Title

Assessment and Treatment for Chronic Pain in Veterans with Serious Mental Illness

NCT Number

NCT04118283

Unique Protocol Id

D3069-W

Protocol Date

07/17/2025

Introduction Page

1 * Abbreviated Title:
CBT-CP for SMI

2 * Full Title:
Improving the Assessment and Treatment of Chronic Pain in Veterans with Serious Mental Illness

3

* Select Type of Submission:

- (●) IRB Application
- ( ) Humanitarian Use Device (for FDA approved indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW:4DF8709A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Letitia Travaglini

CITI Training:

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
( ) Yes (●) No

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Letitia Travaglini

CITI Training:

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
( ) Yes (●) No

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View Adriana Loecher	no	no	Research Team Member	no	
View Cynthia Giron-Hernandez	no	no	Research Team Member	no	
View Alicia Lucksted	no	no	Research Team Member	no	ID00001635
View Lijuan Fang	no	no	Statistician	no	ID00019454
View Melanie Bennett	no	no	Research Team Member	no	ID00006944

Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View Julie Kreyenbuhl	no	no	Research Team Member	no	ID00005683
View Clayton Brown	no	no	Statistician	no	ID00000679
View Belinda Kauffman	no	no	Research Team Member	no	ID00009489
View Howard Turner	no	no	Research Team Member	no	
View Justine Glieger	no	no	Research Team Member	no	
View Kirsten Harvey	no	no	Research Team Member	no	
View Nicole Ciesinski	no	no	Research Team Member	no	
View Gabriella Coakley	yes	no	Research Team Member	no	
View Brian Brandler	no	no	Research Team Member	no	ID00010434
View LAN LI	no	no	Statistician	no	ID00019102

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
Dr. Travaglini will devote approximately 30 hours per week of her VA time to conduct and complete this research study.

2 * Describe the facilities where research procedures are conducted:
This project is being completed at the VA Maryland Health Care System (VAMHCS). Specifically, Veterans will have the option of completing study procedures (screening, consent, EMA instructional session, assessments, intervention sessions) at the Baltimore VA Medical Center (VAMC) or the Perry Point VAMC. MIRECC has private rooms available at each location (Baltimore: Main Hospital 6C-124, Annex rooms 506-509; Perry Point: Building 80, rooms 230 and 209) that are furnished with all equipment necessary to complete study procedures (computers with internet and intranet access, digital audio recording equipment and software).

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
We do not anticipate that participants will need medical or psychological resources following their participation in this minimal risk study. However, the VA does provide medical and/or psychological treatment for participants who take part in VA research, as outlined in the mandated VA consent form.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Study staff working on this protocol will be specially trained in working with participants with serious mental illness. Their assigned duties on this project will be described to them in detail prior to working with research participants. They will become very familiar with the protocol through ongoing study team meetings and trainings. All of our staff are extensively trained on obtaining informed consent and the study assessments and study intervention. Study staff practice study procedures beforehand and are observed a number of times prior to meeting with a research participant alone. Furthermore, they are observed on a quarterly basis obtaining informed consent and conducting the study assessment. Supervision for those conducting the manualized treatment interventions is also held on a regular basis by Drs. Travaglini and Bennett.

ID: VIEW4DF83CB976490
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● No

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● No

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date
There are no items to display		

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● No

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ○ No

6 * Institution(s) where the research activities will be performed:

- ☐ University of Maryland, Baltimore
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☑ VAMHCS
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Maryland Department of Health
- ☐ Maryland Proton Treatment Center
- ☐ Mount Washington Pediatric Hospital
- ☐ Institute of Marine and Environmental Technology (IMET)
- ☐ Other Sites
- ☐ University of Maryland Medical System (Select below)

Funding Information

1 * Indicate who is funding the study:

- [x] Federal
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [x] Device
- [x] Staff
- [x] Participant Compensation
- [x] Procedures
- [ ] Other

3 Please discuss any additional information regarding funding below:
Funding will be provided by the VA Rehabilitation Research and Development (RR&D) Service

ID: VIEW4DF85DF452400
Name: v2_Funding Information

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

- ○ Yes
- ● No

2 You may upload any grant documents here:

Name	Created	Modified Date

There are no items to display

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1 * Agency Name:
Department of Veterans Affairs

* Address 1:
810 Vermont Ave. NW

Address 2:

* City:
Washington

* State:
DC

* Zip Code:
20420

* Contact Person:
Shirley Groer

* Phone Number:
202-443-5767

* Federal Agency Email:
shirley.Groer@va.gov

Grant Number 1 (if applicable):
1-IK2-RX003069-01A2- OR - Check here if Grant 1 is not assigned a number. ☐

If Grant 1 has no number, please provide the following information:
Title of Grant 1:

PI of Grant 1:
Letitia Travaglini

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☐

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

ID: VIEW4DF8584874400
Name: v2_Federal Agency Sponsor Information

Research Protocol

1 * Do you have a research protocol to upload?

○ Yes

● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E00581F8D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID VIEW4E02805225800
Name v2_Risk Level

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 3: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

☐
i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Category 4: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☐
i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate,

improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Category 6. Taste and food quality evaluation and consumer acceptance studies.

☐ i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☑ **The research does not qualify as Exempt.**

ID VIEW8D50FF499486A05
Name v2_Exempt Categories

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- ☐ Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- ☐ Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- ☐ Use of device(s) whose use is specified in the protocol
- ☑ **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- ☐ Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- ☑ **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- ☐ None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● Yes ○ No

ID VIEW4EC2805895000
Name v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Chronic pain is one of the most common physical health diagnoses among individuals with serious mental illness (SMI, e.g., schizophrenia, bipolar disorder; Park et al., 2012, Stubbs et al., 2016). Individuals with SMI and chronic pain report worse mental and physical health functioning relative to people with other mental or physical health conditions (de Almeida et al., 2013; Falide et al., 2013). Despite knowing about high rates of chronic pain among individuals with SMI, little research has been conducted to further understand the complex relationships between pain and psychiatric symptoms and consider the usefulness or appropriateness of nonpharmacological pain management approaches. What is known is problematic. Veterans with SMI are largely not provided options for nonpharmacological pain management strategies, including CBT-CP, and are more likely to be prescribed pain medications that pose unique risks to this population (Edlund et al., 2010; Nimah et al., 2017).

The proposed research will address research and clinical gaps by better assessing relationships among chronic pain, psychiatric symptoms, and related functional impairment; and testing the feasibility and acceptability of CBT-CP in Veterans with SMI. The first step of this research will focus on completing a small randomized controlled trial of CBT-CP to examine feasibility and acceptability and explore changes to functioning and quality life in Veterans randomized to CBT-CP (n=30) relative to a Health & Wellness intervention (n=15). The second step will use ecological momentary assessment to collect real-time data (three times daily for one week) on Veterans' pain, SMI symptoms, and their impact on functioning using a phone-based survey. The final step of this research will involve conducting a process evaluation to consider ways to optimize CBT-CP for future clinical trials to improve functional recovery for Veterans with SMI and chronic pain.

ID VIEW4EC2805CF7000
Name v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

The purpose of this research study is to close research and clinical gaps by focusing on the following aims:
Aim 1: Complete a pilot randomized controlled trial (RCT) with 50 Veterans with co-occurring SMI and chronic musculoskeletal pain to examine feasibility and acceptability of CBT-CP and preliminarily evaluate participant responses to intervention when comparing outcomes of the CBT-CP condition (n=30) to those of a health and wellness control condition (n=15).
Aim 1a (Primary): Determine feasibility by demonstrating adequate rates of recruitment and completion of and fidelity to the CBT-CP intervention as well as quality and acceptability of chosen assessments.
Aim 1b (Primary): Determine acceptability by obtaining favorable ratings from satisfaction questionnaires and interviews.

Aim 1c (Exploratory): Preliminarily evaluate participant responses to intervention by exploring changes in functioning and quality of life among Veterans randomized to the CBT-CP condition (n=30).

Aim 2: Determine the feasibility of collecting EMA data to examine the temporal relationships among mental health symptoms, pain severity, and health-related functioning. Data will be collected at baseline from the 50 Veterans in the Aim 1 RCT.
Aim 2b (Primary): Determine feasibility of this approach through adherence to the EMA call schedule and overall response rates.
Aim 2b (Exploratory): Explore relationships among mental health symptoms, pain severity, and health-related functioning captured in real time.

Aim 3: Complete a well-specified process evaluation to explore how to optimize CBT-CP for use in Veterans with SMI and chronic musculoskeletal pain in future clinical trials. Overseen by the mentoring team, this evaluation will integrate qualitative data from 15 interviews with Veterans in the CBT-CP condition, CBT-CP interventionist notes, and quantitative data from Aims 1 and 2.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

We will implement an RCT of CBT-CP with random assignment to: (1) CBT-CP (n=30), or (2) Health and Wellness (comparison, n=15) group. Participants will be randomly assigned at a 2:1 ratio to CBT-CP:Health & Wellness using permuted block randomization with randomly varying block sizes. The purpose of this unequal allocation is to insure we have enough data from individuals who complete CBT-CP to evaluate its feasibility and acceptability for Veterans with SMI before testing the intervention in a large randomized controlled trial (RCT). All participants will complete the EMA (one week prior to RCT baseline assessments). Using an intent-to-treat framework, all participants will also complete assessments via telephone or video at baseline, post-treatment, and 3-month follow-up, regardless of attendance in their assigned condition, to examine data related to pain intensity and interference, functioning, and quality of life.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Veterans with SMI are largely excluded from CBT-CP trials and do not routinely receive CBT-CP in clinical settings, leading to a significant research gap and clinical disparity, and there is limited information on chronic pain experiences, management, and its impact on mood and related functioning in this population beyond an examination of prevalence rates. As such, we have conducted several preliminary studies to gather pilot data to support this research project.

To begin my work in SMI and chronic pain, I wanted to learn about SMI Veterans' and VA clinicians' experiences coping with (Veterans) and treating (clinicians) chronic pain. To explore these topics, I obtained competitive research funding through the VISN 5 MIRECC pilot research program to perform qualitative interviews with 15 Veterans within the VA Maryland Health Care System (VAMHCS) who have both bipolar disorder and a chronic pain condition, and with 15 VAMHCS clinicians (physicians, psychologists, psychiatrists, social workers, nurses, physical therapists) who treat Veterans with bipolar disorder and/or chronic pain disorders. Several themes emerged from Veteran interviews. First, Veterans endorsed a clear relationship between depression and pain ("It's a vicious cycle…[pain's] triggering [depression] to some degree or being triggered by it."), yet the relationship between mania and pain was less clear. When manic or hypomanic episodes were characterized by elevated mood and energy, Veterans had noticeable reductions in pain sensitivity and interference ("I know there's always pain, but I don't feel it…and I think that's why I messed myself up last time, because I was experiencing an episode of mania and I hurt myself."). Second, there were mixed opinions about the use of pain medications. Some Veterans found benefit from medications ("Without medications, I'm like a snail. And with medications I'm good to go."), whereas others were concerned about addiction ("I can't do medication 'cause I like it. I'm trying not to medicate myself, and I'm being medicated from various different doctors at different times.") or being overmedicated ("I'm trying to get off of them because I take a boatload of meds [for both mental and physical health problems]."). Third, many Veterans benefited from behavioral and alternative strategies such as exercise, stretching, yoga, acupuncture, and chiropractic care to manage pain ("Exercising has been a big thing that keeps me in manageability of the chronic pain."). Most Veterans were unaware of behavioral pain treatments such as CBT-CP provided through the VA, using primary care as their main source of pain management or looking outside the VA for alternative treatments. Interesting themes are emerging from the from the providers interviews. Providers acknowledged that pain conditions are often overlooked, minimized, or attributed to mental health symptoms rather than a standalone health problem. They also expressed concern that mental health symptoms (e.g., impulsivity, symptom exacerbation, substance use) could interfere with engagement and adherence to pain management services. Importantly, mental health providers feel ill-equipped to manage chronic pain and so refer Veterans with pain disorders to primary care, complicating the process of obtaining effective treatment. Overall, this study allowed me to learn from Veterans' experiences in their own words as I formulate my thinking on how to study behavioral pain treatments. It also offered a look into the provider experience trying to effectively treat multiple complex disorders. The introduction to qualitative research methods was essential. All of these factors are critical components of my CDA-2 proposal.

I have also looked at VA administrative data to look at use of medications and specialty pain services among Veterans with bipolar disorder and schizophrenia. Using administrative data from fiscal year 2015, I found that 59% of Veterans with SMI (65.7% of veterans with bipolar disorder and 50.0% of Veterans with schizophrenia) had at least one pain diagnosis documented in their medical record. Of these individuals, 67.5% of Veterans received at least one opioid prescription, whereas only 4.1% received services through a specialty pain service, where they are more likely to receive nonpharmacological approaches to pain management.

Lastly, I have examined secondary data from VISN 5 MIRECC research studies looking at the relationship between pain and other psychosocial variables among Veterans with SMI. First, I collaborated with VISN 5 MIRECC investigator and current RR&D CDA-2 recipient Dr. Elizabeth Klingaman to examine the relationships among pain, sleep, and quality of life in 56 Veterans with SMI who participated in her pilot study on sleep and psychosis. In a linear regression we found that pain interference ($p < .01$) and mental health symptoms ($p<.001$), but not sleep quality, were significant predictors of quality of life.37 These preliminary findings suggest that pain is an independent predictor of functioning and quality of life in Veterans with SMI. Second, I have examined the relationships between pain and psychosocial functioning among 242 Veterans with SMI enrolled in Dr. Richard Goldberg's RCT on Living Well, a 12-session group treatment focused on strategies and skills for chronic disease management. Preliminary data show Veterans with greater pain severity were more likely to experience worse mental health symptoms ($r=.36$, $p<.001$), have more chronic medical conditions (e.g., arthritis, cardiovascular disease; $r=.32$, $p<.001$), and report poorer physical ($r=-.64$, $p<.001$) and mental ($r=-.27$, $p<.001$) health. Veterans with greater pain severity were more likely to use behavioral and cognitive strategies (e.g., relaxation, distraction, positive self-talk) to manage physical and emotional distress ($r=.17$, $p=.008$). When compared to an active control, Living Well did not significantly affect pain intensity.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Scientific/Scholarly Background: Much is known about co-occurring chronic pain in people experiencing depression, anxiety, trauma, and substance use (Birgenheir et al., 2013; Crofford, 2015; Higgins et al., 2014; Phillips et al., 2016). However, absent is a group that is highly impacted by chronic pain: individuals with serious mental illness (SMI; e.g., schizophrenia, bipolar disorder). Individuals with SMI have high rates of co-occurring chronic pain (Birgenheir et al., 2013; Stubbs et al., 2016; Cerimele et al., 2014; Falide et al., 2013; Koyanagi & Stickley, 2015; Stubbs et al., 2015; Subramaniam et al., 2013); my preliminary work using VA administrative data has shown that 59% of Veterans with SMI have at least one chronic pain condition. These individuals experience increased psychiatric symptoms, more hospitalizations, further impairments in already compromised functioning, and heightened risk for suicide (Cerimele et al., 2014; Cook et al., 2015; Falide et al., 2013). My work on chronic pain in Veterans with bipolar disorder found a complex link between pain and mood symptoms and resulting functional impairments (e.g., loss of employment, limited social and physical activities; Travaglini et al., under review). However, a limitation of this work and other research in this area is the reliance on retrospective report rather than real-time assessment that can capture the dynamic nature of these experiences and their relationships.

Veterans with SMI are persistently underserved when it comes to nonpharmacological management of chronic pain (Kerns et al., 2003; Williams, Eccleston, & Morley, 2012; Hoffman et al., 2007). Opioid and other pain medications pose significant medical and psychosocial risks yet are overprescribed in this population (Edlund et al., 2010; Gonzalez-Pinto et al., 2001; Hassan et al., 2013; Kohler et al., 2016; Nimah et al., 2017). My pilot research has shown that Veterans with SMI are more likely to receive medications than behavioral pain management services. Cognitive Behavior Therapy for Chronic Pain (CBT- CP) - has been well-tested and is the gold standard of care for chronic pain in the general population (Williams et al., 2012; Hoffman et al., 2007; Hofmann et al., 2012, Stewart et al., 2015). It has been widely disseminated in the VA via its Evidence-Based Psychotherapy initiative, greatly increasing Veteran access to CBT-CP. However, Veterans with SMI are largely excluded from CBT-CP trials and do not routinely receive CBT-CP in clinical settings, leading to a significant research gap and clinical disparity.

Rational and Significance: The VHA has embraced the need for an integrative approach to treating mental and physical health problems (Murphy et al., n.d.). The urgent need for non-pharmacological treatments for chronic pain has been intensified given the context of the national opioid crisis (National Institutes of Health, 2017). Veterans with SMI and chronic pain deserve access to behavioral treatments that work so they can pursue recovery and lead lives of their choosing. VHA and RR&D

share this goal. VHA has prioritized the use of non-pharmacological pain management interventions on several fronts: the national roll-out of CBT-CP, the Three Step model of pain management, the dissemination of findings from the HSR&D SOTA Conference on Non-pharmacological Approaches to Pain Management, and the VA/DoD/NIH collaboration to increase funding for research on non-pharmacological pain management approaches (National Institutes of Health, 2017). RR&D has prioritized research on behavioral interventions for chronic pain for Veterans. My proposal is squarely in line with RR&D priorities promoting research on "non-pharmacological activity-based interventions for chronic pain impacting outcomes that may include pain reduction, medication use, ADL, and QoL". These priorities must extend to SMI Veterans. This proposal will make important contributions to research on chronic pain and will begin the process of closing the gap in pain treatment for SMI Veterans. Individually, chronic pain and SMI are associated with poorer quality of life, functioning, general well-being, and treatment engagement; when co-occurring, their impact on functioning and symptom severity is even more debilitating. The VHA Uniform Mental Health Services Handbook states that Veterans with SMI must be offered quality interventions comparable to that received by other Veterans (Dixon et al., 2010), in the case of chronic pain, this is not happening. In addition, more information is needed to understand the complex relationships among pain, mental health symptoms, and related functioning. Retrospective reports are limited and cannot fully explore the nuanced patterns within these relationships.

This research study will address critical gaps in our understanding and management of chronic musculoskeletal pain in Veterans with SMI. First, Veterans with SMI must have access to effective behavioral pain treatments. There is currently no research examining whether CBT-CP is effective in reducing pain and improving functioning for Veterans with SMI, nor whether adaptations are needed to optimize it for this group of Veterans. Second, in-depth knowledge of the complex relationships among pain, psychiatric symptoms, and functioning is needed. Commonly used cross-sectional, retrospective assessment methods cannot fully capture the direction and nuance of these relationships. In contrast, ecological momentary assessment (EMA), in which individuals provide information on symptoms and functioning as they experience them in real-time26 offers fine-grained data on changes in pain, psychiatric symptoms, and functioning naturalistically and longitudinally. The proposed research study will examine the feasibility and acceptability of CBT-CP in SMI Veterans (Aim 1), enable a more complete understanding of the complex relationships among chronic pain, mental health symptoms, and their impact on health-related functioning (Aim 2), and understand how to fully optimize CBT-CP to improve functional recovery (Aim 3). Findings from this work can translate into a larger program of research examining non-pharmacological pain management strategies for SMI Veterans.

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Over 50% of Veterans (approximately 5 million) within the Veterans Health Administration (VHA) have chronic pain conditions. Chronic pain is defined as pain that lasts beyond the usual course of recovery (typically 3-6 months) and adversely affects functioning and well-being (Task Force, 1994). Chronic pain is the most common reason for seeking medical care and is a leading cause of disability among Veterans (Institute of Medicine, 2011; Murray et al., 2013). Co-occurring chronic pain and mental health disorders – especially serious mental health disorders – is alarmingly common and confers substantial functional impairment. Individuals with SMI, defined here has having a diagnosis of schizophrenia spectrum and bipolar disorders (Kilbourne et al., 2015), have higher prevalence rates of chronic pain (ranging from 30-60%) than the general population (Birgenheir et al., 2013; Stubbs et al., 2016; Cerimele et al., 2014; Falide et al., 2013; Koyanagi & Stickley, 2015; Stubbs et al., 2015; Subramaniam et al., 2013). Having co-occurring chronic pain and SMI has been linked to greater disability, suicidality and functional impairment, worse overall health status, and poorer rehabilitation outcomes than having either condition alone.4-8,37 Bidirectional effects between pain and depressed mood negatively affect treatment engagement, self-care, coping, and outcomes (Birgenheir et al., 2013; Crofford, 2015; Higgins et al., 2014; Phillips et al., 2016; Kerns et al., 2003.), ultimately worsening functioning.

Little research has examined the complex relationships between chronic pain and SMI symptoms. While research has examined links between major depression and chronic pain (e.g., depressive states can exacerbate pain which in turn further worsens mood; Crofford et al., 2015; Goesling, Clauw, & Hassett, 2013; Vadivelu et al., 2017), almost nothing is known about how SMI symptoms such as mania and psychosis impact and interact with pain experiences and related functioning. One of the few studies in this area included 201 individuals with bipolar disorder undergoing a surgical procedure to treat chronic pain. During a pre-surgical evaluation, 64% of participants reported reductions in pain intensity during their most recent manic or hypomanic episode (Boggero & Cole, 2016). While this study added to the literature by examining how pain is specifically related to manic or hypomanic episodes, it had several design limitations, including being cross-sectional, retrospective, and only including a single question in a targeted sample of individuals undergoing surgery. Other studies of chronic pain in schizophrenia focus on impaired pain processing, perception, and sensitivity (Engels et al., 2014; Grignon, Stavro, & Potvin, 2014). In a cross-sectional analysis of data from the World Health Survey, participants were categorized based on number of psychotic symptoms and lifetime history of schizophrenia or another psychotic disorder. Individuals with a greater number of psychotic symptoms – regardless of having a diagnosed psychotic disorder – reported worse pain severity (Koyanagi & Stickley, 2015). Another study used data from the World Health Organization (WHO) World Mental Health Surveys to examine the relationships between psychotic episodes and 12 general medical conditions, four of which were pain conditions (arthritis, back or neck pain, headaches, and other chronic pain).42 Psychotic episodes preceded onset of all four pain conditions, while headache and other chronic pain conditions were also noted to precede onset of psychotic episodes. While this study showed temporal relationships between onset of chronic pain and psychosis, the study relied on retrospective reports and was unable to confirm causal relationships between pain and symptoms (Scott et al., 2018). In summary, studies on pain and mental health use cross-sectional and retrospective designs that preclude examination of the complex relationships (e.g., causal pathways) between pain and mental health symptoms.

Research has not addressed how pain and SMI symptoms interact to affect overall functioning. Ecological Momentary Assessment (EMA) is an innovative and powerful longitudinal methodological approach well-suited to studying the complex relationships among chronic pain, mental health symptoms, and health-related functioning. EMA collects real-time data on an individual's behavior and experience as it occurs in the natural environment and uses these data to understand how experiences vary across time and situation (Shiffman, Stone & Hufford, 2008). EMA allows for a more accurate picture of symptoms and functioning and can reduce the reporting bias found in the retrospective data collection most often used in physical and mental health research. EMA also supports data collection over multiple time points, allowing for a better examination of how changes in mental health symptoms (e.g., psychosis, mania) in real time relate to fluctuations in pain and functioning and vice versa. Emerging research has used this method to better understand the relationship between depression and chronic pain (Tennen, Affleck, & Zautra, 2006). EMA has been used successfully in studies of SMI (Bell et al., 2017) and studies of chronic pain (May et al., 2018), but has yet to be used to examine the relationships among chronic pain, mental health symptoms, and functional outcomes in SMI populations.

Individuals with SMI primarily receive pharmacological treatments for chronic pain. Pharmacological pain treatments pose significant risks in SMI. Individuals with SMI have higher rates of substance use disorders; this raises concerns about the use of long-term opioid therapy in terms of both addiction and overdose potential (Edlund et al., 2010; Martins et al., 2009; Wasan et al., 2007). Other pain medications, including nonsteroidal anti-inflammatory drugs (NSAIDs) and antidepressants, can be problematic in SMI as they can exacerbate mental health symptoms or negatively interact with psychiatric medications (Gonzalez-Pinto et al., 2001; Nimah et al., 2017; Hassan et al., 2013; Martins et al., 2009; Wasan et al., 2007). Despite these substantial risks, opioids and other pharmacological pain treatments are generally the first, and frequently the only, treatment provided to individuals with SMI and co-occurring chronic pain. SMI Veterans need non-pharmacologic interventions for chronic pain yet have little access to behavioral pain management services. While the VHA has prioritized non-pharmacological approaches for chronic pain management, including behavioral approaches such as Cognitive Behavioral Therapy for Chronic Pain (CBT-CP; National Institutes of Health, 2017), there continues to be a lack of access to such strategies among Veterans with SMI. Specifically, CBT-CP has not been studied in individuals with SMI. CBT-CP is an active, self-management approach to cope with chronic pain challenges. It is a structured, time-limited psychotherapy that focuses on challenging negative thoughts and feelings associated with chronic pain as well as improving engagement in meaningful physical and social activities (Murphy et al., n.d.). The effectiveness of CBT-CP has been demonstrated in several large RCTs showing significant improvements in improving functioning and overall quality of life (Williams et al., 2012; Hoffman et al., 2007; Hofmann et al., 2012; Stewart et al., 2015). Within the VHA, CBT-CP has been identified as an EBP, and VHA has trained the mental health workforce in its delivery through the VA national roll-out program. Despite this, no research has evaluated CBT-CP in individuals with SMI, who have been excluded from CBT-CP RCTs. This represents an enormous gap in both research and clinical care for individuals with SMI. CBT-CP may be particularly advantageous in SMI given the effectiveness of other CBT interventions in this population. Many first line treatment recommendations for SMI employ a cognitive and behavioral approach to symptom management (Dixon et al., 2010; Hunt et al., 2013; Hones et al., 2012). Given that CBT interventions are effective for managing mental health symptoms and are familiar to patients, it is likely that SMI Veterans would be able to engage in CBT-CP and use CBT skills to improve pain and related functioning, just as they are able to employ these skills to manage mental health symptoms and promote recovery.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
References(0.01)	10/15/2019 1:52 PM	10/15/2019 1:52 PM

ID: VIEW-EC2805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

Fifty (N=50) Veterans with comorbid chronic pain and serious mental illness will participate in a) a pilot RCT to examine the feasibility and acceptability of Cognitive Behavioral Therapy for Chronic Pain (CBT-CP) for this population; and b) a one-week ecological momentary assessment (EMA) to examine temporal relationships between mental health symptoms, pain experiences, and related functioning. Veterans will be randomly assigned to either CBT-CP (n=30) or a Health and Wellness control condition to preliminarily evaluate treatment outcomes. A process evaluation will then take place that includes findings from the RCT and EMA as well as information from interventionists' notes and qualitative interviews with a subset of individuals in the CBT-CP condition (n=15) to consider ways to optimize CBT-CP in future clinical trials. Participant involvement includes: 1) initial screening for eligibility and consent; 2) completing the ecological momentary assessment; 3) Baseline assessment; 4) Intervention; 5) Post-treatment assessment; 6) 3-month Follow-up assessment; and 7) if approached, a qualitative interview about their study experiences.

Veterans will have the option of completing study procedures (assessment, intervention sessions, qualitative interviews) over the phone or through video/telehealth using approved VA/ORD telehealth services. Research staff conducting study procedures have government furnished equipment (GFE, laptops) furnished with all equipment necessary to complete study procedures (e.g., digital audio recording equipment and software; VA share drive access, study databases).

1) SCREENING AND PRECONSENT SCREENING AND CONSENT(N=50): Potential participants will be identified through review of clinic rosters via HIPAA waiver (to minimize participant burden), provider referrals (notification of study through emailed flyers and announcements at meetings), and self-referral (flyers posted in clinic waiting areas). Screening will initially involve review of medical record via HIPAA waiver to identify individuals that have an SMI diagnosis and chronic pain condition in their problem list. Those interested will be contacted by telephone or in-person to participate in a screening interview. For in-person screening, potentially eligible Veterans (based on CPRS screening) will be approached before or after a scheduled clinical visit, and research staff will have a private space in the area to complete additional screening to determine eligibility; this in-person contact is for recruitment/screening only; if the person is eligible and wishes to move forward, all additional study appointments (e.g., consent session, assessments, intervention sessions) will be conducted remotely via telephone or video.

Prior to eliciting any information, we will describe the nature of the study, including the number of visits, protections and confidentiality. If the participant is still interested in participating, we will obtain verbal consent for the screening. Screening questions include confirmation of regular telephone access that has internet access, the Defense and Veterans Pain Rating Scale (DVPRS) to assess current pain severity (ranging from 0 [no pain] to 10 [worst pain]) and related functional impairment, ability to walk a city block, and a question asking about current or previous enrollment in CBT-CP. Any participants with a DVPRS pain severity score of >4, the cut-off for moderate-to-severe pain, will be eligible to participate in the study. Those eligible will discuss the study with research staff who will obtain informed consent using IRB-approved procedures including assessment of the prospective participant's competence to consent, including capacity to fully understand study procedures and related risks and benefits and how to let study staff know if they wish to discontinue study participation.

2) ECOLOGICAL MOMENTARY ASSESSMENT (EMA, N=50): After completing the informed consent process, participants will complete a remote visit (telephone or video) with a research assistant (RA) to discuss the EMA procedures. Participants will be asked to complete a Subject Locator Form that includes their preferred phone number(s) and will be instructed on the times of day they will receive a phone call or a text message with a link to the EMA questionnaire. Participants will be able to choose whether they prefer to receive a text message with a survey link or a phone call from a study RA to complete the EMA survey. Regardless of preferred method, participants will be provided with an overview of the EMA protocol and have a chance to practice completing the survey with the RA to trouble shoot any concerns. Participants will be given an information sheet with the EMA items and response options to take with them and review as needed. Over the next 7 days, participants will receive either a phone call or an automated text message three times per day at random times during block periods (morning, 8am-12pm; midday, 12pm-4pm; and evening, 4pm-8pm). If their preferred method is a phone call, they will complete the survey over the phone with a study RA; if the preferred method of delivery is text message, they will click on the link that is texted to them to complete the online survey. The EMA study includes a series of 20 items about pain, mental health symptoms, and related functioning. All data will be time stamped in order to be analyzed with respect to time of the assessment. It will take approximately 7-10 minutes to complete each survey. Veterans will be compensated up to $33 dollars for their participation: $5 for the EMA training session; and up to $28 dollars for completing the EMA protocol (up to $4 per day; $2 for one completed survey per day and $1 for each additional completed survey).

3) BASELINE (Timepoint 1; TP1) ASSESSMENT (N=50): Participants who complete the DVPRS and score 4 or higher will be invited to complete the CBT-CP Intake Interview and an assessment battery that will take up to 120 minutes. The assessment battery includes measures that assess pain, pain interference, health behaviors, functioning, and quality of life. Participants will be paid $30 for completion of these assessments.

4) TREATMENT WITH CBT-CP OR HEALTH & WELLNESS: Participants will be randomized to either the CBT-CP (treatment) condition (n=30) or the Health and Wellness (control) condition (n=15). Interventionists will be Master's level RAs who will be trained on treatment protocols and monitored for fidelity. Participants will attend approximately 10 treatment sessions over the span of approximately 4 months. Participants in both conditions will be given a pedometer at the first session, and weekly steps will be recorded at each subsequent session (Sessions 2-10). Participants in the CBT-CP condition will complete the DVPRS at each session, and the Pain Catastrophizing Scale (PCS), West Haven-Yale Multidimensional Pain Inventory-Interference subscale (MPI-Int), PROMIS Depression scale, and WHO Quality of Life-BREF questionnaire (WHOQOL-BREF) at week 7 (in addition to at baseline and post-treatment assessments), as directed in the CBT-CP manual. We will use approximately 10 minutes at the end of every CBT-CP session to pose open-ended questions to attending participants about reactions to that week's session content, recommendations for changes, and their views of the usefulness of the session to them as Veterans with SMI. Additionally, participants in the CBT-CP condition will complete the one treatment satisfaction surveys at or after session 5 (mid-point). As the treatment satisfaction survey will be separate from the intervention session at mid-point, Veterans will be compensated $5 for completing this assessment.

Interventionists are delivering cognitive behavioral therapy for chronic pain (CBT-CP) to participants. Occasionally, participants request that the interventionist describes the treatment to a significant person in their lives (e.g., friend, family member, acquaintance) in order to obtain support from this person in pursuing treatment efforts. Sometimes this may happen during an audio recorded intervention session. If a participant would like to involve a third party in their sessions, a VAMHCS release of information form would need to be completed by the participant. Additionally, the third party would need to sign a VAMHCS Consent for Audio/Video Recording form for the significant person to sign if they will likely be heard on audio recordings. Both of these forms are uploaded in the Additional Documents section.

5) POST-TREATMENT (TP3) ASSESSMENT: At the end of their participation in either CBT-CP or Health and Wellness, participants will complete the assessment battery

administered in during TP1, with the exception of the CBT-CP Intake Interview. The assessment will take up to 90 minutes. Participants will be paid $30 for participation in this assessment battery.

6) 3-MONTH FOLLOW-UP (TP4) ASSESSMENT: At 3 months following the intervention, participants will complete the TP 4 (Follow Up) Assessment Battery, which is the same as that used in TP3. Participants will be paid $30 for participation in the follow up quantitative assessment battery.

7) QUALITATIVE INTERVIEW: At the end of their participation in the intervention, a purposeful sample of 15 participants who were randomized to CBT-CP will be invited to complete a qualitative interview about their experience with the intervention. To achieve a broad, diverse sample, Veteran participants will be selected to ensure roughly equal proportions of CBT-CP completers and non-completers and different mental health diagnoses (bipolar disorder, schizophrenia) enrolled across the study period. We will also target specific Veterans to ensure maximize diversity on other characteristics (e.g., age, gender, pain conditions). Interviews will begin with broad open questions exploring individuals' initial reactions to CBT-CP and proceed to questions that elicit specific information about each facet of the intervention. The interviews will focus on why participants decided to enroll, their initial expectations, their experiences with participation in the intervention, barriers (e.g., mental health or other physical health concerns, functional limitations, logistical limitations) and facilitators of CBT-CP engagement, perceived benefits of participation (e.g., improved health-related functioning, reduce pain intensity or interference), and suggested improvements to better integrate psychiatric symptom management with pain treatment. Interviews will also ask about the perceived utility of the intervention, including specific skills, educational material, and home practice elements. Finally, participants will be asked about real-world implementation of CBT-CP to help improve functional recovery of Veterans with SMI, specifically, it will be helpful to get their perceptions of where it would best fit into VA services that they currently or may use as a Veteran with SMI. The qualitative interview will be audio recorded. Audio recordings will be transcribed by an experienced VA-approved transcriptionist. The transcriptionist will not know the identities of the participants on the recordings and recordings will not include any identifying information. Research staff will ensure that the audio recordings are transferred in a secure manner (encrypted) to the transcriptionist. Participants will be paid $20 for completion of the qualitative interview.

8) OTHER: Participants completing the surveys by phone or telehealth/video will be mailed their participation compensation funds upon receipt of the survey data. If Veterans are completing study sessions remotely (telephone or video), then Veterans will be sent materials (e.g., consent forms, study questionnaires/response options, CBT-CP handouts and resources) beforehand. Materials can be mailed to participants or Veterans can also agree to having materials emailed to them (see sample language below and additional email scripts uploaded to Additional Documents section). We will use VA email to communicate with veteran participants, and will only send these materials at the veteran's request. Staff will discuss proper procedures for communication via email with the veterans ahead of time to ensure understanding. The emails will also include a clear statement that no completed forms or personal identifying information should be sent to staff via email correspondence. All emails will be deleted upon receipt to help ensure security. Veteran participants may choose to be reminded about appointments via a text message from staff using their VA issued cell phone. The texts will also include a clear statement that they do not need to respond, and personal identifying information should not be sent via text. Staff will discuss proper procedures for communication via text with the veterans ahead of time to ensure understanding.

9) MISSED APPOINTMENTS: If a Veteran misses a scheduled appointment (assessment timepoint, intervention session), study staff will first try to contact them by telephone to reschedule. After three failed telephone calls (at least one per week), study staff will follow-up with a letter or email acknowledging the missed appointment and encouraging Veteran to call to reschedule if interested (see Missed Appointment letter template in Additional Documents section). Veterans will have up to three months to re-engage in intervention sessions; if they don't respond to outreach attempts after three months, they will be contacted to complete the post-treatment assessment (TP3).

SAMPLE EMAIL TEXT:

Hello,
As you requested, attached are the response cards you will use if completing the assessment at home via phone. Our call is scheduled for [day], [date] at [time]. Research staff will call you at your preferred number. Please contact the research study team at [VA phone number] if you have any questions prior to our phone call or if you need to reschedule.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!
The VA Research Study Team

and

Hello,
As you requested, attached are blank electronic copies of the worksheets/resources we discussed. Our next call is scheduled for [day], [date] at [time]. Research staff will call you at your preferred number. Please contact the research study team at [VA phone number] if you have any questions prior to our phone call or if you need to reschedule.
We cannot guarantee email is secure so please do not reply back to this message with any personal information or personal health information.
Thank you and have a great day!
The VA Research Study Team

And
SAMPLE TEXT MESSAGE

Hello,
Our next appointment is scheduled for [day], [date] at [time]. Please contact the research study team at [VA phone number] if you have any questions prior to our meeting or if you need to reschedule. We cannot guarantee text messaging is secure so please do not reply back to this message with any personal information or personal health information.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
N/A

3 * Describe the duration of an individual participant's participation in the study:
Each participant's participation in the study will last approximately 24 weeks and will include:
1. Screening and Consent: Week 1, 45 minutes
2. EMA session, followed by data collection: Week 1, 30 minute session followed by one week of completing surveys (7-10 minutes per survey) completed three times per day (morning, midday, evening)
3. Baseline (TP1) Assessment: Week 2, up to 120 minutes
4. Treatment with CBT-CP or Health and Wellness: Weeks 3-12, 60-minute weekly individual sessions, including a mid-treatment assessment of treatment outcomes and acceptability (TP2)
5. Post-treatment (TP3) Assessment: Week 13, up to 90 minutes
6. Qualitative interview: Weeks 14-20, 60 minutes
7. Three-month follow-up (TP4) Assessment: Week 24, up to 90 minutes

4 * Describe the amount of time it will take to complete the entire study:
The entire study will last approximately 4 years.

5 * Describe any additional participant requirements:
N/A

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
RCT sample size: Treatment development guidelines suggest involving 30-60 participants (15-30 per study arm) in small-scale pilot trials. This is the primary reason we have chosen to randomize 45 total patients. We have also chosen to randomize 30 participants to CBT-CP and 15 to the H&W control condition. The purpose of this unequal allocation is to insure we have enough data from individuals who complete CBT-CP to evaluate its feasibility and acceptability for Veterans with SMI before testing the intervention in a large randomized controlled trial (RCT). MIRECC investigators have successfully retained >80% of Veterans with SMI in behavioral intervention studies, however, the demands of CBT-CP may impact these retention rates and therefore we want to ensure we obtain a sufficient amount of data to evaluate CBT-CP. The purpose of utilizing the Health & Wellness control group, which we have prior experience administering to other SMI populations, is to preserve the concurrent parallel groups clinical trial design and have a measure of control and comparison when evaluating response to CBT-CP. To assess the feasibility and acceptability of CBT-CP we will estimate key parameters regarding recruitment, engagement, retention rates, and participant satisfaction with 95% confidence intervals (CIs). The appropriate analytic approach for pilot studies is estimation with 95% CI's rather than hypothesis testing. Ninety-five percent CIs provide a range of estimates for the "true" population value of the parameter consistent with the observed data.

EMA sample size: The multi-level model specified in the data analysis section below is similar to a simple linear regression model except for the addition of a random participant effect to account for correlation between observations (clustering) from the same participant. We therefore computed the reduced "effective" sample size for the baseline EMA period (as if the observations were independent) based on the design effect formula for clustered responses.103 This reduction depends on how correlated responses are and the average number of responses per individual. Furthermore, the beta coefficient from simple linear regression, in our case of pain severity score regressed on depression score, is a rescaled Pearson's correlation coefficient. Therefore, in Table 6, we convey the level of precision in estimating the linear relationship between momentary pain severity and depression in terms of a Pearson correlation which we set to a small to medium value of $r = .25$. If all participants (N=45) responded to all prompts during the baseline EMA period (N=21), there would be 945 responses in total.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
AIM 1: PILOT RCT
Our primary data analyses will focus on estimation of feasibility and acceptability parameters. Point and interval estimation with 95% CI's will be used. Our exploratory analyses will be to preliminarily evaluate responses to the CBT-CP intervention. We will examine key outcomes at the individual level to see if they suggest changes occurred. The trial will be conducted according to the "intent-to-treat" (ITT) principle in that outcomes will be assessed and analyzed regardless of individual level of participation in treatment. We expect the outcome measures (questionnaires listed above) to be approximately normally distributed and we will otherwise modify analysis models to fit outcome distributions or employ variable transformations.

Missing Data. To assess potential bias due to missing assessments, we will compare TP1 characteristics of participants who were assessed at TP2 (as well as TP3) versus those who were not assessed. Our procedures and analyses will be based on the ITT principle: we will attempt to assess all participants at TP2 and TP3 including those who discontinue treatment early, and we will use all available data for analyses. We expect loss-to-follow-up to be 20% at TP2 and 30% at TP3.

Primary Aim 1a: Determine feasibility by demonstrating adequate rates of recruitment and completion of and fidelity to the CBT-CP intervention as well as quality and acceptability of chosen assessments. We will examine a) the feasibility of the CBT-CP intervention, demonstrated by adequate rates of recruitment, initial intervention engagement, and completion (assessment at post-treatment), and attendance at intervention sessions, and b) therapist fidelity to intervention protocols. Feasibility: We will summarize the feasibility of CBT-CP by using point and 95% CIs to estimate: 1) recruitment percentages (# consented divided by # approached; # randomized divided by # consented); 2) percent who engaged in treatment (% of randomized who attend first 3 sessions), mean number of sessions attended and treatment completion percentage (# who completed post-treatment assessment divided by # randomized); and 3) mean number of reminders and outreach contacts made for each participant; and 4) the mean (and SD) number of completed CBT-CP homework assignments, assessed weekly by CBT-CP interventionists. Feasibility will also extend to measurement selection. While measures have been carefully selected based on their use in studies of chronic pain, CBT-CP, and/or serious mental illness, it would be important to consider the acceptability of all study measures with this group of Veterans, and whether or not Veterans enrolled in the study can tolerate the assessment battery given issues such as pain interference, pain-related fatigue, and cognitive load. RAs will record the time it takes for Veterans to complete the assessment battery at each time point, any breaks (e.g., amount, duration), and potential need to complete assessments over the course of multiple days. Any qualitative information about the Veteran's approach to assessment (e.g., behavioral observations, mental status, Veteran comments) will also be noted and reviewed by the PI.

Primary Aim 1b: Determine acceptability by obtaining favorable ratings from a satisfaction questionnaire and qualitative interviews. Acceptability will be reflected in positive average scores on the CSQ-8 (>2.5) and SSS-16 (>3). Additionally, interventionist notes from weekly questions about session content and use of skills and resources will be summarized by the Interventionists and PI into a series of topics and recommendations for future CBT-CP research, implementation, and optimization for Veterans with SMI.

Exploratory Aim 1c: Preliminarily evaluate participant changes in functioning and quality of life in response to the CBT-CP intervention and in comparison to changes in the Health and Wellness control condition. The focus of these analyses is to explore whether study data suggest CBT-CP is a promising treatment for pain in this population that should be studied in a large RCT. These analyses will start with examining individual change scores from pre- to post-treatment on the health-related functioning and QOL outcomes within the CBT-CP treatment group. We will calculate the percentage of individuals who showed improvement to address the question "Were changes in the right direction?" We will attempt to establish minimally clinically meaningful benchmarks a priori based on literature review and clinical experience and calculate the percentage of individuals who achieved this amount of change. We will perform the above analyses for the H&W control group as well for comparison. Within- and between-group mean change and effect sizes will be estimated with 95% CI's, however it would be inappropriate to use these estimates for planning a larger RCT given the small sample size.109 Covariate balance between the two treatment conditions on demographic and clinical variables will be examined. Exploratory regression will be used to adjust if there is an out-of-balance covariate (e.g. symptom severity) associated with an outcome, however there won't be enough degrees of freedom to adjust for multiple covariates.

AIM 2: EMA
Aim 2a (Primary): Feasibility. The feasibility of the EMA protocol will be evaluated using usability statistics on the number of answered calls or completed surveys (accessed through text message), percent of all survey items responded to (overall and within each category), and time it took to complete each survey (duration of phone call or time to complete online survey). Number of calls placed to research staff regarding survey-related issues will also be documented. At the TP1 assessment, participants will be asked for feedback about the EMA protocol.

Aim 2b (Exploratory): Examination of Temporal Relationships. Distributions will be screened for non-normality, errors, and outliers using frequency tables and plots. Transformations will be considered for substantially skewed variables to be used as dependent variables. The design of this pilot EMA is longitudinal, collecting data three times per day (morning, midday, evening) for seven days. The sample size will be N = 45. Different subsets of the total data may be selected to address specific research questions. How the data will be structured and analyzed may also vary depending on the research question. However, the first general analytic approach will be

to use multi-level models with momentary assessments at the 1st level and the individual (e.g., individual characteristics) at the second level. One key set of questions will be: 1) Is pain intensity related to symptoms of depression, mania, and psychosis, and 2) do these relationships vary across individuals? In the case of depression, the two levels of the model for (1) will be: Level 1: Pain = $\pi 0i + \pi 1i$ Deprit + εit, Level 2: $\pi 0i = \beta 00 + \delta 0i$, $\pi 1i = \beta 10$. In this specification, Pain intensity varies over measurement occasions t within individuals i. The average pain intensity is represented by $\pi 0i$ which randomly varies across individuals. The random effects $\delta 0i$ and εit are assumed to have zero means and be normally distributed. However, the linear relationship between depression (Depr) and Pain does not vary across individuals. To address question (2) (does the relationship vary across individuals?), the model would be specified to allow the slope, $\pi 1i$ to vary across individuals, i.e. let $\pi 1i = \beta 10 + \delta 1i$ and if Var($\delta 1i$) is greater than zero, model fit will be improved, and the estimate for Var($\delta 1i$) or SD($\delta 1i$) quantifies how much variability there is. Finally, person level covariates can be added to Level 2. For example, age could be added as a predictor of $\pi 1i$ to address the question: Is the variability in the relationship between depression and pain partly explained by age differences. Unlike conventional multi-level models, with randomly prompted EMA responses over time, the responses are unbalanced in the sense that individuals are not assessed at the same time points. To address this, we will use an autocorrelation function to model serial correlation for the εit term. The best fitting function will accurately account for the decay in correlation the further apart in time two successive momentary assessments are.93 Because this study is exploratory, the primary analysis will be to estimate parameters using point and interval estimation (95% CIs). Multi-level models can readily handle unbalanced data due to missing values and generally produce unbiased estimates under the Missing at Random (MAR) assumption.

The second analytic approach we will use to explore the temporal dynamics of our variables of interest is Vector Autoregression (VAR), a type of multiple time-series. This statistical model links the time series of two or more variables (pain, mental health symptoms, functioning) using regression and allows examination of temporal ordering (e.g. prior pain severity □ mania versus prior mania □ pain severity). This analysis is an idiographic approach where the time series for each individual are analyzed and then results are summarized across individuals. The temporal relationship between pairs of variables, both are treated as endogenous (i.e. as explanatory and response variables) and each variable is regressed (as response or lead variable) at each time point on a small number of prior measurements (2 to 3 prior measurements) of both the response variable and the second variable of interest. Covariate adjustment is possible, and the fit of the model is assessed by common methods (e.g. Likelihood Ratio test, AIC, BIC). The parameters of interest will be the effect of prior measurements of the 2nd variable on the 1st variable as response and vice versa. Thus, the primary analysis will be to estimate differences between parallel effects of the two time-series with point and interval estimation.

AIM 3: QUALITATIVE INTERVIEWS
Data will be used to develop a deeper understanding of the barriers and facilitators to engaging CBT-CP and to add context to quantitative findings, particularly related to how and why the intervention did or did not work. We will use rapid assessment process (RAP) to analyze interviews. RAP uses a team-based coding approach and focuses data analysis to answer specific research questions. Study staff will code the interviews. All members of the coding team will independently read and code the first two interviews and will then meet to discuss them and resolve any significant coding differences to consensus. Then, each remaining interview will be coded by two coders independently and then compared. Any coding differences that cannot be resolve in the coding dyad will be brought back to the larger study team for discussion and resolution. After coding is complete, the team will examine the data in each domain across all interviews to articulate themes and identify implications for future CBT-CP refinement, implementation, and research and clinical work.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 *Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
Participants can request overall results of this study if interested. Results of this study will be shared through publications. Participants' test results and progress in the intervention may be shared with their VA medical providers in order to coordinate the delivery of this intervention with the rest of participants' medical care.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 *Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [x] **Key informant or semi-structured individual interviews**
- [ ] Focus groups or semi-structured group discussions
- [x] **Audio or video recording/photographing**
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [x] **Psychosocial or behavioral interventions**
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 *List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
Screening: Defense and Veterans Pain Rating Scale (DVPRS)

AIM 1: RCT
1. Mid-treatment Treatment Satisfaction Survey (includes Service Satisfaction Scale (SSS-30) and Client Satisfaction Questionnaire (CSQ-8))
2. Post-treatment Treatment Satisfaction Survey (includes Service Satisfaction Scale (SSS-30) and Client Satisfaction Questionnaire (CSQ-8))
3. Additional CBT-CP Acceptability Items: 4-item weekly questionnaire
4. MIRECC Demographics
5. CBT-CP Clinical Interview
6. Defense and Veterans Pain Rating Scale (DVPRS) – supplemental items
7. Pain Numeric Rating Scale (PNRS)
8. West Haven Yale Multidimensional Pain Inventory (WHYMPI)-Interference Subscale
9. Veterans RAND 12-item Health Survey (VR-12)
10. World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0)
11. World Health Organization Quality of Life Scale (WHOQOL-BREF)
12. Pain Catastrophizing Scale (PCS)
13. Physician Health Questionnaire-9 item version (PHQ-9)
14. Behavior and Symptom Identification Scale (BASIS-24)
15. Internal States Scale (ISS)
16. PROMIS Anger - Short Form (5-item)
18. Depression, Anxiety, and Stress Scale-21 Item (DASS-21)
19. Suicide Behaviors Questionnaire-Revised (SBQ-R)
20. PROMIS-Applied Cognition
21. Insomnia Severity Index (ISI)
22. Smoking History Form (SHF)
23. Fagerstrom Tolerance Scale (FTS)
24. Addiction Severity Index, including the Alcohol Use Disorders Identification Test (ASI-AUDIT)
25. PROMIS Prescription Pain Medication Misuse-short form
26. PROMIS Pain Behavior
28. PROMIS Fatigue
29. PROMIS Satisfaction Social Roles and Activities - Short Form (6-item)
30. PROMIS Self Efficacy for Managing Symptoms - Short Form (8 item)
31. PROMIS Self-Efficacy for Managing Medications and Treatment
32. Medical Conditions Questionnaire (MCON)
33. Instrument to Measure Self-Management (IMSM)
34. Chronic Illness Anticipated Stigma Scale (CIASS)
35. Brief Resilience Scale
36. Brief COPE
37. Pain Management Collaboratory COVID-19 Measure (PMC COVID)

AIM 2: EMA Survey
38. EMA Survey

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
21. ASI_Audit Combined_updated for REDCap_12.2021.docx(0.02)	3/26/2021 4:12 PM	12/9/2021 11:35 AM
28. PROMIS - Self-Efficacy_Symptoms-SF.pdf(0.02)	3/26/2021 4:10 PM	6/24/2021 9:04 AM
27. PROMIS - Satisfaction_Social Roles-SF.pdf(0.02)	3/26/2021 4:10 PM	6/24/2021 9:03 AM
15. PROMIS - Anger SF.pdf(0.02)	3/26/2021 4:12 PM	6/24/2021 9:01 AM
16. Internal States Scale (ISS).pdf(0.01)	4/22/2021 10:39 AM	4/22/2021 10:39 AM
PROMIS_SF_v1.0_-_Prescription_Pain_Med_Misuse_7a_06-29-2018.pdf(0.01)	4/22/2021 10:38 AM	4/22/2021 10:38 AM
22. Fagerstrom (FTS).pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
21. Smoking History Form (SHF).docx(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
20. Insomnia Severity Index (ISI).pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
19. PROMIS SF v1.0 - Applied Cog General Concerns.pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
18. Suicide Behaviors Questionnaire Revised (SBQ-R).pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
17. Depression, Anxiety, and Stress Scale (DASS-21).pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
14. Behavior and Symptom Identification Scale (BASIS-24).pdf(0.01)	3/26/2021 4:12 PM	3/26/2021 4:12 PM
13. Physicians Health Questionnaire (PHQ-9).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
12. Pain Catastrophizing Scale (PCS).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
11. WHO Quality of Life-BREF (WHOQOL-BREF).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
10. WHO Disability Assessment Schedule 2.0 (WHODAS 2.0).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
09. Veterans RAND Health Survey (VR-36).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
08. West Haven-Yale Multiphasic Pain Inventory (WHYMPI-INT).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
07. Pain Numeric Rating Scale (PNRS).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM

Name	Created	Modified Date
06. Defense and Veterans Pain Rating Scale (DVPRS).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
05. CBT-CP Clinical Interview.pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
04. MIRECC Demographics (DEMO).pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
03. Acceptability Weekly Questions.pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
02b. HW Satisfaction with Treatment Form - Post-treatment.docx(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
02a. CBT-CP Satisfaction with Treatment Form - Post-treatment.docx(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
01b. HW Satisfaction with Treatment Form - Mid-point.docx(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
01a. CBT-CP Satisfaction with Treatment Form - Mid-point.docx(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
36. EMA Survey 11.10.20.pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
35. PMC Coronavirus Pandemic Measure.pdf(0.01)	3/26/2021 4:11 PM	3/26/2021 4:11 PM
34. Brief COPE.docx(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
33. Brief Resilience Scale.docx(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
32. Chronic Illness Anticipated Stigma Scale (CIASS).pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
31. Instrument to Measure Self-Management (IMSM).pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
30. Medical Conditions (MCON).pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
29. PROMIS SF v1.0 - Self-Effic-ManagMeds.pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
26. PROMIS SF v1.0 - Fatigue.pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM
24. PROMIS - Pain Behavior.pdf(0.01)	3/26/2021 4:10 PM	3/26/2021 4:10 PM

3 * What is the total length of time that each survey is expected to take?

Baseline (TP1) Assessment: approximately 120 minutes (CBT-CP interview guide, demographic form, and full assessment battery #7-32).

Mid-Treatment (TP2) Assessment: approximately 60 minutes (5 CBT-CP measures [PNRS, WHYMPI, WHOQOL-BREF, PHQ-9, PCS], mid-point treatment satisfaction survey).

Post-Treatment (TP3) and 3-month Follow-up (TP4) Assessments: approximately 90 minutes (assessment battery #7-19, 22-26, 28-32)

EMA Survey: ~5 minutes per time point, completed three times per day for 7 days prior to start of RCT assessments.

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

● Yes ○ No

5 * Do any questions elicit information related to the potential for harm to self or others?

● Yes ○ No

5.1 If Yes, what procedures are in place to assure safety?

The Physicians Health Questionnaire (PHQ-9) includes one item asking about thoughts of death and self-harm in the past two weeks, and the Suicide Behaviors Questionnaire-Revised (SBQ-R) asks four questions about history of suicidal thoughts and behavior, current thoughts of suicide (past year), whether the person talked so someone about thoughts of suicide, and likelihood of future suicide attempt. If participants endorse a positive response on the PHQ-9 (≥ 1) any items on the SBQ-R (score ≥ 1), then trained RAs will complete a suicide risk assessment aligned with the MIRECC's Risk Assessment SOP, which includes the potential need to contact the study PI for more in depth risk assessment and/or contact the participant's mental health provider to alert them of potential risk. Participants will also be provided suicide prevention resources at all RCT assessment time points as well as during the EMA survey, including information about the Veterans Crisis Line.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

○ Yes ● No

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
Qualitative Interview Guide_08.30.22.docx(0.02)	10/16/2019 4:19 PM	9/26/2022 10:28 AM

3 * What is the individual duration of each interview and what is the entire duration of the interviews?
One interview lasting approximately 60 minutes

4 * How will the interview responses be recorded and by whom?
The data will be recorded as written responses on the interview form by the study staff conducting the interview, audio recordings of interviews, and transcripts of the audio recorded interviews by an experienced VA-approved transcriptionist.

5 * Do any questions elicit information related to the potential for harm to self or others?
○ Yes ● No

5.1 If Yes, what procedures are in place to assure safety?
N/A

ID VIEW4E0947A633C00
Name v2_Interviews

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1 * Indicate the type of recording (check all that apply):
- ☐ Video
- ☑ **Audio**
- ☐ Still Photo
- ☐ Other

1.1 If Other, specify:

2 * What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)
We are audio recording the individual sessions in order to provide feedback, supervise study staff on the intervention, and for quality assurance purposes. We are also recording qualitative interviews for the purpose of capturing main themes and perspective of Veterans.

3 * Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?
○ Yes ● No

4 * How will individuals' identities be protected?
Digital audio recording files are stored electronically behind the VA firewall. Research staff will label all digital audio recording files using an anonymous study code only. All digital recordings and the file that links participants' identities to their anonymous study code are stored on a secure VA computer network (behind the VA 'firewall').

Audio recordings of interviews will be transcribed by an outside VA-approved transcription agency. All transcriptions will be stored on a secure VA computer network (behind the VA 'firewall'; \\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study).

ID VIEW4E094C128C800
Name v2_Audio or Video Recording / Photographs

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

1 * Describe the intervention (duration, number of sessions, focus, etc.):
Cognitive Behavioral Therapy for Chronic Pain (CBT-CP) is a well-established evidence-based intervention for chronic pain management. Sessions will be conducted in accordance with the Cognitive Behavioral Therapy for Chronic Pain: Therapist Manual and the VA evidence-based practice (EBP) roll-out training. CBT-CP consists of a

12-session protocol, including an initial assessment session (baseline/TP1 assessment; Session 1), 10 content-specific sessions (pain education, goal-setting, cognitive and behavioral skill building; Sessions 2-11), and a booster session scheduled approximately one month after the final CBT-CP sessions (Session 12). Participants randomized to the CBT-CP condition (n = 30) will complete one 60-minute individual session per week. Each CBT-CP session will be led by a trained study interventionist using a manualized curriculum, following a basic structure including review of previous session material, introduction of new information or skills, and discussion of how to implement learned material into a home action plan. The booster session will be offered after the Veteran completes all other study procedures (i.e., Timepoint 4). The assigned interventionist will contact Veteran by phone to schedule the booster session (if Veteran is interested); if the Veteran cannot be reached by phone, a letter will be mailed or emailed to Veteran about the session (see Additional Documents section for letter template).

The comparison condition will be a Health and Wellness self-management intervention providing education and support related to the management of physical and emotional well-being. The curriculum will be based on an existing program developed by other VISN 5 MIRECC investigators that is being used in other MIRECC/VA-funded trials. Similar in structure to CBT-CP, Health and Wellness is delivered in approximately 10 sessions, each lasting approximately 60 minutes. Each Health and Wellness session is led by a trained interventionist using a manualized curriculum. Sessions will focus on health and wellness issues and education on ways to better manage health-related concerns following a basic structure that includes: review of the previous session's material, new educational content, and discussion/application. Topics will include: an overview, physical activity, nutrition and healthy eating, relaxation, stress management, substance use, medication and side effects, and a review.

ID: VIEW-4E0BC12A9F800
Name: v2_Behavioral Interventions

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- [ ] Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- [x] **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● No

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● No

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW-4E0E254BCA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [ ] Other

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

Chart Review data to be collected include name, address, dates, telephone numbers, mental health and medical diagnoses, most recent pain rating (Vital Signs) and name, dosage, and amount of time on current medications.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date

There are no items to display

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?
○ Yes ● No

2 * Has this trial been registered?
● Yes ○ No

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
● Yes ○ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
○ Yes ○ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT04118283

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
6000

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
50

Worldwide - the number being enrolled total at all sites (including local enrollment):
50

3 * Gender:
- [x] Male
- [x] Female

4 * Age(s):
- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] 18 to 88 years (Adult)
- [x] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● No

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID VIEW-E0E519C1D000
Name v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged

☑ None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID VIEW4E0E519917800
Name v2_Vulnerable Populations

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?
● Yes ○ No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
Eligibility Checklist SOP_Mod 16 Clean.docx(0.01)	11/4/2022 9:05 PM	11/4/2022 9:05 PM
Eligibility Checklist SOP_Mod 13 Clean.docx(0.02)	2/14/2022 2:16 PM	5/5/2022 12:22 PM
Eligibility Checklist SOP.docx(0.01)	11/15/2019 10:41 AM	11/15/2019 10:41 AM

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	18 years of age or older
View	2	Enrolled in outpatient programming within the VAMHCS at the time of study enrollment.
View	3	Have a chronic musculoskeletal pain condition, per medical record
View	4	have a Defense and Veterans Pain Rating Scale (DVPRS) pain severity rating of >=4 (moderate-to-severe pain)
View	5	Meet criteria for an SMI diagnosis (schizophrenia, schizoaffective disorder, unspecified psychotic disorder, bipolar disorder, major depressive disorder with psychotic features), per medical record
View	6	Regular access to a telephone

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Engaging in moderate-to-severe substance use that would impact their ability to participate and/or would require a higher level of care (as determined by treating provider)
View	2	Engagement in individual CBT-CP, whether currently or in the past
View	3	Current acute pain condition or other medical condition that would interfere with their ability to engage in CBT-CP interventions (e.g., activity pacing/walking program)
View	4	Unable to walk at least one city block
View	5	Currently enrolled in another intervention based research study through the VISN 5 MIRECC or other pain related research studies

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00088491_16 v11-4-2022-1667610363205(0.01)

ID VIEW4ECE5165F9000
Name v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
All participants for this study will be Veterans who are receiving care within the VA Maryland Health Care System (VAMHCS). Recruitment will take place at mental health clinics/programs within the VAMHCS. Potential VA participants will be identified by several methods: (1) CPRS chart review and screening via use of a HIPAA waiver, (2) VA clinician referrals of participants who meet inclusion criteria and who might be interested in participating, (3) Self referrals by participants who hear about the study and are interested in participating or who have participated in other MIRECC studies and have indicated a willingness to be contacted for studies in the future, (4) Self-

referral via IRB approved study flyer, (5) self-referral via IRB approved announcements in the MIRECC newsletter/website.

Potential participants will also be identified through the VA Informatics and Computing Infrastructure (VINCI) system, which will allow research staff to contact them informing them of their potential eligibility for our study. We will use VINCI to identify Veterans who are likely to meet general inclusion criteria by diagnoses in their problem list (e.g., bipolar disorder, psychosis, chronic pain), age between 18 and 85, and participation in outpatient services at a designated study site.

Participants will be screened for eligibility via CPRS chart review. Per VA requirements, initial contact with potential veteran participants identified through CPRS chart review or provider referral will be made in person, by letter, or by email prior to any telephone contact. Specifically, we will approach individuals before or after their VA appointments. We may also send out a letter or email to potential participants to see if they are interested in participating in the study. In this letter/email, they will be given contact information for the study staff as well as either a) a pre-stamped postcard (letter) to mail back, or b) opportunity to respond Yes/No via email to indicate their interest or lack of interest in the study. If after a few days, we do not hear from them, a follow-up phone call may be made to ensure the potential participant received the mailing. This follow-up phone call is mentioned in the mailing, so that potential participants will not be caught off guard when they receive a call from study staff. Once called or approached, if interested in the study, participants will participate in a pre-consent phone screen.

Further, it should be re-iterated that research assistants who will interact with participants are all specially trained to work with persons with serious mental illnesses. Research staff will notify the participant's treatment team to alert them that their patient is eligible for the study and will be contacted to begin the consent process, allowing time for a participant's provider to notify study staff know if Veteran may be in crisis or may not be able to comprehend the study procedures, risks, and benefits.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Our research team has extensive experience recruiting and obtaining informed consent from individuals with serious mental illness. Research staff is trained to recognize symptoms of serious mental illness and cognitive impairment that could undermine the ability to provide informed consent.

If approached for consent, the recruiter will assess competency to understand and sign the consent form by asking the individual a set of IRB approved questions (See attached evaluation to sign consent questions in Additional Documents). If the individual is unable to answer the questions correctly the RA will review aspects of the study that the individual did not understand. The RA will then ask the questions a second time. If the individual cannot answer them a second time they will be judged not competent to give consent, he or she will not be included in the study. Individuals will be told that their participation is completely voluntary and that they can choose to stop their participation at any time without any negative consequences.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] PI
- [x] Study Staff
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Pre-Consent Phone Screen_Clean_Mod 19.docx(0.05)	11/4/2022 9:08 PM	4/24/2023 2:41 PM
Pre-Consent Phone Screen_Track Changes_Mod 19.docx(0.03)	11/4/2022 9:08 PM	4/24/2023 2:40 PM
Email Scripts_Clean.docx(0.01)	1/6/2023 3:55 PM	1/6/2023 3:55 PM
Email Scripts_Track Changes(0.03)	3/11/2021 2:36 PM	1/6/2023 3:55 PM
Recruitment Postcard LT contact_6.6.22.docx(0.03)	10/22/2019 2:41 PM	6/10/2022 9:30 AM
Recruitment Letter_6.6.22.docx(0.03)	10/22/2019 2:41 PM	6/10/2022 9:29 AM
Pre Consent Phone Screen CBT-CP_track changes(0.03)	3/23/2021 1:58 PM	5/5/2022 12:37 PM
Pre-Consent Phone Screen_Clean(0.05)	5/29/2020 10:52 AM	5/5/2022 12:37 PM

ID VIEW4E0BCAA0A8C00
Name v2_Recruitment

Advertising

1 * Will you be using advertisements to recruit potential participants?

(●) Yes ( ) No

ID VIEW4E0BCCF811000
Name v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio

- [x] Internet
- [x] Print
- [ ] Television
- [x] Other

1.1.1 If Other, specify:
Various VA newsletters or bulletins

1.2 * Provide exact text of all proposed advertisement(s):
INTERNET/OTHER (MIRECC Matters Announcement):
Assessment and Treatment of Chronic Pain among Veterans with Serious Mental Illness
Veterans who are diagnosed with both chronic pain and a serious mental illness (e.g., schizophrenia, bipolar disorder, depression with psychosis) are invited to participate in a research study about behavioral chronic pain management.
You will be paid for your participation. Research will be conducted remotely.
Please call Letitia Travaglini at 410-637-1867 to see if you are eligible.

PRINT (flyer/handout, remote study sessions):
Bothered by chronic pain? Our team is looking for Veterans (18 and older) to participate in a research study on behavioral chronic pain management. You may qualify for this study if you:
Have been diagnosed with serious mental illness (ex. schizophrenia disorders, bipolar disorder, or depression with psychosis)
Have been experiencing chronic or persistent pain
Are currently engaged in outpatient care within the VA Maryland Health Care System

Please call Letitia Travaglini at 410-637-1867 to see if you are eligible.
You will be paid for your participation.

This research is conducted under
Letitia Travaglini, PhD
VISN 5 Mental Illness Research Education and Clinical Center
VA Maryland Health Care System (VAMHCS)

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Recruitment Flyer PPVA(0.01)	12/1/2023 4:29 PM	12/1/2023 4:29 PM
Recruitment Flyer_6.6.22.pdf(0.03)	11/13/2019 9:31 AM	6/10/2022 9:40 AM
Recruitment Flyer virtual flyer_6.6.22.pdf(0.02)	1/14/2021 3:24 PM	6/10/2022 9:39 AM
Recruitment Flyer Tabbed virtual_6.6.22.pdf(0.02)	1/14/2021 3:24 PM	6/10/2022 9:39 AM
MIRECC Matters Announcement LT contact, remote_6.6.22.docx(0.03)	11/13/2019 9:31 AM	6/10/2022 9:33 AM

ID: VIEW4E0BCE82B6C00
Name: v2_Advertising Detail

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:
(1) Some participants may feel embarrassed or uncomfortable when they have to answer questions that they may feel are personal (small likelihood, low degree of seriousness). To minimize this risk, participants are told before each assessment the nature of the questions being asked and are told to answer honestly but to feel free to not answer questions that make them feel uncomfortable. Study interviewers are trained to talk about personal material with patients and to engage in discussions in a supportive and empathic and nonjudgmental way.

(2) Participants may feel bored or tired due to the length of time required to complete the interview/assessments (moderate likelihood, low degree of seriousness). To address this risk, participants will be given the option of scheduling the assessments over two appointments on two different days. In cases in which a participant is tired or bored during an assessment, he/she will be offered breaks or allowed to end the assessment and finish the remainder on another day.

(3) Distress During Assessments (small likelihood, low degree of seriousness). Before consent and before and during each data collection, participants are informed that they are free to decline to answer any interview question(s) or to discontinue the interview at any time. If participants feel uncomfortable or fatigued, or seem so to the RA, they are encouraged to take a break and continue again later, or to stop the interview. In our research with people with serious mental illnesses over the past several years, few research participants have expressed distress from participating in the assessments and interviews. Nonetheless, all RAs have been trained to stop the interview if a participant becomes distressed and will have the resources needed to assist him/her in obtaining the level of support or assistance they require, including crisis intervention if needed.

(4) Participants may feel some discomfort with discussing their cognitions related to chronic pain or working through a pacing program within the CBT-CP protocol (moderate likelihood, low degree of seriousness). Additionally, as participants are asked to increase physical activity, they may notice some initial muscle soreness; participants will be educated on the difference between hurt/soreness and harm, and will be told that if they have any concerns about potential injury or acute pain they can stop the intervention and seek medical care. Likewise, participants may feel some discomfort with discussing their health behaviors in the Health and Wellness intervention. However, the CBT-CP and the Health and Wellness intervention protocols are not generally considered unpleasant and more severe reactions are uncommon based on prior studies using CBT-CP and Health and Wellness.

(5) Potential loss of confidentiality (small likelihood, moderate degree of seriousness). All project staff are thoroughly trained in issues relating to maintaining confidentiality of research data. Statistical analyses will be based on group data; no individual data will be reported. There is a slight risk of a confidentiality breach

related to data collected for research purposes from participant interviews and medical records. Study participants will be informed that information obtained through research interviews is confidential, potential risks to data security and the measures we take to protect it will be reviewed with them during the informed consent process. Numerous steps will be taken to ensure research data confidentiality and security. To protect confidentiality, electronic research data that contain PHI or PII, including consent documents (e.g., eligibility checklist, evaluation to consent) and the file that links participants' identities to an anonymous study code, are kept on a secure VA computer network (behind the VA firewall). The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly.

Electronic research data derived from REDCap surveys (ecological momentary assessments and the RCT assessments), which are identified only by an anonymous study code assigned to each research participant, are collected via VA REDCap and kept on a VA secure network. Prior to VA Redcap having public facing capabilities (prior to modification 23 approval date), EMA surveys were collected via UM Redcap, and the data from the 26 participants enrolled prior to modification 23 approval date will be maintained on a secure UM computer network for data analysis until study completion. Electronic research data derived from medical record screening, which are identified only by an anonymous study code assigned to each research participant, are kept on a secure VA computer network and protected by the VA firewall. The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly. In the event of any incidents, unauthorized access of sensitive data or storage devices or noncompliance with security controls, the PI or another member of the research staff will immediately contact the VAMHCS Information Security Officer, Privacy Officer and the VAMHCS Research Compliance Officer and the University of Maryland IRB.

(6) Potential loss of privacy (small likelihood, moderate degree of seriousness). Some participants may be concerned that they may be identified as a study participant and/or that others may overhear them sharing information pertinent to the study during assessment procedures or intervention sessions. Research staff are thoroughly training to protect the privacy of research participants. To minimize this risk, we employ the VA Video Connect CAPS Lock procedures, which including gathering information about the participant's address/current location, contact information, emergency contact information, and ensuring that they are in a private, safe space to conduct the study session; if the person is not in a private or safe space, study staff will work with the participant to reschedule the appointment for when privacy and safety is ensured.

(7) Some participants may feel uncomfortable with being audio recorded (small likelihood, low degree of seriousness). Participants will be told that the recording device may be turned off at any time during the research visit if this occurs. There is also a slight risk of a breach of confidentiality regarding the identities of the participant on the recording. To minimize this risk, research staff will label all digital audio recording files using an anonymous study code only. All digital recordings and the file that links participants' identities to their anonymous study code are stored on a secure VA computer network (behind the VA 'firewall'). The network and computer files are password protected and passwords are only known by authorized study team members. All digital files are stored in restricted folders, accessible only to authorized study team members. Electronic research files are backed up regularly.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
Participants in this study may learn strategies/tools and receive resources to improve pain-related functioning and quality of life.

2 * Describe the importance of the knowledge expected to result from the study:
This study aims to examine the feasibility and preliminary efficacy of CBT-CP for Veterans with SMI. This research will contribute to our understanding of how CBT-CP helps with pain-related quality of life and functioning in Veterans with SMI. Knowledge derived from this study could inform future efforts to design interventions to improve Veterans' rehabilitation and enhance functioning and recovery due to pain-related concerns. Participation in this study may benefit other individuals and Veterans with SMI (i.e., psychotic and bipolar disorders) through the development of evidence-based guidelines, tools, and educational materials to significantly reduce insomnia symptoms and therefore facilitate functional recovery.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The major risks to participants are boredom, embarrassment, and potential loss of confidentiality. These risks are outweighed by the potential benefits of better understanding how CBT-CP helps Veterans with psychotic and bipolar disorders and learning new strategies/tools and resources to improve pain-related functioning and quality of life. This understanding will be used to underlie the development of new strategies to optimize nonpharmacological pain management for people with serious mental illness.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation in this study is voluntary. The alternative is not to participate.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
Veteran Participants will be withdrawn without their agreement under the following circumstances:
1) They have a serious reaction during the study
2) They fail to follow instructions from research staff
3) If the PI decides that the study is no longer in the best interest of the participant.

These circumstances have been outlined in the VA mandated informed consent form.

2 * Describe procedures for orderly termination:
Participants will be notified if they are being withdrawn from the study and will have opportunity to ask any question(s) regarding their withdrawal. Participants will be told that all data already collected will remain in the database, but no new data will be collected from the participant. This information and reasons why a participant may be withdrawn are included in the VA mandated consent form.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
Participants are able to withdraw from the research at any point during their study participation. If a participant decides to withdraw from the research, all data already collected will remain in the database, but no new data will be collected from the participant. This information is included in the VA mandated consent form.

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 *Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
Research staff are thoroughly training to protect the privacy of research participants. To minimize this risk, we employ the VA Video Connect CAPS Lock procedures, which including gathering information about the participant's address/current location, contact information, emergency contact information, and ensuring that they are in a private, safe space to conduct the remote study session; if the person is not in a private or safe space, study staff will work with the participant to reschedule the appointment for when privacy and safety is ensured.

2 *Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
Participants will receive research information after research staff ensure they are in a private, safe space during remote video visits. We employ the VA Video Connect CAPS Lock procedures, which including gathering information about the participant's address/current location, contact information, emergency contact information, and ensuring that they are in a private, safe space to conduct the study session; if the person is not in a private or safe space, study staff will work with the participant to reschedule the appointment for when privacy and safety is ensured.

3 *Describe potential environmental stressors that may be associated with the research:
There are no environmental stressors associated with this research.

4 *Will this study have a site based in the European Union?
○ Yes ● No

5 *Will the study have planned recruitment or data collection from participants while they are located in the European Union?
○ Yes ● No

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

Confidentiality of Data

1 *Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?
● Yes
○ No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 *Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)
Documents for this study include:

1. Documents with identifiable information (e.g., Informed Consent Forms (ICF's), Consent for videotape forms (VA FORM 10-3203), Subject locator forms, Evaluation to sign inform consent forms), participant tracking databases. Electronic research data that contain PHI or PII, including the file that links participants' identities to an anonymous study code, are kept on a secure VA computer network (behind the VA 'firewall': \\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly.

2. Coded data: All data will be randomly assigned a participant number. The link file connecting the participant's name to their ID number will be kept electronically, in a password protected file behind the VA firewall. Electronic research data derived from RCT assessments (Times points 1-4), which are identified only by an anonymous study code assigned to each research participant, are kept in the VA REDCap database. REDCap is a free, secure Web application installed on the VA intranet that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable VA users to quickly develop surveys and databases from conception to production on the web without additional software requirements. This tool helps VA researchers enter, store, and manage their project data in a systematic manner. This service is provided through the VA Information Resource Center (VIReC) that develops resources for and provides guidance to VA researchers using data. The VIReC's staff, scientists, and advisors include database and informatics experts, research methodologists, and experts for various database content areas. The database is configured to use FIPS 140-2 encryption available in the underlying infrastructure to protect sensitive data at rest. In addition, the information system and its dependencies have gone through the VA Assessment and Authorization (A&A) process to evaluate any associated risks and was granted an Authorization to Operate (ATO) as indicated. Primary data are stored at the secure VA Austin Information Technology Center (AITC), located in Austin, Texas on a VINCI Server. Data are backed up nightly and REDCap provides detailed audit trails and specific controls over user rights. Users must have a VA account to log in to REDCap. The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly. Electronic research data derived from the EMA assessments, which are identified by an anonymous study code assigned to each research participate, will be collected and stored through VA REDCap. Prior to the VA REDCap capabilities for public interfacing, this protocol used UM REDCap surveys and database. The data collected from 26 participants enrolled prior to VA REDCap (prior to modification 23 approval date) use will be maintained in the UM REDcap database behind UM secure network for data analysis for study completion. UM contracts with Azure Rights Management Services (RMS), that uses encryption, identity, and authorization policies to secure file attachments and email both within and outside VA. Azure RMS as been approved by VHA to communicate PHI/PII and collect PHI and non-PHI information from participants. Azure RMS provides encryption through email for compliance with FIPS 140-2 and other VA Sensitive Information (VASI) compliance requirements. UM REDCap (versus VA REDCap) was used for 26 enrolled participants for EMA data collection as VA REDCap was only accessible through the VA Intranet at the start of

this study. Similar study procedures have been used at the VA Connecticut Health Care System, with researchers using the Yale University (university affiliate) REDCap to collect EMA data. VA REDCap has expanded accessibility outside of the VA intranet and data collection will be continued through the remainder of the study with VA REDCap (following modification 23 approval date).

3. Audio or video recordings
The VISN 5 MIRECC uses microphones that attached directly to VA computers via USB, so all recording goes directly to the computer and is saved behind the VA firewall in a secure folder only available to members of the study team (\\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). Audio Recordings may be reviewed for supervision and quality assurance purposes by the PI and the other members of the research staff that conduct and help supervise intervention sessions. Research staff will label all digital audio recording files using an anonymous study code only. All digital recordings and the file that links participants' identities to their anonymous study code are stored on a secure VA computer network (behind the VA 'firewall', \\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). The network and computer files are password protected and passwords are only known by authorized study team members. All digital files are stored in restricted folders, accessible only to authorized study team members. Electronic research files are backed up regularly. For back up, we will be using digital audio recorders that are VA approved and FIPS 140-2 compliant, for back up purposes only.

3 * How will such data be secured?

No VA sensitive information will leave the VA protected environment. Sensitive electronic data for this study will remain securely behind the VA firewall and will only be accessible through secure VA computer accounts. The network and computer files are only accessible by authorized study team members. Electronic research files are backed up regularly. All study paper records will be securely stored in locked file cabinets behind locked doors at the location(s) specified in item 2. Finally, all research data is stored coded and subject identifiers, such as names, are not stored in the same files that contain the research data.

1. Documents with identifiable information

(1a) All hard copies of documents with identifiable information (PHI/PII) which contains participants' names but not their project ID number are kept in a separate locked cabinet in a locked office at the VA (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor Room 733 and 5th floor Room 509, Baltimore, MD 21201).

(1b) Electronic files: The file that links participant names to their project ID number will be stored behind the VA firewall on the MIRECC Share Drive (\\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). Access to the link file will be limited to only study staff listed on this protocol. The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly.

2. Coded data: (2a) hard copies of forms, (2b) coded electronic files

(2a) Hard copies of forms: Hard copies of research data (e.g., paper-and-pencil research assessments, medical record abstractions), which are identified only by an anonymous study code assigned to each research participant, will be transported by hand in a locked bag to our VA approved data entry contractor (University of Maryland School of Medicine). Data will be stored in a locked cabinet in a locked office at the UM Department of Psychiatry, Division of Psychiatric Services Research (737 W. Lombard Street, Suite 595, Baltimore, MD 21201), and access to hard copies of coded research assessments will be limited to only study staff listed on this protocol.

(2b) Coded electronic files: Electronic research data derived from RCT assessments (Times points 1-4), which are identified only by an anonymous study code assigned to each research participant, are kept in the VA REDCap database. REDCap is a free, secure Web application installed on the VA intranet that facilitates the collection and entry of research data. User-friendly electronic data capture (EDC) tools enable VA users to quickly develop surveys and databases from conception to production on the web without additional software requirements. This tool helps VA researchers enter, store, and manage their project data in a systematic manner. This service is provided through the VA Information Resource Center (VIReC) that develops resources for and provides guidance to VA researchers using data. The VIReC's staff, scientists, and advisors include database and informatics experts, research methodologists, and experts for various database content areas. The database is configured to use FIPS 140-2 encryption available in the underlying infrastructure to protect sensitive data at rest. In addition, the information system and its dependencies have gone through the VA Assessment and Authorization (A&A) process to evaluate any associated risks and was granted an Authorization to Operate (ATO) as indicated. Primary data are stored at the secure VA Austin Information Technology Center (AITC), located in Austin, Texas on a VINCI Server. Data are backed up nightly and REDCap provides detailed audit trails and specific controls over user rights. Users must have a VA account to log in to REDCap. The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly. Electronic research data derived from the EMA assessments, which are identified by an anonymous study code assigned to each research participate, will be collected and stored through VA REDCap. Prior to the VA REDCap capabilities for public interfacing, this protocol used UM REDCap surveys and database. The data collected from 26 participants enrolled prior to VA REDCap (prior to modification 23 approval date) use will be maintained in the UM REDcap database behind UM secure network for data analysis for study completion. UM contracts with Azure Rights Management Services (RMS), that uses encryption, identity, and authorization policies to secure file attachments and email both within and outside VA. Azure RMS as been approved by VHA to communicate PHI/PII and collect PHI and non-PHI information from participants. Azure RMS provides encryption through email for compliance with FIPS 140-2 and other VA Sensitive Information (VASI) compliance requirements. UM REDCap (versus VA REDCap) was used for 26 enrolled participants for EMA data collection as VA REDCap was only accessible through the VA Intranet at the start of this study. Similar study procedures have been used at the VA Connecticut Health Care System, with researchers using the Yale University (university affiliate) REDCap to collect EMA data. VA REDCap has expanded accessibility outside of the VA intranet and data collection will be continued through the remainder of the study with VA REDCap (following modification 23 approval date).

3. Audio or video recordings
The VISN 5 MIRECC uses microphones that attached directly to VA computers via USB, so all recording goes directly to the computer. Research staff will label all digital audio recording files using an anonymous study code only. All digital recordings and the file that links participants' identities to their anonymous study code are stored on a secure VA computer network (behind the VA 'firewall', \\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). The network and computer files are password protected and passwords are only known by authorized study team members. All digital files are stored in restricted folders, accessible only to authorized study team members. Electronic research files are backed up regularly.

4 * Who will have access to research data?

The PI, co-investigators, and authorized research study staff listed on this protocol will have access to the research data. Access to data will be terminated for study staff that are no longer part of the research study. The data collected for this study will be used for research purposes only.

Audio recordings of interviews collected for this study will be sent securely to a VA-approved transcription agency, Alpha Transcription. Alpha Transcription is staffed by VA WOC contractors who are able to log on to the VA system remotely to access the audio files for transcription. These audio recordings will not contain any identifiable information. Audio recorded therapy sessions and qualitative interviews and the transcription files will be stored electronically behind the VA firewall on the VISN 5 MIRECC Share Drive, with access only available to authorized research study staff listed on this protocol (\\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study).

5 * Will study data or test results be recorded in the participant's medical records?

● Yes ○ No

6 * Will any data be destroyed? **(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)**

● Yes ○ No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

The investigator's VA research records and any VA participant identifiers will be retained until the maximum retention period is reached, as defined by the Dept. of Veterans Affairs Records Control Schedule (RCS 10-1). When the maximum retention period is reached, the VA data may be destroyed using the most current data destruction methodologies that are available at the time of data destruction.

7 Do you plan to obtain a Certificate of Confidentiality?

○ Yes ● No

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

Please note that this project will keep within the following VA guidelines: a) full social security numbers of veterans will not be solicited, b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol, c) initial contact with veterans must be made in person or by letter prior to telephone and initial contact with veterans must be made in person prior to email contact, and d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

In accordance with VA policy, procedures are in place for reporting incidents, i.e. theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls. Upon learning of such an incident, study staff will immediately report the incident to the VAMHCS PO, ISSO, and R&D Service.

ID VIEW-4E1B5265E0400
Name v2_Confidentiality of Data

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

○ Will use/defer to the external sponsor's Data Safety Monitoring Plan

○ Data Safety Monitoring by a Committee

● Data Safety Monitoring by an Individual

○ There is no data safety monitoring plan in place

ID VIEW-4E1B00E30D400
Name v2_Monitoring Plan Selection

Monitoring Plan - Individual

You indicated that the monitoring will be done by an individual.

1 * Identify the individual who will be performing the safety monitoring:

Letitia Travaglini

2 * Describe this individual's role in relation to the protocol:

PI

3 * What data will be reviewed?

- ☑ Adverse Events
- ☑ Enrollment Numbers
- ☑ Patient Charts/Clinical Summaries
- ☐ Laboratory Tests
- ☐ Medical Compliance
- ☑ Procedure Reports
- ☑ Raw Data

- [x] **Outcomes (Primary, Secondary)**
- [x] **Preliminary Analyses**
- [x] **Other**

3.1 If Other, specify:
The Principal Investigator/Protocol Safety Monitor will maintain ongoing internal records regarding progress with study accrual, all study adverse events, compliance with eligibility criteria, participant adherence to study requirements, accuracy and completeness of data, and the findings of data checks and audits performed as a part of the VA Maryland Health Care System's study protocol standard procedures. These records will be made available to the IRB or other regulatory agencies upon request.

4 * What will be the frequency of the review?
- ○ Annually
- ○ Bi-Annually
- ● **Other**

4.1 If Other, specify:
Review of the research data specified above by the protocol safety monitor will occur on an ongoing basis throughout the duration of the study.

5 * Safety monitoring results will be reported to:
- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [x] **Other**

5.1 If Other, specify:
If Other, specify:
The Principal Investigator/Protocol Safety Monitor will maintain ongoing internal records regarding progress with study accrual, all study adverse events, compliance with eligibility criteria, participant adherence to study requirements, accuracy and completeness of data, and the findings of data checks and audits performed as a part of the VA Maryland Health Care System's study protocol standard procedures. These records will be made available to the IRB or other regulatory agencies upon request.

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?
- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:
- [x] **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- [ ] Investigational or Study Device
- [ ] Investigational or Study Drug
- [x] **Investigational Procedure(s)**

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?
- [ ] Participant
- [ ] Sponsor
- [ ] UM
- [ ] Other

☑ There will be no uncovered research-related costs

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID VIEW4E1B5D9641800
Name v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

○ Yes ● No

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

● Yes ○ No

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

The VA mandated consent form indicates the following for participants:

If you are injured as a result of taking part in this study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

1.2.2

Name	Created	Modified Date
Informed Consent - Research-related injury section.docx(0.01)	10/17/2019 9:07 AM	10/17/2019 9:07 AM

ID VIEW4E1B629EEC000
Name v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● Yes ○ No

ID VIEW4E1C52A5D7800
Name V2_Payment to Participants

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- ☐ Travel
- ☐ Parking
- ☐ Meals
- ☐ Lodging
- ☑ Time and effort
- ☐ Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***
$163

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
Participants can receive up to $163 for study participation:
- Consent: $10
- EMA training: $10
- Completion of all EMA surveys: $28
- Baseline (Timepoint 1) Assessment: $30
- Mid-point Treatment Satisfaction Scales: $5
- Post-treatment (Timepoint 2) Assessment: $30
- 3-month Follow-up (Timepoint 3) Assessment: $30
- Qualitative Interview: $20
- If participants don't complete the full battery (TP1/TP3/TP4) they can receive $15 for completing CPT-CP specific measures.
- They would not receive anything if they just complete WHYMPI and PNRS. We will encourage participants to complete a greater amount of measures, but offering the WHYMPI and PNRS to those who do not want to complete more measures will help us obtain important outcome data. This will likely be a limited number of people, if any, and this would likely occur over the phone when someone does not want to continue with the study, but allows us to still get some data on the main outcomes. This would take 2-3 minutes of the participants time if they chose to do so.

Participants will receive payments at each session that involves compensation-related activities. Participants will receive payment for completion of the EMA data when they come in for the baseline (TP1) assessment. Participants will not be paid for attending treatment sessions.

4 * Method(s) of payment/reimbursement to be Used:
- [ ] Cash
- [x] **Check**
- [ ] Money Order
- [x] **Gift Certificate/Gift Card**
- [x] **Other**

4.1 If Other, specify:
A check from the VA Cashier or electronic gift card will be sent to Veterans who complete study procedures over the phone or telehealth (video).

ID: VIEW:4E1C54A8ACC00
Name: v2_Payment Detail

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*
- (●) **Yes** ( ) No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?
- (●) **Yes** ( ) No

ID: VIEW:4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [x] **Dates**
- [ ] Ages over age 89
- [x] **Telephone numbers**
- [ ] Fax numbers
- [x] **Email addresses**
- [x] **Social Security numbers**
- [ ] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [x] **Biometric identifiers, including fingerprints and voiceprints**
- [ ] Full-face photographic images and any comparable images
- [x] **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification**
- [ ] None

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
This PHI is necessary in order to identify and screen for study eligibility criteria. We collect names, addresses, email addresses and phone numbers to be able to contact participants for all aspects of their participation in the study, and to be able to send them a letter if needed. Date of birth is collected in order to verify age and identify them in our study database. The last four digits of participants' social security numbers will be collected for the purpose of accessing medical records; VA medical record numbers consist of the person's last name initial and last four digits of their social security number. Full social security numbers will not be collected. Each participant in the study is assigned an ID number that will be linked to their name, so identifying number/code has been checked for this purpose.

Voiceprints are collected through our audio recordings, and these are used to collect data, for training and supervision of staff, and for quality assurance purposes.

3 * What is the source(s) of the PHI?
We collect this information from participant's medical records or from the participant during the course of their participation in the study.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
PHI collected for this study will only be used for the purposes described in this protocol. This information will not be reused or disclosed to any other entity outside this study.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)
- [ ] Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")*
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW-4E1B0A21AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
We request a full waiver of HIPAA authorization for this study for recruitment and study related purposes. This waiver of HIPAA authorization for recruitment purposes is justified because the use of information includes no more than minimal risk to the confidentiality of the participants' information. We are also requesting this full waiver of authorization in order to collect data from the medical record (e.g., medication information, updated contact information) throughout the duration of the individual's participation in the study without having to obtain a signature on the HIPAA authorization form. Given the study is low risk enough to allow for a waiver of written documentation of informed consent (due to telehealth/remote delivery of the study), it would present an undue burden on study participants to come in person to sign the HIPAA authorization. All study procedures are being conducted remotely, including intervention sessions, so we currently do not have a need for participants to come into the VAMHCS for any parts of the study. Since the VA requires a full waiver of HIPAA due to verbal HIPAA authorization is not appropriate per VA guidelines as noted in an audit, this full waiver is in accordance with a corrective action plan that the site provided in a RNI reviewed by the IRB. Information collected through this waiver will only be used by study staff listed in this protocol and will not be shared with anyone outside of the project.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
The information requested for use in our waiver of HIPAA Authorization will be protected by study staff from improper use and disclosure. This information will not be reused or disclosed to any other person or entity outside of this research project. These data are kept on a secure VA computer network (behind the VA 'firewall': \\r04balnas21.v05.med.va.gov\BAL_Groups\BAL_MIRECC_Share\TISHA_CBT-CP for SMI study). The network and computer files are password protected and passwords are only known to authorized study team members. Electronic research files are backed up regularly. Only study staff will have access to this information.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
After the sample is recruited all identifiers from potential participants who did not agree to participate or who were found to be ineligible will be destroyed/shredded within approximately 6 months of closing the study.

4 * Why could the research not practicably be done without access to and use of this PHI?
This research could not practicably be conducted without access to and use of this PHI. Access to this PHI allows research staff to screen medical records and determine eligibility prior to approaching Veterans about the study. Without access to this PHI we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. A burden would also be placed on study staff whose time would be wasted by approaching non-eligible Veterans.

The full waiver of HIPAA Authorization also allows staff to collect , important information about enrolled participants from the medical record (e.g., medications, updated contact information) during other phases of the study. Notably, collecting medication information from the medical record at baseline assessment allows staff to collect accurate medication data rather than placing additional burden on the participant to provide an accurate list at these timepoints. In the event a participant is unreachable via contact information (phone number, mailing address, email address) provided at the start of the study, research staff can also look into the medical record to see if any contact information has been updated since last study contact.

5 * Why could the research not practicably be done without the waiver or alteration?
This Waiver of HIPAA Authorization will serve three purposes. First, this waiver will allow us to screen and recruit in a streamlined way. With this waiver, we can screen medical records for study eligibility criteria and then only approach those Veterans who appear eligible based on this screening. Without this waiver, we would be placing an undue burden on Veterans by approaching those who may not be eligible for this research study. This waiver will also ease the burden on study staff whose time would be wasted by approaching non-eligible Veterans.
Second, following a triennial audit by the VAMHCS RCO (see RNI #HRE-HP-00088491-4), we recently (July 2023) learned that only a hard signature is allowed on the HIPAA authorization form. That is, verbal agreement of this form is not permitted. This study is being conducted fully via telehealth, in order to reduce barriers to participation such as lack of transportation, inability to travel to the study site due to physical health limitations, and ever changing COVD safety protocols. Given that all study participation is continuing to be conducted via telehealth, we cannot readily obtain a hard signature – we do not see people in person. This waiver will allow us to forgo any signature on the HIPAA authorization form. If we were to require that participants come to the study site simply to sign this form, this would negate the benefits of our telehealth methodology. Thus, written documentation of HIPAA authorization must be waived in conjunction with waiving written documentation of informed consent, which we already have for this study.
Third, we also request that this full HIPAA waiver apply retroactively to all participants that have been enrolled thus far (9 participants). These participants were consented under our approved waiver of written documentation of informed consent, and given the HIPAA rules were combined with the informed consent, HIPAA contents were reviewed with all participants. All of these individuals have completed their study participation and we cannot obtain their signature on a hard copy form. This waiver will let us forgo any signature on the HIPAA authorization form for the participants enrolled thus far. If we were to require that participants come to the study site simply to sign this form, this would negate the benefits of our telehealth methodology and burden participants that have completed study participation. Moreover, these participants gave their time and effort and contribution to this study. Without this waiver, the contributions of these people will have been for naught.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
● Yes ○ No

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.
This is a VA study, employing VA staff. The VA study staff will have access to PHI.

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- ☐ Not applicable (study may qualify as exempt)
- ☐ Request to Waive Consent/Parental Permission (Consent is not being obtained)
- ☐ Request to Alter Consent (Some Elements of Consent Waived)
- ☑ **Request to Waive Documentation of Consent (Verbal/Oral Consent)**
- ☐ Written Consent Form
- ☐ Electronic Consent

2 * Describe the Informed Consent process in detail:

Given the remote nature of this study, verbal informed consent will be obtained from all participants. Our research staff are carefully trained on obtaining consent from participants with serious mental illness and supervised by senior staff members.

If a potential participant indicates interest in participating, the study interviewer will remotely (via telephone/telehealth) meet the participant, introduce him/herself to the participant, provide an overview of the project, and invite him/her to participate. Potential participants are provided an informed consent form via mail or email, and staff will ensure they have a copy of the consent form prior to the consent review session. Staff members are trained to recognize symptoms of severe mental illness and cognitive impairment that could undermine a participant's ability to provide informed consent. The consent form is summarized to all participants in detail, and participants are given time to ask any questions they may have and to discuss the form and its contents with the research staff.

After the consent form has been reviewed in detail with the participant and all questions have been answered, the staff confirms that the participant is still interested in participating by soliciting a verbal response. Those who express willingness to provide consent must complete a brief questionnaire to assess competency and understanding of the consent form (see evaluation to sign consent questions in additional documents). If the participant is unable to answer the questions correctly, staff re-reviews the aspects of the study that the participant did not understand. The staff member asks the questions a second time. If the participant cannot answer all questions correctly, he/she will not be enrolled in the study.

Per IRB regulations, a copy of the participant's consent form is given to the participant (via mail or email), and the original electronic document noting verbal consent was obtained is kept in behind a VA firewall within a restricted drive at the VA Maryland Health Care System.

In keeping with the requirements put forth in the Department of Veterans Affairs: a) full social security numbers of veterans will not be solicited; b) research staff will restrict telephone and other contacts with veterans to the procedures and data elements outlined in the IRB approved protocol; c) initial contact with veterans must be made in-person, by letter, or by email recruitment prior to telephone contact; d) verification of the study will be provided following the guidelines set forth in HRPP/IRB policies and procedures 10G.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

● Yes ○ No

4 * Describe who will obtain Informed Consent:

The research staff listed on this protocol.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*

N/A

6 * Describe the setting for consent:

Informed consent will take place remotely by either telephone or video (using approved VA video/telehealth software). Research staff will ensure that Veterans are in a private, safe space and have access to a copy of the consent form prior to initiating the consent review session.

7 * Describe the provisions for assessing participant understanding:

Participants must correctly answer a set of questions regarding the study. If they do not answer all of the questions correctly after 2 attempts, they will not be eligible to participate.

8 * Describe the consideration for ongoing consent:

Staff will review the procedures of the protocol, potential risks and benefits, right to withdraw and how confidentiality of research data will be maintained with the participant before each assessment time point and at the start of the study intervention. If they are not able to provide continued consent, they will be removed from the study.

ID VIEW4E1C661D0AC00
Name v2_Informed Consent Process

Waiver of Documentation of Consent

You indicated that a waiver of documentation of consent (verbal/oral consent) is requested.

1 * Indicate why a waiver of documentation of consent is being requested for the study:

○ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

● **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.**

2 * Provide a justification/explanation for the choice above:

A waiver of written documentation of consent is being requested to inform participants of the option to complete assessments and intervention sessions via telephone or telehealth/ video (telehealth options approved by VA/ORD for use with Veterans) if needed, as well as to be emailed resources, materials, and/or response cards. We will request verbal consent by informing current participants as soon as possible, either via telephone or an in-person appointment, whichever would occur first, so they do not have to wait until their next study appointment to receive the information. Since this is believed to be a minimal risk, we wanted to minimize the burden that would be placed on participants to complete a written reconsent process. We also believe that this new information will not change participants' willingness to continue

participation, as we are broadening their options to include remote participation. Study staff will use the script provided in "additional documents" and document this in participants' study records.

ID VIEW-IE1C6EF6F5000
Name #2_Waiver of Documentation of Consent

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
Informed Consent and HIPAA _TC Mod 28.docx(0.01)	8/23/2024 2:26 PM	8/23/2024 2:26 PM
Informed Consent and HIPAA _Clean Mod 28.docx(0.01)	8/23/2024 2:26 PM	8/23/2024 2:26 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
Informed Consent and HIPAA _TC Mod 25.docx(0.01)	1/22/2024 2:01 PM	1/22/2024 2:01 PM
Informed Consent and HIPAA _Clean Mod 25.docx(0.01)	1/22/2024 2:01 PM	1/22/2024 2:01 PM
Informed Consent Form _clean Mod 20.docx(0.04)	6/10/2022 9:42 AM	8/18/2023 3:13 PM
Informed Consent Form _TC Mod 20.docx(0.04)	6/10/2022 9:42 AM	8/18/2023 3:12 PM
Informed Consent and HIPAA _clean Mod 13.docx(0.01)	5/23/2022 1:53 PM	5/23/2022 1:53 PM
Informed Consent and HIPAA _TC Mod 13.docx(0.01)	5/23/2022 1:53 PM	5/23/2022 1:53 PM
Informed Consent and HIPAA _TC_KP 9.10.21.docx(0.01)	9/10/2021 11:59 AM	9/10/2021 11:59 AM
Informed Consent and HIPAA _CLEAN_KP 9.10.21.docx(0.01)	9/10/2021 11:59 AM	9/10/2021 11:59 AM
Informed Consent and HIPAA _Clean Mod 8 KP 6.17.21.docx(0.01)	6/17/2021 12:55 PM	6/17/2021 12:55 PM
Informed Consent and HIPAA _TC Mod 8 KP 6.17.21.docx(0.01)	6/17/2021 12:54 PM	6/17/2021 12:54 PM
Informed Consent and HIPAA 3.11.21 MOD 7 track changes KPH.docx(0.01)	4/1/2021 3:28 PM	4/1/2021 3:28 PM
Informed Consent and HIPAA _Clean.docx(0.01)	4/1/2021 3:27 PM	4/1/2021 3:27 PM
Informed Consent and HIPAA(0.02)	5/22/2020 1:29 PM	3/26/2021 4:53 PM
Informed Consent and HIPAA track changes(0.02)	5/22/2020 1:30 PM	3/26/2021 4:53 PM
Informed Consent and HIPAA .docx(0.01)	1/22/2020 2:56 PM	1/22/2020 2:56 PM
Informed Consent and HIPAA track changes.docx(0.03)	12/10/2019 11:08 AM	1/22/2020 12:52 PM

2 Upload any HIPAA authorization forms here:

HIPAA_Waiver_Request_vha-10-0521-RCT_signed.pdf(0.02)	8/9/2023 10:28 AM	9/7/2023 11:36 AM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID VIEW-IE1C7712D3000
Name v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Psychiatry

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● No

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● No
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Please answer the following question to determine whether review by the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) is required:

* Does this protocol involve oncology patients and/or oncology data in any capacity? This includes, but is not limited to, the inclusion of cancer patients, as well as research related to prevention, treatment, or diagnosis of oncological diseases. ○ Yes ● No

If Yes, or if you have any questions regarding Cancer Center review, please contact the UMGCCC Regulatory Office at UMGCCCRegulatory@umm.edu.

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● No

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ● Yes ○ No
* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ● Yes ○ No
* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ● Yes ○ No

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

VA-Specific Criteria

1 * What is the relevance of this research to the mission of VA and the Veteran population that it serves*?

Veterans with SMI (serious mental illness, i.e., psychosis and bipolar disorders) are at elevated risk of disability, high health care spending, reduced quality of life, and early mortality. Thus there is an urgent need to develop empirically-derived guidelines for the clinical use of VA EBPs which would target functional outcomes for this population. Chronic pain treatment for Veterans with SMI is imperative in this regard. Chronic pain is prevalent among people with SMI, causes them significant impairment and distress, and is associated with long-term negative consequences for their physical, emotional, and psychosocial recovery. Further, chronic pain represents a significant obstacle to the recovery of Veterans with psychosis and bipolar disorders specifically. However, it is likely that most of these Veterans are not offered Cognitive Behavioral Therapy for Chronic Pain (CBT-CP), a VA evidence-based practice for managing chronic pain and improving pain-related functioning and quality of life. The VHA Uniform Mental Health Services Handbook clearly states that Veterans with SMI must be offered quality interventions comparable to the care received by other Veterans. This research will address this inequity by testing the feasibility and acceptability of CBT-CP for Veterans with SMI, preliminarily examine the impact of CBT-CP on functioning and quality of life, and consider possible ways to optimize CBT-CP for Veterans with SMI.

2 * Describe who will be enrolled in this study:

- ○ Non-veterans will be enrolled in this study
- ● **Only veterans will be enrolled in this study**
- ○ Veterans and Non-veterans will be enrolled in this study

2.1 * If non-veterans will be enrolled in this study, provide a description of non-veterans who will be enrolled (For example: community members, family members/caretakers of Veterans, clinicians/caregivers to Veterans, etc.):

Non-Veterans will not be enrolled in this study.

2.2 If non-veterans will be enrolled in this study, provide a substantive justification** for the enrollment of non-veterans in this research:

2.3 * If this is a VA-funded study, was the use of non-veterans discussed within your merit award proposal?

- ○ Yes
- ○ No
- ● **N/A**

*

http://www.va.gov/about_va/mission.asp

VA Mission Statement
To fulfill President Lincoln's promise "To care for him who shall have borne the battle, and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans.

VA Core Values
VA's five core values underscore the obligations inherent in VA's mission: Integrity, Commitment, Advocacy, Respect, and Excellence. The core values define "who we are," our culture, and how we care for Veterans and eligible beneficiaries. Our values are more than just words – they affect outcomes in our daily interactions with Veterans and eligible beneficiaries and with each other. Taking the first letter of each word—Integrity, Commitment, Advocacy, Respect, Excellence—creates a powerful acronym, "I CARE," that reminds each VA employee of the importance of their role in this Department. These core values come together as five promises we make as individuals and as an organization to those we serve.
Integrity: Act with high moral principle. Adhere to the highest professional standards. Maintain the trust and confidence of all with whom I engage.
Commitment: Work diligently to serve Veterans and other beneficiaries. Be driven by an earnest belief in VA's mission. Fulfill my individual responsibilities and organizational responsibilities.
Advocacy: Be truly Veteran-centric by identifying, fully considering, and appropriately advancing the interests of Veterans and other beneficiaries.
Respect: Treat all those I serve and with whom I work with dignity and respect. Show respect to earn it.
Excellence: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.

**

a. Non-Veterans may be entered into a VA-approved research study that involves VA outpatient or VA hospital treatment (38 CFR 17.45, 17.92), but only when there are insufficient Veteran patients suitable for the study. The investigator must justify including non-Veterans and the IRB must review the justification and provide specific approval for recruitment of non-Veterans.
b. Non-Veterans may be recruited for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. Examples include surveys of VA providers, studies involving Veterans' family members, or studies including active duty military personnel. Although active duty military personnel are not considered Veterans, they should be included in VA studies whenever appropriate.
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e. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator.

[VHA Handbook 1200.05 §24]

ID: VIEW4E1C7A737E600
Name: v2_Use of Non-Veterans

VA Prohibited Research

1 * Is the research planned emergency research in subjects from whom consent can not be prospectively obtained?
○ Yes ● No

2 * Does the study involve children **AND** is greater than minimal risk?
○ Yes ● No

3 * Will recruitment phone calls involve asking veterans for their Social Security numbers?
○ Yes ● No

ID: VIEW4E1C8AF03A400
Name: v2_VA Prohibited Research

Additional VA

1 * For data that is combined, which site is the "Data Coordinating Center"?
Data is not combined

2 If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored.
N/A

3 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data collected? (This answer may overlap with Research Related Procedures. If so, please refer to that section.)
N/A

4 If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data received and combined with the data from the other non-VA institution(s)?
N/A

ID: VIEWBD5931EAC5B1E6E
Name: v2_Additional VA

VA Maryland Health Care System Review Required

1 **Note:** Based on the answers provided in your submission, this protocol qualifies as a VA study and therefore requires VA-specific reviews to ensure that all VA regulatory requirements are met. The VAMHCS Research & Development Committee (RDC) review is included in these VA-specific reviews and RDC approval is required prior to engaging in any research activities. **Importantly, you must submit this protocol to the VAMHCS RDC for review within 60 days of IRB approval.** Please see below for a summary of required VA-specific review steps.

****Before you initiate any of the following VA-specific review steps, please contact Kelly Lloyd (Kelly.Lloyd@va.gov), VAMHCS Research Protections Officer (RPO), to ensure full compliance with VA requirements.**

1. Ensure that you have already created a new project shell in IRBNet and that the title matches the title for this IRB application. Before drafting the IRB submission, the PI **should have completed Package 1 – ACOS New Project Review Form** found in the VAMHCS IRBNet library (log in to IRBNet first and then click on link), gotten it signed by the PI's VA Service Chief, and submitted it to the Research Service as a single document package within this project shell in IRBNet.
2. After you have received ACOS sign-off, you may submit your protocol application in CICERO. The application will be routed to designated reviewers including Kelly Lloyd, VAMHCS RPO. She will conduct a VA Administrative Pre-Review and the results will be communicated to the study team through the CICERO platform and may include suggested edits to the application and consent/HIPAA form(s). The study team will be responsible for implementing these edits in CICERO.
3. While the VA Specialty Review is being conducted in CICERO, complete the Information System Security Officer (ISSO) review form and email to Kelly so she can prepare her request for that additional, required review. You can find the form used for ISSO review in the VAMHCS IRBNet library (log in to IRBNet first and then click on link): **RDC – Information Security Officer Review Form.pdf.**
4. After all suggested edits have been made in the CICERO application and consents/HIPAA by the study team, Kelly will then send for VAMHCS ISSO and Privacy Officer (PO) review and the study team will be copied on these correspondences. (Please Note: Kelly will prepare PO review form).
5. Once you receive approval from ISSO and PO, Kelly will finalize her review and send the CICERO application on to the next UMB HRPO-required reviewing body.
6. You will then create another new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review) to submit the protocol documents for Subcommittee on Research Safety (SRS) review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide: **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**
7. After your protocol has been approved by the IRB, you'll create a third, new package in your IRBNet project shell (i.e., the same project shell you already created for ACOS review and used to submit documents for SRS review) to submit the protocol documents required for Research and Development Committee (RDC)

review. You can find all applicable submission forms in the VAMHCS IRBNet library (log in to IRBNet first and then click on link). Please use this form within the library as a submission guide. **IRBNet Admin Review Checklist – Used only as a guide for submitters – Does not have to uploaded.**

8. Only after you have been approved by RDC, you may initiate study activities.

2 **Questions answered on 'Organizational Review Requirements' page**

The research will be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments):	**Yes**
The research will utilize VA resources (e.g. equipment, funds, medical records, databases, tissues, etc.):	**Yes**
The research will be conducted on VA property, including space leased to and used by VA:	**Yes**

Questions answered on 'VA Prohibited Research' page

The research is planned emergency research in subjects from whom consent can not be prospectively obtained:	**No**
The study involves fetuses:	
The study involves in vitro fertilization:	
The research involves work with embryonic stem cells:	
The study involves children AND is greater than minimal risk:	**No**
Recruitment phone calls involve asking veterans for their Social Security numbers:	**No**

If the answers to these questions are wrong, use the Jump To menu to return to the 'Organization Review Requirements' page to change your answers.

3 * **Confirm** - You have read the above information and understand that in addition to this IRB application form (CICERO), you are required to send a submission to the VAMHCS R&D Committee **within 60 days of receiving IRB approval.**

(●) Yes ( ) No

ID VIEW:4E1CBF0D7B000
Name v2_VA Review Required

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Psychiatry	Complete

ID VIEW:4E1CAD9AE4000
Name v2_Summary of Required Reviews (other than IRB)

Additional Documents

1 Upload all additional documents here:

Name	Created	Modified Date
VA_Gov_Ethics_LanLi_092324.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA_CITI_HSP_LanLi_032424.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
Li, Lan 2_19_16.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
Brandler.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
CITI Group 2_Brandler.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA Privacy and Information Security Awareness and Rules of Behavior_Brandler_2025.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA Government Ethics_Brandler.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA Privacy and HIPAA_Brandler_2025.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VAMHCS Research Service Laboratory Safety Manual Signature Page (2)_LanLi_signed_111324.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA_WBT_LanLi_042425.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
VA_Pricacy_and_HIPPS_LanLi_042825.pdf(0.01)	7/1/2025 8:23 AM	7/1/2025 8:23 AM
Rnguyen citiCompletionCertificate_7227309_64714499.pdf(0.01)	8/30/2024 9:36 AM	8/30/2024 9:36 AM
Ciesinski - Scope of Practice Final.pdf(0.01)	8/23/2024 2:18 PM	8/23/2024 2:18 PM

Name	Created	Modified Date
Ciesinski CITI Human Subjects Protection Refresher Certificate.pdf(0.01)	8/23/2024 2:18 PM	8/23/2024 2:18 PM
Ciesinski CITI Good Clinical Practice Certificate.pdf(0.01)	8/23/2024 2:18 PM	8/23/2024 2:18 PM
Ciesinski VHA Mandatory Training 6.27.24.pdf(0.01)	8/23/2024 2:18 PM	8/23/2024 2:18 PM
Ciesinski HIPAA 201 - Human Research Certificate.pdf(0.01)	8/23/2024 2:17 PM	8/23/2024 2:17 PM
Ciesinski HIPAA 203 - Information Technology Certificate.pdf(0.01)	8/23/2024 2:17 PM	8/23/2024 2:17 PM
Rnguyen Mandatory Training for Trainees 2024.pdf(0.01)	8/23/2024 2:17 PM	8/23/2024 2:17 PM
Nguyen_Scope of Practice Final.pdf(0.01)	8/23/2024 2:17 PM	8/23/2024 2:17 PM
Rnguyen Privacy and HIPAA Training 2024.pdf(0.01)	8/23/2024 2:17 PM	8/23/2024 2:17 PM
Loecher.pdf(0.01)	4/23/2024 4:41 PM	4/23/2024 4:41 PM
Loecher_privacy and information security awareness.pdf(0.01)	4/23/2024 4:41 PM	4/23/2024 4:41 PM
Loecher_govethics.pdf(0.01)	4/23/2024 4:41 PM	4/23/2024 4:41 PM
Loecher_CITIhumanresearch.pdf(0.01)	4/23/2024 4:41 PM	4/23/2024 4:41 PM
Loecher_VA HIPPA privacy.pdf(0.01)	4/23/2024 4:41 PM	4/23/2024 4:41 PM
Giron-Hernandez.pdf(0.01)	4/19/2024 4:43 PM	4/19/2024 4:43 PM
Giron_VA Privacy and Information Security Awareness and Rules of Behavior_2024.pdf(0.01)	4/19/2024 4:42 PM	4/19/2024 4:42 PM
Giron_VA Privacy and HIPAA training_1.8.2024.pdf(0.01)	4/19/2024 4:42 PM	4/19/2024 4:42 PM
Giron_Government Ethics 2024.pdf(0.01)	4/19/2024 4:42 PM	4/19/2024 4:42 PM
Giron_CITI Program Refresher course_2022.pdf(0.01)	4/19/2024 4:42 PM	4/19/2024 4:42 PM
Harvey_Privacy and Info Security.pdf(0.01)	10/2/2023 2:35 PM	10/2/2023 2:35 PM
Harvey_Privacy and HIPAA.pdf(0.01)	10/2/2023 2:35 PM	10/2/2023 2:35 PM
Harvey_Scope.pdf(0.01)	10/2/2023 2:35 PM	10/2/2023 2:35 PM
Harvey_Gov Ethics Essentials.pdf(0.01)	10/2/2023 2:34 PM	10/2/2023 2:34 PM
Harvey_CITI cert 2023.pdf(0.01)	10/2/2023 2:34 PM	10/2/2023 2:34 PM
Harvey_2023 CITI plus GCP refresher TMS report.pdf(0.01)	10/2/2023 2:34 PM	10/2/2023 2:34 PM
HIPAA_Waiver_Request_vha-10-0521-RCT_signed.pdf(0.03)	8/9/2023 10:28 AM	9/7/2023 11:36 AM
Travaglini_Privacy-HIPAA 04.24.23.pdf(0.01)	4/24/2023 2:43 PM	4/24/2023 2:43 PM
Travaglini_Gov Ethics 04.24.23.pdf(0.01)	4/24/2023 2:43 PM	4/24/2023 2:43 PM
Missed Appointment Letter_1.6.23.docx(0.01)	1/6/2023 3:56 PM	1/6/2023 3:56 PM
Booster Appointment Letter_1.6.23.docx(0.01)	1/6/2023 3:56 PM	1/6/2023 3:56 PM
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Kacmarek_CITI_Human Subjects(0.01)	12/19/2022 3:29 PM	12/19/2022 3:29 PM
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Vivino_citi_SBERCR.pdf(0.01)	11/10/2022 12:07 PM	11/10/2022 12:07 PM
Vivino_govtethics.pdf(0.01)	11/4/2022 9:12 PM	11/4/2022 9:12 PM
Vivino_InfoSecROB.pdf(0.01)	11/4/2022 9:12 PM	11/4/2022 9:12 PM
Vivino_HIPAA.pdf(0.01)	11/4/2022 9:12 PM	11/4/2022 9:12 PM
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Achee - Privacy-Info Sec-ROB 2022.pdf(0.01)	9/26/2022 10:29 AM	9/26/2022 10:29 AM
Achee - Privacy and HIPAA 2022.pdf(0.01)	9/26/2022 10:29 AM	9/26/2022 10:29 AM
Achee - Citi completion report.pdf(0.01)	9/26/2022 10:29 AM	9/26/2022 10:29 AM
Achee - Training for Trainees.pdf(0.01)	9/26/2022 10:29 AM	9/26/2022 10:29 AM
Achee.pdf(0.01)	9/26/2022 10:28 AM	9/26/2022 10:28 AM
2020 - CITI VA Human Subjects Protection Refresher - Gabriella Coakley.pdf(0.01)	5/27/2022 11:06 AM	5/27/2022 11:06 AM
2020 - VA CITI Plus Good Clinical Practices Refresher - Gabriella Coakley.pdf(0.01)	5/27/2022 11:06 AM	5/27/2022 11:06 AM
Miles-McLean_VA Privacy Information Security_8.20.21.pdf(0.01)	9/10/2021 10:48 AM	9/10/2021 10:48 AM
Miles-McLean_Privacy HIPAA_7.12.21.pdf(0.01)	9/10/2021 10:47 AM	9/10/2021 10:47 AM
Miles_McLean_Group 1 CITI Course_8.23.21.pdf(0.01)	9/10/2021 10:47 AM	9/10/2021 10:47 AM

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2019 - Privacy and HIPAA Training - Kinnera Atluri.pdf(0.01)	9/9/2021 9:55 AM	9/9/2021 9:55 AM
2019 - VA Privacy and Information Security Awareness and Rules of Behavior - Kinnera Atluri.pdf(0.01)	9/9/2021 9:54 AM	9/9/2021 9:54 AM
2019 - VA CITI Refresher - Kinnera Atluri.pdf(0.01)	9/9/2021 9:54 AM	9/9/2021 9:54 AM
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UMB COVID Risk STatement CBT-CP 4.7.21.docx(0.02)	4/1/2021 3:13 PM	4/7/2021 8:40 AM
2020 - Privacy and HIPAA Focused Training - Print - Howard Turner.pdf(0.01)	3/26/2021 4:55 PM	3/26/2021 4:55 PM
2020 VA CITI Refresher - Howard Turner.pdf(0.01)	3/26/2021 4:55 PM	3/26/2021 4:55 PM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Howard Turner.pdf(0.01)	3/26/2021 4:54 PM	3/26/2021 4:54 PM
Consent for Audio/Video Record(0.01)	3/11/2021 2:39 PM	3/11/2021 2:39 PM
ROI for third parties(0.01)	3/11/2021 2:39 PM	3/11/2021 2:39 PM
Subject Locator Form_RCT - track changes(0.01)	1/29/2021 8:08 AM	1/29/2021 8:08 AM
Subject Locator Form_clean.docx(0.03)	11/13/2019 9:58 AM	1/29/2021 8:08 AM
2020 - Travaglini Privacy_Info Security.pdf(0.01)	1/15/2021 10:38 AM	1/15/2021 10:38 AM
2020 - Travaglini Privacy_HIPAA.pdf(0.01)	1/15/2021 10:38 AM	1/15/2021 10:38 AM
2020 - Travaglini - Govt Ethics.pdf(0.01)	1/15/2021 10:38 AM	1/15/2021 10:38 AM
2020 Privacy and HIPAA Training - Deborah Medoff.pdf(0.01)	1/15/2021 10:37 AM	1/15/2021 10:37 AM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Deborah Medoff.pdf(0.01)	1/15/2021 10:37 AM	1/15/2021 10:37 AM
2020 - Mandatory Training for Transient and Part-Time Intermittent Clinical Staff MTTCS - Deborah Medoff.pdf(0.01)	1/15/2021 10:37 AM	1/15/2021 10:37 AM
2020 - CITI plus Good Clinical Practice - Deborah Medoff.pdf(0.01)	1/15/2021 10:37 AM	1/15/2021 10:37 AM
2020 Mandatory Training for Transitory Part-time and Intermittent Clinical Staff - Alicia Lucksted.pdf(0.01)	1/15/2021 10:36 AM	1/15/2021 10:36 AM
2020 VA Privacy and Information Security Awareness and Rules of Behavior - Alicia Lucksted.pdf(0.01)	1/15/2021 10:36 AM	1/15/2021 10:36 AM
2019 - VA CITI Refresher - Kelly Lloyd.pdf(0.01)	1/15/2021 10:35 AM	1/15/2021 10:35 AM
2020 - Privacy and HIPAA Training - Kelly Lloyd.pdf(0.01)	1/15/2021 10:35 AM	1/15/2021 10:35 AM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Kelly Lloyd.pdf(0.01)	1/15/2021 10:35 AM	1/15/2021 10:35 AM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Belinda Kauffman.pdf(0.01)	1/15/2021 10:32 AM	1/15/2021 10:32 AM
2020 - Privacy and HIPAA Training - Belinda Kauffman.pdf(0.01)	1/15/2021 10:32 AM	1/15/2021 10:32 AM
2020 - Mandatory Training for Transitory Part-time and intermittent Clinical Staff MTTCS- Belinda Kauffman.pdf(0.01)	1/15/2021 10:32 AM	1/15/2021 10:32 AM
2020 - CITI Plus Good Clinical Practived Referesher TMS Certificate- Belinda Kaufman.pdf(0.01)	1/15/2021 10:32 AM	1/15/2021 10:32 AM
Brown CITI Human Subjects07292020.pdf(0.01)	1/15/2021 10:31 AM	1/15/2021 10:31 AM
VA Privacy & IS Awareness & ROBs_12192020.pdf(0.01)	1/15/2021 10:31 AM	1/15/2021 10:31 AM
VA Privacy and HIPPA12202020.pdf(0.01)	1/15/2021 10:30 AM	1/15/2021 10:30 AM
2020 - Mandatory Training for Transient Clinical Staff Non-Trainbees - Melanie Bennett.pdf(0.01)	1/15/2021 10:30 AM	1/15/2021 10:30 AM
2020 - VA CITI Refresher - Melanie Bennett.pdf(0.01)	1/15/2021 10:29 AM	1/15/2021 10:29 AM
2020 - VA Privacy and Inforamtion Security Awareness and Rules of Behavior - Melanie Bennett.pdf(0.01)	1/15/2021 10:29 AM	1/15/2021 10:29 AM
Bennett_CITI report_ 6 18 2020.pdf(0.01)	1/15/2021 10:29 AM	1/15/2021 10:29 AM
2020 - CITI Plus Good Clinical Practices Refresher - Jeanette Robinson.pdf(0.01)	1/15/2021 10:28 AM	1/15/2021 10:28 AM
2020 - Mandatory Training for Transitory Part-Time and Intermittent Clinical Staff MTTCS - Jeanette Robinson.pdf(0.01)	1/15/2021 10:27 AM	1/15/2021 10:27 AM
2020 - Privacy and HiPAA training- Jeanette Robinson.pdf(0.01)	1/15/2021 10:27 AM	1/15/2021 10:27 AM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Jeanette Robinson.pdf(0.01)	1/15/2021 10:27 AM	1/15/2021 10:27 AM
2020 - Mandatory Training for Transient Clinical Staff Non Trainees - Julie Kreyenbuhl.pdf(0.01)	1/15/2021 10:25 AM	1/15/2021 10:25 AM
2020- VA Privacy and Information Security Awareness and Rules of Behavior - Julie Kreyenbuhl.pdf(0.01)	1/15/2021 10:25 AM	1/15/2021 10:25 AM
2020 - VA Privacy and Information Security Awareness and Rules of Behavior - Gabrielle Coakley.pdf(0.01)	1/15/2021 10:25 AM	1/15/2021 10:25 AM
2020 - VA CITI Plus Good Clinical Practices Refresher - Gabrielle Coakley.pdf(0.01)	1/15/2021 10:25 AM	1/15/2021 10:25 AM
2020 - Privacy and HIPAA Training - Gabrielle Coakley.pdf(0.01)	1/15/2021 10:25 AM	1/15/2021 10:25 AM
2019 - Privacy and HIPAA Training - Kirsten Poston.pdf(0.02)	1/15/2021 10:20 AM	1/15/2021 10:24 AM

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2020- Human Research VA HSP Refresher.pdf(0.01)	1/15/2021 10:21 AM	1/15/2021 10:21 AM
2020 - VA CITI Human Research GCP Refresher - Kirsten Poston.pdf(0.01)	1/15/2021 10:20 AM	1/15/2021 10:20 AM
2019 - VA Privacy and Information Security Awareness and Rules of Behavior - Kirsten Poston.pdf(0.01)	1/15/2021 10:20 AM	1/15/2021 10:20 AM
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TongeCITI.pdf(0.01)	1/15/2021 10:17 AM	1/15/2021 10:17 AM
2019 - VA CITI GCP Refresher - Lynn Calvin.pdf(0.01)	1/15/2021 10:17 AM	1/15/2021 10:17 AM
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2019 _VA Privacy and Information Security Awareness and Rules of Behavior_ Lillian Hammer.pdf(0.01)	1/15/2021 10:16 AM	1/15/2021 10:16 AM
2019 - VA Privacy and HIPAA - Lillian Hammer.pdf(0.01)	1/15/2021 10:16 AM	1/15/2021 10:16 AM
2018 - HIPAA 201 - Lillian Hammer.pdf(0.01)	1/15/2021 10:15 AM	1/15/2021 10:15 AM
2018 - HIPAA 125 - Lillian Hammer.pdf(0.01)	1/15/2021 10:15 AM	1/15/2021 10:15 AM
Poston CITI training(0.01)	1/22/2020 12:55 PM	1/22/2020 12:55 PM
ISSO Compliance Review- Travaglini 88491 - FINAL.pdf(0.01)	12/10/2019 11:10 AM	12/10/2019 11:10 AM
PO Compliance Review- Travaglini 88491 - signed by PO.pdf(0.01)	12/3/2019 11:37 AM	12/3/2019 11:37 AM
Evaluation to Sign Consent.doc(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2017- CITI Refresher- Julie Kreyenbuhl.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2017 - Good Clinical Practice and ICH - Basic Course.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2019 - VA Privacy and Information Security Awareness and Rules of Behavior - Julie Kreyenbuhl.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2019 - Mandatory Training for Transient Clinical Staff Non Trainees - Julie Kreyenbuhl.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2019 - CITI GCP through 11-22.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2019 - CITI Biomedical through 11-22.pdf(0.01)	11/13/2019 9:58 AM	11/13/2019 9:58 AM
2017-UMB CITI GCP and ICH Certificate- Alicia Lucksted.pdf(0.01)	10/17/2019 10:15 AM	10/17/2019 10:15 AM
2017 - UMB CITI Good Clinical Practice and ICH- Alicia Lucksted.pdf(0.01)	10/17/2019 10:15 AM	10/17/2019 10:15 AM
2018 - VA CITI Refresher - Alicia Lucksted.pdf(0.01)	10/17/2019 10:15 AM	10/17/2019 10:15 AM
2018 VA CITI - GCP refresher training record - Letitia Travaglini.pdf(0.01)	10/17/2019 10:14 AM	10/17/2019 10:14 AM

ID: VIEW4E096251 3A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Psychiatry	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEWIE1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Adriana Loecher

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Adriana Loecher is a research assistant at the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 * Select Team Member:
Cynthia Giron-Hernandez

2 Research Role:
Research Team Member

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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Cynthia Giron-Hernandez is a research assistant at the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 * Select Team Member:
Alicia Lucksted

2 Research Role:
Research Team Member

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○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Alicia Lucksted has been research faculty in the Psychiatry Department for more than 10 years. She has been the Principal Investigator or a Co-Investigator on numerous mental health services studies using quantitative, qualitative and mixed methods. Much of her past and current work involves the same or similar populations at the same or similar settings as the current proposed study. She is very familiar with the local and regional mental health and humans services systems, the proposed sites for this study, and the cultural and social contexts relevant to the proposed study.

Add a Team Member

1 * Select Team Member:
Lijuan Fang

2 Research Role:
Statistician

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○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lijuan Fang is a statistician for the study and works with the study data. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

Add a Team Member

1 * Select Team Member:
Melanie Bennett

2 Research Role:
Research Team Member

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○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Melanie Bennett has been a member of the faculty within the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS for a number of years. She has served as the Principal Investigator or a Co-Investigator on numerous studies of mental health services interventions for individuals with serious mental illnesses. Dr. Bennett has conducted or participated in research involving this population at the study sites where the proposed research will take place. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

Add a Team Member

1 * Select Team Member:
Julie Kreyenbuhl

2 Research Role:
Research Team Member

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○ Yes ● No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Julie Kreyenbuhl has been a member of the faculty within the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS for a number of years. She has served as the Principal Investigator or a Co-Investigator on numerous studies of mental health services interventions for individuals with serious mental illnesses. Dr. Kreyenbuhl has conducted or participated in research involving this population at the study sites where the proposed research will take place. She is very familiar and knowledgeable about the study sites, culture and society related to working on this protocol.

Add a Team Member

1 * Select Team Member:
Clayton Brown

2 Research Role:
Statistician

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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Clayton Brown is a statistician for the study and works with the study data. He has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

Add a Team Member

1 * Select Team Member:
Belinda Kauffman

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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○ Yes ● No

5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Belinda Kauffman has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

Add a Team Member

1 *Select Team Member:
Howard Turner

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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○ Yes ● No

5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Howard Turner has been serving as a Certified Peer Support Specialist within the VA Maryland Health Care System for several years and also serves as a research staff member within the VISN 5 MIRECC. His status as a Peer Support Specialists as well as his involvement in MIRECC studies has provided him with great personal and professional experiences with the VAMHCS and the serious mental illness population.

Add a Team Member

1 *Select Team Member:
Justine Glieger

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Justine is a research assistant at the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 *Select Team Member:
Kirsten Harvey

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Kirsten is a research assistant at the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 *Select Team Member:
Nicole Ciesinski

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Nicole Ciesinski is a doctoral psychology intern with the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 *Select Team Member:
Gabriella Coakley

2 Research Role:
Research Team Member

3 *Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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○ Yes ● No

5 *Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 *Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Gabriella is a psychology trainee at the MIRECC and has training and experience with the SMI population.

Add a Team Member

1 *Select Team Member:
Brian Brandler

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Brian has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.

Add a Team Member

1 * Select Team Member:
LAN LI

2 Research Role:
Statistician

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○ Yes ● No

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Lan LI is a statistician for the study and works with the study data. She has worked with the Mental Illness Research, Education and Clinical Center (MIRECC) at the VAMHCS as a research team member for a number of years and is quite familiar with our data management procedures.