Caregiver SOS: An Intervention for Employed Caregivers

NCT04337021

December 27, 2023

Application and Submission Instructions (IRB Form 101)

DO NOT CHANGE THE FORMATTING OF THIS DOCUMENT.
DO NOT USE THIS FORM ON A MAC; IT WILL CHANGE THE FORMATTING OF THIS DOCUMENT, WHICH WILL MAKE IRB REVIEW MORE DIFFICULT AND LENGTHIER.

☐ - FOR CHECKBOXES - DOUBLE CLICK THE BOX - CHOOSE 'CHECKED'; HIT OK.

[ ] - FOR TEXT BOXES - CLICK IN SHADED BOX AND TYPE.

The Principal Investigator (PI) is required to use this form to submit new research projects to the IRB. This form is to be used when there is interaction with human subjects.

Each section of the application requires a response.

Ensure all responses are consistent with the approved funded project, the informed consent, and the HIPAA Authorization, if applicable. **Ensure all sections of the application are completed or marked "Not Applicable."**

One single-sided hard copy of this application form must be submitted to the IRB Office with ALL required signatures.

The **electronic version** sent to the IRB Coordinator **must** be **Word** documents, **unless** the form is already a PDF.

This application form was designed to be self-explanatory with embedded instructions and guidance to follow as the form is being completed. However, if any questions arise as the form is being completed, contact one of the IRB Coordinators, Eileen.McCarthy-Dorsey@va.gov or Joan.Havey@va.gov.

THERE MAY BE OTHER DOCUMENTS YOU WILL NEED FOR YOUR PROJECT, SUCH AS THE RESEARCH STAFF FORM, INFORMED CONSENT, HIPAA AUTHORIZATION/REVOCATION FORMS, ETC., WHICH CAN BE OBTAINED FROM
Eileen.McCarthy-Dorsey@va.gov or Joan.Havey@va.gov

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SECTION 1: PI'S INFORMATION

Project Title: *Caregiver SOS: An Intervention for Employed Caregivers*	**Initial** ☒ **Revised** ☐ **CMCVAMC Version Date/Version #:** **10/27/2023; V12**

1. **Name of Principal Investigator (PI)** *Amy Helstrom*

PI's VA Email:	Amy.Helstrom@va.gov
PI's VA Telephone Number:	215 823 4164
PI's VA Mailing Address:	MIRECC – B228
PI's Other Business Email:	N/A
PI's Other Business Telephone Number:	N/A

2. **PI's Academic Degrees**: *PhD*

2.1. **PI's Board Certifications, if applicable**: *N/A*

3. **PI's Employment Status**: *(Check all that apply)*

☒ VA Employee (#8ths)	8/8ths
☐ Other (VA WOC, IPA)	
Specify Appointment Type:	

3.1. For ORD-funded studies, is the PI at least a 5/8ths VA employee?
Yes ☒ - (skip to question 4) **No** ☐ - (answer question 3.2) **N/A** ☐

3.2. **If the response to 3.1 is no**, is a copy of the ORD funding service approval waiver included as part of this submission*?*
Yes ☐ **No** ☐ - ***If no****, indicate when submitted for approval:*

4. Describe the PI's qualifications to act in the capacity as PI to do the research in this project and attach a copy of his/her biosketch (Merit Review or NIH Format)**:**

The proposed randomized study seeks to evaluate the impact of a novel intervention designed to provide evidence-based, role performance-focused telephonic self-management counseling to employed caregivers of Veterans who have a diagnosis of, or clinically significant symptoms of depression, anxiety, TBI, or PTSD. Given my methodological, substantive, and statistical experience, I hope to serve as the Principal Investigator on the proposed project, devoting 35% time and effort. I have expertise in psychosocial and mental health interventions and services research as well as quantitative and qualitative data analysis methods. My research focuses on the association between psychosocial factors and mental and physical well-being, particularly among individuals with behavioral and neuropsychiatric conditions, with an emphasis on understanding psychosocial correlates of patient and caregiver behavioral health outcomes. I have recently worked on a number of clinical trials that have focused on the comparative effectiveness of different modalities and health service delivery models for the treatment of behavioral health conditions. Specific to this project, I recently served as the PI on a Department of Veterans Affairs-funded pilot clinical intervention trial that evaluated the feasibility and outcomes of a patient/caregiver-centered dementia care management program. Similar to the program proposed in this application, the pilot program emphasized training in caregiver coping and self-management strategies. I also currently serve as a Co-PI on a multi-center, randomized clinical trial comparing the effectiveness of a group vs. individually-delivered collaborative care management program for caregivers of Veterans with dementia. The intervention proposed in this project builds upon, in part, our intervention for caregivers of Veterans with dementia and the PACE/PACENET Supporting Seniors Receiving Treatment and Intervention (SUSTAIN) and Caregiver Research, Education, and Support (CREST) programs (of which I am the PI). As both a PI and a Co-I on other projects, I also have been involved in the study design and analysis of data from studies examining the role of Veterans' caregivers/relationship partners in other contexts (e.g., depression, substance use, Parkinson's

Disease, post-deployment). Past studies have required that I develop and refine intervention material (e.g., caregiver workbooks, training material), manage study teams comprised of research and clinical staff, provide supervision and ensure model fidelity, collaborate with stakeholders, and manage both small and large datasets. Moreover, I have a number of years of experience extracting, managing, and analyzing both VA and non-VA patient level and program data. Thus, I feel I have the organizational, methodological, and analytic experience to successfully lead, manage, and guide all aspects of the proposed project. This includes staff training, data acquisition, management, analysis, and evaluation efforts, program quality and fidelity monitoring, protocol preparation and modifications, and dissemination of study results.

5. Complete the questions below regarding the PI's current research activities:

5.1. What current percentage of the PI time is devoted to research activities? *100%*

5.2. What percentage of the PI's time will be devoted to this project? *35%*

5.3. How many active studies is the PI currently overseeing? *3*

5.4. How many of the above are multisite studies in which the PI is the overall PI? *1*

6. Is/Are there Co-PI (s)? Yes ☐ -(see additional questions below) **No** ☒

6.1. **If yes,** indicate the following for each: **Name**: **Site**:

SECTION 2: PI'S STUDY TEAM INFORMATION

1. **Study coordinator's contact Information.** ☐ **N/A**

1.1. **Name of Study Coordinator**: Marybeth Groot

Study Coordinator's VA Email:	*Marybeth.Groot@va.gov*
Study Coordinator's VA Telephone Number:	*215 823 5800 ext. 203870*
Study Coordinator's VA Mailing Address:	Annex: Suite 202
Study Coordinator's Other Business Email:	*N/A*
Study Coordinator's Other BusinessTelephone Number:	*N/A*

2. Does the above-named Study Coordinator have prior experience coordinating:

2.1. A VA research study? Yes ☒ **No** ☐

2.2. Obtaining informed consent at the CMCVAMC? Yes ☒ **No** ☐

If yes, provide the date study coordinator took the Research Compliance Officer training course. *Circa 2021*

3. Does this project involve a designated Coordinating Center(s)? Yes No ☒

3.1. **If yes**, provide the name of the Coordinating Center(s) and contact information below.

3.1.1. **Name of Coordinating Center**:

3.1.2. **Contact Name (Program Manager or other POC)**:

3.1.3. **Phone Number**: **Email address**:

SECTION 3: PROJECT OVERVIEW

1. **What organization is funding this study?** *(Check all that apply)*

☐ **CSP** ☐ **CSR&D** ☒ **HSR&D** ☐ **RR&D** ☐ **BSLR&D** ☐ **QUERI**

☐ **VHA Central Office** ☐ **Private Nonprofit**: **Please specify**:

☐ **Department of Defense (DoD)** ☐ **Commercial Sponsor**: **Please specify**:

☐ **None;** If none is checked**, provide justification why there is no funding source**.

Funding Agency Project number: *1 I01 HX002824-01A2*

2. **What are the research questions or hypotheses to be studied?**

Aim 1 *is to determine whether a novel intervention, Caregiver Self-Management of Stress (Caregiver SOS, providing evidence-based telephonic work/CG stress self-management counseling, is superior to usual care (UC) in reducing caregiver (CG) psychological distress* ***(primary outcome; Aim 1a)****, and improving ability to function effectively in work and CG roles* ***(secondary outcome; Aim 1b)****. We hypothesize that, compared to CGs in UC, CGs in the intervention arm will have significantly less distress* ***(Hyp. 1a),*** *and a better ability to function effectively in their work and CG roles* ***(Hyp. 1b)****.* ***Aim 2 (Exploratory)*** *is to determine whether, relative to UC, the intervention improves CGs' overall physical health and mental well-being* ***(Aim 2a)****, and CGs' and care recipients' (CRs') access to needed healthcare and social services* ***(Aim 2b)****. We hypothesize that relative to those in UC, CGs assigned to the intervention arm will have higher levels of physical and emotional well-being* ***(Exploratory Hyp. 2a)****. We also hypothesize that CGs/CRs in the intervention arm will report higher utilization of needed services (e.g., CR MH and primary care and CG-related services)* ***(Exploratory Hyp. 2b).***

3. **Describe the relevance to Veterans of studying the above questions or hypotheses and the importance of the knowledge this project is likely to generate:**

Approximately 5.5 million Veterans rely on CGs to help them with their daily care. CGs often cope with stress and strain from CG/work roles. This may be particularly true of CGs of Veterans coping with behavioral health issues related to conditions such as depression, posttraumatic stress disorder (PTSD), anxiety, and traumatic brain injury (TBI). Programs that specifically address caregiving-work role stress may be especially effective in improving CGs' wellbeing and work/financial stability and the quality of Veterans' care. Given this project's focus, it is responsive to multiple ORD and HSR&D priority areas, including long-term care/aging, access to care, mental health/PTSD, and health equity, expanded Veteran/CG access to high quality clinical trials, and legislative priorities such as the MISSION Act, which emphasizes research on new models that support and benefit both Veterans and CGs and maximize the ability of Veterans to age in place.

4. **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	☐ Other *(Specify)*:

5. **Does the project involve usual care? Yes** ☒ **No** ☐ - **If no,** skip to question 6.

5.1. **If yes,** answer the following additional questions:

5.1.1. Who will provide the usual care, i.e., the study team or the participant's health care provider? *With the exception of 1 phone call by a study CM, CGs' (and Veterans') health care provider (please see 5.1.2. below for details of usual care)*

5.1.2. **Clearly differentiate what is usual care and what procedures and/or interventions are being performed solely for research purposes. Indicate if usual care is limited to one arm of the study or if it is being delivered to all participants**:

Research procedures: *CGs randomized to the intervention arm will participate in the CG SOS program. SOS care is a comprehensive approach to helping CGs gain the knowledge, skills and confidence to achieve success in stress self-management. The intervention concept was developed by Dr. Debra Lerner and her research group and adapted for the VA context. Through a range of techniques, CGs develop abilities to modify psychological and social sources of stress, including the stress associated with performing both caregiving and work roles. SOS care is brief, telephonic care (6 one-hour sessions over 3-4 months) offered during either work or non-work hours, and tailored to the CG's needs, preferences, and priorities. Supportive visual aids and CG workbook material are distributed via mail or email. SOS is delivered by SOS-trained VA CMs; clinicians with a Master's degree or higher in Social Work or Psychology. SOS care is an opportunity for CGs to form an alliance with a VA healthcare professional ready to meet their health and psychosocial needs, including concerns about CR health and treatment.*

SOS care addresses both work and caregiving stress. Each domain receives equal emphasis. The five pillars of behavior change in SOS care are: 1) knowledge of work and CG stress; 2) stress management skills and abilities; 3) supports and resources (VA and non-VA); 4) confidence and motivation to modify stress; and 5) work and CG-focused problem-solving skills. These pillars are built in a CG-centered and collaborative relationship. The pillars are addressed through seven modules (please see Appendix 2). In six sessions, the CM will cover each module at least once (more than one module can be covered per session), after which certain modules will become more or less important depending on a shared understanding of the CG's preferences and self-management needs. SOS care involves an ongoing process of formulating self-management goals and action plans and preparing CGs to succeed in implementing them. This process reflects theory and research pertaining to achieving self-management behavior change and the psychosocial mechanisms of stress. Addressing both the work and caregiving contexts, CMs will educate CGs about stress and its biopsychosocial dimensions. CMs introduce strategies for self-managing stress and collaboratively design experiments to test these strategies ("homework"). Modules address cognitive-behavioral (including emotional and problem-focused coping), work, and CG role redesign and role behavior change strategies, approaches for strengthening and reinforcing workplace and personal social supports, reducing barriers to managing stress at work and in the caregiving context through problem-solving and self-monitoring, and motivational support. The CG's progress is monitored to identify strategies that effectively achieve self management goals. CMs assess CG progress every other session in a clinical interview using criteria from the Caregiver-Work Limitations Questionnaire (C-WLQ).[22] The final session solidifies a self-management plan. The process of care is supported by ongoing supervision with Drs. Adler, Lerner, and Helstrom (Co-Is).

Usual Care*: CGs randomized to the usual care (UC) arm will be contacted telephonically once by a Care Manager (CM). After a brief needs assessment, the CM will provide contact information for appropriate VA (e.g., local CSP clinicians) and non-VA community resources/services. CGs will be sent brochures for the national VA Caregiver Support Program (CSP). Information on both the program's website (which includes links to training, education, resources, and outreach programs for CGs) and the national CG hotline number will be included in the mailed packet. Receipt of information regarding the VA CSP is consistent with the standard of care for informal CGs in the VHA since 2010.[30] After this initial contact, CGs in this group will only be contacted again 4 and 9 months after baseline for administration of follow-up research assessments. CGs will be encouraged to seek medical,*

psychological, social support, and social services that are available to them through VAMCs or any other non-VA/community source. CGs in the SOS group will be offered similar information.

6. Does this project involve international research? Yes ☐ No ☒

***NOTE:** International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.*

7. Does this project involve collaborative research? Yes ☐ - See below No ☒

7.1. **If yes,** delineate which research activities will be conducted as the VA portion of the overall collaborative research study:

N/A

***NOTE**: Collaborative studies do not include studies conducted under a Cooperative Research and Development Agreement (CRADA) with pharmaceutical companies or other for-profit or non-Federal partners.*

SECTION 4: POTENTIAL RISK/BENEFIT ANALYSIS

1. **Indicate the potential risk level of the project:** *(Minimal Risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")*

☒ **Minimal** ☐ **Greater than Minimal**

***NOTE:** The IRB will make the final risk level determination.*

2. What are the potential risks or harms for participants in this project?
(*List in bullet or number format)*

1. Potential breach of confidentiality;
2. Potential discomfort due to answering questions about psychological concerns or the caregiving experience.

***NOTE:** Risks or harms can be physical, psychological, financial, social, or legal. They may involve breaches of confidentiality and privacy. Do not include the risks of usual care unless usual care is part of the research interventions being performed.*

3. What are the anticipated benefits, if any, to participants or to society from this project?
(*List in bullet or number format)*

1. Potential improvement in CG well-being, stress management, and work functioning
2. Potential improvement in the quality of the Veterans' care.

4. Briefly describe the procedures for the orderly withdrawal or termination of subjects if this study involves any medical therapy. N/A ☒

5. Will any of the following be administered to participants or will they be exposed?

	YES	NO
Ionizing Radiation	☐	☒
Radioactive Materials	☐	☒

6. Check one of the boxes below based on your study design and provide the references from the protocol for the information in the table:

☒ **Prospective Study** ☐ **Retrospective Study** ☐ **Both**

***NOTE:** If retrospective is checked, some of the below categories may not apply and can be marked as "Not applicable."*

Safety Issues	Reference the protocol page and section.	If not referenced in the protocol, cite document type, page and section where it is referenced.
What Safety Information is Collected	*p.8, Section 4, #7*	
How will Safety Information be collected	*p.8, Section 4, #7*	
Frequency of Safety Data Collection	*p.8, Section 4, #7*	
Safety Conditions that Trigger Immediate Suspension of Research	*N/A*	
Procedures to notify participants or PCP of findings affecting participants' health or welfare	*N/A*	
Procedures to minimize risk	*p. 4, Section 4, #1-4; p. 31, Section 16, #4.1.2*	
Inclusion Criteria	*p. 34, Section 7, #7*	
Exclusion Criteria	*p. 34, Section 7, #7*	

7. Will an independent Data Safety Monitoring Board (DSMB) or a Data Monitoring Committee (DMC) monitor the project? Yes ☒ No ☐

7.1. **If yes**, provide a description of responsibilities to include frequency of meetings:
As part of HSR&D's Just in Time process, we have been instructed to submit a Data Analysis Plan (DAP) in order to determine assignment to a DSMB (see Appendix 4 for DAP). Once we receive feedback and guidance from HSR&D, we will submit a protocol modification with greater detail regarding frequency of meetings, etc.

7.2. **If no,** provide the protocol section and/or page where the data safety and monitoring plan is described, to include statistical tests to be used for analyzing the safety data to determine if harm is occurring.

8. If the PI is not a clinician, is there an appropriately credentialed and privileged clinician who has been designated as a member of the study team to make required decisions to help protect the health of the subject, review data on adverse events, and report new findings? Yes ☒ No ☐ N/A ☐

9. How will you manage information from participating sites that might be relevant to participant protection and describe how that information will be conveyed to the IRB (i.e., reports of problems, interim results)?

Should there be any breaches of confidentiality, improper use or disclosure, or deviations to the protocol at either of the two study sites (i.e., CMCVAMC and the VISN 2 Center for Integrated Healthcare), the PI will report these incidents to the IRB, Associate Chief of Staff for Research, and Research Compliance Officer at the local site. All breaches of confidentiality will be immediately reported to the Information Security Officer and Privacy Officer. PHI extracted for the purposes of this project will under no circumstances leave the CMCVAMC or VINCI servers. 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 each site as required by their IRB guidelines. With respect to record retention,

all research records will 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. Until a schedule for local research records is published, all records including identifiers will be retained.

SECTION 5: HUMAN PARTICIPANT INFORMATION

NOTE: *A participant is considered "enrolled" at the time the consent is signed so this number should include an allowance for screen failures prior to randomization.*

1. **How many participant records will be reviewed PRIOR to enrollment/consent occurring?**
   4800 (this is a very conservative estimate; we anticipate that most of our sample will be referred directly by clinicians and Caregiver Support Program coordinators; this number assumes identification of patients by our VINCI query (which will then require us to identify their providers, etc.))

2. **How many participants will be screened PRIOR to enrollment/consent occurring?**
   2400 (this takes into account presence/absence of a CG)

3. **How many participants will be enrolled (total number to include randomized and screen failures AFTER consent is obtained)?**
   1200 (this takes into the account that roughly 50% of those approached from #2 above will agree to screening)
   3.1. Will all research activity be the same at all sites? **Yes** ☒ **No** ☐ **N/A** ☐
   3.2. **If no,** please describe the activity that is different or limited (For example; 2 sites will analyze data only, or, 1 site will consent and enroll all participants etc.): *N/A*

4. Are there any further screening procedures after enrollment? **Yes** ☐ **No** ☒
   4.1. **If yes,** describe: *N/A*

5. **Are non-Veterans being enrolled?** ***NOTE:*** *This does* ***not*** *include non-Veterans enrolled at* ***non-VA*** *sites.* **Yes** ☒ **No** ☐
   5.1. **If yes**, provide justification. *The study is specifically designed to target caregivers of Veterans with depression, anxiety, posttraumatic stress disorder, or traumatic brain injury. Thus, non-Veterans must be enrolled.*

NOTE:

- ***Every non-Veteran should sign VA form 10-0483**, Acknowledgement of the Notice of Privacy Practices (ANOP)*
- ***Once the ANOP is signed**, the research study staff must send the non-Veteran's name to the CMCVAMC Privacy Officer via encrypted e-mail. The signed ANOP must be kept in the research study binder.*
- ***If an oral informed consent is used**, the NOP should be sent to the non-Veteran via postal mail. In addition, the research study staff must write a Note-to-File that the NOP was sent to the non-Veteran.*

6. Does this project target a specific race, gender or ethnic group as participants?
Yes ☐ **No** ☒

6.1. **If yes,** indicate which group and why this group is being targeted.
N/A

7. **What is the age range of participants?** *(Check all that apply.)*

Neonates *(See note below)*	☐
Children Under 18 *(See note below)*	☐
Young Adults (18-21)	☒
Adults (22-65)	☒
Seniors (Over 65)	☒

***NOTE:** If neonates or children is checked, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.*

8. **Does the project involve the potential enrollment of any of the following populations or categories of participants? That is, are you targeting a specific group. *NOTE:** These populations must be checked "Yes" if they are not being excluded from the research.*

	Yes	No	N/A
a. Employees	☐	☒	☐
b. Students at the VA or Penn	☐	☒	☐
c Individuals with impaired decision-making capacity	☐	☒	☐
d. Pregnant women *(See below)*	☐	☒	
e. Economically and/or educationally disadvantaged persons	☐	☒	
f. Prisoners *(See Below)*	☐	☒	
g. Illiterate, limited, or no English language proficiency	☐	☒	
h. Terminally ill patients	☐	☒	☐
i. Children (See Below)	☐	☒	☐

Section 6: Informed Consent

1. **Will the study team obtain ☒ information or ☐ biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the prospective subject's legally authorized representative (LAR)?** **Yes** ☒ **-** See below **No** ☐

1.1. **If no,** *skip to question 2.*

1.2. **If yes,** check one or both of the below boxes if they apply to this study:

1.2.1. ☐ Information will be obtained through oral or written communication with the prospective subject or the subject's LAR

1.2.2. ☒ Identifiable information or biospecimens will be obtained by accessing records or stored identifiable biospecimens.

***NOTE:** If either or both of the above boxes is checked an informed consent waiver request does not have to be submitted for this activity. However, a request for a HIPAA waiver will still need to be submitted and informed consent obtained for any research interventions after eligibility is established. If neither box was checked, this activity will need to be included in a request for an informed consent waiver.*

2. **Will the project involve requesting any waiver or alteration of the consent process or a waiver of documentation of consent for any part of the project? Yes ☒ -** See below **No** ☐
2.1.**If no,** s*kip to question 3.*
2.2. **If yes,** check one or more of the following boxes and submit the applicable waiver request(s).

☐	An alteration of the informed consent process ***NOTE**: If deception is involved this box should be checked.*
☒	Waiver of informed consent for only a specific portion(s) of the study (not including recruitment). ***Specify for what portion(s) of the study the request is being submitted**:* *This study will examine the impact of a psychoeducational and support intervention on caregiver outcomes; accordingly only caregivers will be consented and enrolled. However, in order to utilize Veterans' medical records for the purpose of identifying potentially eligible participants and recruitment, we are requesting a waiver of all elements of informed consent, including HIPAA. We also are requesting a waiver of informed consent/HIPAA in order to extract Veterans' medical record data for research purposes. Without the waiver, we cannot verify the Veterans' diagnoses or extract and analyze clinical data, as only their 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.*
☒	Waiver of documentation of informed consent. ***Specify for what portion(s) of the study the request is being submitted**:* *Since this study/intervention takes place primarily via phone and mail, we also request a waiver of documentation of informed consent so we can obtain oral consent for the convenience of the CGs and to expedite the enrollment process.*

3. **Will documented informed consent be obtained from participants? Yes No** ☒
3.1. **If no,** g*o to question 4.*
3.1.1. If yes, will there be the use of surrogate consent? **Yes** ☐ **No** ☐
3.1.2. **If yes and this is a repository study,** will a broad consent be used?
Yes ☐ **No**

***NOTE:** Reference the CMCVAMC IRB Form 104 template, Combined ICD/HIPAA Authorization, and follow the instructions. If planning to obtain surrogate consent, check applicable state and local laws to ensure compliance.*

4. **Does the project involve photos, videos or voice recordings of a participant that are done for research purposes? Yes** ☒ **No** ☐
4.1. **If yes,** this must be covered in the informed consent document (ICD), information sheets, telephone screen scripts*)*

SECTION 7: HIPAA AUTHORIZATION FOR PROJECT PARTICIPANTS

***NOTE**: Written HIPAA Authorization signed by the individual to whom the information or record pertains is required when VA health care facilities need to utilize individually-identifiable health information for a purpose other than treatment, payment, or health care operations, e.g., research. (VHA Handbook 1605.1).*

1. **Check all of the following that apply if Protected Health Information (PHI) will be used. If more than one box is checked, specify the part or phase of the study to which the specific checked boxes apply:** ☐

☐	A project specific HIPAA Authorization is combined with the informed consent document.
☐	A separate project specific participant HIPAA Authorization form (VA Form 10-0493) is attached. ***NOTE**: This is highly recommended when enrolling individuals with impaired decision making or with longitudinal studies requiring reconsent*
☒	A request for a HIPAA Waiver of Individual Authorization is attached to cover the entire study.
☐	A request for a HIPAA Waiver of Individual Authorization for recruitment purposes only is attached.
☒	A request for a HIPAA Waiver of Individual Authorization is attached to cover a portion of the study. ***Specify portion of study**: In order to utilize Veterans' medical records for the purpose of identifying potentially eligible participants and recruitment, we are requesting a waiver of all elements of informed consent, including HIPAA. We also are requesting a waiver of informed consent/HIPAA in order to extract Veterans' medical record data for research purposes. Without the waiver, we cannot verify the Veterans' diagnoses or extract and analyze clinical data, as only their 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.*

2. **Will the project require that participants authorize release of medical records or health information from non-VA sites?** ☐ Yes ☒ No

SECTION 8: PARTICIPANT RECRUITMENT INFORMATION

1. **Describe the recruitment strategy for the just, fair, and equitable recruitment and selection of subjects, and reference recruitment procedures as cited in the protocol to include the following: *Step-by-step*** *how recruitment will take place, i.e., obtaining names from CPRS or other databases, use of recruitment letters, referrals, posters, phone calls etc., to include any screening procedures prior to enrollment.* ***Number steps or use bullets.***

Guided by our prior IRB-approved intervention trials, there will be three recruitment strategies (we will document and analyze the recruitment source of each potential participant):

1) The first strategy will involve direct referrals from clinical staff at the CMCVAMC and VA Western New York Health System (VAWNYHS)
Prior to recruitment, study staff will meet with various CMCVAMC and VAWNYHS staff, including, for example, Caregiver Support Program (CSP) clinicians and clinical staff from local Mental Health Clinics, Geriatric clinics, Home Based Primary Care, and theBehavioral Health Laboratory (BHL). The BHL is the Primary Care- Mental Health Integration program at the CMCVAMC and is responsible for triaging the majority of Veterans who are seeking mental healthcare and provides clinical behavioral health assessments for referred Veterans. During these meetings, study staff will provide a brief overview of the project's aims and procedures and review study referral procedures. Study staff will document in an electronic database (stored on the shared secure, password-protected MIRECC server) the names and phone numbers of individuals who have been referred by clinical staff.

2) The second strategy will involve placing IRB-approved advertisements targeted specifically at employed CGs in patient waiting rooms in the Mental Health Clinics. The advertisements will include a study phone number that potential participants can call in order to learn more about the study.

3) Third, using data extracted from VINCI, we will prepare a list of Veterans who have appropriate diagnoses and are receiving care at each of the sites (i.e., attended at least one appointment in the past 6 months). The list will also include each Veteran's respective provider. To facilitate referrals, 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 the CG would benefit from the SOS program. This recruitment strategy has been used successfully in our

past (and current) IRB-approved clinical trials at the VA, and our experience indicates that providers typically support contact the majority of Veterans on the list.

CGs referred by the Caregiver Support Program coordinators or by self-referral will be contacted directly (in person or by phone) to assess interest in participating and to complete necessary informed consent procedures prior to screening.

Veterans/CGs referred to study staff through non-Caregiver Support Program provider referrals will either be contacted directly (where appropriate) or will receive a letter describing the study. Patients identified via VINCI also will receive a letter describing the study. The letter will include a telephone number to call, which can be used if they want more information or do not want to be contacted for recruitment. Within two weeks of receiving this letter, the Veteran/CG will be called by study staff to assess interest in participating. We will use a stepped process whereby we will first ask the Veteran for verbal assent to allow research staff to speak with his/her care partner (i.e., CG). The designated CG will then be contacted to assess interest in study participation.

NOTE: *VA policy prohibits "cold calls" to potential VA research participants. Initial contact must be made in person or by letter prior to making any telephone contact, unless there is written documentation that the subject is willing to be contacted by phone about the specific study or the specific kind of research. The initial telephone contact must also provide a telephone number or other means for the potential participant to use to verify the study constitutes VA research (VHA Handbook 1200.05)*

2. Will the recruitment strategies described above be allowed to vary among sites?
Yes No ☒ N/A

3. Are any model recruitment materials going to be made available? Yes ☒ No

3.1. **If *yes*,** list all type of materials that will be used and indicate whether each type of material is being submitted with this application or whether it will be submitted later as an amendment. ***If there will be telephone contact during the recruitment process, a script must be provided and listed below.***

Recruitment Material Type	Included with Application
Phone Script	Yes ☒ No ☐ Will submit an amendment
Recruitment letter	Yes ☒ No ☐ Will submit an amendment
Study brochure	Yes X☐ No ☒ Will submit an amendment

Additional rows can be added as required.

NOTE*: All recruitment materials **must** be reviewed and approved by the IRB **prior** to use as part of any recruitment activities. All recruitment materials **must include** a statement that the study involves VA research and a telephone number or other means for the potential participant to use to verify that the study is VA research.*

SECTION 9: PAYMENT TO PARTICIPANTS

1. Will participants receive compensation in this study? Yes ☒ No ☐
(**If *no*,** skip this section and go to Section 10.)

NOTE: *If applicable, the method (and relative amounts) of payment should be the same at all participating sites whenever possible. Investigator will be asked to provide justification to the IRB for differences in method and/or relative amounts.*

2. Indicate the preferred method and mode of payment as follows:
2.1. What form of payment will be used, i.e., check, voucher, gift card?
☐ Electronic payment through direct bank deposit or debit card.

2.2. What is the schedule of payments, i.e., one-time or after specific visits?
After the baseline assessment, after the 4 month assessment, and after the 9 month assessment.

2.3. Provide the total amount for entire participation
Enrolled CGs will receive $40 for their baseline data collection session and then $25 for each of the two subsequent follow-up sessions (4M and 9M) for a total of $90 per participant. CGs who complete the qualitative interview (n=30) will receive $35 at the 4M follow-up (for a total of $100)

3. Provide justification that the proposed payments are reasonable and commensurate with the expected contributions of the participant to the project:
Participation in the study assessments will take approximately 1-2 hours (depending on whether CGs also complete the qualitative interview). The amount of payment proposed is commensurate with the time and commitment required to complete the assessments, and is comparable to that offered in our previous and current intervention work.

4. Does the payment include transportation costs? Yes ☐ No ☒
4.1. If no, will transportation costs be paid separately? **Yes** ☐ **No** ☒
4.2. **If yes**, explain

5. Specify the source of payment:
☒ CMCVAMC ☐ Other (specify):

6. Will a social security number (SSN) be requested and/or used in making payment/compensation? Yes☒ No

***NOTE:* If yes,** *be sure to include in the 'combined ICD/HIPAA' or the separate HIPAA authorization and informed consent the name of the organization making payment.*

SECTION 10: BIOLOGICAL SPECIMENS

1. Will biological specimens be used in this protocol? Yes ☐ No ☒
(**If *no***, skip this section and go to the next.)

2. **List the specimens that are being collected and indicate the purpose of the collection** *(one or both boxes may be checked.)*

		☐	☐
		☐	☐

Additional rows may be added as required.

3. Respond to the following questions by checking the appropriate box:

	YES	NO
a. Does the project involve genetic testing? *If yes, see below:*	☐	☐
1) Does this include whole genome sequencing?	☐	☐
2) Will participants be informed of the results of any DNA testing?	☐	☐
b. Will specimens be kept for future use in other studies? ***If yes**, see question 7 below.*	☐	☐
c. Will samples be made anonymous to maintain confidentiality? ***NOTE:** Coding data is not considered making it anonymous.*	☐	☐
d. Will specimens be destroyed after the project-specific use is completed?	☐	☐

e. Will specimens be used for commercial profit? ***If yes,*** *see below:*	☐	☐
1) **If yes,** will participants share in this commercial profit?	☐	☐
f. Will participants be informed of the results of the specimen testing?	☐	☐
g. Are there any implications for family members based on specimen testing results? ***(If yes,*** *the family members may be participants.)*	☐	☐

4. Will specimens be de-identified? Yes☐ No☐

4.1. **If *yes***, describe how the data will be de-identified, who will do it, and at what point in the process will the specimens be de-identified.

5. What measures will be taken to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy resulting from unauthorized access to or loss of the specimens?

6. Describe how the destruction of samples will be substantiated:

7. If specimens are to be banked for future use in other studies, the following questions must be answered: ☐ N/A

7.1. **Indicate where the specimens will be banked**.

7.2. **If above is a VA location**, what IRB is responsible for overseeing the operations of the tissue bank (i.e., local IRB or other multi-site IRB?).

NOTE*: If the bank is located at CMCVAMC, a Standard Operations Procedures (SOP) manual is required. Contact one of the IRB Coordinators to obtain the SOP template.*

SECTION 11: PRIVACY, CONFIDENTIALITY, AND INFORMATION SECURITY IN RESEARCH

1. What type of data will be recorded/collected by the Principal Investigator study team?

Check all that apply:

☐ **De-identified** – Data does not contain any identifiers that could link the data to a specific participant. *(See VHA Handbook 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.)*

☒ **Identified** – Data contains direct identifiers sufficient to identify participants as indicated in VHA Handbook 1605.01, Appendix B, para 2b. *ALL HIPAA IDENTIFIERS INCLUDING DATES.*

☒ **Coded** – Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information (PHI) only someone possessing the code can link the data to a particular participant.

1.1. **If coded data is checked,** specify how the link or code will be maintained, and list each person/role who will have access to the link or code: *PI, RA, RC, Care Manager. It will be maintained in a password protected file on the MIRECC server.*

2. Indicate how the PHI will be obtained by checking one or more of the boxes below:

☒ **From existing sources such as medical records, clinical databases, or research records.**

If the above box is checked, specify each source and who maintains the database:

Database Name	Who Maintains the Database
VINCI	Corporate Data Warehouse
CPRS	

Additional *rows may be added as required.*

☒ **Directly from project participants during protocol procedures as described elsewhere in this application or in the protocol.**

3. Check which of the following HIPAA identifiers will be collected and recorded during the course of the study:

☒ Names	☒ Social Security (or scrambled SSNs)/Medical record numbers	☐ Device identifiers and serial numbers
☒ E-mail addresses	☐ IP Addresses (Internet Protocol	☐ URLs (Universal Resource Locator)
☒ All elements of dates (except year) and any age over 89 *Specify: Ages (may be over 89); dates of Veteran VHA appointments*	☐ Health plan beneficiary numbers	☒ All geographic subdivisions' smaller than a state *Specify: Participant address*
☒ Telephone numbers	☐ Account numbers	☐ Biometric Identifiers including finger and voice print
☐ Fax numbers	☐ Certificate or license numbers	☐ Full face photographic images and comparable images
☐ Vehicle ID and serial numbers including license plate numbers	☐ Other unique identifying number, characteristic, or code *Specify:*	☐ HIV (testing or infectious disease) records
☐ Sickle Cell Anemia	☐ Drug Abuse Information	☐☒ Alcoholism or Alcohol Use

4. Will a non-VA entity have access to VA sensitive data? Yes ☐ - See below **No** ☒

4.1. **If *yes***, specify each entity and identify their roles in the study:

Name of Non-VA Entity	Role in Study

Additional rows may be added as required.

4.2. **If yes,** will a copy of a Data Use Agreement (DUA) or a Cooperative Research and Development Agreement (CRADA) with this application? **Yes** ☐ **No** ☐ **N/A** ☒
***NOTE: If no**, a DUA or CRADA **must** be provided to the IRB for review prior to initiation of any research procedures.*

5. **List the study team members by title who will have access to the data.** *(Specify approximate number of personnel and their job categories, e.g., 2 Co-investigators, 4 Nurse Coordinators, etc.)*
1 Principal investigator; 3 Co-Investigators; 1 Care Manager; 1 Research Coordinator; 2 Research Assistants

☐ ☒

6. Will specially obtained software be used? Yes - See below **No**

6.1. **If *yes***, describe the software, the source of the software, whether a license will be required and who will fund the license, as well was any data that will be stored in temporary files on the computer's hard drive.

7. Will any web-based applications be used? Yes ☒ - See below **No** ☐

7.1. **If yes**, identify the application and its security features. Indicate how it will be used, e.g., for recruiting subjects, completing questionnaires, or processing data.

REDCap; the VA approved web-based application can only be accessed on the VA Intranet and requires a log-in for each user. It will be used for completing questionnaires. We also will use Qualtrics for completing questionnaires/entering research assessment data. Only coded data will be used in these applications (PHI will not be entered or stored).

8. How will electronic data and/or paper records be secured? If data is being stored on a computer hard drive, indicate if it is encrypted per VA guidelines.

Electronic research records will be stored on the MIRECC server. Paper records will be secured in locked cabinets in the CHERP suite in the Annex, room 202 or at the Center for Integrated Healthcare (CIH); VA Western New York - Buffalo Bldg. 20, Rm 128-8.

***NOTE:** Electronic research records should be stored/secured on the Research and Development server (Z drive), MIRECC server, PADRECC server or CHERP server.*

9. Will mobile devices be used in the study, i.e., laptops, audio recorders? Yes ☒ **No** ☐

9.1. **If yes**, indicate that mobile devices will be encrypted and that the encryption is FIPS 140-2 validated.

The recorder we use is encrypted and it is FIPS 140-2 validated.

10. How will data be transmitted and/or shipped, and how will it be protected during transmission or shipping?

N/A

11. How will project research data be stored?

11.1. Indicate precisely where data will be stored to include physical site, network location/server name, type of mobile storage device, building and room number etc.

Paper data – CHERP suite, Annex, Room 202; VAWNY CIH, Room 128-8electronic data – MIRECC server

***NOTE:** If data will reside on a non-VA server or non-VA equipment, specify that the server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FIMSA) and that the required permissions for use of a non-VA server have been obtained. Contact the CMCVAMC Information System Security Officer (ISSO) for more information.*

11.2. If any of the 18 HIPAA identifiers (VA sensitive information) is being stored outside the protected VA environment, the following questions must be answered: ☒ **N/A**

11.2.1. How are the data being protected?

11.2.2. Indicate what VA information will be returned to the VA, how the information will be returned, and/or the plans for its eventual destruction at the alternate non-VA site.

11.2.3. Is there a Memorandum of Understanding (MOU) and/or a Data Use Agreement (DUA) in place regarding the transfer and storage of the data outside the VA environment?

Yes ☐ **No** ☐

a) **If yes,** specify and/or attach agreement.

b) **If no,** indicate why not.

12. How long will the research data be stored and describe how the data will be destroyed once the maximum retention period as specified by the VHA Records Control schedule or the indicated retention period, if longer, is met?

With respect to record retention, all research records, including those with identifiers, will be retained according to the current instructions and schedule set forth in VHA's Records Control Schedule (RCS 10-1). VHA Handbook 1200.05 §26.h.

13. **What is the plan for protecting project research data from improper use or disclosure?**
NOTE: *As part of the response to this question, indicate that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team. Include that the ISO and Privacy Officer will be notified within one hour of the 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 numerical study IDs 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. Access to research study data will be immediately removed for study personnel who are no longer part of the research team.

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 (i.e., within 1 hour) 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.

14. **Will a Certificate of Confidentiality (CoC) be obtained?** **Yes**☐ **No**☒
14.1. **If yes**, include this information in the informed consent document (ICD).

NOTE: *If this is a qualifying NIH Study, the CoC will be assumed. A CoC helps investigators protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. For more information on CoCs go to: http://grants.nih.gov/grants/policy/coc/.*

15. **Will data be disclosed (copy given) outside of VHA?** **Yes**☐ **No**☒
15.1. **If yes**, describe to whom the data are to be disclosed, the justification for such disclosure, and the authority for the disclosure, e.g., HIPAA authorization or VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information.

16. **Will data be banked for re-use in future studies?** **Yes**☐ - See Below **No**☒
16.1. **Where will the data be banked**?
16.1.1. **Name of entity**:
16.1.2. **Location**:

16.2. Is this an existing data repository with appropriate oversight mechanism per VHA Handbook 1200.12 or, if a non-VA entity, are the appropriate safeguards addressed in the CRADA or DUA? **Yes**☐ **No**☐
16.1.1. **If no,** indicate for VA entities that approval will be sought from the local IRB where the repository will be housed, whether a separate study or amendment

will be submitted to the IRB for review for creation of the data repository, OR for non-VA sites, whether the CRADA or DUA is still being negotiated.

SECTION 12: FDA-REGULATED AND OTHER PRODUCTS

1. **Does the project require use of drugs, biologics, supplements, or devices?**
   Yes ☐ **No** ☒ - **If no,** skip to Section 13

2. **Indicate the type of clinical trial if applicable?**
   ☐ **Phase I** ☐ **Phase II** ☐ **Phase III** ☐ **Phase IV**

3. **Does the project involve an Investigational New Drug Application (IND) or Investigational New Device Exemption (IDE), Abbreviated IDE, or IND Exception? Yes** ☐ **No** ☐
   3.1. **If *yes***, attach a copy of any applicable correspondence with the FDA and complete the following:
   3.2. **If applicable**, indicate the name of the person or organization holding the IND or IDE.
   3.3. Is there a plan for onsite data monitoring? **Yes** ☐ **No** ☐
   3.3.1. **If yes,** specify who will conduct monitoring responsibilities and how often.

4. **How will FDA-regulated products used in this study be dispensed and tracked to participating sites?**

5. **If using FDA-regulated drugs or biologics, indicate use: N/A** ☐

☐	Approved Drug(s) or Biologics For Approved Uses
☐	Approved Drug(s) or Biologics for Unapproved Uses (Use will be inconsistent with product labeling or involves a new use, labeling, advertising change, or a change in dose, dosage form, administration schedule, or recipient)

6. **List all drugs, biologics, or supplements to be used below. N/A** ☐

Generic Name	Trade Name	Manufacturer	Use Consistent with Product Labeling? Yes/No	IND Number if Applicable

Add additional rows to table if necessary

6.1. Is an Investigator's Brochure included with the application materials? **Yes** ☐ **No** ☐
6.1.1. **If no,** indicate why?

6.2. For all approved drugs used for an unapproved use, describe the unapproved use: ☐ **N/A**

6.3. If an IND is **not** required, explain and/or provide sponsor or FDA documentation**:** ☐ **N/A**

7. **If using FDA-regulated devices, indicate use: N/A** ☐

☐	Approved Device(s) for an Approved Use
☐	Approved Device(s) for an Unapproved Use
☐	Other *(e.g., humanitarian use device; 510k clearance) Specify:*

8. **List the FDA-regulated devices that will be used. N/A** ☐

Name	Manufacturer	Use Consistent w/ Product Labeling? Yes, No, or N/A	Significant Risk (SR) or Non-significant Risk (NSR), Unknown, or N/A	IDE Number if Applicable

8.1. Is manufacturer's device information included with the application materials? **Yes** ☐ **No** ☐

8.2. If this is a non-significant risk device study, is documentation attached with the application materials explaining the manufacturer's or a sponsor's determination why the device is not a Significant Risk (SR) device ? *(See 21 CFR 812)* **Yes** ☐ **No** ☐

8.3. If applying for an IDE, is a copy of the dated IDE application letter to the FDA attached? **Yes** ☐ **No** ☐ **N/A** ☐

SECTION 13: REQUEST FOR EXPEDITED REVIEW

☐ Check if **NOT** requesting expedited review

1. Check the below boxes as applicable for this study. All three boxes must be checked in order for the study to qualify for expedited review:

☒ The project presents no more than minimal risk to participants.

☒ The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

☒ The project is not classified.

2. If all three boxes are checked above, indicate one or more categories below for which this study would qualify for expedited review:

☐ Category **1:** Clinical studies of drugs and medical devices only when one of the following conditions is met.

☐ **1a:** Research on drugs for which an investigational device exemption application (21 CFR Part 812) is not required.

☐ **1b:** Research on medical devices for which:

(i) an investigational device exemption application (21 CFR Part 812) is not required; or

(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

☐ **2a:** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ **2b:** From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the

lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.

☐ **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x- rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

☐ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category also includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.

☐ **Category 6:** Collection from voice, video, digital or image recordings made for research purposes.

☒ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

If the project does not fit into one of the above categories, it does not qualify for expedited review.

SECTION 14: ABSTRACT

1. **Objectives(s):** *The objectives of this study are to, 1) determine the extent to which, relative to usual care, a novel intervention providing evidence-based, telephonic CG/work stress self-management counseling is related to changes in CG psychological distress and ability to function effectively in work and CG roles, and 2) evaluate whether participation in the intervention is related to CGs' overall wellbeing and CRs' health care utilization.*

2. **Research Design:** *Randomized controlled, longitudinal trial*

3. **Methodology:** *We will compare pre/post changes among 300 CGs allocated to the Caregiver SOS (for Self-Management of Stress) program or usual care. CGs who, 1) care for Veterans diagnosed with depression, anxiety, PTSD, and/or TBI and, 2) screen positive for clinically significant distress and CG/work role difficulty will be recruited to participate from two VA Medical Centers and their affiliated outpatient clinics. A novel intervention, Caregiver SOS includes 6, 1-hour telephonic sessions with a care manager. Usual care will consist of 1 telephonic session with a care manager. Primary and secondary outcomes will be pre-post change in CG distress and work functioning, respectively. Additional CG and CR outcomes (i.e., physical mental and interpersonal functioning) also will be measured and analyzed. CRs' VA health utilization data will be extracted from clinical patient records and non-VA health utilization data will be collected via CG self-report. Intent to treat analysis using mixed effects models will be used to test the study hypotheses. We anticipate that CGs in the intervention arm will show significantly greater improvements in outcomes compared to those in usual care.*

4. **Clinical relationships:** *N/A*

5. **Impact/Significance:** *Approximately 5.5 million Veterans rely on CGs to help them with their daily care. CGs often cope with stress and strain from CG/work roles. This may be particularly true of CGs of Veterans coping with behavioral health issues related to conditions such as depression, posttraumatic stress disorder (PTSD), anxiety, and traumatic brain injury (TBI). Programs that specifically address caregiving-work role stress may be especially effective in improving CGs' wellbeing and work/financial stability and the quality of Veterans' care. Given this project's focus, it is responsive to multiple AORD and HSR&D priority areas, including long term care/aging, access to care, mental health/PTSD, and health equity, expanded Veteran/CG access to high quality clinical trials, and legislative priorities such as the MISSION Act, which emphasizes research on new models that support and benefit both Veterans and CGs and maximize the ability of Veterans to age in place.*

SECTION 15: LIST OF ABBREVIATIONS

Provide a list of all abbreviations used in the protocol and their associated meanings.

ADLs=activities of daily living
ANCOVA=analysis of covariance
BHL=Behavioral Health Laboratory
BHP=behavioral health practitioner
BTC=Behavioral Telehealth Center
BVAMC=Buffalo VA Medical Center
CARE=Caregiver Appreciation Recognition and Education
CG=caregiver
CHERP=Center for Health Equity Research and Promotion
CI=confidence interval
CIDER=Center for Information Dissemination and Education Resources
CIH =Center for Integrated Healthcare
CM=Care Manager
CMCVAMC=Corporal Michael J. Crescenz VA Medical Center
COE=Center of Excellence
Co-I=Co-Investigator
CR=care recipient
CSP=Caregiver Support Program
C-WLQ=Caregiver Work Limitations Questionnaire
DSMB=Data and Safety Monitoring Board
ES=effect size
GAD-7=Generalized Anxiety Disorder-7
GPS=Geographic Information System
HERC= Health Economics Resource Center
HIPAA=Health Insurance Portability and Accountability Act
HSR&D=Health Services Research & Development
IADLs=instrumental activities of daily living
IMR=Illness Management and Recovery
IRB=Institutional Review Board
K10=Kessler Psychological Distress Scale
MAR=missing at random
MDES=minimum detectable effect size
MH=mental health
MIRECC=Mental Illness, Research, Education, and Clinical Center
MISSION Act=Maintaining Systems and Strengthening Integrated Outside Networks Act
NIOSH=National Institute for Occupational Safety and Health
ORD=Office of Research and Development
PC-MHI=Primary Care-Mental Health Integration
PCP=primary care provider
PHQ-9=Patient Health Questionnaire-9
PI=Principal Investigator
PROMIS=Patient-Reported Outcomes Measurement Information System
PTSD=posttraumatic stress disorder
QUERI=Quality Enhancement Research Initiative
RAISE=Recognize, Assist, Include, Support, and Engage
RCT=randomized controlled trial
REDCap=Research Electronic Data Capture
RRP=Rapid Response Project
SAIL=Strategic Analytics for Improvement and Learning
SD=standard deviation
SDP=Service Directed Project
SOS= Self-Management of Stress

TBI=traumatic brain injury
TBN=To be named
US=United States
VA=Veterans Affairs
VAMC=Veterans Affairs Medical Center
VAWNYHS=VA Western New York Health System
VAWNYHS CIH=VA Western New York Health System Center for Integrated Healthcare
VCAB=Veterans Community Advisory Board
VEG=Veterans Empowerment Group
VHA=Veterans Health Administration
VINCI=VA Informatics and Computing Infrastructure
VISN=Veterans Integrated Service Networks
VR12=Veterans RAND 12-item Health Survey

SECTION 16: PROTOCOL SUMMARY

1. Introduction

1.1. Provide scientific background and rationale for study.

A. Caregiving and Workplace Stress – The Challenge of Balancing Multiple Roles:

Stress is a significant public health problem for informal CGs, with added consequences for the health and well-being of CRs. Among the 44 million CGs who provide mainly unpaid assistance to an ill, disabled and/or aging relative, almost 40% suffer from severe, often chronic stress.[1,2] Stress is assumed to be at least partly responsible for the higher rates of physical and mental morbidity[1,10] and mortality risk observed for CGs compared to non-CGs.[25] CGs also exhibit greater impairment in stress-related disease mechanisms such as weaker immune function and metabolic syndrome.[10] CG stress also has been associated with poorer CR outcomes, including increased behavioral symptoms, institutionalization, morbidity, and mortality.[1,27-29]

CG stress is partly explained by the objective burden of care (e.g, care hours and intensity of tasks), CG coping style and resources, and the availability of social supports.[12,13] Research suggests that interactions with social contexts such as employment also contribute.[2] Though generally, employed CGs have certain financial advantages over working-age CGs who are not employed, the negative effects of work on CG MH are partly explained by the fact that at least 45% of employed CGs perform the same complex medical/nursing tasks as unemployed CGs (e.g., medication management).[2,83] Further, while work may provide occasional respite from caregiving, many CGs go to work in stressful jobs: work is a leading source of stress in America.[6,7]

By any measure, stress is a large problem for employed CGs. Either by choice or necessity, most CGs (60%) work; 56% full-time. For CGs under age 65, the employment rate is 68%. National CG surveys estimate that approximately 60% of employed CGs experience economic and psycho-social shocks that, in the parlance of stress research, represent major stressors.[2] These shocks include giving up work hours, taking unwanted leaves of absence, receiving warnings, giving up a job, turning down promotions, and/or losing job benefits. Workday interruptions occur regularly. Also, employed CGs bear higher burdens than employed non-caregivers including poorer health, more lost work time due to sickness,[79] more absences due to caregiving, and more difficulty performing routine job tasks.[23,46] These stressors can have repercussions for CG earnings and job satisfaction as well as for their CRs, and translate into higher employer and societal costs.

Between potentially doing harm by continued exposure to high levels of stress or exiting the labor market and losing the rewards of working, employed CGs have few places to turn for help. Intervention research has been slow to respond to the needs of employed CGs,[6,7] and there are few studies identifying the most effective means of supporting CGs who need and/or want to work.[2,4,31,32] CGs assisting Veterans with behavioral health conditions, many of whom are post-9/11 military CRs, may especially benefit from work and CG focused stress intervention. These CGs are more likely to report depressive symptoms[12] and more likely to stop working than other CGs.[12,13] A comprehensive evaluation of the personal impact of participating in work and CG roles, and addressing stress through interventions that focus on adapting roles and contexts, are key steps towards improving CG outcomes.[33-35]

B. The Need for Multicomponent Interventions to Address Working Caregivers' Needs

Designing such interventions is challenging. Despite stress and their own chronic illnesses,[1] CGs frequently do not take care of their health and report high levels of health distress.[2,36] Help-seeking requires time, energy, motivation, and resources, which often are in short supply. CGs report time constraints, conflicts with other roles and responsibilities (e.g., work), financial strain, failure to recognize stress as a health issue and limited social supports.[1,2,11-13]

Two critical barriers hinder progress in developing and disseminating interventions for employed CGs. First, while evidence for CG-based interventions has improved,[15,16,37] it remains fragmented, making it difficult to apply results. Many CG studies use highly restrictive eligibility criteria, and small convenience samples, and/or lack a realistic comparator or control.[16,37,54]

Second, the focus, content, and outcomes considered in CG interventions rarely include stress due to employment or managing work and CG demands.

However, two discrete areas of theory and research pertaining to the self-management of health and illness and the stress process offer conceptual pillars for developing interventions. Self-management conceptual frameworks[18,40] mostly focus on supporting positive health behavior change for patients with long-term chronic illness, but they could be applied to conceptualizing the challenge to reduce CG stress. Generally in self-management frameworks, acquiring a new health behavior, such as managing stress, is a complex process involving steps to activate the person with the health problem, establish an alliance with healthcare providers, and address enabling and constraining factors at the level of the individual, healthcare system, social network and/or community.[18,41] For example, according to Individual and Self-Management Theory,[18] health outcomes (distal outcomes) are regarded as the result of using appropriate self-management behavior (proximal outcomes). The degree to which behavior is adopted is related to contextual factors (the individual's health, physical and social environment and family factors), and process factors, such as developing accurate health knowledge, confidence and beliefs, acquiring skills and abilities, and using social supports. Acquiring skills and abilities is a structured process of setting behavioral goals and developing action plans, managing emotional reactions to health challenges, and problem-solving to reduce individual and social barriers to change. In this and other models, the social context is regarded as a change barrier or enabler: as conditioning self-management behavior. In this study, we consider both caregiving and work roles and contexts to be stress risk factors partly modifiable through guided self-management behavior at the individual level.

While self-management theory serves as a conceptual pillar for intervening, the stress process model provides a more detailed specification for an intervention's content; it describes the nature of the health problem and modifiable targets.[8,9] According to Folkman and Lazarus's Transactional Model of Stress and Coping,[8,17] stress occurs when coping is ineffective for confronting life events and experiences perceived as threatening or harmful ("stressors"). These perceptions ("primary cognitive appraisals") evoke coping behaviors and secondary appraisals (reassessing threat and need for further coping), resulting in either adaptation or distress. Coping effectiveness is related to approach (e.g., problem-focused such as searching for a solution, or emotion-focused such as wishful thinking), resources, and social supports. Guided by this model, CG stress can be explained partly by exposure to social role demands of working and caregiving and constraints in the social contexts that overwhelm the CG's capacity to cope, as well as the efficacy of available coping resources.[19] According to Pearlin, CGs experience both primary objective stressors (e.g., severity of CR problematic behavior), and primary subjective stressors (CGs' emotional reactions to or appraisals of the primary stressors), which accumulate and impact other life domains such as work, causing secondary stressors to emerge (e.g., caregiving-work conflict).[19,31] The stress-inducing influence of multiple demands of caregiving and work are bidirectional, impacting each other.[31,42]

Stress process models have been tested with positive results in various trials of support programs for CGs of patients with dementia,[15,16,43,44] and a supportive online stress management nursing intervention for CGs of chronically ill elderly.[45] No intervention has specifically sought to reduce CG distress by: 1) addressing work and caregiving as major sources of CG stress with the potential for cumulative and bi-directional effects; and 2) applying the model to CGs of individuals with behavioral health problems

C. Conclusions and Conceptual Framework for the Current Study

The proposed intervention, Caregiver SOS, is a novel program employing intervention principles guided by Individual and Self-Management Theory and the science of stress,[8,9,17] which utilizes knowledge and techniques from an evidence-based telephonic care program for employees with depression.[47,48,50] Caregiver SOS will be delivered by specially-trained CMs who, in a collaborative relationship with the participating CGs, will tailor the intervention to CG needs, preferences, work situation, and health status. They will provide knowledge and skills necessary to help CGs manage stress at work and at home, help CGs access and use appropriate VA and community services and resources, provide psycho-education about CR behavioral health problems, and teach strategies for coping with behavioral symptoms. We hypothesize that

providing tailored, comprehensive care that includes psycho-education, support, and skills training, via our brief, manualized, telephone-delivered Caregiver SOS program will reduce CGs' distress, improve CGs' work functioning, and result in positive changes in additional domains (e.g., CGs' well-being, CRs' healthcare utilization).

1.2. **Include summary of gaps in current knowledge, relevant data, and how the study will add to existing knowledge**.

Recognizing that family members play an essential part in supporting Veterans' health and well-being, VA clinical practice guidelines encourage involving families and CGs in ensuring quality care outside of the medical care setting. However, the guidelines and current configuration of services are insufficient. First, the guidelines promote providing general education and offer generic suggestions for engaging CGs in family interventions and are not targeted to employment issues.[13,54] Second, many caregiving services and programs require the CG to be a primary family member to be eligible.[13] Third, programs and interventions frequently are not evidence-based and, of those that are, most are designed for CGs of older Veterans with conditions such as dementia.[13,16,54] Perhaps in response to these gaps, a recent QUERI review was commissioned to consolidate the evidence base for interventions that support CGs or families of Veterans with conditions such as TBI and PTSD, many of whom are post-9/11 CGs.[54] Findings from the review cite the poor quality of many studies and clinically insignificant results. The research was characterized by design flaws such as testing interventions that are too diffuse in their focus, lacking in a theoretical foundation, and unclear with regard to the intervention target (i.e., CG or patient), and neglecting to include patient/CG-reported outcomes.[54] Also, though many Veterans and their families report financial strain, few interventions attempt to improve the economic status or financial stability of CGs and, by extension, their CRs. These gaps have prompted calls for interventions that address financial issues and include relevant outcome measures.[13,54,86] While stipend programs compensate for income loss due to caregiving, there are no interventions that focus on helping CGs stay productive at work and employed. Such programs could reduce the productivity loss and costs of caregiving that affect CGs and their families, employers, and the nation.

The proposed study will address many of the cited gaps, and accelerate progress towards achieving more cost-effective, coordinated, and focused services for CGs and Veterans. We include the work role and context as having a direct impact on stress and health. This innovative perspective is woven throughout the intervention protocol. The intervention techniques and principles have been refined over many years in other populations, and our preliminary research suggests it has promise for improving CG distress and functioning.[47,48,50] Moreover, the study's comprehensive, well-validated approach to measurement and analysis using CG-reported outcomes as well as its focus on CGs of Veterans with depression, PTSD, anxiety, or TBI, will help service providers and policymakers in their efforts to better support CGs, and by extension Veterans, at home, at work, and in the community.

1.3. Include rationale for including or excluding certain populations – in particular vulnerable populations.

Non-Veterans are necessary for recruitment purposes by virtue of the fact that this study examines the impact of an intervention designed specifically for employed CGs of Veterans with behavioral health issues. Special vulnerable populations, such as fetuses, neonates, children, prisoners, and institutionalized individuals, will not be included in the project. There is a possibility, however, that the CG sample may include pregnant women.

2. Objectives

2.1. **Describe the study's purpose, specific aims, or objectives**.

Our goal is to enhance the well-being and functional performance of employed CGs experiencing distress and work difficulty due to caregiving and improve CR health outcomes.

Aim 1 is to determine whether this novel intervention, providing evidence-based telephonic work/CG stress self-management counseling, is superior to usual care (UC) in

reducing CG psychological distress (primary outcome; Aim 1a), and improving ability to function effectively in work and CG roles (secondary outcome; Aim 1b).

Aim 2 (Exploratory) is to determine whether, relative to UC, the intervention improves CGs' overall physical health and mental well-being (Aim 2a), and CGs' and CRs' access to needed healthcare and social services (Aim 2b).

2.2. State the hypotheses to be tested.

Aim 1 Hypotheses: We hypothesize that, compared to CGs in UC, CGs in the intervention arm will have significantly less distress (Hyp. 1a), and a better ability to function effectively in their work and CG roles (Hyp. 1b).

Aim 2 Hypotheses: We hypothesize that relative to those in UC, CGs assigned to the intervention arm will have higher levels of physical and emotional well-being (Exploratory Hyp. 2a). We also hypothesize that CGs/CRs in the intervention arm will report higher utilization of needed services (e.g., CR MH and primary care and CG-related services) (Exploratory Hyp. 2b).

3. Resources and Personnel

3.1. Include where and by whom the research will be conducted.

Study procedures will take place at the CMCVAMC's Mental Illness, Research, Education, and Clinical Center (MIRECC), VA HSR&D Center for Health Equity Research and Promotion (CHERP), and the VAWNYHS Center for Integrated Healthcare (CIH). All telephone-delivered components of the study (i.e., recruitment, screening, research assessments, care management calls) and completion of mailed/e-mailed CG assessment packets (in cases where CGs prefer to complete the packet themselves at home) will take place in the participants' homes. The sample will be recruited from the CMCVAMC's Primary Care-Mental Health Integration program (i.e., the Behavioral Health Laboratory (BHL)), both VA sites' Mental Health Clinics and CSPs, and via VINCI. Tufts researchers will administer the SOS CM training and supervision procedures telephonically. Each site and team contribute to the overall feasibility of implementing the study; they have experience recruiting CG intervention study participants, a history of successful collaboration, and, in the CMCVAMC and VAWNYHS, the ability to provide a representative sample of Veterans with depression, anxiety, TBI, and/or PTSD and their CGs.

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 and Research Coordinator (and, where appropriate, Care Manager). Care management will be provided by Care Managers. Supervision will be provided by Drs. Amy Helstrom, Debra Lerner, and David Adler and Ms. VanTreese. Data collection and quality assurance activities will be conducted by the Research Assistants and Research Coordinator, PI, and Biostatistician, respectively. Data analyses will be conducted by the Biostatistician and PI.

3.2. Provide a brief description of each individual's role in the study. Be sure to indicate who will have access to protected health information and who will be involved in recruiting subjects; obtaining informed consent; administering survey/interview procedures; and performing data analysis.

-Amy Helstrom, PhD: Principal Investigator; supervise and participate in all the proposed activities including staff training; data acquisition, management, and analysis; protocol modifications; staff supervision; manuscript preparation; dissemination of findings; training and weekly supervision of care managers, review data to monitor CM performance, provide expert consultation to the PI on specific quality improvement issues.

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-Greg Beehler, PhD: Co Principal Investigator; supervise and participate in all the proposed activities including staff training; data acquisition, management, and analysis; protocol modifications; staff supervision; manuscript preparation; dissemination of findings; training

and weekly supervision of care managers, review data to monitor CM performance, provide expert consultation to the PI on specific quality improvement issues.
Marybeth Groot, MS: : Research Coordinator; Recruit, screen, randomize, and track participants; conduct chart reviews, research assessments, data entry; under guidance of PI, manage data and help ensure data integrity
-Brenda Jeffries-Silmons, BA: Research Assistant; Recruit and screen participants; conduct chart reviews; collect, enter, and clean baseline and follow-up data; maintain study records

-Katharine Vantreese, LCSW:; assist with oversight of the study RA; facilitate IRB recruitment activities/ Care Manager/Supervisor; provide clinical supervision to the care manager; provide care management

-Debra Lerner, PhD: Consultant; supervise implementation; provide consultation of intervention procedures; contribute to dissemination activities; provide clinical supervision
-David Adler, MD:; Consultant; participate in dissemination; provide clinical supervision
-David Oslin, MD: Consultant; engage in dissemination of results

Catherine Westerduin, LCSW: Care Manager; provide care management; recruit/ consent participants (as needed)
Suzanne DiFilippo, RN: Care Manager; provide care management/usual care
Marybeth Groot, MA: Research Coordinator; recruit and screen participants; conduct chart review, collect, enter and clean baseline and follow-up data; maintain study records

Of note: Drs. Lerner and Adler will not discuss PHI during supervision.

3.3 If applicable provide information on any services that will be performed by contractors including what is being contracted out and with whom.

N/A

3.4 If applicable provide information on any Memoranda of Understandings (MOUs) or Data Use Agreements (DUAs) that are being entered into including with whom and for what reason.

N/A

4 Study Procedures

4.3 Study Design

4.3.1 Describe experimental design of the study. Include sequential and/or parallel phases of the study, including durations, and explain which interventions are standard of care.

A. Overview

We will conduct a prospective, longitudinal, randomized control trial (RCT) with (n=300) CGs randomly assigned in equal proportion to the experimental CG SOS Program or a usual care (UC) arm. CGs will include employed, informal CGs of Veterans with depression, anxiety, PTSD, and/or TBI, who themselves screen positive for psychological distress and work performance limitations due to caregiving. CGs will be involved in providing regular assistance with IADLs. Following referral, recruitment, consent, and screening, eligible CGs will be surveyed at pre-intervention baseline, with post-intervention follow-ups at 4 and 9 months. Research data will be obtained from self-report telephone interviews using validated tools (with a mail/email version option) and chart-review of clinical patient record data from the VA Informatics and Computing Infrastructure (VINCI). SOS care managers (CMs) will provide the intervention telephonically. Neither the SOS nor the UC group will be restricted in its use of VA or non-VA care. Our proposed study design and methods were chosen to minimize known weaknesses in the extant, primarily observational CG research.[54] We use a pre/post randomized design, well-validated, CG-reported measures to capture the primary and secondary outcomes of psychological distress (K10 Psychological Distress Scale) [20,21] and CG work functioning (the C-WLQ),[22] rigorous eligibility criteria, and a realistic intervention approach reflecting CG input with a clear intervention goal.

B. Study Procedures

B.1 Screening, Baseline and 4 and 9 month Follow-up Research Assessment Procedures: Once the CG is identified (by self-referral, VA providers, or VINCI), indicates an interest in study participation, and consents (in-person or by phone), the RA will complete the initial screening and, if the CG is eligible, the baseline research assessment. Next, to ensure blinding of the RAs, the Project Coordinator will use a random number table to inform each CG of their group assignment. Procedures for the assigned study arm will commence (see B.2 and B.3). All CGs will be contacted again for 4- and 9-month follow-ups, at which point the majority of baseline assessments will be re-administered. Before each assessment, RAs will remind CGs not to disclose their assigned study arm. Data on care recipients' (CRs') health and service utilization will be extracted from the CRs' clinical record via VINCI, while CG VA and non-VA CG/CR health

and service utilization will be captured by CG assessment. All research assessments (including follow-ups) will be completed by the RA by telephone (with an email/mail-in option, if preferred) and include validated questionnaires regarding CR- and CG-level sociodemographic, clinical, work- related, and psychosocial variables (Appendix 1; Table 1). In-depth qualitative interviews will be conducted at 4-month follow-up with a subgroup of CGs (n=30) from the SOS arm. These qualitative interviews will be audio recorded.

B.2 Caregiver SOS Intervention Procedures: SOS care is a comprehensive approach to helping CGs gain the knowledge, skills and confidence to achieve success in stress self-management. The intervention concept was developed by Dr. Lerner and her research group and will be adapted for the VA context. Through a range of techniques, CGs develop abilities to modify psychological and social sources of stress, including the stress associated with performing both caregiving and work roles. SOS care is brief, telephonic care (6 one-hour sessions over 3-4 months) offered during either work or non-work hours, and tailored to the CG's needs, preferences, and priorities. Supportive visual aids and CG workbook material are distributed via mail or email. SOS is delivered by SOS-trained VA CMs; clinicians with a Master's degree or higher in Social Work or Psychology. SOS care is an opportunity for CGs to form an alliance with a VA healthcare professional ready to meet their health and psychosocial needs, including concerns about CR health and treatment.

SOS care addresses both work and caregiving stress. Each domain receives equal emphasis. The five pillars of behavior change in SOS care are: 1) knowledge of work and CG stress; 2) stress management skills and abilities; 3) supports and resources (VA and non-VA); 4) confidence and motivation to modify stress; and 5) work and CG-focused problem-solving skills. These pillars are built in a CG-centered and collaborative relationship. The pillars are addressed through seven modules (please see Appendix 2). In six sessions, the CM will cover each module at least once (more than one module can be covered per session), after which certain modules will become more or less important depending on a shared understanding of the CG's preferences and self-management needs. SOS care involves an ongoing process of formulating self-management goals and action plans and preparing CGs to succeed in implementing them. This process reflects theory and research pertaining to achieving self-management behavior change and the psychosocial mechanisms of stress. Addressing both the work and caregiving contexts, CMs will educate CGs about stress and its biopsychosocial dimensions. CMs introduce strategies for self-managing stress and collaboratively design experiments to test these strategies ("homework"). Modules address cognitive-behavioral (including emotional and problem-focused coping), work, and CG role redesign and role behavior change strategies, approaches for strengthening and reinforcing workplace and personal social supports, reducing barriers to managing stress at work and in the caregiving context through problem-solving and self-monitoring, and motivational support. The CG's progress is monitored to identify strategies that effectively achieve self management goals. CMs assess CG progress every other session in a clinical interview using criteria from the C-WLQ.[22] The final session solidifies a self-management plan. The process of care is supported by ongoing supervision with Drs. Adler, Lerner, and Helstrom (Co-Is).

B.3. UC Comparator Procedures: CGs in this arm will be contacted telephonically once by a CM. After a brief needs assessment, the CM will provide contact information for appropriate VA (e.g., local CSP clinicians) and non-VA community resources/services. CGs will be sent brochures for the national VA CSP. Information on both the program's website (which includes links to training, education, resources, and outreach programs for CGs) and the national CG hotline number will be included in the e/mailed packet. Receipt of information regarding the VA CSP is consistent with the standard of care for informal CGs in the VHA since 2010.[30] After this initial contact, CGs in this group will only be contacted again 4 and 9 months after baseline for administration of follow-up research assessments. CGs will be encouraged to seek medical, psychological, social support, and social services that are available to them through VAMCs or any other non-VA/community source. CGs in the SOS group will be offered similar information.

B.4. Training and Supervision: The SOS care CM will have 16 hours of training (telephone and webinar) that will cover the study protocols, modules, assessment tools, care documentation and performance standards. Training will continue during team supervision sessions (telephone

and webinar) and on an individual ad hoc basis (with Drs. Helstrom, Lerner, and Adler). Supervision sessions, held weekly, will involve review of specific cases.

Fidelity to the SOS protocols will be measured at the CG and CM level. At the CG-level, we will assess the extent to which the CG is adequately exposed to the intervention (i.e., intervention dose, which is the number of sessions completed).[60] After each session, the CM will complete a session checklist, rating six coaching process items and seven content items, using a three-point rating scale (0=none, 1=some, 2=a great deal). The process items are: 1) identifying caregiving stressors; 2) identifying workplace stressors; 3) assigning homework; 4) reviewing homework; 5) reinforcing motivation; and 6) addressing problem-solving. The content items are: 1) building the knowledge base; 2) collaborative goal setting and action planning; 3) skill building in cognitive behavioral strategies; 4) skill building in CG/work role modification; 5) preparing for individual and social barriers to change; 6) linking to resources and social supports; and 7) problem-solving and self-monitoring. A total dose score on each content item will be calculated as the sum across all coaching sessions for each participant. In order to monitor and ensure the quality of the care management sessions and CMs' fidelity to the model, 15% of the sessions will be randomly selected for audiotaping using a random number generator and reviewed. A fidelity checklist, which we have developed and used in our other intervention work, will be completed by raters (Drs. Helstrom and Mavandadi), analyzed, and used to provide feedback to the CM.

C. Assessment and Data Collection Procedures

C.1. Measures and Data Collection Timeline: Table 1 (Appendix 1) describes the proposed assessment tools and timing. These data will be collected by the RAs. As part of SOS care, the CM will administer and document results from a brief C-WLQ every other session. For purposes of tracking the care process, the CM will document each contact with CGs, referrals to VA/community service agencies, and each contact with Veterans' PCPs/providers (when indicated) and results. Finally, in cases where CGs report needing assistance with the Veterans' care, CMs will track whether concerns were discussed with the Veterans' PCPs and whether recommendations were made or help was coordinated for scheduling in primary and specialty care. To complement the quantitative data analyses, we will use rapid qualitative content analysis to evaluate the intervention's acceptability, appropriateness, and value of the content from the CGs' perspective.

We propose to collect screening, baseline, intervention, and 4 and 9-month follow-up data in 42 months. Study enrollment will be on a rolling basis, and participation in the SOS intervention will occur over the span of 3-4 months. Research assessments will take up to 60 minutes by phone. Qualitative interviews with the subset of CGs will take up to 30 minutes. CGs will be paid $40 for the baseline and $25 for each follow-up research assessment ($90); this is similar to the amount of compensation provided to participants in our other studies.[44] CGs completing qualitative interviews will get an additional $10 at the 4-month follow-up.

4.3.2 Include a description of how anticipated risk will be minimized and include an analysis of risk vs. potential benefit.

There is minimal risk to CGs due to their participation in this study. There is also minimal risk to the Veterans whose medical records are accessed and extracted for recruitment and research purposes.

With respect to CGs' participation, all assessment batteries include standardized, well-validated measures of sociodemographic variables, CR- and CG-characteristics, and psychosocial functioning. Thus, in light of the relatively non-invasive nature of the assessment procedures, we do not foresee any serious risks. There is a small risk of some inconvenience and/or anxiety due to the time required to complete questionnaires. Finally, there is a small risk that being asked questions about some psychological concerns and discussing feelings related to caring for the CR may lead to some uncomfortable feelings. To minimize any risk, no matter how small, 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 or intervention sessions at any time.

We would like to note that the study team has conducted a number of studies employing similar methods and assessments and has experienced very few issues. Our VISN 4 MIRECC

and VAWNYHS CIH teams have extensive experience in conducting telephone-based interventions. As such, we have written guidelines for managing distress or expression of clinically significant symptoms while on the phone. We have the capacity to work with local police and can provide direct access to the VA suicide hotline. In our experience this level of intervention is rarely needed, but it is very important for staff to be prepared for the possibility. In short, we do not anticipate the procedures will pose a significant risk.

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. To minimize this risk, every effort will be taken by study staff to ensure participants' privacy and confidentiality. Our team also has extensive experience with research studies that have used medical record data and PHI. Thus, we do not anticipate this to pose a significant risk either.

There are no alternative treatments and procedures to participating in the proposed research. CGs need not participate in this project in order for their Veteran CRs to continue receiving any services they are entitled to.

There are no guaranteed benefits to participating in the proposed study. However, if assigned to the Caregiver SOS intervention arm, CGs (and, by extension, CRs) might benefit from the self-management strategies, psychoeducation, community resource connection, and health coaching that the CM provides. Coaching employed CGs on various strategies to reduce stress and more effectively cope with demands from work and other social roles (including caregiving) may shed light on effective methods of improving work performance and psychosocial outcomes.

In sum, the risks of study participation are minimal. Thus, the risk/benefit ratio of study participation is judged to be acceptable.

4.3.3 Provide description of the study population (delineate all categories of subjects – patients, providers, family members, employees, etc.). Include anticipated enrollment numbers.

We will enroll 300 employed, informal CGs of community-dwelling Veterans with a confirmed diagnosis (per provider/self-report and verified upon medical chart review) or clinically significant symptoms of depression, PTSD, anxiety, or TBI receiving care at the CMCVAMC, VAWNYHS, or affiliated CBOCs. Using a definition adapted from the National Alliance for Caregiving,[2,12] a current informal CG is a person who regularly provides (or arranges for) help to a relative or significant other who is a Veteran with one of the included conditions. To be eligible, CGs must endorse assisting the Veteran with at least 2 IADLs (e.g., help with household chores, finances or personal, medical, or psychosocial needs). The caregiving assistance must be provided on an unpaid basis (not as paid job). We will not exclude CGs who receive payments under VA programs or other health insurance plans. Eligibility also requires CGs to work for pay outside of the home ≥10 hours per week, be 18 years of age or older, score ≥6 on the Kessler-6 or 4 with a score of 2+ on the Perceived Stress Scale[20,21] (indicating mild/moderate distress) and >3% on the C-WLQ.

4.3.4 As applicable, provide information on any added protections for vulnerable populations.

N/A

4.3.5 If applicable include information on data and specimen banking.

N/A

5 Recruitment Methods

5.3 State how many subjects will be needed.

300 caregivers

5.4 Describe when, where, how and by whom potential subjects will be identified and recruited.

Recruitment will take place over the course of 2.75 years. Participants will be identified and recruited via direct referrals from providers at each site (e.g., providers from the Caregiver Support Program (CSP), Home Based Primary Care, and Geriatric and Mental Health Clinics), through direct mailings to potential participants identified via VINCI, or via self-referral.

CGs referred by the Caregiver Support Program coordinators or by self-referral will be contacted directly (in person or by phone) to assess interest in participating and to complete necessary informed consent procedures prior to screening. The Behavioral Health Laboratory (BHL) health technicians may also refer to study staff after contacting Veterans for a behavioral health assessment if Veterans score 15 or more on the PHQ-9 or GAD-7, or score 31 or more on the PTSD Checklist (PTSD-C). Care managers/clinicians from the BHL/Primary Care-MH Integration program may also refer potentially eligible Veterans/CGs to study staff over the course of MH care management.Veterans/CGs referred to study staff by provider referrals or identified through VINCI will either be contacted directly (where appropriate) or will receive a letter describing the study . The letter will include a telephone number to call, which can be used if they want more information or do not want to be contacted for recruitment. Within two weeks of receiving this letter, the Veteran/CG will be called by study staff to assess interest in participating. We will use a stepped process whereby we will first ask the Veteran for verbal consent to allow research staff to speak with his/her care partner (i.e., CG) and access his/her medical record to collect research data. We will inform the Veteran that their CG will be told their diagnosis. We will then document the Veteran's assent or dissent in the recruitment log. If the Veteran provides assent, the designated CG will then be contacted to assess interest in study participation. If the CG is interested in enrolling him/herself in the study, informed consent procedures will commence.

The research team also will participate in the Veterans Research Town Hall Philadelphia CHERP Veterans Community Advisory Board (VCAB) Platform. Members of the research team will participate in information sessions with veterans who are interested in learning about research being carried out at the CMCVAMC. At the virtual breakout session, the research team will provide information about the research study and why it is being done. They will answer questions about the study. Because of confidentiality concerns, the research team will only provide a contact number that Veterans can use to contact the research team. Veterans cannot directly provide their contact information. Approved posters and handouts will be distributed.

5.5 Describe materials that will be used to recruit subjects, e.g., advertisements. Include materials as an appendix or separate attachment

Providers will be given an IRB-approved study brochure/flyer (either in person or via e-mail), and IRB-approved advertisements will also be placed in clinic waiting areas. Flyers will also be distributed to caregivers via e-mail. Study introduction letters will be mailed.

5.6 Describe any payments to subjects, including the amount, timing (at the end of the study or pro-rated for partial study participation), method (e.g., cash, check, gift card), and whether subjects will experience a delay in receiving the payment.

Enrolled CGs will receive $40 (by electronic deposit) for their baseline data collection session and

then $25 for each of the two subsequent follow-up sessions (4M and 9M) for a total of $90 per participant. CGs who complete the qualitative interview (n=30) will receive $35 at the 4M follow-up (for a total of $100).

6 Informed Consent Procedures

6.1 Indicate if informed consent will be obtained and/or if you are requesting a waiver of informed consent or waiver of documentation of informed consent. If the research involves multiple phases, specify for which phases of the research the waiver(s) is being requested and/or the informed consent will be sought.

In order to utilize Veterans' medical records for the purpose of identifying potentially eligible participants and recruitment, we are requesting a waiver of all elements of informed consent for Veterans, including HIPAA. We also are requesting a waiver of informed consent/HIPAA in order to extract Veterans' medical record data for research purposes. Without the waiver, we cannot verify the Veterans' diagnoses or extract and analyze clinical data, as only their 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 are also requesting a waiver of documentation of informed consent and HIPAA for study/intervention takes place primarily via phone and mail, we would like to obtain oral consent for the convenience of the CGs and to expedite the enrollment process. CG consent for participation in this study will be obtained either in person or over the phone. Informed consent procedures comply with current standards of the Institutional Review Boards at the CMCVAMC and VAWNYHS. After telephone discussion of the information in the consent form, and encouraging the asking of questions/concerns, the CG will be asked if s/he gives consent to 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. 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.

The electronic ICF data will be kept separate from any coded, de-identified data. Following the consent and baseline process, CGs will be randomized to either usual care or Caregiver SOS using a random number table.

6.2 Describe who will be obtaining informed consent, if applicable, and any circumstances that may need to be addressed (e.g. subjects with impaired decision making ability and the use of a legally authorized representative, etc.)

The Research Coordinator and Research Assistants (and, if needed, Care Manager) will be obtaining informed consent.

6.3 If applicable, indicate how local site study personnel will be trained regarding human subjects' protections requirements and how to obtain and document informed consent.

All study personnel will complete and remain current on CITI and VA Human Subjects Training; PI and Research Coordinator will train staff on consent procedures.

7 Inclusion/Exclusion Criteria

7.1 Describe the criteria that determine who will be included in or excluded from the study.

Inclusion Criteria:

1. *Veteran receives care at the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC), VA Western New York Healthcare System (VAWNYHS), or affiliated community-based outpatient clinics*
2. *Veteran and CG are 18 years of age or older*
3. *Veteran and CG are community dwelling*
4. *Veteran has a confirmed diagnosis OR clinically significant symptoms of depressive disorder, generalized anxiety disorder, PTSD, and/or TBI (per medical chart).*
5. *CG is a relative or significant other who endorses that s/he assists the Veteran care recipient (CR) with two or more instrumental activities of daily living (IADLs). IADLS include: housework, managing finances, arranging/providing transportation (e.g., to medical appointments and community services), grocery shopping, preparing meals, health management and maintenance (e.g., giving medications, minimizing exposure and response to stress triggers), and arranging for and/or supervising the delivery of services for assistance with everyday activities.*
6. *CG is employed (i.e., works for pay ≥10 hours per week)*
7. *CG screens positive for at least mild-moderate distress (i.e., score ≥6 on the Kessler Psychological Distress 6-item Scale or a score ≥4 on the Kessler 6-item Scale and a score ≥2 on the Perceived Stress scale)*
8. *CG screens positive for at least moderate work role difficulty due to caregiving (i.e., >3% on the Caregiver Work Limitations Questionnaire)*
9. *CG is willing and able to provide informed consent.*

Exclusion Criteria:

1. *CG cognitive, hearing, visual, or other physical impairments leading to difficulty with informed consent process, assessment, or participation in intervention visits*
2. *CG unable to speak or read English*

8. Study Evaluations

8.1. Describe all evaluations to be conducted (including screening; tests/questionnaires that will be administered; any procedures that subjects will be required to complete) and data collection methods. Include materials as an appendix or separate attachment.

We propose to use validated measures that capture multiple aspects of CR/CG psychosocial physical functioning. The survey tools have excellent psychometric properties and minimal response burden. Assessments were chosen to specifically capture CG-related factors that the intervention is designed to target or modify. Several measures were included to meet the Common Data Elements requirement (these measures are italicized in Table 1 (Appendix 1)) and from the Caregiving in the US 2015 Survey[61] to facilitate comparison across studies. All data will be gathered and analyzed adhering to IRB and HIPAA requirements.

Table 1 (Appendix 1) describes the proposed assessment tools and timing. We will use the validated, widely-used K10 as our global measure of psychological distress.[20,21,35,70] Psychological distress embodies negative emotions and feelings that one might experience when they cannot effectively cope with a stressor, and often occurs when perceived stress is prolonged, severe, or both.[8,19] We determined that it is better suited as a primary outcome than CG burden, which is conceptually different from stress and distress (i.e., burden generally is a measure of tasks and subjective evaluations and specific to the caregiving role). Our secondary outcome measure, the C-WLQ, has been extensively validated and is sensitive to the intensity of caregiving demands and responsive to change.[22,23] The measure includes 25 items capturing the extent to which caregiving has impacted work performance and productivity. Its four scale scores reflect the percentage of time (0% to 100%) in the past 4 weeks the CG was limited in performing time management, physical tasks, mental and interpersonal tasks, and output tasks. Item responses range from all of the time (5) to none of the time (1) with a "does not apply to my job" option. Scale scores are computed as the average of item scores within each scale and then converted to a score ranging from 0 to 100. These data will be collected by the RA.

As part of SOS care, the CM will administer and document results from a brief C-WLQ every other session. For purposes of tracking the care process, the CM will document each contact with CGs, referrals to VA/community service agencies, and each contact with Veterans' PCPs/providers (when indicated) and results. Finally, in cases where CGs report needing assistance with the Veterans' care, CMs will track whether concerns were discussed with the Veterans' PCPs and whether recommendations were made or help was coordinated for scheduling in primary and specialty care.

To complement the quantitative data analyses, we will use rapid qualitative content analysis to evaluate the intervention's acceptability, appropriateness, and value of the content from the CGs' perspective. Rapid qualitative content analysis is a "telescoped", action-oriented approach to consolidating and summarizing qualitative data.[77] At the end of the first follow-up research visit (i.e., 4 months), 30 CGs will be purposively sampled on characteristics that can inform interpretation of results and future implementation efforts (i.e., CR condition, age) and asked semi-structured questions (e.g., which outcomes do they value most/least, positive/negative program experiences, what components they found most helpful, what they would change about the program, etc.) (see Appendix 3). After each interview (which will be conducted by the Research Coordinator), we will create a structured, summative memo (organized into summary matrices) that documents responses to a predetermined set of domains (e.g. positive/negative experiences, helpful components, recommendations, perceived value). Based on prior experience, each interview will take approximately 1 hour to review and summarize. Summaries will be compared across groups by Drs. Mavandadi andLerner, each of whom has experience with the use of qualitative methods and analyses in clinical trials.

-Data Collection Technology and Tools: Most data will be collected by RA-administered telephone interview and entered electronically via a free, password-protected, web-based data collection system, VA REDCap. VA 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. A blank copy of the assessment will be sent in advance of the scheduled assessment calls to help facilitate the interview. Alternatively, CGs will have the option of completing the measures on paper and returning via postal mail or email. CGs also will have the option of completing self-report surveys via Qualtrics. During the baseline assessment, participants will be invited to provide an email address where surveys can be sent. Qualtrics will generate no-reply reminder emails containing a link to complete the assessments. Participants will be assigned a unique ID number; this ID number will be used to complete the Qualtrics survey and will link the

participants' Qualtrics responses to the lookup file (which will only be accessible to study staff and will have the code that matches this ID number to identifiable information (please see details in Section 12.2)). The code will be kept secure in a password-protected electronic file in the study folder on the MIRECC server. Data will be routinely downloaded from Qualtrics and saved in the secure study folder.

CMs also will enter clinical data into VA REDCap and the Behavioral Health Laboratory (BHL) software. The BHL software is a VA approved and network-wide installed software package that allows providers to track participants and to graphically display assessment reports. The software has been in use for more than 10 years in the VA. All REDCap and BHL data collection, transfer, and storage of data will be performed on the VA Intranet and thus access to the system is user based and requires maintenance of all relevant employee trainings. CR and CG- related VA and non-VA healthcare and service utilization will be obtained using VINCI or by self- report. When estimating non-VA utilization of care, we plan to follow HERC's guidebook which provides detailed documentation and suggestions for analyzing non-VA data on procedures.68 The utilization database will include a "time window" variable spanning one year prior to and one year following the final CM call. Extracting clinical patient record data electronically to the greatest extent possible will improve validity and reduce respondent burden. Detailed procedures will be followed to protect against potential risks to privacy and breaches of confidentiality.

9. Data Analysis

9.1. Provide sample size determination and analysis (include anticipated rate of screen failures, study discontinuations, lost to follow-up etc.).

Power calculations were computed for Aim 1 based on 300 consenting CGs. Estimating a maximum of 20% attrition from follow-up (final n=120/group), typical correlation of .70 between baseline and each of two follow-ups, 5% significance tests, and 80% power, we will be able to find a minimum detectable effect size (MDES) of 0.235 standard deviations (SD). This is within the range of effect sizes found in other CG intervention studies.[37] For the primary outcome (Aim 1a) we expect a standard deviation for the K10 of about 10,[58] suggesting that we could detect a difference of 2.35 points between treatment and control based on mixed effects models. A clinically meaningful treatment-control difference of 3 points is well within the range of detectable differences. Similarly, for the secondary outcome measure (Aim 1b), a C-WLQ summary score improvement of lost productivity due to caregiving burden (SD=4.4%), will yield a MDES of 1.0%. Exploratory analyses will be underpowered.

9.2. Describe how, where and by whom the data will be analyzed.

All analyses will be run by the PI or Biostatistician.

Power, Sample Size, and Missing Data: As described above, the MDES is 0.235 SD for 5% significance tests and 80% power with a starting sample of 300. Questionnaires will be administered by RAs using software that encourages response and does not permit multiple or out-of-range responses, for which missing data rates of 1-3% are typical and are easily resolved with multiple imputation techniques. While non-VA care will be assessed by self-report, VA claims databases are complete by design. We will conduct attrition analyses to assess differences in CG characteristics between those with complete vs. incomplete data. If differences are found, covariates will be included in final adjusted models. We acknowledge that we may be underpowered to address sample heterogeneity and moderators of treatment effect. Thus, to maximize the interpretability and utility of our findings, in addition to the models described below, the central tendency, variation and potential trends over time will be evaluated using means, standard deviations, and 75%, 85%, and 95% confidence intervals (CIs) plotted across time for each condition.[76] CIs will be interpreted with respect to clinically meaningful treatment group differences. Results from qualitative analyses also will be used to provide a context for treatment effects across potential moderators.

Preliminary Analyses: We will continually assess data quality and randomization success, testing for baseline group differences in key variables (e.g., gender, age, race/ethnicity, job flexibility, K10 and C-WLQ scores, and CR condition). If early analyses indicate group

differences, we will include the variables as covariates in the final adjusted models. We will review summary statistics (e.g., percentages, means and medians) to evaluate whether responses on the major variables (e.g., K10 distress score) are consistent with distributions obtained in other studies and psychometric performance is maintained (e.g., Cronbach's alpha statistics). We will apply appropriate transformations to highly skewed continuous variables. All preliminary analyses will be conducted using SAS version 9.3 (SAS Institute, Cary, NC).

Specific Aims 1 and 2-Assessing Randomization Group Differences in Outcomes: In order to analyze the degree to which randomization group is associated with changes in our primary (CG distress) and secondary (CG work functioning) outcomes over time (Hyp 1a and 1b), we will run separate intent-to-treat, mixed effects linear regression models (using SAS PROC MIXED). Mixed models account for multiple observations (baseline and follow-up) and make use of all available data for each CG (regardless of drop-out or missing assessment periods). Specifically, we will specify a mixed effects model $Yt = \beta 1T + \beta 2Z + \beta 3TF + \beta 4t + \varepsilon$, *where T is the indicator for treatment group (1 for SOS and 0 for UC), t=0, 1, 2 for baseline and the two follow-ups (F=1 for both), and Z is the vector for all other covariates and Yt is the outcome score measured at time t. We will specify CG distress (K10 score) and CG work functioning (C-WLQ score), respectively, as dependent variables to test Hyp 1a and 1b. The overall treatment effect (improvement from the baseline) will be measured by b3. For exploratory purposes, we will test for the treatment trajectory difference by expanding the mixed model to estimate TF interactions separately for each time point.*

To yield findings that will be used to inform future research and implementation endeavors, we will run exploratory analyses (using the analytic strategy outlined above) that address Aim 2. Overall CG physical and mental well-being and CR utilization of VA and non-VA services (including CG-related services), will be modeled as dependent variables. Given that we are underpowered for a full-scale quality of care analysis, we will compare summary statistics and estimates (with confidence intervals) across groups for descriptive purposes as opposed to formal statistical hypothesis testing. We will model group differences in CR service use (using negative binomial models and chi-squares) using count data of utilization/appointments from VINCI and CG self-report surveys (which will ask about CR non-VA healthcare use and CG use of VA/non-VA support services). Service utilization will be operationalized as the number (simple count) and occurrence of any (yes/no) outpatient visits and inpatient admissions/hospitalizations, and the total number of days hospitalized/bed days. Outpatient visits will be further classified based on the visit stop code into medical or surgical, psychiatric/substance use, social work, occupational therapy, other specialty care, and ER encounters. Inpatient hospitalizations will be further classified based on the primary diagnosis for admission into medical or psychiatric/substance use hospitalizations. For each participant, all utilization data will be summed and compared over two intervals (1 year pre-baseline and 1 year post-4 month assessment). Inpatient and outpatient utilization will be analyzed separately. We will also carefully examine specific domains of utilization where we expect to see an effect, such as MH, social work, and occupational health visits. While the differences may not be statistically significant, even clinically meaningful increases in service use by the Veteran and CG would be consistent with the VA mission of improving access to care.

If the treatment is statistically significant in the appropriate direction, we will conduct exploratory treatment modification analyses (i.e., treatment heterogeneity), of the interaction term of β5 (fixed portion) and β6t (random portion). Again, we will base our interpretations on clinical meaningfulness of the effect size estimates and CI's. We will also test if the treatment effect varies by the CR's diagnosis, CG sociodemographics (e.g., CG gender, age, ethnicity), CG job type (flexible vs. inflexible) and CG occupational factors. We will conduct an exploratory dose-response analysis within the SOS care group. Finally, to further guide the interpretation of study results across subgroups of intervention participants and support future implementation efforts, we will also compare summaries derived from the rapid qualitative content analyses.

10. Withdrawal of Subjects

10.1. Describe any anticipated circumstances under which subjects will be withdrawn from the research without their consent.

N/A

10.2. Describe the consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject (e.g., the subject contacting the investigator for an end-of-study visit).

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. Since the caregivers are the participants, they are the ones who can request to withdraw from the study.

11. Reporting

11.1. Include procedures for reporting unanticipated problems, serious adverse events, and protocol deviations.

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. All breaches of confidentiality will be immediately (within 1 hour) reported to the ISO and Privacy Officer. Non-serious adverse events and anticipated adverse events and problems will be logged and discussed in the routine supervision of research staff. The PI 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. All serious adverse events and non-serious unexpected events will be reported to the 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 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.

The Principal Investigator will be responsible for reviewing any adverse events or issues with the protection of subjects. Should there be a need for a clinical intervention, one of the clinicians on the study (Dr. Helstrom, Ms. VanTreese, Ms. DiFilippo, or Ms. Westerduin) will provide said intervention.

12. Privacy and Confidentiality

12.1. Describe whether the study will use or disclose subjects' Protected Health Information (PHI).

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 CPRS or VINCI will remain in the designated study folder on the MIRECC or VINCI secure servers. PHI will primarily be used for recruitment and tracking purposes. PHI will not be disclosed.

12.2. Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, Certificates of Confidentiality, and separation of identifiers and data)

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 and care management 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. 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. 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 CM's office. 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 and research staff 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 CPRS or VINCI will remain in the designated study folder on the VINCI or MIRECC secure servers. However, 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 CM 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 Biostatistician will be 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 or MIRECC server and routinely monitored by the PI .

Should there be any breaches of confidentiality, improper use or disclosure, or deviations to the protocol during this process, the PI will report these incidents to the IRB, Associate Chief of Staff for Research, and Research Compliance Officer at the local site. All breaches of confidentiality will be immediately reported to the Information Security Officer and Privacy Officer. PHI extracted for the purposes of this project will under no circumstances leave the CMCVAMC or VINCI servers. 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.

13. Communication Plan for Multi-Site Studies or Studies being done at Non-CMCVAMC Locations

☐ N/A; skip to question 14

13.1. Include plan for ensuring all required local site approvals are obtained and notifying the Director of any facility where the research in being conducted but the facility is not engaged.

This is a two-site study. We have conducted intervention trials in collaboration with the VAWNYHS CIH before (including a current two-site caregiver study). During weekly meetings, staff will discuss any IRB-related activities (approvals, modifications, reporting, etc.) and discuss recruitment and enrollment numbers.

13.2. Include plan for keeping all engaged sites informed of changes to the protocol, informed consent, and HIPAA authorization.

We will discuss any changes to the protocol, IC, and HIPAA procedures during weekly meetings, and have all IRB documents shared on a shared VA server. This has been effective in managing and tracking procedures and changes across our two sites in past trials.

13.3. Include plan for informing local sites of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study.

All serious adverse events and non-serious unexpected events will be reported to the 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 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.

13.4. Include plan for ensuring the study is conducted according to the IRB-approved protocol.

The PI and Research Coordinator will routinely evaluate and assess data quality and adherence to the IRB-approved protocol. Updates and issues will be discussed during weekly team meetings.

13.5. Include plan for notifying all local facility directors and LSIs when a multi-site study reaches the point that it no longer requires engagement of the local facility (e.g., all subsequent follow-up of subjects will be performed by the PI from another facility).

We will discuss updates and enrollment numbers during weekly calls.

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SECTION 17: KEYWORDS

(**NOTE:** Provide three (3) keywords. Use MeSH Headings only (Central Office Requirement). Enter one item per line. http://www.nlm.nih.gov/mesh/MBrowser.html)

1. ☐
2. ☐
3. ☐

SECTION 18: INSTITUTIONAL SUPPORT

(**NOTE:** If yes is marked next to any Service/Section listed below, you **MUST** obtain the signature of the Service Chief or Designee of any Service/Section involved in research. **OR**, a letter/e-mail should be provided to the investigator from the Service Chief or Designee of any Service/Section involved in this research.)

Laboratory	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Pharmacy	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Nuclear Medicine	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Psychiatry	**Yes** ☒ **No** ☐	**Signature OR Letter/E-mail**
Medicine	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Radiology	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Nursing	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Outpatient	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Union	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Lab Space	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**
Other, specify ☐	**Yes** ☐ **No** ☐	**Signature OR Letter/E-mail**

SECTION 19: DATA MANAGEMENT AND ACCESS PLAN (DMAP)

***NOTE**: This Data Management and Access Plan (DMAP) should be used **for Unfunded** VA Research or VA Research Funded by Entities **Without** a Specific DMAP.*

IF THE FUNDING AGENCY HAS A DMAP, SUBMIT IT, INSTEAD OF THE BELOW.

Section 1 - Funding **–** *(Check applicable box and indicate funding source if present.)*	
☐ VHA Program Office **without** Specified DMAP Format	**Name of Program Office**:
☐ External Funder **without** Specified DMAP Format	**Name of Funder**:
☐ **Unfunded**	
☐ **Not applicable**; see separate DMAP from funding source	

Section 2 - Public Access to Publications Resulting from the Research - *(Check all applicable boxes.)*

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

☐ The proposed research **will not be funded by VA.**

☐ Publications will be made available to the public through **PubMed Central** within one year after the date of publication. *[See ORD website noted above.]*

☐ Publications **will be made available to the public** in another way. *[Briefly describe plans below.]*

Publications will **not** be made available to the public. *[Provide a brief rationale below.]*

Additional details related to plans for public access to publications results from the research, as indicated in section 2 above.

Section 3 - Public Access to Final Data Sets Underlying Publications Resulting from the Research - *(Check all applicable boxes.)*

☐ Final data sets underlying publications resulting from the proposed research **will be shared** outside VA in **electronic format** through the mechanism(s) indicated in Items #6 through #10 below.

☐ Final data sets underlying publications resulting from the proposed research **will be shared** outside VA **ONLY in hard copy** through the mechanism(s) indicated in Items #6 through #10 below. *[Provide a brief rationale below].*

Final data sets underlying publications resulting from the proposed research **will <u>not</u> be shared** outside VA, except as required under the Freedom of Information Act (FOIA) *[Provide the rationale below.]*

Additional rationale(s) for plans to access data sets underlying publications, as indicated in Section 3 above.

Section 4 - Mechanisms for Public Access to Final Data Sets Underlying Publications Resulting from the Research **–** *(Check all applicable boxes.)*

☐ As indicated in Item #5 above, final data sets underlying publications resulting from the proposed research **will <u>not</u> be shared** outside VA.

The project involves **basic science research**. Final data sets underlying publications resulting from such research will be shared ☐ as described in the space below. *[Describe mechanisms for sharing, e.g., upon request, through a databank or repository, via a website]*

The research involves **human subjects**. Data sets based on information obtained from human subjects will be shared as	☐ **Individually Identifiable Data** will be shared pursuant to valid HIPAA Authorization, Informed Consent, and an appropriate written agreement limiting use of the data to the conditions described in the authorization and consent.

follows. Check appropriate box.	**A Limited Dataset (LDS)** will be created and shared pursuant to a Data Use Agreement (DUA) that indicates adherence to any applicable Informed Consent provisions, appropriately limits use of the dataset and prohibits the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset. *NOTE: An LDS does not necessarily imply de-identified data per HIPAA.*

	☐ **A De-identified, Anonymized Dataset** will be created and shared. *NOTE: ORO recommends that such sharing take place under a written agreement that adheres to any applicable Informed Consent provisions and prohibits the recipient from identifying or re-identifying (or taking steps to identify or re-identify) any individual whose data are included in the dataset. However, it is permissible for final datasets in machine-readable format to be submitted to and accessed from PubMed Central (and similar sites) provided that care is taken to ensure that the individuals cannot be re-identified using other publicly available information.*
It is <u>likely</u> that requests for data from outside researchers (or other entities) may correspond to one or both of the following **special conditions:**	☐ **Individually Identifiable Data**, excluding Veterans' names and 38 USC §7332-protected information, will be shared, <u>pursuant to a written request and IRB approved waiver of HIPAA authorization, with the approval of the Under Secretary for Health,</u> in accordance with VHA Handbook 1605.1 §13.b(1)(b) or §13.b(1)(c) or superseding versions of that Handbook. Note: Subject to all other listed requirements, Veterans' names may be shared with other Federal agencies (38 USC §5701), and with non-Federal investigators who provide the names and addresses of the individual subjects.
	☐ **Individually Identifiable Data,** including 38 USC 7332-protected information, will be shared, pursuant to the above requirements <u>and</u> a written assurance from the recipient that the information will be maintained in accordance with the security requirements of 38 CFR Part 1.466, or more stringent requirements, the information will not be re-disclosed except back to VA, and the information will not identify any individual patient in any report of the research or otherwise disclose patient identities.
Additional details on mechanisms for sharing final data sets as indicated in Section 4 above.	

Section 5 - Briefly summarize **how, where, when, to whom, and the extent to which** data resulting from the research will be made available outside VA.

Section 5 answer:

Section 6 - Describe **how and where** data resulting from the research will be **stored and maintained** (e.g., data will be stored and maintained in a secure ORD data repository or resource; data will be stored on VA servers behind the VA firewall and backed up to a hard drive maintained and secured in the investigator's lab; etc.).

Section 6 answer:

Section 7 - Describe the mechanisms for ensuring the **protection of personal privacy,** the **confidentiality of individually identifiable information,** and the **security of proprietary data and information.**

Section 7 answer:

Section 8 - Describe the **scientific and/or public purposes** for making the data available (i.e., how will scientists and/or the public benefit from making the data available) **and** explain how the data available for sharing will permit **validation of results** by the recipients (e.g., sufficient data and descriptors will be made available to confirm conclusions in the publication, duplicate statistical analysis, perform additional analyses, etc.).

Section 8 answer:

Section 9 - Describe the mechanisms for ensuring the **protection of personal privacy,** the **confidentiality of individually identifiable information,** and the **security of proprietary data and information.**

Section 9 answer:

Section 10 - Describe the **scientific and/or public purposes** for making the data available (i.e., how will scientists and/or the public benefit from making the data available) **and** explain how the data available for sharing will permit **validation of results** by the recipients (e.g., sufficient data and descriptors will be made available to confirm conclusions in the publication, duplicate statistical analysis, perform additional analyses, etc.).

Section 10 answer:

Section 11 - **As Principal Investigator** for the proposed research, **I attest** to the accuracy of the information provided above, and **I** understand that –

- Final data sets must be maintained locally in accordance with VA Records Control Schedule 10-1 or until enterprise-level resources become available for long-term storage and access (unless otherwise required or permitted by the relevant VHA Program Office)
- Failure to implement this DMAP may result in restrictions to subsequent research activities

SECTION 21: ATTESTATION TO FOLLOW FEDERAL REGULATIONS

As the Principal Investigator for this project, I certify that I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05, paragraph 5g and that these include but are not limited to the following:

- Giving first priority to the protection of human subjects; upholding professional and ethical standards and practices; and adhering to all applicable VA and other Federal requirements, include IRB and the local VA Facility's policies and procedures regarding the conduct of research and the protection of human subjects.

- Ensuring all investigators and other staffs participating in this human subjects research are qualified; have the appropriate training, education, and experience to perform procedures assigned to them; and that they have been appropriately credentialed and privileged as applicable per current local facility and VA requirements.

- Submitting all amendments to the project or changes in the informed consent to the IRB for review and approval prior to initiation, except when necessary to eliminate immediate hazard to the participants. Any changes implemented as a result of an immediate hazard will be promptly reported to the IRB as a project deviation and an amendment submitted if determined necessary.

- Obtaining and documenting legally effective informed consent of the subject or the subject's legally authorized representative (LAR), as well as a HIPAA authorization, unless the IRB approves an applicable waiver.

- Reporting problems, adverse events, and apparent serious or continuing noncompliance, including local research deaths, in accordance with VHA Handbook 1058.01, local VA Facility requirements, and IRB SOPs (to include the IRB Table of Reporting Requirements.)

- Ensuring appropriate research records are maintained that includes all information made or received by a VA Investigator over the entire lifecycle of the research activity and that these records are maintained in accordance with the VA Records Control Schedule and local policies and procedures.

- Providing continuing review and/or requested updates for the study as applicable in a timely manner and in accordance with the VA and IRB policies and procedures. This includes submission of a closure reports for both local sites and the overall study upon completion. noncompliance.

- Ensuring research does not start until final approval has been received from the IRB, and writte notification from the local Facility ACOS/R&D in accordance with local R&D Committee approval policies and procedures.

Signature or E-Signature of Principal Investigator, ONLY	Date Signed
	12.13.19

SECTION 22: INSTITUTIONAL APPROVALS

(I have read this proposal and find it in compliance with federal, state and local policies and regulations. I have read and deemed the scientific quality of this proposal to be adequate and the proposal has scientific relevance to both the VA's mission and the facility's research program. Resources necessary for the performance of this proposed study are available and adequate.)

Signature or E-Signature of Section Chief:	Date:
Signature or E-Signature of Service Chief: DAVE W OSLIN 1416420 Digitally signed by DAVE W OSLIN 1416420 Date: 2019.12.11 18:31:27 -05'00'	**Date:**
Signature or E-Signature of Chief of Staff: ***(Chief of Staff's signature needed for ACOS investigators only.)***	**Date:**