CRE 12-083, Motivational Coaching to Enhance Mental Health Engagement in Rural Veterans

Funding Agency: **VA HSR&D Merit**

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Abstract

Project Background: One in five OEF/OIF/OND veterans resides in rural areas and primarily receives care from VA CBOCs. Compared to their urban counterparts, rural veterans experience a significantly greater MH burden and poorer outcomes. Nevertheless, less than 10% of OEF/OIF/OND veterans with a new PTSD diagnosis attend a minimum number of sessions required for evidence-based treatment, with rurality being one of the strongest predictors of poor engagement. Our pilot study in urban OEF/OIF/OND veterans demonstrated that telephone Motivational Interviewing (MI) delivered by research staff significantly improved MH treatment initiation and retention in care. However, we do not know whether telephone MI will have as strong an effect on MH treatment engagement when implemented by VA staff in CBOCs serving rural veterans.

Project Objectives: As a part of the CeMOHR CREATE application to improve rural veterans' access to evidence-based mental healthcare (Fortney, PI), the overall goal of this project is to adapt, implement and test an MI-based coaching intervention to improve MH services engagement at CBOCs serving rural veterans. The specific aims of this project are: (1) Conduct a developmental formative evaluation of perceived barriers to MH treatment engagement and adapt the MI-based treatment engagement intervention and implementation strategy to the needs of stakeholders; (2) Conduct a randomized multi-site pragmatic effectiveness trial comparing MH Referral alone with MH Referral plus MI-based coaching; and (3) Conduct an implementation-focused formative evaluation and use this information to make mid-course corrections to the implementation strategy based on stakeholder and key informant input.

Methods: We propose a 4-year Hybrid Type 2 effectiveness-implementation project that uses mixed qualitative and quantitative methods. In order to maximize generalizability, we will conduct this study in geographically distinct rural CBOCs in VISNs 16 and 21. The PARIHS and RE-AIM frameworks will guide the implementation and formative evaluation strategies, respectively. During Phase 1 (months 0-10,) using Evidence-Based Quality Improvement (EBQI) meetings, semi-structured interviews, and quick ethnography, we will conduct a developmental formative evaluation to learn about barriers impacting veterans who use VA CBOCs and we will adapt the MI-based engagement intervention and implementation strategy to the needs of project stakeholders (Aim 1). During Phase 2 (months 10-48), we will conduct the pragmatic effectiveness trial of the telephone motivational coaching intervention to determine whether, in comparison to MH Referral alone, telephone MI coaching improves MH treatment initiation and retention, the use of e-health MH resources, and perceived need and readiness for and access to MH treatment among veterans who use CBOCs (Aim 2). Also during Phase 2, using the same qualitative methods described for Aim 1, we will conduct an implementation-focused formative evaluation to obtain information which will allow us to further refine the implementation strategy based on stakeholder and key informant input (Aim 3).

Impact: This research will help close the knowledge gap about barriers to care and preferences for MH services among rural veterans. In addition, information from this project will be used to develop implementation toolkits for MH treatment engagement interventions for rural veterans. Finally, this project will determine the effectiveness of a telephone Motivational Interviewing engagement intervention using e-health adjuncts, thereby filling a gap in the scientific literature about whether novel interventions can be used by VA staff in CBOCs to overcome rural-urban disparities in MH treatment engagement.

List of Abbreviations

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

ANCOVA	-	Analysis of covariance
CAHCS	-	Central Arkansas Health Care System
CAVHS	-	Central Arkansas Veterans Healthcare System
CBOC	-	Community-Based Outpatient Clinic
CBT	-	Cognitive Behavioral Therapy
CI	-	Confidence Interval
CPRS	-	Computerized Patient Record System
DFE	-	Developmental Formative Evaluation
DoD	-	Department of Defense
EBP	-	Evidence-Based Practice
EBQI	-	Evidence Based Quality Improvement
GAD	-	Generalized Anxiety Disorder
HBC	-	Health Behavior Coordinator
HIPAA	-	Health Insurance Portability and Accountability Act
ICD	-	International Classification of Diseases
IRB	-	Institutional Review Board
IRR	-	Incidence Rate Ratio
ITT	-	Intent-To-Treat
MH	-	Mental Health
MI	-	Motivational Interviewing
MINT	-	Motivational Interviewing Network of Trainers
NCP	-	National Center for Prevention
NCPTSD	-	National Center for PTSD
NIDA	-	National Institute on Drug Abuse
OEF	-	Operation Enduring Freedom
OIF	-	Operation Iraqi Freedom
OND	-	Operation New Dawn
PACT	-	Patient Aligned Care Team
PARiHS	-	Promoting Action on Research Implementation in Health Systems
PCMH-I	-	Patient-Centered Medical Home Initiative
PDSA	-	Plan-Do-Study-Act
PTSD	-	Post-Traumatic Stress Disorder
QE	-	Quick Ethnography
RA	-	Research Assistant
RCT	-	Randomized Controlled Trial
RE-AIM	-	Reach, Effectiveness, Adoption, Implementation, Maintenance
RN	-	Registered Nurse
RR	-	Relative Risk
RUCA	-	Rural-Urban Commuting Area

SFVAMC	-	San Francisco VA Medical Center
SLVHCS	-	Southern Louisiana Veterans Health Care System
SOTA		State Of The Art
TBI	-	Traumatic Brain Injury
UAMS	-	University of Arkansas for Medical Sciences
VISN	-	Veterans Integrated Service Network
VistA	-	Veterans Health Information Systems and Technology Architecture

Contents

Protocol Title: Motivational Coaching to Enhance Mental Health Engagement in Rural Veterans

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2.0 Introduction

There is a substantial burden of mental health (MH) problems in rural OEF/OIF/OND veterans. After a decade of war, over 51% of OIF, OEF, and OND veterans in VA healthcare have received MH diagnoses; the majority (27%) have received diagnoses of posttraumatic stress disorder (PTSD).[1] Studies show that veterans residing in rural areas experience significantly greater MH severity and poorer outcomes than their urban counterparts[2, 3, 9] Surprisingly, there are no published studies on the differential MH burden among OEF/OIF/OND veterans in VA healthcare based on rurality. To begin to address this knowledge gap, using rural-urban commuting area (RUCA) zip code data to define rurality [10, 11] and national VA administrative data to obtain ICD-9 MH diagnoses codes, our group found that increasing rurality was associated with a higher prevalence of MH disorders in

OEF/OIF/OND veterans nation-wide and in VISNs 16 and 21. (Seal, preliminary data) For instance, compared to the prevalence of MH diagnoses among urban OEF/OIF/OND veterans in VISN 21 (44.7%), the MH burden was higher in rural veterans(47.4%) and even greater in "isolated rural" veterans (54.6%),(Relative Risk=1.22, 95% CI=1.11-1.34 for MH diagnoses in isolated rural vs. urban veterans) (Seal, preliminary data).

The majority of OEF/OIF/OND veterans with MH problems do not receive an adequate course of MH treatment. The VA Uniform Mental Health Services Handbook mandates that all veterans, including those receiving care at CBOCs serving rural veterans, have access to evidence-based MH treatments. Minimally adequate MH treatment has been defined as ≥ 8 MH treatment sessions or receiving ≥ 2 months of psychiatric medication plus > 4 visits within 1 year.[5] Unfortunately, the majority of OEF/OIF/OND veterans has not received an adequate course of MH treatment as found in a nationally representative sample of veterans,[12] and veterans enrolled in VA healthcare.[6, 13] Indeed, at the San Francisco VA Medical Center (SFVAMC), our group demonstrated significantly improved MH treatment initiation in OEF/OIF/OND veterans who presented to our new co-located primary care-mental health clinic compared to usual primary care, but sustained engagement in specialty MH services remained poor with drop-out after 1-2 sessions.[14]

Poor retention in MH services may be even more pronounced for rural OEF/OIF/OND veterans.[6 13] Our own research showed that living > 25 miles from a VA facility was a strong predictor of failing to receive adequate MH treatment.[6] In a more recent analysis of MH utilization in OEF/OIF/OND veterans in the first year of receiving MH diagnoses nationwide, we found a significant association between increasing rurality and drop-out after 1-2 MH visits. Specifically, in VISN 21, only 35% of isolated rural veterans with MH diagnosis compared to 45% of urban veterans completed ≥ 8 MH visits (RR for isolated rural=0.77, 95% CI=0.59, 1.00)(Seal, preliminary data) Geographical distance is a significant logistical barrier, but rurality may also serve as a proxy for other access and engagement barriers such as cultural, financial, and digital barriers, as outlined in the State of the Art Conference (SOTA) Access Framework, developed by Dr. Fortney (see CREATE Overview).[15] SOTA hypothesizes that the most salient barriers to care for rural veterans may be cultural barriers, including heightened levels of stigma, and lack of perceived need including negative beliefs about MH treatment, stoicism, and self-reliance.[16-18]

Motivational Interviewing is an evidence-based practice to promote MH treatment engagement in veterans. Telephone-based referral care management (Behavioral Health Lab) consisting of 1 to 2 telephone MI sessions plus pre-scheduled appointments for 113 older, depressed veterans resulted in significantly improved MH treatment initiation, but no improvements in clinical outcomes.[19, 20] In another study of 114 older veterans (mean age 56 years), those randomized to 4 sessions of group MI demonstrated greater retention in PTSD therapy than veterans who received 4 sessions of psychoeducation.[21] Neither of these MI-based trials was

conducted in OEF/OIF/OND or rural veterans, but results underscored that MI, including telephone MI, improved MH treatment initiation and/or retention in care. In contrast, results from a Cognitive Behavioral Therapy (CBT)-based MH treatment engagement intervention for a small sample of OEF/OIF/OND veterans were mixed. In OEF/OIF veterans, using a pre-post quasi-experimental design, Stecker et al., showed that among 26 National Guard and Reserve veterans, one session of telephone-administered CBT significantly increased veterans' self-reported intention to engage in treatment, but did not result in actual increases in MH treatment initiation.[22]

Our recent pilot RCT demonstrated the efficacy of telephone MI to increase MH treatment engagement in OEF/OIF/OND veterans. This efficacy data supports our taking the next step in conducting a hybrid effectiveness-implementation study. Seventy-three OEF/OIF veterans who screened positive for one or more MH problem(s), but were not engaged in treatment, received an MH referral and were randomized to either 4 brief sessions of telephone MI or 4 brief neutral attention-control telephone sessions at baseline, 2, 4, and 8 weeks. Of note, MI was conducted by non-clinician Master's-level research staff who had been trained in MI for this study. Blinded assessment occurred at 8 and 16 weeks. In intent-to-treat analyses, 62% assigned to telephone MI initiated MH treatment compared to 26% of Controls [Relative Risk (RR) =2.41, 95% Confidence Interval (CI) =1.33- 4.37, p= 0.004], which represented a large effect size (Cohen's h=0.74). We also observed significant reductions in stigma about MH treatment and in marijuana use (both p-values<0.05). In addition, while this MI trial was not focused on MH treatment retention, the MI group also demonstrated significantly greater retention in MH treatment than Controls (Incidence Rate Ratio (IRR) =4.36, 95% CI=1.96-9.68), signaling that telephone MI could be used to enhance MH treatment retention in OEF/OIF/OND veterans.[7] While the evidence from this pilot study supports progression toward implementation, because we are now targeting a rural, and not urban population, and VA staff as opposed to research staff will deliver the intervention, we propose a pragmatic effectiveness study using a hybrid design that will also allow us to critically evaluate the implementation strategy at the same time as the interventions' effectiveness.[8]

The conceptual underpinnings of Motivational Interviewing (MI) support an MI-based coaching intervention to enhance MH treatment engagement in rural veterans. MI is a patient-centered counseling style for enhancing intrinsic motivation for change by exploring and resolving ambivalence.[23] MI is based on the principles of interpersonal, patient-centered psychotherapy [24] and the Transtheoretical Model of Change [25] which posits that patients move in graduated stages from pre-contemplation through contemplation to action. Rollnick places the construct of "readiness to change" at the center of his model and identifies two elements:

"importance" and "self-confidence" regarding change that contribute to readiness.[23] A specific MI strategy that we will use in this study, involves the use of the "Readiness Ruler" to gauge an individual's perception on a scale from 0 to 10 of the importance, their confidence, and readiness to make behavioral changes such as engaging in MH treatment.[23] In multiple randomized controlled trials, MI has been shown to enhance both MH treatment initiation as well as retention in care, [26,27] and MI has been successfully adapted for administration by telephone.[28,29]

MI has been effectively used in culturally diverse populations, including rural populations; peer counselors who "speak the same language" may be highly effective in engaging rural veterans in care. [30, 31] Cultural meanings of MH problems may be reflected back to patients to explore ambivalence, negative beliefs and stigma regarding MH treatment. In addition, culturally-based strengths and coping mechanisms, e.g., spirituality, family and peer supports may be leveraged to promote treatment engagement.[32] Indeed, ancillary healthcare staff and peer counselors have been successfully trained to conduct MI.[33, 34] VA has a long-standing tradition of peer counseling as evidenced by 207 Vet Center Centers nationwide, many of which are staffed by veteran peers.[35] Veteran peer counseling programs capitalize on shared experience and camaraderie to foster credibility and trust, decrease stigma and promote help-seeking in veterans.[35] VA has also successfully used peer counseling in substance abuse and MH treatment programs.[36, 37] In January 2011, the VA/DoD Defense Centers of Excellence produced a White Paper identifying best practices in peer support, drawing on the experience and outcomes of numerous veteran peer counseling programs, e.g., Vet2Vet, Vets 4 Vets, Vet Center etc….[38] The White Paper serves a blueprint that will guide us in the hiring, training, and monitoring of experienced veteran peer counselors who will become part of an MI coaching team (see below). As an adjunct to MI coaching, this study will also refer study participants to "Considering Professional Help," https://www.myhealth.va.gov/course/ConsiderProffHelpPresentation/index.html an Office of Mental Health Services program available on MyHealtheVet, which, consistent with MI principles, features veteran peers working through and resolving their ambivalence about engaging in MH treatment.

The PARiHS framework will guide us in adapting and implementing the MI treatment engagement intervention for veterans who use CBOCs serving rural veterans. To evaluate the impact of rural culture on prevailing MH referral and engagement processes at rural CBOCs and use this information to adapt and implement the MI coaching intervention, we will use the Promoting Action on Research Implementation in Health Systems (PARiHS) Framework.[39] The components of PARiHS: Evidence, Context and Facilitation will guide the identification of the necessary conditions under which MI, as an evidence-based practice (EBP), may be implemented in clinical practice at CBOCs. According to PARiHS, successful implementation is most likely to occur when scientific evidence supporting an intervention fits with providers' experience and local cultural norms, the healthcare organizational context is supportive of implementation, and there are culturally appropriate mechanisms to

facilitate and maintain implementation.[40] The RE-AIM framework [41] (see below) will provide a framework to evaluate the progress and outcomes of the implementation strategy. PARiHS fits well with the theoretical underpinnings of MI because both require an interactive partnership of behavioral change agents (researcher and VA leadership and staff) with the targets of behavioral change (patients and VA providers) who may be ambivalent about the need/desire to change. To implement an MH engagement intervention that is culturally appropriate, responsive to the needs of the recipients, and readily adopted and maintained in clinical practice, it will be critical to develop an ethnographic understanding of rural veterans and VA CBOC staff and incorporate these cultural understandings in the MI coaching intervention and implementation plan.

"Secretary Shinseki talks about the tyranny of distance –the distance that separates veterans from care at their nearest VA medical facilities…Distance can mean rural veterans don't have access to the care and services they've earned." [42]

Of the 758,683 OEF/OIF/OND veterans who have separated from military service and have enrolled in VA healthcare nationwide, a quarter receives the majority of their care from VA CBOCs. (Seal, preliminary data) This project focuses on testing the effectiveness of an MH treatment engagement intervention for veterans who use CBOCs serving rural veterans for the following reasons:

First, this is a sub-group of veterans with a disproportionate burden of recent military service-related MH problems. Since the conflicts began in 2002, more than half of all OEF/OIF/OND veterans have received one or more MH diagnoses. Mental illness not only hinders successful reintegration, including obtaining education and gainful employment, but also can leave deep and enduring scars on families, potentially impacting generations to come. Moreover, several studies have shown that compared to their urban counterparts, rural veterans experience more severe MH symptoms and have poorer MH outcomes, the most tragic of which is suicide.[3, 43] Although not a specific aim of this project, we will capitalize on our group's data analytic strengths to further investigate rural-urban disparities in MH burden and utilization among veterans. [6, 44-46]

Second, sustained engagement of veterans in MH treatment is poor; rurality is a strong predictor of poor engagement.[6] Quality evidence-based MH treatment is mandated for all veterans, including veterans receiving care in CBOCs serving rural veterans. The VA has gone to extraordinary lengths to fulfill this mandate by hiring large numbers of new MH personnel, providing training in evidence-based MH therapies, initiating telemental health, and by establishing PCMH-I and the Office of Rural Health.[47, 48] Nevertheless, engagement in MH treatment remains disappointing, particularly among rural veterans.[6] For young veterans, failing to engage in MH treatment early may result in chronic mental illness and associated social and occupational dysfunction with high costs to individuals, families, and society. [49, 50] Our group and others have demonstrated strong links between mental illness, negative health behaviors and physical health problems, such as smoking,

hypertension, and drug and alcohol abuse, resulting in disproportionately high medical (non-MH) services utilization.[46, 51-53] Promoting MH treatment engagement and targeting negative health behaviors early may prevent costly morbidity and excessive services utilization as this generation ages. With our VA clinical and operations partners, Aim 2 will test the effectiveness of an MI-based treatment engagement intervention that aims to not only improve MH treatment engagement, but also to reduce unhealthy behaviors in rural veterans.

Third, a knowledge gap exists with regard to barriers to MH care that differentially impact rural veterans. It is likely that rurality exacerbates many of the same patient-level barriers that impact urban veterans,[12, 17] but there may be other barriers that are unique to rural veterans. Distances to care are greater for rural veterans, requiring increased travel times, more time off from work or school, and childcare etc…Rural veterans are less likely to have the financial resources to orchestrate these logistics, especially for weekly MH appointments. In addition, rural culture may present powerful barriers to MH treatment engagement.[15] These "barriers" include the central importance of family, community, and religion, which may be perceived as better resources for addressing personal MH problems than MH professionals.[54] Rugged individualism, self-reliance, pride, and stigma may deter rural veterans from asking for help.[48] Finally, altruism and humility may lead rural veterans to believe they are not deserving of help.[48] MI, used skillfully, may transform these cultural "barriers" into actual strengths.[32] For instance, family can be encouraged to motivate treatment engagement, clergy may provide initial counseling, and veteran peer coaches may be able to communicate in a way rural veterans understand.[37, 54, 55] Moreover, rural veterans are disproportionately impacted by VA system barriers such as lower MH staffing ratios at CBOCs, resulting in longer wait times.[56] While the proposed MI coaching intervention will not directly change systemic barriers to care, it may encourage veterans to pursue MH treatment despite barriers, as well as motivate veterans to seek non-traditional MH treatment options, including telemental health and online resources. During Phase 1 formative evaluation, we will partner with our stakeholders to achieve a deeper understanding of the salient barriers to care so that we can tailor the MI coaching intervention and implementation plan (Aim 1). Aim 3 will consist of an implementation-focused formative evaluation that will inform mid-course adjustments to our implementation strategy.

Fourth, innovations to enhance treatment engagement in OEF/OIF/OND veterans with MH problems are a national US priority. In separate testimonies to the Government Accountability Office (2011) and the House Committee on Veterans Affairs (2011)[57], Dr. Seal (PI) argued that while evidence-based MH treatments are available within VA, there is a significant engagement gap in which OEF/OIF/OND veterans, particularly rural veterans, are lost between VA primary care (where they first present with MH symptoms) and VA specialty MH clinics, where they are referred for MH treatment. Until we: (1) develop an evidence-base to guide the effective delivery of MH treatments, and (2) successfully implement effective MH

treatment engagement strategies, rural-urban disparities in MH services use and outcomes will likely persist.[58] In her Congressional testimony, Dr. Seal proposed innovative strategies to address this engagement gap which may be attractive to young, rural OEF/OIF/OND veterans: (1) employing experienced veteran peer counselors to promote MH treatment engagement,[38] and (2) expanding the use of e-health technologies to augment engagement interventions and MH resources. Recent meta-analyses and studies indicate that Internet therapy is an efficacious, effective and acceptable treatment for depression and anxiety disorders, including PTSD, and produces results comparable to face-to-face treatment. [59] [60] [61] Aim 1 will use qualitative methods to identify effective, feasible, and culturally acceptable engagement strategies and MH options for young rural veterans, testing the hypothesis that telephone-, smartphone- and internet-based options will increase perceived access. Aim 2 will test the effectiveness of the MI coaching intervention, in part delivered by experienced veteran peer counselors.

3.0 Objectives

This hybrid effectiveness-implementation project [8] will use mixed qualitative /quantitative observational and experimental methods to achieve the following study objectives and test related hypotheses in veterans who receive care at CBOCs serving rural veterans:

<u>Aim 1</u>: Prior to implementing the intervention, to conduct a developmental formative evaluation of perceived barriers to MH engagement among rural veterans, identify feasible, acceptable and effective MH treatment options, and adapt a proven MI-based MH treatment engagement intervention to the needs and preferences of CBOC staff and veterans who receive care at CBOCs.

H1a. Among rural veterans, cultural attitudes such as stigma and lack of perceived need (e.g., stoicism, and self-reliance) present significant barriers to care.
H1b. veterans will favor online, telephone- and smartphone-based MH treatment options.
H1c. veterans will favor a treatment engagement intervention that is, in part, conducted by experienced veteran peer counselors.

<u>Aim 2:</u> In a randomized multi-site pragmatic effectiveness trial, compare the effectiveness of MH Referral alone with MH Referral plus MI-based coaching to improve MH services engagement in veterans receiving care at CBOCs.
<u>Compared to MH Referral alone, MI coaching will significantly:</u>
H2a. Increase MH services initiation and retention (number of MH visits) **(Primary Hypothesis)**.
H2b. Increase the use of e-health "self-help" MH treatment options, such as afterdeployment.org.

H2c. Increase perceived need and readiness for MH treatment, and decrease barriers to MH services.

Secondarily, we will evaluate change in mental health symptoms, high-risk behaviors (e.g., driving under the influence, etc…), functioning, quality of life, perceived access to MH care, and satisfaction with VA healthcare.

Aim 3: During the pragmatic effectiveness trial, conduct an implementation-focused formative evaluation with stakeholders to collect information that will allow us to refine the implementation strategy and further tailor the MI coaching intervention to the needs of veterans and CBOCs serving rural veterans.

4.0 Resources and Personnel

The main aim of this research is to implement telephone or e-Motivational Coaching in order to enhance engagement of rural Veterans in mental health treatment at local VA Community-Based Outpatient Clinics (CBOCs) or in their own communities. The study will be based at the San Francisco VA Medical Center (SFVAMC), the Central Arkansas Health Care System (CAHCS) and the Southeast Louisiana Veterans Health Care System (SLVHCS). SFVAMC and CAVHS will serve as "Motivational Coaching Centers", where the coaches will conduct outreach to Veterans. Recruitment in VISN16 will take place in CBOCs located in the SLVHCS. CAVHS staff will travel to SLVHCS to enroll participants and conduct most study procedures. Some assistance with semi-structured interviews (for both sets of participants) will be provided by over the phone by the SFVAMC Qualitative team. The first phase of the study (first 10 months) will be used to define exactly which affiliated 2-3 CBOCs in SFVAMC and SLVHCS are best suited as mental health referral sites for this research. We already have letters of support from heads of primary care and mental health at each VA Medical Centers agreeing to this process. Study staff members at SFVAMC and CAVHS will conduct study procedures for participants in both VISN 16 and VISN 21.

San Francisco VA Medical Center (SFVAMC)

Karen H. Seal, MD, MPH, *Principal Investigator* Dr. Seal is a VA staff physician and Director of the Integrated Care Clinic for Iraq and Afghanistan veterans at the San Francisco VA Medical Center. Dr. Seal is an Associate Professor in Residence in the Departments of Medicine and Psychiatry at the University of California, San Francisco. For the proposed study, Dr. Seal will oversee all aspects of the study at both study sites. This includes communication with affiliated VA operations partners, staff hires and training, qualitative and quantitative data collection activities, recruitment and enrollment of study subjects, fidelity to the motivational interviewing intervention, human subjects compliance, data management and analysis, and dissemination of study results, including manuscript preparation. Practically, Dr. Seal will manage the multi-site study by holding conference calls with study staff at both sites twice monthly with additional calls and e-mail correspondence with individual staff members as needed. Dr. Seal will travel to Little Rock once a year for a site visit. **Access to PHI-YES**

Christopher Koenig, PhD, *Co-Investigator* Dr. Koenig is a medical sociologist and qualitative researcher. Dr. Koenig (in collaboration with Drs. Curran and Abraham, see below) will be responsible for all qualitative aspects of the proposed study including the conducting the developmental formative evaluation and process evaluations of the MI coaching intervention. Dr. Koenig will assist with the development of the semi-structured interview scripts, conduct semi-structured interviews with VA CBOC and community mental health staff and veteran patients, attend and take notes at all EBQI meetings, and conduct "quick ethnography". These activities will both inform the adaptation of the MI coaching intervention as well as evaluate the effectiveness of the implementation strategy. In addition, together with the other two qualitative analysts on the study, Dr. Koenig will conduct qualitative data analysis and assist with manuscript preparation. **Access to PHI- YES**

Jennifer Manuel, PHD, *Co-Investigator* At the SFVAMC, in her current role as the HBC, Dr. Manuel will assist Dr. Seal with the selection of VA staff and the hiring of an experienced veteran peer counselor for this project. In addition, after initial MI training by the MI trainer, Dr. Manuel will conduct at least monthly supervision sessions with the MI coaches (in part, informed by MI fidelity coding), in addition to the quarterly booster trainings by the MI trainer. As with Dr. Mesidor, the HBC counterpart at CAVHS, Dr. Manuel will be in close communication with the MI trainer to calibrate the MI coaching intervention across sites and to discuss the results of MI fidelity coding. **Access to PHI- YES**

Brian Borsari, PHD, *Co-Investigator* At the SFVAMC, in his current role as the HBC, Dr. Borsari will assist Dr. Seal with the selection of VA staff and the hiring of an experienced veteran peer counselor for this project. In addition, after initial MI training by the MI trainer, Dr. Borsari will conduct at least monthly supervision sessions with the MI coaches (in part, informed by MI fidelity coding), in addition to the quarterly booster trainings by the MI trainer. As with Dr. Mesidor, the HBC counterpart at CAVHS, Dr. Borsari will be in close communication with the MI trainer to calibrate the MI coaching intervention across sites and to discuss the results of MI fidelity coding. **Access to PHI- YES**

<u>Other Study Staff- SFVAMC</u>

Project Coordinator an experienced project coordinator will oversee all field operations of the proposed study, including the hiring and supervision of study staff (particularly the RA and data manager), coordinating regular meetings of co-investigators and consultants, development of study materials, subject recruitment, verifying study eligibility, enrollment and informed consent procedures, randomization, and all data collection activities, including conducting baseline phone assessments. The Project Coordinator will also be responsible for maintaining Central IRB approval and ensuring human subjects protections. In addition, the coordinators at both study sites will set up the EBQI meetings with research staff and stakeholders and coordinate communication

between the EBQI meetings. The project coordinator based at the SFVAMC will be supervised by Dr. Seal. **Access to PHI- YES**

Research Assistant An experience research assistant (RA) will be provide assistance to the PI and Project Coordinator. Specifically, this Research Assistant will be responsible for assisting with the submission of protocol changes to the VA Central IRB and for conducting the some of the quantitative assessments (baseline and follow-up) during the RCT. **Access to PHI- YES**

Research Assistant This Research Assistant will collaborate with Dr. Koenig in the collection of qualitative and ethnographic data through the EBQI meetings, semi-structured interviews, and observations with both providers and veterans. He/she will also conduct quantitative assessment (both baseline and follow-up) in the RCT portion of the study. **Access to PHI- YES**

Veteran Peer Counselor The Veteran Peer Counselor will implement the Motivational Interviewing intervention in RCT study participants. They will be trained by the MI Trainer and will be supervised by the HBCs at each of the participating medical centers. He/she will also help support other study operations such as recruitment, informed consent procedures, and qualitative assessments. **Access to PHI- YES**

Motivational Interviewing Trainer This individual will be a certified MI trainer by the Motivational Interviewing Network of Trainers (MINT). For the proposed study, the MI Trainer will provide a standard initial 8-hour MI training session for VA staff and veteran peer counselors. Following this initial training, he/she will conduct at least quarterly in-person or V-Tel booster training sessions. He/she will supervise the MI fidelity coder (as she has done in the past) and communicate the results of MI coding to the HBCs who will directly supervise the MI coaches at the CBOCs in each of the VISNs. He/she will also help to calibrate the MI coaching intervention across sites. **Access to PHI- YES**

Statistician, MPH This individual will be responsible for conducting all planned study analyses in consultation with the PIs and Co-Investigators and will participate in manuscript preparation. **Access to PHI- YES**

Statistician, PhD Working in tandem with the other Statistician, this individual will be responsible for conducting all planned study analyses in consultation with the PIs and Co-Investigators and will participate in manuscript preparation. **Access to PHI- YES**

Data Programmer/Manager The data programmer and manager will be responsible for uploading the quantitative study questionnaire to our web-based data management system, for secure electronic data entry. He/she will maintain the study database in compliance with VA standards for data security and conduct data quality checks periodically. Subsequently, prior to data analysis, he/she will "clean," validate, and prepare data for analysis by the statistician, assuring data quality. **Access to PHI- YES**

***Research Assistant, PhD*:** The research assistant is a post-doc at the SFVAMC. He will participate in data analysis, interpretation, publication, and dissemination. **Access to PHI- YES.**

CONSULTATION SERVICE

Annabel Prins, PhD Dr. Prins has served as clinical psychologist within the VA for the past 15 years and has cultivated expertise in the areas of PTSD assessment and web-based trainings and interventions. She has served as PI and Co-PI on a number of VA grants in these areas and is thus well situated to serve as consultant for Dr. Seal's grant proposal. She is extremely familiar with VA and DoD e-health resources for mental health treatment, and will assist Dr. Seal and the MI coaching staff in using these, as appropriate. Dr. Prins is currently stationed at the National Center for Telehealth and Technology (T2) where she is evaluating the effectiveness of several online self-help workshops, as well as the overall clinical utility of *afterdepoloyment.org*, a web-site with wellness resources for the military and veteran community. She has also worked closely with Dr. Rusek at the National Center for PTSD to develop PTSD smartphone apps, such as "PTSD Coach". In this capacity, she will provide trainings to VA providers on bringing technology into clinical care through the use of specific e-health tools. Because this project is so closely aligned with her own clinical and research interests, Dr. Prins will donate her effort as a consultant on this project.

Craig Rosen, PhD, *Consultant* As Deputy Director of the NCPTSD Dissemination & Training Division, Dr. Rosen's main research focus is in increasing veterans' access to high quality PTSD care. For this study, he will lend his expertise to the refinement and execution of the motivational coaching intervention to improve engagement in mental health treatment for rural OEF/OIF/OND veterans.

Central Arkansas Veterans Healthcare System (CAVHS)

KEY PERSONNEL

Jeffrey Pyne, MD, ***Co-Investigator*** Dr. Pyne is a Psychiatrist/Research Health Scientist and a full-time VA employee and Staff Physician. Dr. Pyne has experience conducting studies in VISN 16 CBOCs and will assist Dr. Seal in implementing the study intervention in these CBOCs. Dr. Pyne will serve as the site lead for this project and, as such, will directly supervise the Project Coordinator based at CAVHS. Dr. Pyne will also oversee the activities of the qualitative research team that is conducting the developmental and formative evaluations of the intervention and implementation strategy. Dr. Pyne will participate in the bi-weekly study calls with Dr. Seal and will have additional correspondence with Dr. Seal as needed to coordinate study activities at the 2 sites. **Access to PHI- YES**

Marie Mesidor, PHD, *Co-Investigator.* Dr. Mesidor currently serves as the Behavior Health Coordinator (BHC) at the CAVHS. Her role on this project will be to supervise the veteran peer coach. After initial MI training by the MI trainer, Dr. Mesidor will conduct at least monthly supervision sessions with the MI coaches (in part, informed by MI fidelity coding), in addition to the quarterly booster trainings by the MI trainer. As with Dr. Manuel, the HBC counterpart at SFVAMC, Dr. Mesidor will be in close communication with the MI trainer to calibrate the MI coaching intervention across sites and to discuss the results of MI fidelity coding. **Access to PHI- YES**

Other Study Staff- CAVHS

Project Coordinator Is an experienced Project Coordinator who will oversee all field operations of the proposed study, at CAVHS. This includes hiring and supervising of study staff, coordinating regular meetings of co-investigators and consultants, development of study materials, subject recruitment, verifying study eligibility, enrollment and informed consent procedures, randomization, and all data collection activities, including conducting baseline and follow-up phone assessments. The Coordinator will also be responsible for maintaining Central IRB approval and ensuring human subjects protections. In addition, the Coordinators at both study sites will set up the EBQI meetings with research staff and stakeholders and coordinate communication between the EBQI meetings. The Coordinator based at the CAVHS will be supervised by Dr. Jeffrey Pyne. **Access to PHI- YES**

Research Assistant will assist with obtaining informed consent, scheduling qualitative interviews, recruiting, scheduling, and conducting baseline and follow-up telephone assessments. She will make travel arrangements and assist with correspondence. She will also assist with the development, publication, and dissemination of study products. **Access to PHI- YES**

Veteran Peer Counselor The Veteran Peer Counselor will implement the Motivational Interviewing intervention in RCT study participants. They will be trained by the MI Trainer and will be supervised by the HBCs at each of the participating medical centers. He/she will also help support other study operations such as recruitment, informed consent procedures, and qualitative assessments. **Access to PHI- YES**

Qualitative Analyst will conduct the semi-structured interviews with veterans and VA providers and administrative staff in VISN 16 CBOCs. In addition, he/she will attend and take field notes during the EBQI meetings and will conduct quick ethnography in the participating CBOC. He/she will collaborate closely with her SFVAMC-based counterpart, in coordinating data collection methods, analysis and coding of data, and in manuscript preparation. **Access to PHI- YES**

Data Programmer/Manager The data programmer will support the SFVAMC Data Programmer, as needed. The manager will be responsible for uploading the quantitative study questionnaire to our web-based data management system, for secure electronic data entry. He/she will maintain the study database in compliance with VA standards

for data security and conduct data quality checks periodically. Subsequently, prior to data analysis, he/she will "clean," validate, and prepare data for analysis by the statistician, assuring data quality. The Data Programmer will also assist with the Research Assistants on recruitment and assessments, as needed. **Access to PHI- YES**

Southeast Louisiana Veterans Health Care System (SLVHCS)

KEY PERSONNEL

Madeline Uddo, PhD, *Co-Investigator-* Dr. Uddo's clinical, administrative, and research experience in PTSD has prepared her to serve as the Co-Investigator of this study. As supervisor of the Outpatient PTSD Program since its inception in 1989, she has extensive experience in both clinical and administrative aspects of working with PTSD veterans. The PTSD Program is extremely active with approximately 100 consults per month for PTSD treatment. Additionally, she has solid working relationships with Mental Health staff members, including Mental Health and administrative staff at all CBOCs. Throughout the duration of her 25 year career at the VA, she has been involved in PTSD research as a PI, Co-PI, or Co-I, including serving as site investigator for four VA Cooperative Studies in the area of PTSD. **Access to PHI- YES**

Michelle Hamilton, PhD, *Co-Investigator-* As a clinical psychologist, Dr. Hamilton has specialized in the treatment of mental disorders, more recently in the area of PTSD. In her work in the PTSD program she has treated numerous veterans and is thus aware of the challenges in getting veterans in for treatment and compliance with treatment. The program she works in addresses barriers to mental health treatment for rural veterans quite regularly. She is connected with the CBOC's in her area and has relationships with many of the providers. Most recently she spent time at the rural CBOCS implementing a yoga project for veterans. She is well qualified to serve as co-investigator for this project bringing her many years of experience in mental health as well as numerous collaborations with providers in the SLVAHCS CBOC's. **Access to PHI- YES**

Other Study Staff- SLVHCS

Project Coordinator will serve as the project coordinator and provide assistance to the PIs in SLVHCS. Specifically, he will be responsible for maintaining the regulatory binder at SLVAHCS and making sure participant's medical records get updated with research progress notes and informed consent forms. **Access to PHI- YES**

Contractors:

John Fortney, PhD, ***Co-Investigator*** Dr. Fortney is a Medical Geographer/Research Health Scientist located at the Seattle HSR&D Center of Innovation for Veteran-Centered and

Value-Driven Care, VA Puget Sound Health Care System, 1660 S. Columbian Way, S-152, Seattle, WA 98108, Tel: 206-764-2430. Dr. Fortney is a Geographer and health services researcher at the Seattle HSR&D Center of Innovation for Veteran-Centered and Value-Driven Care, VA Puget Sound Health Care System.
He has conducted ground-breaking research as PI of a study implementing telemedicine strategies to identify and manage depression in VA CBOCs and has served as the co-chair of a state of the art (SOTA) conference on Access to Care in the VA. Dr. Fortney is the PI of the CEMHOR CREATE application. He has already assisted Dr. Seal in the development of this mental health engagement project proposal. Dr. Fortney will donate his effort to this study and thus no salary support is requested. **Access to PHI- No**

Paul M. Garton Inc., *Transcription company*. As in our prior studies, we will record a total of approximately 220 semi-structured and unstructured interviews using audio digital voice recorders with providers, administrators, managers, clinic staff, and veterans. A private, non-VA company, Paul M. Garton, Inc., will be contracted with to render the digital audio files into textual transcripts for data management and analysis. We will devise unique transcription formatting for the project and use strict data management and security protocols he developed at the SFVAMC. When transferring the audio files, the research team will encrypt the recordings using FIPS-approved encryption software that will require a unique password to de-crypt the file. This encrypted volume will then be uploaded through secure means to the transcription company for transcription. **Access to PHI- YES**

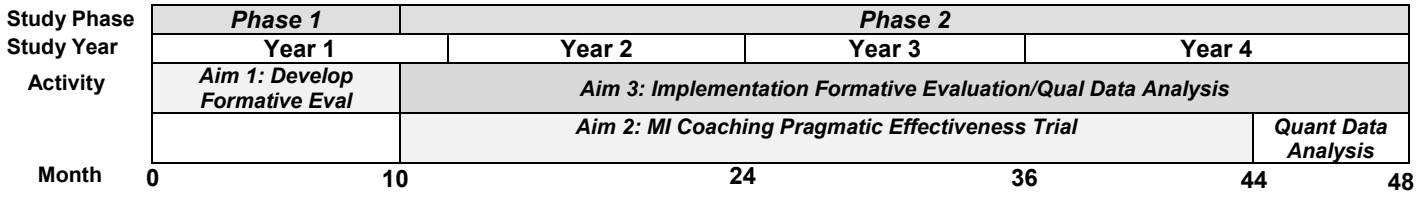
5.0 Study Procedures

5.1 Study Design

We propose a 4-year Hybrid Type 2 effectiveness-implementation project.[8] In this design, the results of the two components under study, intervention and implementation effectiveness, will reciprocally inform one another to facilitate the adaptation of each to the needs of our stakeholders and individual CBOC sites. To maximize the generalizability of our findings, we will conduct this mixed methods study in geographically distinct CBOCs in Northern California (VISN 21) and VISN 16. The PARiHS framework will guide the development of the implementation strategy, which will include Evidence Based Quality Improvement (EBQI), a multi-stakeholder facilitation process that we have used successfully in prior studies to adapt evidence-based practices (EBPs), promote uptake, and provide audit and feedback during implementation.[62] The RE-AIM framework[41] will guide the formative evaluation of the implementation strategy. During Phase 1 (*months 0-10*,) we will conduct a developmental formative evaluation to learn how to adapt the MI engagement intervention and implementation strategy to the needs of CBOCs serving rural veterans (Aim 1). During Phase 2 (*months 10-48),* we will conduct the randomized pragmatic effectiveness trial of the MI-based coaching intervention and determine its effectiveness for MH treatment engagement in CBOCs serving rural veterans (Aim 2). While

conducting the trial, we will conduct a formative evaluation of the implementation strategy based on stakeholder and key informant input which will allow us to further refine the implementation strategy and intervention to increase the likelihood that it will be adopted and maintained in clinical practice. (Aim 3)

Study Timeline (Table 1):



This study will be conducted in at least 4 medium to large VA CBOCs serving rural veterans: at least 2 CBOCs in VISN 16 and at least 2 CBOCs in VISN 21 (Northern California). We are choosing geographically distinct locations to maximize generalizability and medium to large CBOCs because of the imperative to provide evidence-based MH treatment in CBOCs of this size. Leadership in VISNs 16 and 21 will assist the research team in selecting medium to large VA CBOCs with the following characteristics: (1) sufficient volume of rural veterans (≥ 20%), (2) CBOC leadership and staff that are enthusiastic about implementation of an MH engagement project, (3) adequate PACT, PCMH-I and MH personnel, i.e., at least 1 PACT social worker or RN care manager,1 on-site psychologist or psychiatrist affiliated with PCMH-I or specialty mental health, and/or a functioning telemental health program, and (4) access to a Health Behavior Coordinator.

The SFVAMC will recruit and enroll participants in throughout designated CBOCs in VISN 21. The identified CBOCs are as follows:

Clearlake VA Clinic
15145 Lakeshore Drive
Clearlake, CA 95422
Phone: 707-995-7200

Eureka VA Clinic
930 W. Harris
Eureka, CA 95503
Phone: 707-269-7500

San Bruno VA Clinic
1001 Sneath Lane, Suite 300, Third Floor
San Bruno, CA 94066
Phone: 650-615-6000

San Francisco VA Downtown Clinic
401 3rd Street
San Francisco, CA 94107
Phone: 415-281-5100

Santa Rosa VA Clinic
3841 Brickway Blvd
Santa Rosa, CA 95403
Phone: 707-569-2300

Ukiah VA Clinic
630 Kings Court
Ukiah, CA 95482
Phone: 707-468-7700

There will be no participants enrolled from CAVHS CBOCs, instead CAVHS staff will recruit and enroll study participants from SLVHCS CBOCs in VISN 16. In addition SFVAMC staff will assist CAVHS staff in conducting phone interviews with SLVHCs participants across all aims of the study. The following are the identified SLVHCS CBOCs:

St. John
247 Veterans Blvd.
Reserve, LA 70084
Phone: 504-565-4705

Slidell
60491 Doss Dr Ste B
Slidell, LA 70461
Phone: 985-690-2626 Or 985-690-2626

Hammond
1131 South Morrison Avenue
Hammond, LA 70403
Phone: 985-902-5100
Fax: 985-902-5030

New Orleans
1601 Perdido Street
New Orleans, LA 70112

Implementation Strategy (Aims 1 & 3)

In this study, we will use the PARiHS framework to guide our implementation strategy.[39] The PARiHS framework proposes that successful implementation of an EBP, in this case, Motivational Interviewing (MI), is a function of: (1) evidence, (2) context, and (3) facilitation.[40] Below, we discuss how each element contributes to the implementation of a new MI coaching intervention to promote MH treatment engagement in veterans who use CBOCs serving rural veterans.

Evidence from our own RCT that demonstrates MI's efficacy in promoting MH treatment engagement, decreasing stigma, and increasing positive behavioral change will be presented to stakeholders[7] (**see Appendix, Manuscript**). PARiHS melds local

clinical expertise with research evidence because ultimately clinicians and leadership are more likely to rely on "practice-based evidence" in their decision-making.[40]

Organizational Context refers to organizational culture, climate and capacity that influences whether or not EBPs such as MI are adopted into clinical practice.[63, 64] Culture is generally conceptualized as the values and expectations of an organization. Climate is conceptualized as activities and experiences of workers (e.g., ratio of MH staff to caseload). [64] Capacity is conceptualized as an organization's ability to make changes (e.g., resources, staff skill set, etc.).[65] We expect that some CBOCs will be more likely to have the organizational context to support implementation of an innovative MH engagement intervention. Context will be ascertained by observing EBQI meetings (see below), through semi-structured interviews with VISN, Medical Center and CBOC staff, ethnographic fieldwork, including informal interviews and participant observation at the CBOCs.

Facilitation involves an integrated set of implementation strategies including identifying and engaging key stakeholders at all organizational levels, academic detailing, staff training, audit and feedback, and quality improvement with the goal of promoting adoption of a new EBP. [66, 67] For this study we will use a well-validated facilitation strategy that includes most of these elements, known as Evidence-Based Quality Improvement (EBQI).[68] We are choosing EBQI because it has been used successfully in other recent VA implementation projects, [62, 69]it meshes well with our implementation frameworks (PARiHS and RE-AIM), and it is consistent with CREATE partnered research. In EBQI, both researchers and local staff and administrators participate fully in the implementation process, with researchers facilitating rather than dictating the implementation strategy. EBQI thus fosters a researcher and clinician/ administrator partnership that activates staff participation in the implementation effort and promotes buy-in from leadership, which is critical to successful implementation.[70]

EBQI facilitation also emphasizes continuously revising the adapted EBP (i.e., MI coaching intervention) based on audit and feedback with stakeholders during a series of Plan-Do-Study-Act (PDSA) cycles. [68, 69] This results in the implementation of EBPs that are robust and feasible to deploy in real-world practice settings. Specifically, we will hold two in-person 90-minute EBQI meetings during study phases 1 and 2 (total of 4 in-person EBQI meetings in each VISN, 2 in Y1 and 2 in Y2-3) (see Appendix). If there are key stakeholders that cannot attend the meeting in person, we will offer the option of phoning into the EBQI meetings on a VANTS line. This will be available upon special request to VA employees only. The EBQI meetings will be composed of CBOC clinical and administrative staff, the Health Behavior Coordinator at each Medical Center, patient representatives, and a community MH provider, as well as members of the research team (PI, Project Coordinator, Qualitative Researcher). During Phase 1 of the study, EBQI meetings will focus on the "Planning" phase in the PDSA cycle.

Researchers will present evidence for the EBP (MI for MH treatment engagement), and elicit clinicians' experience with acceptable and effective local MH treatment resources for rural veterans, details about the CBOC MH referral process, including barriers and facilitators of MH treatment engagement (including caseload and wait-times), experiences evaluating readiness for MH treatment and using EBPs such as MI to promote MH treatment engagement. During subsequent EBQI meetings, data derived from Phase 1 semi-structured interviews and ethnography (see below) will be fed-back to EBQI participants in order to adapt the MI coaching intervention and plan for implementation during Phase 2 (Plan). During Phase 2 EBQI meetings, the focus will shift to Do, Study and Act after the start of the MI coaching effectiveness trial (Do). Guided by the RE-AIM framework, researchers will continue to audit and feed-back information from formative evaluations of the implementation process (Study). In turn, this information will be used to make mid-course corrections to further adapt and refine both the intervention and the implementation strategy (Act).

Implementation of Phase 2 (RCT):

We will conduct a pragmatic effectiveness RCT of MH referral plus MI-based coaching intervention vs.MH referral only (control) in veterans who receive care in VA CBOCs serving rural veterans. The RCT will be conducted over the course of 34 months with recruitment and enrollment in the first 26 months. All participants will be enrolled and followed for 8-10 months. Enrollment will begin at study month 10 and will conclude at study month 44. The last wave of enrollment will begin at month 36 to allow a full 8-10 month follow-up period until month 44. This leaves 4 months for data analysis and manuscript preparation.

The RCT will occur at the same VA CBOC sites identified during the Phase 1 Developmental Formative Evaluation (DFE). Veteran participants will be recruited as outlined in section 5.2. During the initial phone contact between the veteran and study staff, the study staff will use a phone script and eligibility screener to determine if the veteran is willing and eligible to participate in the baseline assessment. If the patient is interested in participating, the study team member will schedule a time to conduct the baseline assessment. If the veteran is not interested in participating in the study, the study team will no longer contact the veteran.

The participant will be contacted at week 0 for a baseline assessment. Before the baseline assessment, a study team member will go through the informed consent process described in section 5.3. If the veteran consents to participate, the study team member will conduct the baseline assessment. The baseline assessment will include demographic questions and quantitative measures described in section 5.5. If the participant is still considered to be eligible after the baseline assessment, the study team member will enroll the participant in the study and use computer software to randomize the participant into the intervention or control arm. The control arm will receive a MH referral list in a neutral manner. The intervention arm will receive their first

dose of MI coaching for treatment initiation from the Veteran Peer Coach and their MH referral list. If the participant is not considered to be eligible after the baseline assessment, the participant will be thanked for their time and will no longer be contacted by the study staff.

After the initial does of MI coaching for treatment initiation, the intervention arm will be contacted by the Veteran Peer Coach for up to 3 additional doses of MI coaching for treatment initiation and for up to 2 additional doses of MI coaching for treatment retention. During the MI coaching sessions, the Veteran Peer Coach will also administer a brief assessment to determine where the participant is in terms of mental health care engagement. Once it is determined by the study staff that the participant has initiated mental health treatment, the participant will transition from the MI coaching for treatment initiation track to the MI coaching for treatment retention track. Therefore, the number of doses of MI coaching will vary between participants depending on if and when the participant initiates MH treatment. The varied MI coaching will reflect real life differences between veterans engagement in MH treatment as this implementation study.

Both the intervention and control groups will be contacted for a full assessment 2 months after the baseline assessment, for another full assessment 2 months after the first full assessment, and for a final, brief assessment 4 months after the second full assessment. We will allow a 30 day window of time at these assessments to mitigate any issues in scheduling or contacting the participant. The full assessments will be conducted by a blinded study team member. They will assess outcomes and include quantitative measures described in section 5.5. The final, brief assessment will be conducted by a blinded study team member. It will assess outcomes and include some of quantitative measures as described in section 5.5.

Participant Payment*: In the RCT portion of the study Veteran subjects are paid for assessments only (at baseline, 2 full assessments, and final brief assessment). They are not paid for MI Coaching sessions, since this could not also be offered to the control group, or for engaging into mental health treatment. Subjects will be compensated $20 for each assessment, the same amount of compensation that we pay subjects in our other studies.*

A thank you letter will be sent via US Mail to the participants after each of the 4 assessments. This will thank them for their participation and, if scheduled, will remind them of future appointments. The letters except for the final letter will also include the mental health referrals.

5.2 Recruitment Methods

Recruitment of Providers- Provider participants include the providers working within our CBOC study sites (clinicians, nurses, social workers, advocates and administrative personnel), VISN level leadership, and community providers who serve veterans within

the communities associated with the CBOC study sites. VA potential Provider participants will be referred through Co-investigators and admin contacts at identified CBOCs and by their colleagues. Community Providers who serve veterans will be referred through VA Providers. Providers will be recruited via email asking them if they are interested in the study. We have attached an example of the type of e-mail that will be sent, although each e-mail will be tailored to the individual we are recruiting (VA provider, VISN leadership, community provider). All e-mail recruitment correspondence will include an attachment with the Study Information Sheet. Potential Provider participants will be asked in the email to respond with whether or not they are interested in participating in the study. We will not contact those Providers who opt-out via email response. If we do not receive a response from Providers we will wait 1 week and then follow-up with a phone call or email as indicated in the Provider Recruitment Phone Script.

Study Recruitment/Enrollment Strategy for Veterans*:* Information derived from the Phase 1 DFE will inform the research team about which CBOC providers (e.g. MH social workers, PCMH-I staff, or RN nurse care managers etc...) at each participating CBOC facility will pass information along to patients. During Phase 2 formative evaluation (Aim 3), the research team and the Health Behavior Coordinator (HBC) will monitor the adoption. This will contribute to the evaluation of *adoption and implementation* fidelity as outlined in the RE-AIM framework. Finally, as in our pilot study which enrolled 36% female veterans and 55% ethnic minorities, which far exceeds the proportions of each among veterans enrolled in VA nationwide, we will plan to over-sample women and ethnic minorities .[7]

Recruitment streams for Veterans are as follows

1. CBOC providers will refer veterans who they believe are moderately or highly ambivalent about engagement in mental health treatment. In addition, they will refer potential participants who have frequent NO SHOWs or who have prematurely dropped out of MH treatment during the past year. The CBOC Providers will refer eligible patients to the research staff to be assessed for study enrollment. Prior to referring veterans, CBOC staff will have the option to briefly explain the study, provide veterans an information sheet, and ask for their permission to be mailed recruitment materials. The research staff will then send recruitment materials outlined in (3) to the potential participant.
2. In addition, CBOC Providers will also identify their patients which they believe would meet study inclusion criteria and refer these names and last 4 of the SSN to the research staff (approved for a HIPAA Waiver for Recruitment). The research staff will then find the patient's contact information in CPRS and send recruitment materials outlined in (3) to the potential participant.
3. VA administrative data will be used to identify additional veterans in VISNs 16 and 21 who have received care at participating CBOCs within 1 year of the study start date. We will identify veterans who screened positive on VA MH screens or received MH diagnoses, but have never attended a MH visit (treatment naïve), or attended ≤ 2 MH visits without follow-up (treatment drop-out) ≥ 90 days prior to the study start date. Potentially eligible veterans will be mailed Patient Letters, Study Information Sheets,

Opt-out Letters (including a VA return envelope addressed to the local study site) using previously described IRB-approved "opt-out" methods. We will wait 2 weeks for Opt-out Letters to be returned. If subjects do not opt-out we will contact them via phone call. No cold calls will take place.
4. Self-referral will be used to identify Veterans interested in participating in the study through the use of various advertisement methods and word of mouth. Advertisement methods will include: posting flyers at places such as the VA clinics, Veteran Service Organizations, and public areas, using e-bulletins (example- www.craigslist.com), direct outreach by the study team at events where large numbers of veterans congregate. Since the veteran will be contacting us directly to inquire, we will provide information over the phone and go into the eligibility screen if the veteran is still interested.
5. Finally, we will use a technique called "snowball sampling" to increase recruitment. After completing an interview, participants will receive a "thank you" letter which thanks them for their time and efforts as well as provides the names, addresses, and phone numbers of the referrals they received during the phone session. Enclosed in the letter will be small contact cards that the veterans can pass onto their peers who they think may be interested in participating in the study. Participants are under no obligation to distribute these cards or disclose that they are participating in the study. Choosing not to distribute the contact cards will in no way jeopardize their ability to continue participation in the study. The contact cards include study information. If a veteran who receives a contact card calls the study staff, the study staff with provide the veteran with information over the phone and go into the eligibility screen if the veteran is still interested.

5.3 Informed Consent Procedures

Requesting a waiver of written consent for participants enrolled in the RCT portion of the study (Aim 2) and also those participants under Aims 1 & 3 that are contacted solely via telephone (both veteran participants and provider participants). Subjects in Aims 1 & 3 will have the choice to have their semi-structured interviews take place in-person or over the telephone. This is necessary because many participants would have to travel long distances to participate in in-person interview.

46.117(c) (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. It is not practicable to conduct the research without the waiver, nor is it practicable to conduct the research without access to the requested information. Waiving consent/authorization will not adversely affect subjects' rights and welfare.

Verbal consent will take place for the participants whose participation is conducted over the phone. Study Interviewers will read information sheets describing the purpose of the study, the study procedures, and the risks and benefits of the study will be read to potential participants over the telephone. After each major section of the script, the interviewer will pause and ask whether the participant understood what was read and/or has any questions about what was read. At the script's conclusion, subjects will be

invited to give verbal consent. We enter in every participant's consent decision to participate in our study in our ACCESS database. Records of such are kept electronically in our database. Prospective study participants will be given as much time as they need to consider study participation, limited only by the length of the study period; those wishing to consider study participation further will be invited to call study staff back if and when they are ready to participate. Justification for verbal consent lies in the fact that this group of veterans experiences substantial barriers to accessing mental health treatment. Requesting that potential participants mail back a signed informed consent sheet may constitute a further barrier to participating and potentially accessing mental health treatment, if necessary.

For those subjects that come in to a VA facility for the EBQI meeting or scheduled interview we will obtain written consent. The research staff will explain the study, read an informed consent *emphasizing that there is no obligation to participate in the study.* The research staff will stop periodically to elicit questions and make sure the subject understands the study procedures, risks, etc. For those participants that request to take part in the EBQI meeting via a VANTs line, verbal consent will take place prior to the meeting as described in the paragraph above.

Consenting of SLVHCS veteran participants:
CAVHS personnel will obtain written consent from SLVHCS subjects Aims 1 & 3 using CAVHS consent form since CAVHS personnel is responsible for consenting. If subjects under Aims 1 & 3 participate in a phone interview instead of an in-person interview the CAVHS personnel will obtain verbal consent via the phone. For in-person consent, the consent form will be signed in duplicate (copy for participant and CAVHS). CAVHS personnel will transport consent documents to CAVHS. CAVHS/SFVAMC personnel will verbally consent Aim 2 SLVHCS veteran subjects over the phone. CAVHS will maintain original written consent documents. CAVHS/SFVAMC personnel will maintain verification of verbal consent.

For all participants, a member of the study staff will walk through the study procedures with them, pausing several times to confirm that the subject understands or check to see if the participant has any questions. We will use clear, declarative statements when describing the questions. When interviews are conducted in person, we will look for non-verbal signs of understanding, such as head nods, and vocal signs of understanding, such as "uh huh" to gauge understanding. At the conclusion of reviewing sections of the informed consent we will ask the subject questions to see if they are able to repeat back important aspects of the trial and answers certain questions regarding the trial. We will re-review the informed consent when necessary.

5.4 Inclusion/Exclusion Criteria

Sample Size:
Veterans: 1000
Stakeholder/Provider: 400

Total: 1400

Aims 1 &3 SSIV:
VISN/ Medical Center/CBOC Leadership, VA CBOC providers, Community Providers: Leadership at the selected CBOCs will assist Drs. Seal (PI),Pyne (site lead, VISN 16) and Uddo in recruiting CBOC providers, i.e., primary care, Mental Health (MH), or PCMH-I providers, social workers, and nurse care managers distributed across *each* of the 4 or more CBOC sites. We will also recruit CBOC, Medical Center, and/or VISN administrators and Health Behavior Coordinators across each of the 2 VISNs. Finally, we will identify and recruit community MH providers (e.g. Vet Center providers, other non-VA community providers) in rural areas in each VISN. Total is approximately 120 (60 each VISN).

Veterans- For Phase 1

Inclusion criteria: (1) a Veteran of military service over age 18, (2) receives care at VISN 16 or 21 CBOC sites (3) fall into one of 3 strata of Veterans who have differential MH treatment engagement within 1 year of a positive MH screen or MH diagnosis and a documented referral for MH treatment who: failed to attend any MH visits (n=20), have attended 1-2 MH visits only (n=20), or have attended ≥ 6 MH visits (n=20)

Exclusion Criteria: (1) hearing impaired, (2) no working telephone

For Phase 2, implementation formative evaluation, another semi-structured interview will be conducted with approximately 40 *different* Veterans who are participating in the pragmatic effectiveness trial and have been randomized to the MI coaching arm (see below). As above, we will use purposive maximum variation sampling to select 2 groups of veterans after 8 weeks of study enrollment. One group of Veterans who have engaged in MH treatment by 8 weeks and another group who have not engaged in mental health treatment by 8 weeks after study enrollment (See RCT inclusion/exclusion criteria below). The Phase 2 semi-structured interview will be scheduled with the veteran at a time that is convenient for the veteran participant and interviewer. All interviews will be conducted via telephone. This can occur in conjunction with a RCT visit or be a separate study visit. The interview will last an hour or less. We plan for a sample of 40 Veterans (n=20 per each VISN) and to be in overlap with the RCT enrollment of Aim 2.

Aim 1&3 EBQI:
VISN/ Medical Center/CBOC Leadership, VA CBOC providers, Community Providers: These individuals will likely come from the SSIV or be referred by the leadership at the local CBOCs. We will seek providers that have a good understanding of the local health care environment and resources in the community.

Veterans: We will seek veterans who are local to the participating CBOC. These Veterans should have a good pulse on the local veteran community and feel comfortable representing their veteran peers.

Inclusion criteria: (1) a Veteran of military service over age 18

Exclusion criteria: (1) hearing impaired

Aim 2 RCT:
As a pragmatic effectiveness trial, there are minimal exclusion criteria to maximize generalizability and facilitate future implementation. We approximate that up to 940 Veterans would need to be contacted and screened at baseline in order to enroll our target sample size into the RCT.

***Inclusion criteria*:** from initial phone screen: (1) a Veteran of military service, over age 18 (2) a resident of VISN 16 or 21 catchment areas receiving with no plans to re-locate within 8 months of enrollment, and from baseline assessment: (3) positive for ≥ 1 of the following disorders PTSD, depression, generalized anxiety disorder, panic disorder, high-risk drinking, and/or illicit substance use (as ascertained at the baseline assessment).

***Exclusion criteria*:** from initial phone screen: (1) hearing- impaired, (2) no working telephone, (3) Veterans with self-reported (and/or CPRS-confirmed) diagnoses of schizophrenia, psychosis or bipolar disorder(4) received mental health treatment within the last 60 days and/or future appointments for mental health treatment scheduled in the next 30 days (these questions will be repeated during the baseline assessment so that the information is documented in Qualtrics for data analysis) and from the baseline assessment: (5) active suicidality or homicidality. Prisoners will be excluded because they will not be able to engage in mental health treatment. Our staff only speaks the English language; therefore we must also exclude those subjects that are not proficient in the English language. We must also exclude those with impaired cognitive function because our psychometric measures are designed for self-response and cannot be validly answered by a subject's caretaker.

5.5 Study Evaluations
Summary of Quantitative Measures (AIM 2):

Participant Characteristics **(Study Co-Variates)**
Sociodemographic and Military Service Characteristics Non-standard instrument used in pilot RCT.[7] **VA TBI Screen**-**Considered positive if veteran reports head injury mechanism and specific consequences (e.g. loss of consciousness)[81]
Psychometric Assessments **(To determine RCT eligibility; binary and continuous scores used to stratify randomization and primary analyses (H.2a); as covariates in H.2. a, b, c, and as outcomes in exploratory analyses, Aim 2)**

World Health Organization Alcohol, Smoking and Substance Involvement Screening Test WHO-ASSIST**-a validated screening instrument to detect presence/absence and severity of alcohol and illicit drug abuse and dependence, and smoking.[82] The **AUD-C** will be used to screen for high-risk drinking across CREATE projects.[83]

PTSD Checklist-Veteran Version (PCL-V)-validated 17-item PTSD inventory; yields a binary determination of PTSD using PTSD symptom cluster criteria or a continuous score for PTSD severity.[84]

PHQ-9 Depression Screen- widely-used, validated measure of depression in primary care. Cut score of ≥ 10 yields sensitivity of .88 and specificity of .88 for Major Depressive Disorder.[85]

GAD-7- validated, brief 7-item scale used to screen for Generalized Anxiety Disorder (GAD)[86]

Panic Disorder Severity Form (PDSS)- validated self-report assessment for panic disorder; produces continuous score to determine moderate PD severity.[87]

Psychosocial Measures **(Covariates used in H.2.a, b, and c and in exploratory analyses, Aim 2)**

World Health Organization Quality of Life Inventory WHOQOL-BREF**-**a 26 item validated brief assessment which measures physical and psychological health, social relationships, and environment.[88]

MH Treatment **(Primary Outcome-H.2.a, and secondary outcomes-H.2.b, and H.2.c)**

Barriers to MH treatment-a published scale of barriers commonly reported by military personnel and veterans regarding mental health treatment, including a 6-item stigma subscale and perceived effectiveness of MH treatment.[17]

MH Treatment experiences-**non-standard inventory of VA and community MH treatment-number of sessions attended and duration of treatment, use and duration of psychiatric medication, and use, frequency, and duration of telephone and e-health (online and smartphone) MH treatment resources.[7]

Modified General-Practice Users Perceived Need Inventory (GUPI)**-assesses degree to which veterans perceive a need for 6 categories of VA psychosocial/ MH services.[92]

Readiness Ruler- Measures importance, confidence and readiness for MH treatment engagement/behavior change on a scale from 0-10.[23]

Satisfaction with VA Healthcare (CSQ-8)-8-item validated client satisfaction survey of VA health services.[93]

Perceived Access Inventory (PAI)*- a questionnaire developed by our sister study, *Development and Validation of a Perceived Access Measure (ACCESS),* to measure veteran's perceived access to mental healthcare at the VA. Including the questionnaire in our study will help the ACCESS study validate and standardize the measure.

***Note about the Perceived Access Inventory (PAI):** During survey administration, should we see the need for changes to correct spelling, grammatical or formatting errors and/or increase clarity by re-wording or reordering items, we will make those changes. We may also drop an item that offends or is misunderstood by many respondents without applying for CIRB approval but will not add anything without CIRB approval. Should any change(s) be needed that substantially affect the content of the questionnaire, we will submit the revised questionnaires for CIRB approval. This is because the questionnaire is still in development.

Aim 2: CPRS Data Collection

In addition to self-report measures, we will use participants CPRS records for outcomes ascertainment. This will help us to verify the self-report data. For CPRS data collection, our statistician will collect the data using the CDW in accordance with our DART approval. He will use relevant stop codes to collect data that includes: mental health diagnoses, mental health visit information, and pharmacotherapy for mental health. If there are discrepancies in the data collected from CDW, we may have a blinded member of the study team verify the data by accessing CPRS directly and verify only

those specific records. The CPRS data will be used alongside the self-report data during data analysis.

Summary of Qualitative study evaluation techniques

Aims 1 and 3:
Evidence-Based Quality Improvement (EBQI) meetings. EBQI are a validated formative evaluation strategy that enables diverse clinical, administrative, and managerial stakeholders to discuss concerns and to formulate problems solutions with the research team members. Multiple EBQI meetings will be held throughout Aim 1 (during Phase 1 and Phase 2) and Aim 3.
Semi-structured interviews. Qualitative semi-structured interviews are a standard data collection technique for developmental formative and summative evaluations and for qualitative research projects more generally. Semi-structured interviews will be held throughout Aim 1 (during Phase 1 and Phase 2) and Aim 3.
Quick Ethnography. Quick Ethnography (QE) is a modified form of ethnographic fieldwork adapted to applied environments, such as CBOC clinics. QE uses focused observational strategies and informal interviews to gather key information for developmental formative and summative evaluations and for rapid qualitative research projects more generally. QE will be conducted throughout Aim 1 (during Phase 1 and Phase 2) and Aim 3.

Evaluation technique: Evidence-Based Quality Improvement (EBQI) meetings.

As part of the study, we will hold two in-person 90-minute EBQI meetings during study Phase 1 (FY1) and Phase 2 (FY2-3) for a total of 4 in-person EBQI meetings in each VISN 21 and VISN 16. The EBQI meetings will be composed of CBOC clinical and administrative staff, patient representatives, and a community MH provider, if available, as well as members of the research team (PI, Project Coordinator, Qualitative Research staff). During Phase 1 of the study, EBQI meetings will focus on the "Planning" phase in the PDSA cycle. Researchers will present evidence for the EBP (MI for MH treatment engagement), and elicit clinicians' experience with acceptable and effective local MH treatment resources for rural veterans, details about the CBOC MH referral process, including barriers and facilitators of MH treatment engagement (including caseload and wait-times), experiences evaluating readiness for MH treatment and using EBPs such as MI to promote MH treatment engagement. During subsequent EBQI meetings, data derived from Phase 1 semi-structured interviews and quick ethnography (see below) will be fed-back to EBQI participants in order to adapt the MI coaching intervention and plan

for implementation during Phase 2 **(Plan).** During Phase 2 EBQI meetings, the focus will shift to Do, Study and Act after the start of the MI coaching effectiveness trial (**Do).** Guided by the RE-AIM framework, researchers will continue to audit and feed-back information from formative evaluations of the implementation process **(Study).** In turn, this information will be used to make mid-course corrections to further adapt and refine both the intervention and the implementation strategy **(Act).** The qualitative team will observe EBQI meetings and record condensed field notes which will be subsequently expanded. Additionally, a summary chart with key issues discussed and the resulting decisions made will be generated after each meeting to facilitate progress reporting and an audit trail of each EBQI meeting.

Evaluation technique: ***Qualitative Semi-Structured Interviews with stakeholders:***

During Phase 1 (Aim 1), separate interview guides will be used for providers, administrators, and clinic staff in VISN 16 and VISN 21 as well as patients in both VISN 16 & 21 about MH problems and MH treatment, preferences regarding in-person, telephone and online VA and non-VA MH treatment resources, current CBOC MH assessment and referral processes, current assessment (if any) of readiness for MH treatment including use of the CPRS "Readiness Ruler", barriers to and facilitators of MH treatment engagement, tracking of No Shows, and current MH treatment engagement strategies (if any). Semi-structured interviews will also solicit preferences for an MH treatment engagement intervention, including the specific use of MI as an engagement technique, delivery of the intervention and by whom (e.g. VA primary care or MH providers, nurses and/or social workers and/or by experienced veteran peer counselors). Interviews with providers, administrators, and staff will last approximately 30 minutes. Interviews with patients will last approximately 45-60 minutes.

During Phase 2 (Aim 3), after the start of the pragmatic effectiveness trial, we will conduct a process evaluation of the implementation of the MI-based intervention. With VA staff, we will conduct semi-structured interviews with VA providers, administrators, managers, clinic staff, and if necessary and relevant, non-VA providers in both VISN 16 and VISN 21. Providers could participate in up to two semi-structured interviews, one during Phase 1 and one during Phase 2 of the study. Providers will not be paid for their participation. Veteran participants in Phase 1 will be conducted only one-time (n=40 total). In Phase 2, we will seek to enroll and interview a total of 40 Veterans who have participated in the RCT and who, after study enrollment after 8 weeks' participation 1) have *already* engaged in MH treatment (n=10 for VISN 16, n=10 for VISN 21); and 2) who have *not yet* engaged in MH treatment (n=10 for VISN 16, n=10 for VISN 21). We will compensate Veteran subjects $20 for each hour long (or less) interview. This is the same hourly amount of compensation that we pay subjects in our other studies. Interviews will be conducted either in-person or over the telephone according to the convenience and preference of both participants and interviewers. Interviews will last an hour or less and will cover topics related to the barriers and facilitators to the implementation according to organizational capacity, staffing, and patient-centeredness, including perceived cultural appropriateness, feasibility, and acceptability. The interview

guides will include open-ended “grand tour” questions followed up by probes to elicit more nuanced detail [77]**(Appendix -Draft Interview Guides).** We will obtain a letter of support from the appropriate leadership official allowing their staff to be interviewed for this study prior to conducting the interviews. Feedback from the interviews will be presented to stakeholders in EBQI meetings and used to make adjustments to the intervention and implementation strategy during Phase 2.

Evaluation technique: *Quick Ethnography*

The qualitative team (VISN 16 & 21) will conduct quick ethnography [75] (QE) in each of the participating CBOC sites. QE uses ethnographic principles in a time-efficient manner by narrowing the focus to identify specific attitudes, beliefs and behaviors (organizational context) as they relate to implementation of the MI coaching intervention. Information gleaned from the QE will thus guide subsequent qualitative evaluation methods. The qualitative team will initiate QE by attending EBQI meetings where they will take notes on who attends and who occupies which organizational roles, as well as other contextual factors that might impact implementation. They will also conduct informal interviews with staff who attend EBQI meetings. Second, they will conduct targeted participant observations within the CBOCs to observe what people actually do, not just what they say they do, and to obtain context-rich understandings of clinic processes that will impact implementation. Specifically, they will observe organizational structure including staff dynamics, & clinic culture/norms. Throughout their fieldwork, the qualitative team will jot down observations that will form the basis for fully expanded field notes that will be transcribed and used for analysis.[76] Data from the QE will then be used to refine our draft semi-structured interview guides and to better interpret data obtained from patients and providers by situating their narratives within the context of the CBOCs. The qualitative team will conduct direct observations of and informal (unstructured) interviews with clinic interactions among clinical, administrative, and managerial staff that result in written condensed field notes, which will be subsequently expanded and used as research and evaluation data and will be reported back to stakeholders during EBQI meetings as noted above.

Evaluation of the Implementation Strategy (Aim 3)

During Phase 2, the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) Framework[41 71] will be used to conduct a formative evaluation of the progress of the implementation strategy. Reach represents the proportion of eligible participants that is referred and enrolls in the study.[72] Adoption represents the proportion of CBOC staff that assesses readiness for MH treatment and refers to the study, as well as adoption of the intervention by the MI coaching teams based at each of the Medical Centers in each VISN.[72] Both Reach and Adoption are readily ascertained through administrative data audit. Implementation represents the fidelity with which the intervention is implemented in routine care. [72] Effectiveness will be evaluated at the conclusion of the pragmatic effectiveness trial as part of Aim 2.

Maintenance represents the degree to which the EBP (MI coaching) is likely to be sustained.[72] This dimension will be assessed during Phase 2 through semi-structured interviews with stakeholders.

5.6 Data Analysis

Statistical Analysis for H.2a. and H.2b In Intent-To-Treat (ITT) analyses, generalized linear models using a poisson distribution and robust error variance (binary outcomes) and traditional poison and truncated-poisson regression (count variables) will be used to determine the effect (relative risk or standardized coefficient) of Motivational Coaching (vs. Control) on MH treatment initiation and retention, respectively, adjusting for clustering by CBOC and region as well as potential confounding by other covariates (see above). The threshold for significant p-values will be set at $p \leq 0.05$. Effect sizes will be calculated using Cohen's d for binary outcomes (MH treatment engagement) and Cohen's h for continuous outcomes (# MH visits).[98] Stratified analyses of MH treatment engagement will be conducted for treatment-experienced vs. treatment naïve participants, MH severity (high vs. low), rurality (urban vs. rural), and if there is sufficient power, gender (men vs. women). Finally, as an alternate analysis for MH engagement based on group assignment, we will compare the binary outcome of attending ≥ 8 visits ***or*** receiving ≥ 2 months of psychiatric medication plus > 4 visits during the 8-month follow-up period, a metric which has been used in prior studies to denote "minimally adequate MH treatment".[5, 12] This is not a primary outcome in this study because this metric is based on a 1-year and not an 8-month follow-up period.[5]

Statistical Analysis for H.2c and exploratory analyses Analysis of covariance (ANCOVA) methods will compare groups on change over time for secondary and exploratory outcomes (detailed above) after adjusting for baseline values.

Power Calculation: Our power calculation is based on the primary hypothesis that telephone MI Coaching (vs. Control) will significantly improve MH treatment initiation *and* retention (H.2a). In our prior pilot trial, for *MH treatment initiation (binary outcome),* we achieved a Cohen's h effect size of 0.74 (62% engaged in MI arm vs. 26% engaged in Control arm), and for MH treatment retention (# of visits), we achieved a Cohen's d effect size of 0.67 among all subjects (ITT) and Cohen's d of 0.48 for retention in the subset of subjects that engaged in MH treatment. Therefore for this study, to achieve adequate power to detect improvement in both MH treatment initiation and retention, we will require approximately 140 participants per study arm across the 2 VISNs (N=280). This sample size accounts for 20% drop-out and achieves > 90% power to detect a Cohen's h effect size=0.60 for binary MH treatment initiation at $\alpha=0.05$ and a Cohen's d effect size =0.55 for MH treatment retention (# of visits) among *all* subjects (ITT) at $\alpha=0.05$. This sample size also achieves 80% power to detect a Cohen's *d* effect

size=0.55 for MH treatment retention (# of visits) at α=0.05 in the *subset* that engages in MH treatment.

Rationale for the RCT sample size:
Sample Size for the RCT (Aim 2): Based on power calculations which already account for a 20% drop-out rate, we will need to enroll 140 participants per study arm (total N=280) into the RCT over 26 months. Different from our efficacy study in which we recruited exclusively from administrative databases and had no prior knowledge of potential study participants, because this is an effectiveness trial, CBOC staff will refer a portionof the total sample of 280 (N=224) directly from CBOC sites, referring veterans to the study who they believe to be eligible and interested in study participation. We project that we will need to recruit and conduct baseline assessments in roughly 940 veterans across both VISNs in 26 months or 36 per month (18 per month per VISN).

Randomization for the RCT (Aim 2): Otherwise eligible participants who screen positive for ≥ 1 MH problem(s) will be randomized to MH Referral + MI Coaching (Intervention) versus MH Referral alone (Control). Block randomization will be stratified by: (1) MH treatment history (treatment naïve or treatment experienced) within the last 5 years, (2) binary MH disorder severity defined as ≥ 2 MH problems ***and*** at least one MH problem with a score indicating severe symptomatology, and (3) the VISN where the participant is located. Strata will optimize random distribution of veterans with differential likelihood of MH treatment engagement between the two study arms.[7]

Plans for and specification of the purpose of any interim analysis of the data (with regard to stopping rules for superiority, futility, or sample size re-estimation):
As a pragmatic effectiveness trial, formal Peto-style stopping rules are not applicable. In the spirit of ongoing data monitoring, at six-month intervals, differences between treatment and control groups will be evaluated and discussed by investigators, and the intervention will be revised in light of lessons learned in the field and insights from the qualitative analyses.

Methods for handling missing data points and subject dropouts: Per Intention to Treat Analysis, participants will be analyzed based on group assignment. The primary outcome, MH treatment engagement, can be ascertained for VA facilities using VisTA/CPRS chart review and will not require continuing patient participation. Self-reported MH treatment outside of VA facilities is also a study outcome, but this cannot be ascertained for subject dropouts. As a sensitivity analysis to assess non-VA utilization, we will repeat the analyses of the primary outcomes based solely on VA utilization and compare those results with the primary results based on all outcomes. We do not anticipate that multiple imputation techniques will be useful for addressing unknown non-VA utilization for study dropouts, based on the limited quantitative information that we will have available for those participants.

Methods for dealing with data transformations: **There are no a priori plans to**

transform outcome measures; during data analysis, if transformations of data appear necessary to satisfy key statistical assumptions, we will revisit at that time.

Definitions of the analytical sets (i.e. intent-to-treat, per protocol, and any other analytical subsets): **For Intention to Treat Analysis, analytical sets will consist of all enrolled patients according to treatment assignment.**

5.7 Withdrawal of Subjects

Subjects (veterans) in the RCT portion of the study (Aim 2) will be withdrawn if it is determined that they are actively suicidal. We will follow the procedure outlined in the "Reporting" section of this protocol (appropriate mental health referrals will be made). If a subject moves outside the catchment area of the study they will also be withdrawn from the study. We will not have access to mental health referrals outside the two VA catchment areas and therefore cannot evaluate the outcome for a subject that moves.

Providers will be withdrawn if they leave their positions at the VA. Non-VA community providers will be withdrawn if they too leave their positions and move outside our catchment area (we are specifically looking for non-VA providers who provide services to veterans in our catchment areas).

6.0 Reporting

The PIs will be notified by the Project Coordinator(s) immediately of any possible event that affects the risk to a subject.

The PIs will promptly respond to the problem and mitigate any negative consequences for the participant(s) involved. The PI and/or Study Coordinator will report the event to the IRB of Record within the timeline as follows:

a. **Unanticipated Problems Involving Risks to Subjects or Others.** Members of the VA research community are required to ensure that unanticipated problems involving risks to subjects or others in research are reported promptly to the IRB within 5 business days.

b. **Serious Unanticipated Problems Involving Risks to Subjects or Others.** Within 5 business days of becoming aware of any serious unanticipated problem involving risks to subjects or others in VA research, members of the VA research community are required to ensure that the problem has been reported in writing to the IRB.

c. **Local Unanticipated SAEs**. Within 5 business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated SAE in VA

research, members of the VA research community are required to ensure that the SAE has been reported in writing to the IRB.

Adverse Events (AEs that do not meet criteria for reporting within five days in accordance with VHA Handbook 1058.01) will be reported to the IRB of Record at Continuing Review.

The PIs have developed a suicide and homicide safety plan for other studies with Veterans that will also be used for this study in the event of active suicidal or homicidal ideation.

If we are unsure whether a document requires submission or reporting, we will contact the VA Central IRB the PRIDE toll free number 877-354-3130 or va.central.irb@va.gov.

7.0 Privacy and Confidentiality

The largest source of material for this study in both study phases will be self-reported information derived from structured or semi-structured interviews. In addition, we will use VA administrative data for the following purposes: recruitment of a small proportion of veteran subjects, safety checks to exclude vulnerable patients with high-risk conditions (e.g. suicidality), and validity checks of self-reported VA MH treatment.

There are some risks to participating in this study. First, for veterans, some of the questions asked (such as questions about mental health symptoms, including drug use) concern sensitive issues and possibly illegal activities involved in drug use. Similarly, some of the questions asked of veterans may evoke memories of combat experiences. Being asked some of these questions may make participants feel uncomfortable however the questions asked do not fall outside what would normally be asked during a clinical mental health appointment. VA staff and non-VA community providers may be concerned that disclosing information about CBOC procedures or programs in the community may negatively impact their jobs or relationships with colleagues. While the researchers will keep information as confidential as possible, complete confidentiality cannot be guaranteed.

Participant data will be identified by study ID numbers only and will be kept separate from research data. Participants' personally identifying information, such as names, addresses, and phone numbers will be secured on an approved SFVAMC or CeMOHR server behind the VA firewall that is accessed through use of a password-protected computer terminal in a locked room. Data will be reported only in group form in any reports or publications; no names of study participants will be used in any reports or publications resulting from this study. In addition, as with our other research studies, this new study will apply for a Certificate of Confidentiality from the National Institutes of

Health. This certificate will provide additional protection for research participants. The Certificate of Confidentiality will allow Dr. Seal and the research team to refuse to release identifying information about participants in any civil, criminal, administrative, legislative or other proceeding at the Federal, State or local level. A Certificate of Confidentiality does not prevent researchers from disclosing information about participants that involves child abuse, elder abuse, and participants' intent to hurt themselves or others. If the research staff learns that a participant intends to hurt him/herself or others, study staff will be obligated to report this information to the authorities and activate the study's safety protocols. Potential participants will be apprised of this possibility during the informed consent procedure.

The linking list will be maintained by the Study Coordinator. Access to the linking list will be limited to the Coordinator and Data Manager. PHI will be obtained from existing sources such as medical records, clinical databases, or research records. We will use national and regional databases, such as CDW and Vista to identify potential participants in the RCT portion of the study (Aim 2, requesting HIPAA Waiver of Authorization for Recruitment). Electronic medical records at the VA (SFVAMC and SLVHCS) will be accessed to attain outcome data (engagement in mental health treatment). Medical Records and Clinical databases are maintained by both the SFVAMC and SLVHCS. Research records are maintained at SFVAMC, SLVHCS and CAVHS.

The following software will be used:
The project will use two software packages for managing qualitative data analysis, ATLAS.ti and MAXQDA. ATLAS.ti is a product of Scientific Software Development GmbH (Berlin, Germany). The software is already licensed through a previous HSR&D grant in 2010 and recently updated in 2013. Once loaded into ATLAS.ti, qualitative data is saved onto a secure folder in a VA research-designated folder (e.g., R: drive) behind the VA firewall that is accessible only through actively granting of permission. ATLAS.ti temporary files are saved into the firewall-protected folder and thus are not saved onto the computer's hard drive (e.g., C: drive).

MAXQDA is a product of VERBI GmbH (Berlin, Germany). The software will be purchased through IT funds once the CREATE projects has been approved for Just In Time funding. Similar to the above, once qualitative data is loaded into MAXQDA, it will be saved into a secure VA research-designated folder (e.g., R: drive) behind the VA firewall that is accessible only through active granting of permission. MAXQDA temporary files are also saved into the firewall-protected folder and are thus not saved onto the computer's hard drive (e.g., C: drive).

The following web application will be used:
Qualtrics will be used for completing questionnaires. Security features include data redundancies, intrusion detection, access control, application software, testing environment, authorizations, demographics / server load, load / stress / penetration testing, and anti-malware. It is FIMSA compliant, please see attached white sheet specifications.

Data will be stored as follows:
Data will be stored on a VA-approved server or locked file cabinet.
Audio recordings will be removed immediately from audio recorders and uploaded to a VA issued encrypted laptop. The laptop will be securely transported back to the VA where the audio recording will then be transferred to the VA sever and removed from the laptops.
Data collected via Qualtrics will be stored on their server which is FIMSA& FIPS compliant. Please see the attached Qualtrics white paper and SFVAMC ISO approval for specifications. Data being stored on Qualtrics server is non-sensitive

Data will be transmitted and/or shipped as follows:
Data will be transmitted via encrypted email and/or password-protected documents.
Data will be transported between the local CBOCs and the medical centers. We will obtain all needed signatures for the Authorization to Transport Information. Information to be transported between CBOCs and medical centers are as follows: Informed consent forms, HIPAA authorization, voice consent, voice recordings of interviews, and hard copy field notes.
Audio recordings will be removed immediately from audio recorders and uploaded to a VA issued encrypted laptop. The laptop will be securely transported back to the VA where the audio recording will then be transferred to the VA sever and removed from the laptops.

Transmission of Audio files for transcription is as follows:
We will upload audio data files on to VA computers and encrypt them using FIPS-approved encryption software. We will then upload these encrypted files via secure connection to the transcription company's server. The file transfer service offers military grade 128-bit Secure Socket Layer (SSL) encryption security in transit and 256-bit AES encryption at rest. Once uploaded, the transcription company will decrypt the file using the unique password and will transcribe the audio files. When the transcription is complete, they will re-encrypt the resulting textual transcript files and send them back to us via secure connection. All servers are behind firewalls and can be accessed only through password-protected computers housed at either the VA or at Paul M. Garton, Inc.

Our local sites in Arkansas and Louisiana will have access to a folder on our secure VA research drive and this is how will we communicate and share our database.

Research data will be stored as follows:
<u>SFVAMC</u>
Data will be stored in SFVAMC secure server room (Bldg. 207) on server R01SFCHSM02.R01.MED.VA.GOV and/or VHASFCTMSSEAL

<u>CAVHS</u>
Paper copies will be stored in a locked file cabinet at the following location:

Central Arkansas Veterans Healthcare System

2200 Fort Roots Drive, (152/NLR), Bldg. 58, Room 134

North Little Rock, AR 72114

SLVHCS

Study-related materials will be stored in a locked filing cabinet within a locked SLVHCS office: 3500 Canal St., Room 215, New Orleans, LA, 70119.

At the conclusion of the study, we will maintain all research data, including subject identifiers and the key which links the unique study identification code to subjects' personal information, in accordance with the VA Records Control Schedule 10-1.The ISO will be contacted for guidance/assistance in destroying the data once the maximum retention period is reached.

All Study related data is either stored in a locked filing cabinet in a locked office or on a VA secure server. Once a team member resigns they no longer have access to the server and are required to turn in their keys to the building and office suit, including all filing cabinets. They are also asked to turn in the VA ID badge.

CAVHS and SFVAMC staff will be responsible for consent and recruitment of SLVHCS subjects. SLVHCS staff will not consent subjects. SLVHCS research staff will keep study records as deemed necessary by the SLVHCS local R& D office.

Transmission of COACH data to CREATE Team

This study was funded as part of a larger suite of projects under the CREATE mechanism. As part of the CREATE suite, each project will send their data to the CREATE main site, CAVHS, to be used in the overall CREATE data analysis.

The COACH study will send identified and de-identified data directly from the SFVAMC server to the CAVHS server via a data transfer. The CREATE data manager at CAVHS will create a local folder on the CAVHS server that the COACH data manager can access. The COACH data manager will place copies of the COACH data into the local folder. The CREATE data manager can then move the COACH data into a folder with the CREATE data. This method allows all data to be kept behind the VA firewall during the entire transfer process.

SFVAMC
Data will be stored in SFVAMC secure server room (Bldg. 207) on server R01SFCHSM02.R01.MED.VA.GOV and/or VHASFCTMSSEAL

CAVHS
Data will be stored in Central Arkansas Veterans Healthcare System
2200 Fort Roots Drive. North Little Rock Ar, 72214
Bldg 102, Room 104
Server R02lithsmdc101.v16.med.va.gov

8.0 Communication Plan

The SFVAMC will keep on file all IRB documentation for both itself and Central Arkansas Veterans Healthcare System and Southern Louisiana Veterans Health Care System, including consent forms, HIPAA forms and supporting documents. The local project coordinators will have weekly telephone check-in appointments. At these meetings the following will be addressed:

- Ensuring all required local site approvals are obtained.
- Keeping both engaged sites informed of changes to the protocol, informed consent, and HIPAA authorization
- Informing each site of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study.
- Ensuring the study is conducted according to the IRB-approved protocol.
- Notifying local facility investigators when the study reaches the point that it no longer requires engagement of the local facility.

All points above are considered time sensitive and will be communicated between and sites immediately. All sensitive materials will be shared between sites via our VA server. The information above will be shared with each site at their own weekly team meeting. Other study related issues will also be addressed (recruitment, challenges, issues and needed any changes). There will also be monthly telephone meeting between the entire project staff at both SFVAMC and CAVHS and SLVHCS. This will allow staff at each site to communicate openly with each other. The SFVAMC PI will travel to Central Arkansas Veterans Healthcare System and Southeast Louisiana Veterans Health Care System once a year to do a site visit and attend a live meeting. At this time the PI will review the CAVHS and SLVHCS IRB files. The CAVHS and SLVHCS PIs will travel to SFVAMC once a year to attend a live meeting. The PI's and Co-investigators will also have quarterly telephone check-ins to discuss the progress of the study.

9.0 References

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