-PI, and Research Coordinator will have access to the link.**

1.3.3 Provide exact details for how the data is coded. **Data for this project will be coded and identifiable. To ensure Veterans' and CGs' privacy, the clinical databases that include Veteran/CG PHI and identifiers (e.g., first, middle, last names; SSN's; addresses and phone numbers; date of birth; age over 90 years; ID numbers/medical record numbers; and dates/procedural codes associated with health service utilization and pharmacy records) extracted from VINCI will remain in the designated study folder on the VINCI secure server. All data from the Clinical Case Registry will be located on the MIRECC sercure, password-protected server.At the point of conducting analyses, a separate research database will be created, de-identified of any personal or identifying information (i.e., all fields with PHI or identifiers will be removed), and kept in a separate password protected file on the shared VA folder created on the MIRECC server. We will merge this file with the self-report research and care management assessment data. To protect confidentiality during the course of coding, cleaning, and analyzing data, we will use these de-identified, merged research databases. The PI and Biostatisticians will be primarily responsible for analyzing the data, and all data entry and analysis will take place on the MIRECC server using the coded databases. To facilitate data tracking and monitoring, the PI and her designee will maintain, under a limited password, a lookup database that links the research database to the original clinical databases with PHI in the event that identification of the individual Veteran is necessary.**

2. **Does the project require the use of existing Protected Health Information (PHI) from a database, medical records, or research records?** ☒YES ☐NO ☐N/A

2.1. If yes,

2.1.1. Specify the source of the existing PHI **VINCI/CPRS, CMCVAMC BHL, and VAWNYHS BTC; Clinical Case Registry**

2.1.2. Indicate the specific data elements/identifiers (e.g., name, address, phone numbers, etc.) on the below table.

2.2. If the study uses an existing database/data warehouse,

2.2.1. Provide a description of the database/data warehouse.

1. CMCVAMC BHL/VAWNYHS BTC: The BHL and BTC are the Primary Care-Mental Health Integration programs at the two respective sites. Data are collected via a software program and saved on secure servers at each location.

2. VINCI: Medical/pharmaceutical utilization, encounter data, and vital status files will be requested and initially exported by the VA Informatics and Computing Infrastructure (VINCI). VINCI is a centralized research data repository that offers consistent, defined, and transparent security and standards for access to data; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter

and more consistent control over the standards and quality of the data included; and the ability to standardize and update terminology and format as technology and methodology improve. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans' data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources will be approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. The designated research staff will access the data in the secure, virtual working environment through a certified VHA network computer using the VA INTRANET. If not working within a VA or VHA hosted office environment containing VA network access, the research staff may access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment will enable analysis of PHI to be done directly on VINCI-CDW servers located at the Austin Information Technology Center, thus keeping all PHI data from being transmitted to local PC hard drives.

3. The Clinical Case Registry is a software tool that draws data from the local VistA system to allow users to generate customized reports on populations with a specific diagnosis/condition.

2.2.2. Make clear who is responsible for maintaining it. **The Austin Information Technology Center maintains VINCI; FITS maintains the BHL/BTC; Population Health Services maintains the CCR.**

2.2.3. Cite any relevant Standard Operating Procedures (SOP) for the database/data warehouse. **Documentation for administrative, clinical, and pharmaceutical data available through VINCI and associated SOP can be easily accessed from their website: http://vaww.vinci.med.va.gov/vincicentral/VINCIPolicies.html**

2.2.4. Provide a copy of the SOP.

3. Will PHI be collected prior to obtaining informed consent? ☒YES ☐NO ☐N/A

3.1.1. If yes, complete and provide a HIPAA Waiver of Individual Authorization for Disclosure of Protected Health Information with this submission.

4. HIPAA Identifiers - Indicate the PHI that will be collected from project participants directly or indirectly.

4.1. ☒ Name

4.2. ☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census

4.3. ☒ All elements of dates (except year) for dates directly related to an individual, and all ages over 89 and all elements of dates (including year) indicative of such age, except

that such ages and elements may be aggregated into a single category of age 90 or older.

4.3.1. ☒ Birth Date ☒ Date of Death
4.3.2. ☒ Discharge date ☒ Admission date
4.3.3. ☒ Appointment Dates ☐ Other Dates (e.g. lab tests, x-rays, MRI, etc.)

4.4. ☒ Telephone numbers
4.5. ☐ Fax numbers
4.6. ☐ Electronic mail addresses
4.7. ☒ Social Security Number
4.8. ☐ Medical record numbers
4.9. ☐ Health plan beneficiary numbers
4.10. ☐ Account Numbers
4.11. ☐ Certificate/license numbers
4.12. ☐ Vehicle identifiers and serial numbers, including license plate numbers
4.13. ☐ Device identifiers and serial numbers
4.14. ☐ Web universal resource locators (URLS)
4.15. ☐ Internet protocol (IP) address numbers
4.16. ☐ Biometric identifiers, including fingerprints, voiceprints, audio recordings
4.17. ☐ Full-face photographic images and any comparable images
4.18. ☐ Any other unique identifying number, characteristic, or code
4.19. ☐ Personal and Family History
4.20. ☒ History and Physical Examination ☐ Progress Notes
4.21. ☐ Discharge Summary(ies) ☐ Photographs, videotapes, other images
4.22. ☐ X-Ray ☐ HIV (testing or infectious disease) records
4.23. ☒ Diagnostic/Laboratory tests ☐ Sickle cell anemia
4.24. ☐ Drug Abuse Information ☐ Behavioral Health notes
4.25. ☐ Alcoholism or Alcohol Use ☐ Operative Reports
4.26. ☐ Billing records ☒ Medication List
4.27. ☐ Health Summary Reports ☐ Anatomic Pathology Report
4.28. ☐ Other Records:

5. Will participants be contacted from existing PHI? ☒YES ☐NO ☐N/A
   5.1. If yes, clearly explain how participants will be contacted (NOTE: this would be the same information as listed under section R.8 identification and recruitment of subjects). **Patients referred to study staff will receive a letter stating that their provider has identified them as someone who might be appropriate for a new program designed to help Veterans with memory problems and their CGs (this will require names and addresses and review of clinical/pharmacy patient records). Within one week of receiving this letter, Veterans and CGs will be called by the Research Coordinator/Research Assistant to assess interest in participation (this will require phone numbers).**

6. Provide the titles of the exact individuals who will have access to the collected data. **The PI, Co-PI, Research Coordinator, Research Assistant, Care Managers, and Medical Director will have access to the data.**
   6.1. Explain why these individual will have access to this data. **Study staff will need access to the data in order to verify that patients meet inclusion/exclusion criteria and to follow-up with CGs regarding scheduling. Data on Veteran medication/medical use will be collected for research and care management purposes. Data will also be made available to the CMCVAMC IRB staff, Research Compliance Officer, Research Compliance staff, and all other federal regulatory agencies for auditing purposes.**

X. **Information Security** (*Contact the Information Security Officer for additional assistance regarding confidentiality (storage/security) of research data.)*

1. Provide the precise plan how data is to be collected or acquired (repeat the same information as listed under "Data Collection" section of this form. **Data will be coded and identifiable.**

   Research Assessment and Care Management Data Collection Procedures: The vast majority of research assessment and care management data will be collected by telephone and entered electronically on a password-protected website run by the CMCVAMC's Data Management Unit (DMU) or on the Research Electronic Data Capture website (REDCAP). The DMU is a closed data entry system that has been designed so that only the responsible data entry person and the DMU supervisor can enter and/or edit data. The PIs or research staff from both sites will be able to access and request the data at any point during the study so that audits of the study's current data input can be conducted and the data's integrity assessed. Data will be stored on the CMCVAMC's DMU or REDCAP for the duration of data collection. REDCap is a web-based application for managing data acquisition during clinical research. REDCap is supported by the VA Information Resource Center and is maintained within the VA firewall so that it is only accessible on the VA intranet. REDCap will be used in this study for data entry.

   For participants completing the interview via phone, a blank copy of the assessment will be sent in advance of the scheduled assessment calls to help facilitate the interview. We will ask each respondent whether they are in a safe, private setting and if they are assured that their responses are not being monitored in order to ensure candid responding. Research assessment data also will be collected using hard copy, paper versions of the data forms should the CG prefer to complete the research assessment on their own. The paper versions will be created using Cardiff Teleform software and mailed to CGs along with a stamped return envelope.

   Medical and Pharmaceutical Claims Data Collection Procedures: We will work with VINCI in order to expedite chart extraction of clinical data including VA and, where possible, non-VA medical/pharmaceutical, encounter, and fee information, as well as mortality status of the care recipients. When estimating non-VA utilization/cost of care (e.g., community nursing home care, home-based care, etc.), we plan to follow HERC's guidebook which provides detailed documentation and suggestions for extracting and analyzing data on cost and procedures.[6] The database will also include a "time window" variable spanning one year prior to and one year following the 3 month research assessment. Specifically, we will ask for stop codes, ICD-9/DSM-IV codes, CPT codes, and pharmacy fill dates/days supply. We also will separately consider high cost health care utilization (e.g., ER visits, walk-in clinic visits, inpatient stays) and utilization of scheduled primary and specialty care services. Extracting clinical patient record data electronically will greatly improve validity and reduce respondent burden.

2. Provide a listing of the exact research data that will be stored, including but not limited to signed, original informed consent and HIPAA authorization forms, case report forms, etc. **care management forms**
3. Indicate how project's research data (original and all copies) will be stored and provide corresponding security systems. **Any hard copies of records that contain direct subject identifiers (e.g., name, assessment dates) will be stored in a separate locked filing cabinet in the Care Manager or PI/Co-PI's office at each site. Moreover, forms with identifiable information will be kept separate from de-identified data forms, which will only be labeled with the participants' Study IDs. Only the PI/Co-PI and research staff at each site will have access to these files, except in the case where the VA IRB and other**

federal regulatory agencies request access for auditing purposes. Electronic data will be saved on either the VINCI or MIRECC secure, password protected servers.

4. CMCVAMC, provide exact location where research data (original and all copies) will be stored and secured. **Hard copies = CMCVAMC CHERP Electronic data = V:\\VHAPHIFPCMIRECC\External Shares\Buffalo ACES and VINCI study folder (address will be assigned once the project is registered with VINCI).**

5. Explain how data is to be transported or transmitted from one location to another. **No hard copies of data will be transmitted off-site; electronic data will be shared across sites using a shared folder on the MIRECC server.**
   - 5.1. Informed Consent discloses PHI transported or transmitted off-site. ☐YES ☐NO ☒N/A
   - 5.2. HIPAA Authorization discloses entities to whom PHI will be transported or transmitted. ☐ YES ☐NO ☒N/A
     - 5.2.1. List all entities or individuals outside CMCVAMC to whom data is to be disclosed, and the justification for such disclosure and the authority. **N/A**
   - 5.3. If yes, list the exact data that will be transmitted. **N/A**
   - 5.4. If yes, explain how data will be protected during transmission outside of CMCVAMC. **N/A**
   - 5.5. Off-site, provide exact location **N/A** (If off-site, attach at least one of the following.)
     - 5.5.1. Data Use/Transfer Agreement ☐YES ☐NO ☒N/A
     - 5.5.2. Off-Site Storage/Transfer of Research Data ☐YES ☐NO ☒N/A
     - 5.5.3. Memorandum of Understanding ☐YES ☐NO ☒N/A
     - *5.5.4. (Note: VA data disclosed to a non-VA investigator at an academic affiliate for research purposes needs to be approved by the Under Secretary of Health or designee.)*

6. List who is to have access to the data and how they are to access it (anyone who has access to the data is responsible for its security). **All research staff will have access to the data. Access to electronic data will require logging on to the MIRECC server using VA-furnished computers. Hard copies of data will be saved in locked cabinets.**

7. Describe who is to have access and be responsible for the security of the information (e.g., the Coordinating Center, the statistician, and PI who has ultimate responsibility). **All research staff will be responsible for the security of the data. The PI will have ultimate responsibility.**

8. Provide mechanisms used to account for the information. **The PI will routinely review the electronic research databases and security of the filing cabinets to ensure that there are no breaches of confidentiality. However, again, given the nature of the study and the fact that the majority of the PHI data will remain on the MIRECC/VINCI servers, we do not anticipate that this is a significant risk.**

9. Give security measures that must be in place to protect individually identifiable information if collected or used. **To ensure patient privacy and confidentiality, all data required for research purposes extracted from the BHL, BTC, and VINCI clinical databases will be entered into research databases and saved on the VINCI/MIRECC server. To safeguard the protection of Veterans' data, the MIRECC, BHL, BTC, and VINCI maintain compliance with the guidelines, policies, and regulations set forth by the Veterans Health Administration (VHA). Research databases containing clinical data will be stripped of identifiers (e.g., name, address) and coded with the numerical study IDs described above. To protect confidentiality during the course of cleaning and analyzing data, we**

will use these research databases. To facilitate data tracking and monitoring, the PI and her designee will maintain, under a limited password, a unique ID number for each subject in the research database. This unique number will be used as the code that links the research database to the original databases with PHI in the event that identification of the individual patient is necessary. The lookup database linking the unique IDs and PHI will be kept on the MIRECC server and routinely monitored by the PI. Hard copies of PHI extracted for the purposes of this project will under no circumstances leave the CMCVAMC.

10. How and to whom a suspected or confirmed loss of VA information is to be reported. **Should there be any breaches of confidentiality, improper use or disclosure, or deviations to the protocol during this process, the Principal Investigator will report these incidents to the IRB, Associate Chief of Staff for Research, and Research Compliance Officer, as appropriate. All breaches of confidentiality will be immediately reported to the Information Security Officer and Privacy Officer. In order to protect participants' privacy and confidentiality, we will follow the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws when handling participants' data. Protocol deviations, serious adverse events, and breaches of confidentiality will be communicated to the IRB as required by their guidelines.**

11. Identify any circumstances that may warrant special safeguards to protect the rights and welfare of subjects who are likely to be vulnerable including, but not limited to, those subjects who may be susceptible to coercion or undue influence, and describe appropriate actions to provide such safeguards. **N/A**

12. Electronic PHI will be stored on the following:
    - 12.1. CMCVAMC desktop computer with password protection and/or encryption. ☐YES ☒ NO ☐N/A
      - 12.1.1. If yes, identify where the desktop is located.
    - 12.2. CMCVAMC secure server. ☒YES ☐NO ☐N/A
      - 12.2.1. If yes, identify the CMCVAMC server. **MIRECC server (V:\\VHAPHIFPCMIRECC\External Shares\Buffalo ACES)**
      - 12.2.2. External drive that is password protected and/or encrypted. ☐YES ☒NO ☐ N/A
        - 12.2.2.1. If yes, identify the external drive.
    - 12.3. Off-Site server ☐YES ☒NO ☐N/A (<u>If off-site, attach at least one of the following.)</u>
      - 12.3.1. Provide exact location and the name of the <u>off-site</u> server. **VINCI-CDW server (VhacdwRB02.vha.med.va.gov);**
      - 12.3.2. Data Use/Transfer Agreement ☐YES ☐NO ☒N/A
      - 12.3.3. Off-Site Storage/Transfer of Research Data ☐YES ☐NO ☒N/A
      - 12.3.4. Memorandum of Understanding ☐YES ☐NO ☒N/A

13. Explain how data is to be transported or transmitted from one location to another. **N/A**

14. Informed Consent discloses PHI transported or transmitted off-site. ☐YES ☐NO ☒N/A

15. HIPAA Authorization discloses entities to whom PHI will be transported or transmitted. ☐YES ☐NO ☒N/A

16. List all entities or individuals outside CMCVAMC to whom data is to be disclosed, and the justification for such disclosure and the authority. **The Co-PI and research team at the VAWNYHS Center for Integrated Healthcare (this is a two-site study, hence they will have to access the electronic files)**

17. Clarify what protection exists for a database.
    17.1. Data is stored:
        17.1.1. With identifiers - ☒YES ☐NO
        17.1.2. Coded - ☒YES ☐NO
        17.1.3. De-Identified - ☐YES ☒NO
        17.1.4. Provide the exact list of identifiers that will be stored. **name, address, telephone number, all elements of dates related to an individual (e.g., birthdate, discharge date, etc.), social security number**

18. Describe the plan for protecting research data from improper use or disclosure. **Participant data will be coded and identifiable. Research databases containing clinical data will be stripped of identifiers (e.g., name, address) and coded with the numerical study IDs described above and merged with the research assessment data. To protect confidentiality during the course of cleaning and analyzing data, we will use this merged research database. To facilitate data tracking and monitoring, the PI and her designee will maintain, under a limited password, a unique ID number for each subject in the research database. This unique number will be used as the code that links the research database to the original databases with PHI in the event that identification of the individual patient is necessary. The lookup database linking the unique IDs and PHI will be kept on the MIRECC server and routinely monitored by the PI.**
    18.1. The Investigator must notify the Information Security Officer, Privacy Officer, IRB, Associate Chief of Staff for Research and Research Compliance Officer within one hour of the improper use or disclosure.

19. Is there a plan to apply for a Certificate of Confidentiality? ☐YES ☐NO ☒N/A
    19.1. If yes, provide a copy of the certificate with this application or to the IRB Office as soon as received.

20. **Record Retention**:
    20.1. The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1). VHA Handbook 1200.05 §26.h
    20.2. Until a schedule for local research records is published, ALL records including identifiers must be retained." ORO/ORD Guidance on Informed Consent Form Modifications Addressing VA Record Retention Requirements (July 23, 2009)

    20.3. If there are additional procedures for record retention, explain further. **N/A**

Y. **Qualification of the Investigators**
1. Provide a description of the qualifications of each investigator/co-investigator and their specific role in the study.
PI: Dr. Mavandadi is a Research Health Science Specialist and Investigator at the Philadelphia VA Medical Center (VAMC) and a lead investigator for the VISN 4 Mental Illness Research, Education, and Clinical Center (MIRECC). She is also an Adjunct Assistant Professor of Psychology in Psychiatry at the Perelman School of Medicine at the University of Pennsylvania. She has experience in psychosocial and mental health services research as well as advanced data analysis methods. She is developing her career in understanding psychosocial correlates of behavioral health and caregiver intervention outcomes. Specifically, she is interested in examining the mechanisms by which informal (e.g., family members, friends) and formal (e.g., health care providers) social networks impact health behaviors, engagement, adherence, and treatment

outcomes among individuals with mental health issues. Dr. Mavandadi is well published at this stage in her career and provides a unique mix of methodological and analytic expertise with clinical acumen. She will be primarily responsible for the scope of work. She will supervise and participate in all the proposed activities including staff training, data acquisition, management and analysis, protocol modifications, manuscript preparation, and presentation at conferences. Along with Dr. Wray, she will hold final responsibility and authority over all scientific, financial, and organizational aspects of this project. She will devote 25% time and effort (3 calendar months) during each year of this project.

Co-PI: Dr. Wray is the Director of the Education/Clinical Core of the VISN 2 Center for Integrated Healthcare (CIH). She has many years of experience in clinical program development and, more recently, multi-site investigations and clinical demonstration projects. Dr. Wray is also supported by Mental Health QUERI as a mentee of Dr. JoAnn Kirchner and a graduate of the CIPRS field training on Implementation Science. She also sits on the VISN 2 Dementia Steering Committee. Further, as chair of the newly formed National PC-MHI Education and Steering Committee, Dr. Wray is well positioned to lead the study in ways that are consistent with the needs of VACO Office of Mental Health Services (OMHS) clinical partners. As Co-PI, Dr. Wray will oversee all scientific and organizational aspects of this project. She will supervise all aspects of the study including recruitment and protocol modifications. She will meet with the staff regarding protocol implementation as well as scientific discussion relevant to the project. She will also provide clinical supervision for the Care Managers. Along with Dr. Mavandadi, she will direct the data analyses and write the major publications from the project. She will review all reports of adverse events and report them to the IRB according to the protocol. She will devote 20% effort (2.4 calendar months) during each year of this project.

2. If applicable, the Principal Investigator must identify a qualified clinician to be responsible for all study related healthcare decisions. **Dr. Laura Wray (Co-PI); Dr. Joel Streim (Project Medical Director)**
3. PI should submit a current, dated CV with each new initial review.