Project Title: A Computer-Assisted CBT Tool to Enhance Fidelity in CBOCs.

Funding Agency: VA Health Services Research and Development Service

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Abstract

Background and Significance: Randomized Controlled Trials (RCTs) have demonstrated that evidence-based psychotherapies (EBPs), particularly Cognitive Behavioral Therapy (CBT), are highly effective in treating anxiety and depression, the most common mental health disorders in primary care settings. Mental health (MH) providers in VA Community-Based-Out-Patient-Clinics (CBOCs) are often located in rural areas and isolated from educational opportunities. Almost half of Veterans now use CBOCs. Studies have shown that the quality of delivery of EBPs (fidelity) impacts clinical outcomes. This study will test a computer-assisted tool (CALM Tools for Living) that increases fidelity to CBT in treating depression and four common anxiety disorders, including PTSD. Although results of a large RCT, the CALM study, suggested that the tool contributed to fidelity to the CBT protocol, this hypothesis has not been tested. This study will test the tool in rural CBOCs in VA VISN16.
Objective: To evaluate the impact of a modified version of a computer-assisted CBT tool on providers' fidelity to the CBT model and clinical outcomes, and to assess how best to support future implementation of this tool within VA CBOCs.
Specific Aims/Hypothesis: This project has two aims. First, we plan to compare MH provider fidelity to CBT and clinical outcomes among providers who used the tool and those who did not. We hypothesize that clinicians who use the tool will have a higher fidelity to CBT and clinical outcomes among patients will be superior. Second, assess how best to support its future implementation in routine VA care.
Methodology: This study will use a Type III hybrid effectiveness design. Thirty-four CBOC MH providers will be trained in CBT and randomized to use the tool or not. Both groups will receive external facilitation to encourage the full implementation of CBT into practice on the clinic level. MH providers will treat a total of 340 veterans. Patients will be assessed at baseline, three-, and six- months post treatment. Provider fidelity to the CBT protocol will be measured, and finally, a tool kit for future implementation of the tool will be disseminated.
Impact: We expect the intervention to improve the technical quality of MH treatment in CBOCs and improve clinical outcomes among depressed and/or anxious Veterans receiving care in these settings.

List of Abbreviations

CALM = Coordinated Anxiety Learning Management

CBOC = Community-based Outpatient Clinic

CBT = Cognitive Behavioral Therapy

EBP = Evidence-based Practices

EMR = Electronic Medical Record

MH = Mental Health

MHP= Mental Health Provider

RCT = Randomized Controlled Trial

VA = Veterans Health Administration

VISN = Veterans Integrated Service Networks

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2.0 Introduction

Multiple randomized controlled trials (RCTs) have demonstrated that evidence-based psychotherapies (EBPs), particularly Cognitive Behavioral Therapy (CBT) [1-3], are highly effective for anxiety and depression, the most common mental health (MH) disorders in primary care settings.[4-6] The national VA Uniform Mental Health Services Handbook [7] clearly emphasizes the VA's commitment to provide evidence-based treatments for Veterans with mental illness. However, broadly disseminating and implementing (a process often referred to as "scaling up") these and other evidence-based practices has been a challenge in many health care systems [8], including the VA.[9, 10] While training of clinicians is needed for scaling up, training

alone is inadequate to assure that these EBPs are not only implemented in clinics but implemented with enough fidelity to assure their clinical effectiveness.[11] Without adequate implementation and fidelity, patients receive few benefits and resources devoted to training clinicians and do not achieve their ultimate goal of improving patient outcomes.

Implementing psychotherapies in small or remote primary care clinics, such as many VA community-based outpatient clinics (CBOCs), can be especially challenging. [A 2008 study showed that only 22% of Veterans with depression, PTSD, or anxiety received at least one session of psychotherapy, and that rural Veterans were even less likely than urban Veterans to receive any psychotherapy [12] and the quality of the psychotherapy received is unknown]. MH providers in these clinics, many of whom are located in rural and highly rural areas, are sometimes the only MH provider at the clinic and may be isolated from their peers and from educational resources. Some of these MH providers, especially those with social work or nursing backgrounds, have no previous training in evidence-based psychotherapies; yet, as "general practitioners" of MH treatment, they are expected to be able to respond to a wide range of MH problems using evidence-based techniques, even though some of these techniques require considerable time to fully master. Approaches or tools to support and assist CBOC-based MH providers to deliver evidence-based psychotherapies for a range of mental disorders are needed with high fidelity.

The NIMH-funded Coordinated Anxiety Learning and Management (CALM) study [13] faced a similar challenge in implementing CBT in 17 non-VA primary care clinics across the US with providers, usually nurses and social workers, most of whom had no previous training or experience in CBT. To meet this challenge, Michelle Craske, PhD, and her UCLA-based team of experts, developed a tool to support primary care-based MH providers to deliver CBT for patients with a range of disorders, including post-traumatic stress disorder (PTSD), panic disorder (PD), generalized anxiety disorder (GAD), and social anxiety disorder (SAD), and depression. The CALM CBT program is unique in that it can be used for any of these disorders. This is possible because the program includes some modules that are common across disorders but additional modules that are disorder-specific.[14] Computer-assisted programs have been used in training in CBT, and in self-directed CBT [15-17], but prior to CALM had not been used for ongoing assistance of the MH provider in the delivery of CBT. Designed to be used as a tool by the provider, the CALM program involves the patient and provider looking at the computer screen together and proceeding through the modules at their own pace.[18] The CALM CBT program was used by 14 providers in treating more than 500 patients in a variety of primary care clinics, was considered acceptable to providers and patients, and achieved a high degree of fidelity. Most importantly, the CALM intervention as a whole was clinically effective (relative to treatment as usual) [19] for all disorders (PTSD, panic, GAD, SAD with or without depression).[14] Further, the improved clinical outcomes achieved in CALM appear to be due to receipt of CBT delivered with this tool.[19] A tool providing fidelity support to MH providers who are social workers, nurses, and masters' level psychologists, in primary care could be invaluable in VA CBOCs.

Our research partners are very interested in adapting the CALM computer-assisted CBT tool for use in VA CBOCs. The tool promotes fidelity by having the provider and the patient use the tool together during the session and by generating homework assignments tailored to each patient. Although we believe that the tool contributed to the high fidelity to the CBT protocol in the CALM study, this hypothesis has not been tested. This project will focus on testing whether computer-assisted CBT can improve technical quality of care within VA CBOCs.

3.0 Objectives

Using a Type III [20] hybrid effectiveness-implementation study design, ***the objectives of this project are to modify the CALM Tool, computer-assisted CBT tool, and its impact on providers' fidelity to the CBT model, and to assess how best to support its future implementation in routine care.*** The study meets the criteria for a Hybrid Type III because the primary focus of the study is to test an implementation intervention at the provider-level. We will provide (1) face to face training in CBT (including three months of clinical supervision to assure clinical competence) coupled with (2) external facilitation to 34 CBOC MH providers; half will receive the computerized CBT tool and half will not. We expect the computerized tool to improve fidelity (quality) of CBT. A secondary focus of the project is to collect patient-level data on clinical impact.

Previous VA training in CBT. The VA has sponsored at least two large-scale initiatives for clinician training in CBT*. Both of these therapies are relatively long (12 – 16 sessions), have been intended for treatment in specialty mental health settings (not primary care settings) and each has targeted only one disorder.* We are unable to confirm the extent to which CBOC mental health clinicians participated in these training efforts. However, the number of CBOCs has expanded considerably since 2000, going from about 600 to more than 800 by 2010, and there has also been a corresponding expansion in mental health providers located at CBOCs. We suspect that the majority of mental health providers in CBOC have not received training.

The first VA training initiative, started in 2004, trained licensed mental health professionals in Cognitive Behavioral Therapy (CBT) for depression. The CBT protocol was designed to be delivered using 16 individual 50-75-minute weekly sessions over the course of 4-6 months of treatment. In this training program, providers could become certified in CBT for depression by attending a multi-day didactic workshop and participating in follow-up consultation. [21] Providers could also use support materials such as treatment manuals, web-based treatment resources, and phone consultation with treatment experts. We were unable to determine the total number of persons who received training in this program but we do know that use of follow-up supervision to assure clinical competence was disappointingly low.

Drawing from lessons learned in this first effort, in 2006 VA began a second national initiative to disseminate Cognitive Processing Therapy (CPT) (a type of CBT specifically for PTSD) as an evidence-based treatment for PTSD in the VA. CPT is a 12-session treatment based on social cognitive theory that focuses on the thoughts and coping behaviors that individuals have in response to a traumatic event. This dissemination initiative has evolved over the six years and currently involves a 3-day face-to-face meeting, followed by 6 months of weekly remote supervision in a small group by an assigned training consultant and the submission of work samples to demonstrate successful completion of the training program. Mental health providers are not followed after they complete the 6 months supervision. As of March 31, 2010, nationally about 2,300 mental health staff have been trained in CPT (There are an estimated 2500 mental health providers in VISN 16 alone) and numerous hard-copy manuals have been distributed.

While these training efforts have reached many VA clinicians, we do not know, as stated earlier, the extent to which CBOC mental health providers have participated in these trainings. All of these trainings have been focused on a single disorder, are relatively long (e.g., 12 – 16 session), and were designed for intensive treatment in specialty (not primary care) treatment settings. (See preliminary studies section below on CBOC interviews). Our research partners at OMHS, OMHO, and the VISN16 MHPL are very concerned that fidelity to the CBT protocol

following national training is considerably less than optimal. Given the time and preparation that is involved in the provision of evidence-based treatments such as CPT, it is often difficult for mental health providers, especially ones that are geographically isolated or practice in fast-paced environments, to maintain fidelity to a hard-copy manualized protocol and to use a different protocol for each disorder. Further, research has shown that after receiving training clinicians typically do not remain true to a model but, instead, pick and choose the elements of the practice that they incorporate into their usual work [8]

Specific Aims:

Specific Aim 1: To compare two different approaches to implement CBT in CBOCs

Hypothesis 1a (primary): Clinicians randomized to receive CBT training and the computer-assisted CBT tool will have higher fidelity than providers randomized to receive CBT training but not tool but receiving a hardcopy treatment manual.

Hypothesis 1b (secondary): Patients of clinicians randomized to receive CBT training and the computer-assisted CBT tool will have clinical outcomes that are superior to patients of clinicians utilizing a manual only.

Specific Aim 2: Prepare for future implementation in routine care by performing an implementation needs assessment with key stakeholders (participating CBOC MH providers and participating CBOC directors).

4.0 Resources and Personnel

This 3.5-year study will be based at the Central Arkansas Veterans Healthcare System (CAVHS). The PI, Dr. Michael Cucciare, and study coordinators will have access to protected health information. Study coordinators will be involved in recruiting subjects and obtaining informed consent for Aims 1 and 2 of the study. For Aim 1, study coordinators will recruit and consent CBOC MH providers to participate in a three-day training to be held in Little Rock, AR, at CAVHS. They will also be responsible for screening, recruiting, and consenting Veteran participants receiving care at VA CBOCs to participate in the randomized trial. Study coordinators will be responsible for administering baseline and follow-up interviews to Veteran participants which will be conducted via using computer-assisted telephone interviewing (CATI).

For Aim 2, the study coordinators at CAVHS will consent CBOC directors from the CBOCs participating in Aim 1 to a short telephone interview (CBOC MH providers will be consented for Aim 1 and Aim 2 simultaneously). Data analysis will be performed by the PI and Co-Is, and supported by the consultants and research staff as detailed below.

Key Personnel – Little Rock, AR

Michael Cucciare, Ph.D (Principal Investigator: 25% (3.0 calendar months) in all years). Dr. Cucciare is a clinical psychologist and Research Health Scientist at the VA HSR&D Center for Mental Healthcare and Outcomes Research (CeMHOR). He is also an Assistant Professor (tenure track) in the Division of Health Services Research at the University of Arkansas for Medical Sciences. Dr. Cucciare has extensive knowledge of cognitive behavioral therapy (CBT) and the use of computerized aids in support of CBT. His career development award, now

completed, had a similar focus (evidence-based practices in medical settings). He is currently a Co-PI on a CREATE project out of Palo Alto that involves implementing and evaluating a computerized brief alcohol intervention for Veterans with hepatitis C and who consume alcohol. Dr. Cucciare will assume overall responsibility for the scientific integrity of the project. He will lead weekly project meetings, manage the budget, and supervise the project coordinator as she oversees day-to-day activities and IRB submissions. He will also oversee recruitment and data collection for Aim 1 and Aim 2 and co-lead implementation needs assessment with Dr. Curran.

Geoffrey Curran, PhD (Co-Investigator: 10% (1.2 calendar months) in all years). Dr. Curran is a sociologist and Research Health Scientist at the VA HSR&D Center for Mental Healthcare and Outcomes Research (CeHMOR). He is also Director of the Center for Implementation Research in the Colleges of Pharmacy and Medicine at the University of Arkansas for Medical Sciences. He is also a Research Health Scientist at the VA HSR&D Center for Mental Healthcare and Outcomes Research (CeMHOR). Dr. Curran developed an online CBT *training* tool using the ADDIE developmental methodology. He recently presented a model for hybrid clinical effectiveness-implementation research trials which has guided the design of this study. Dr. Curran will work closely with Dr. Cucciare to help develop the computer-based CBT tool and co-lead implementation needs assessment.

Study Staff – Little Rock, AR

Kathy Marchant (**Project Director: 100% (6 calendar months for 3.5 years).** Ms. Marchant will be responsible for all IRB submission and correspondence; conduct provider and patient recruitment and consenting; be involved in planning the provider training; assist in the management of qualitative data; oversee the collection of outcome assessments; conduct outcomes assessments; and oversee IRB requirements such as the documentation of informed consent.

Mitzi Mosier (Project Coordinator: 50% (6 calendar months for 3.5 years). Ms. Mosier will be responsible for supporting recruitment efforts for Aims 1 and 2, conducting informed consent of providers, Veterans, and CBOC directors.

Rebecca Doan (Project Coordinator: 20% (2.4 calendar months for 3.5 years). Ms. Doan will provide IRB consultation to the study team; support the team in the development of consent forms, and continuing review documentation.

Xiaotong Han, MS (Biostatistician, 5% -20% (.6 calendar months for year 1, 3 calendar months for years 2-4.) Ms. Han will be the study biostatistician responsible for data analysis to examine our primary and secondary outcomes. She will be also be responsible for the overall management of the database.

Traci Abraham, PhD (Qualitative Interviewer). Dr. Abraham is an anthropologist and health services researcher with expertise in qualitative interviewing. Dr. Abraham will lead the qualitative interviewing efforts for Aim 2.

Key Personnel – Houston, TX

Michael Kauth, PhD (Co-Investigator, 10% (1.2 calendar months for 3.5 years). Dr. Kauth is a clinical psychologist, Co-Director and Associate Director for Education in the SC MIRECC,

overseeing clinical training programs for mental health clinicians. Increasingly, he has focused on strategies for dissemination of training and implementation of training – including the use of technology-enhanced tools for clinical training to reach a wider audience. Dr. Kauth has a strong background in implementation research, specifically external facilitation, to increase the adoption of evidence-based psychotherapy. He has collaborated with VISN 16 Mental Health Product Line to implement evidence-based PTSD psychotherapy in CBOCs, using telehealth technology. Dr. Kauth will assist with provider recruitment, provide guidance and leadership on the implementation strategy and supervise the efforts of the external facilitator. He will also provide consultation on all training activities and assist with the implementation toolkit and manuscripts.

Jeffrey Cully, PhD (Co-Investigator 10% (1.2 calendar months for 3.5 years). Dr. Cully is a clinical psychologist and health services researcher with expertise in the study and implementation of mental health interventions, cognitive behavioral therapy, and the application of psychological interventions outside of traditional mental health specialty care settings (e.g. primary care). Dr. Cully directs the SC MIRECC fellowship program in Houston. Dr. Cully will provide CBT training and on-going supervision to the 34 participating providers. He will assist with the implementation toolkit and manuscripts.

Study Staff – Houston, TX

Jan Lindsay, PhD (External Facilitator: 10% (1.2 calendar months) in year 1; 25% (3 calendar months) in years 2 and 3. Dr. Lindsay will attend the CBT training and build rapport with the 34 participating providers and speak with them at least once a month for the duration of the intervention to problem solve barriers to implementing the CBT protocol and/or the computer-assisted CBT tool. She will also maintain a detailed time-log of all facilitation activities.

5.0 Study Procedures

5.1 Study Design

Specific Aim 1: Randomized Trial

MH provider participants; Mental Health Providers **(**MH providers) will be asked about their previous training and clinical experience with CBT. Because our own VA work and the CALM research both showed that previous training in CBT was moderately related to performance after CBT training, we will attempt to match providers on previous CBT experience. We will randomize 17 providers to receive the tool at the end of training. (Not receiving the computerized tool is in effect “training as usual”). To randomize we will first separate providers empirically into three groups, depending on their previous CBT experience (no, some, most experience). We will then create three pots containing assignment numbers (1 = receives tool; 2 = no tool) for each of the three groups. We will draw a number for each provider from the appropriate pot. Pots will have equal amounts of assignment numbers in each (i.e. equal numbers of 1’s and 2’s). Only the Mental Health Providers will be randomized.

Veteran patients may be existing or new patients to the provider. Patients will be considered eligible if they: (1) are a veteran, (2) their Mental Health provider is a participant in this study; (3) their Mental Health provider has made a clinical determination that CBT is an indicated treatment; (4) the patients plan to continue to receive mental health care at the CBOC, (5) have depression, PTSD, or other anxiety disorder (PD, GAD, SAD), (6) are willing to receive CBT specifically, (7) and are willing and able to participate in clinical assessments (baseline, 3, and 6 months) by phone. Patients will be considered ineligible if they (1) have evidence of significant cognitive impairment, are in crisis (e.g., suicidal), (2) are dependent on alcohol or drugs (substance abuse is allowed), (3) or have a comorbid diagnosis of schizophrenia or bipolar disorder. We will expect the MH providers to recruit a total of 340 veterans for the first two years of the project. For each patient, providers will be asked to proceed through treatment modules in a step-wise fashion; however, we recognize that patients may not complete all modules.

We are adding an additional option of CALM delivery for MHPs randomized to the Computer arm of the study. This would include the option of Video-to-Home delivery. This option would require the following Veteran pre-requisites:

- Computer with reliable internet connection, with a video camera, microphone, and speakers.
- Access to MyHealtheVet to send/receive handouts through secure messaging.
- Active email address.
- Phone availability.
- Consent to telemental health and treatment of ____ (anxiety, depression, etc.) using CALM (standard of care)

On the day of the appointment:

- Veterans receive an email shortly before the scheduled start of the session. The email contains a hyperlink to navigate to the secure webpage/virtual medical room (VMR).
- Veterans access VMR at the time of the appointment, and contact the MHP by phone if they experience technical difficulties.
- If the provider and Veteran are unable to complete the session by video, we may use telephone if appropriate.

Additional logistics:

- MHP logs into CALM online program (Veteran does not have program access)
- MHP shares screen with Veteran over video telehealth connection, walks Veteran through content
- Veteran and MHP able to either switch between viewing each other/the CALM program or view a thumbnail of the alternate screen (i.e., large view of person with thumbnail of program or large view of program with thumbnail of person)

Training and supervision, all 34 MH providers will receive the same training in CBT led by Dr. Michelle Craske (CALM tool consultant) with assistance from our study team. The training will be of the same length and format (3-day, face to face) this structure is

the same as current VA training programs. The training will differ across the two MH provider groups in that the final two hours of each day will involve either practice with the tool or practice with the manual. All providers who complete the training (regardless of randomization) will receive supervision for 3 months. This supervision program will be based on the previous post-training supervision provided by VA for CBT [12, 22] and will consist of small group supervision with the first 4 weeks of clinical supervision to include roleplays with the supervisor giving feedback to each clinician, and all clinicians benefiting vicariously from listening to each other's' role plays and feedback. The following 8 weeks will allow the providers to prepare and discuss actual veteran scenarios. **Site facilitation** our experience has shown that coupling training with a site implementation strategy optimizes the benefits of the training. External facilitation increases providers' success in actually bringing their new skills into their particular clinical setting.[9, 23] All 34 MH providers will receive external facilitation. The external facilitator, Dr. Lindsay, will help each provider develop an implementation plan, including setting individual goals for CBT implementation and negotiate a clinic implementation plan with clinic leadership. She will be present at the training sessions in order to meet the MH provider face to face. Thereafter, the facilitator will meet by phone with each provider at least once following the supervision and as needed during the implementation phase. The calls between the facilitator and MH provider will typically focus on quickly generating solutions to barriers to implementation (e.g., scheduling, time management) and maintaining motivation to practice CBT in the face of multiple barriers. Michael Kauth, PhD, who has facilitated numerous educational interventions in VISN 16 (see preliminary studies) will supervise Dr. Lindsay for this project.

Training and technical assistance for computerized tool The 17 MH providers who receive the computerized tool will receive ongoing technical support by phone for use of the computerized tool. A technical support specialist (to be named) will check weekly with each of the 17 MH providers using the computerized tool during the first month and will trouble-shoot any problems that emerge. Thereafter, the technical support specialist will check in monthly but will also be "on call' to address any problems with implementation and use of the computerized tool.

Risks and Benefits: There are minimal risks anticipated for MH providers and Veterans participating in Aim 1. It is possible that both participant groups will feel some emotional discomfort while being audiotaped during session. However, audiotaping therapy sessions is a well-studied method for examining treatment fidelity and provider activity during a treatment session. Any emotional discomfort typically dissipates once the session begins. Participants may also feel some concern about who will view and have access to audiotaped treatment sessions. We will make a point of emphasizing to both providers and patients that audiotaped sessions will be kept strictly confidential with only authorized research staff having access. Audiotaped sessions will be stored electronically on a secure service drive in password protected folders behind the VA firewall. All hard copy source documents will be kept in a locked filing cabinet at CAVHS, building 58, room 251.

Specific Aim 2: Implementation Needs Assessment

All MH providers who participated in the implementation trial will be invited to take part in a focus group at the end of the trial. In addition, we will recruit 8-10 CBOC directors from those sites who participated in the trial and invite them to take part in a brief telephone interview (up to 15 minutes).

We will conduct focus groups with the MH providers to assess their perspectives about what worked and what did not in terms of the training they received, the use of the tool (or not) in providing CBT, the supervision they received, and the additional facilitation/support provided to them and their CBOCs to provide the CBT. In addition, we will ask them to comment on the likely barriers and facilitators to providing the CBT and the use of the tool *in routine care*. After the focus groups with MH providers are completed, we will conduct interviews with a sample of CBOC directors to assess their perspectives on implementation of the tool under routine care circumstances, and we will get their reaction to the barriers/facilitators raised by the MH providers. The focus groups will take place via telephone. We will attempt to schedule 3 focus groups of up to 10 MH providers each. Given the difficulty of scheduling provider interviews or focus groups during the workday, we will attempt to schedule the focus groups either before/after the usual clinic hours, or during the lunch hour. The CBOC Director interviews will be scheduled at their convenience. The Directors of all participating CBOCS will be invited to participate. All focus groups and interviews will be audiotaped to allow for analyses.

Risks and Benefits: There are no anticipated risks associated with participation in Aim 2. It is possible that CBOC MH providers and/or directors will be uncomfortable providing their opinions about the CBT training and/or use of CALM (or not) at their respective clinic. Again, we will make every effort to address these concerns and make it a point to explain that feedback will be kept strictly confidential and will not be shared with anyone outside of the study environment.

5.2 Recruitment Methods

Aim 1: Provider Participants
We have had extensive experience in training VA providers [9] through the South Central MIRECC Education program. We have learned that it is vital to invite only those who are truly motivated and eager to participate in trainings. We will let all CBOC MH providers in VISN 16 know about this training and research opportunity in three ways. First, we will announce the opportunity on the monthly meeting of MH VISN-wide leaders. Second, we will publicize the opportunity on the SC MIRECC professional networking site designed specifically for CBOC clinicians, called the Mental Health PREP. Third, we will send out study information sheets to providers on the email list-serve of CBOC clinicians maintained by the VISN 16 Mental Health Product Line office. Fourth, we will coordinate via email and telephone conversation with CBOC directors to identify MH providers who might be interested in participating in this project, and approach them via email or telephone, depending on their preference. We will also request that each mental health provider interested in participating obtain permission from their respective supervisors to receive training in CBT and participate. This will include some indication (i.e., email or memo), from their supervisor to the provider, that they have permission to participate in the CBT training in Little Rock. This will ensure that participant providers have discussed the project with their supervisor and have received appropriate permission to leave their work station for the training.

Training will be contingent on willingness to participate in the research project but it will be made very clear that participation is entirely voluntary. Providers who desire training but do not want to participate in the research project will be linked with the VA's national training program in CBT through which they may obtain training. To be eligible, clinicians must (1) currently providing CBT; (2) be located at the CBOC (all disciplines will be allowed); (3) have an office at the CBOC with a computer, (4) be willing to be randomized to a group receiving the computerized tool at the completion of training vs. a group receiving a hardcopy manualized protocol only; and (5)

must be willing to audiotape patients and participate in supervision. There are approximately 180 CBOC-based MH providers in VISN 16. **We will need to recruit a total of 34 MH providers** (or 19% of 180) for the training. We are confident that we can recruit 34 based on our previous experience and interviews with VISN 16 CBOC MH providers. (See preliminary studies above). For any provider interested in participating, we will offer a phone consult to describe the study in detail. Those who are interested in participating will be consented over the phone.

Aim 1: Veteran Participants

A total of 340 patients will also be recruited for Aim 1. Patients may be existing or new patients to the provider. Patients will be considered eligible if they: (1) are a veteran, (2) their Mental Health provider is a participant in this study; (3) their Mental Health provider has made a clinical determination that CBT is an indicated treatment; (4) the patients plan to continue to receive mental health care at the CBOC, (5) have depression, PTSD, or other anxiety disorder (PD, GAD, SAD), (6) are willing to receive CBT specifically, and (4) are willing and able to participate in clinical assessments (baseline, 3, and 6 months) by phone. Patients will be considered **ineligible** if they (1) have significant cognitive impairment, are in crisis (e.g., suicidal), or have a comorbid diagnosis of schizophrenia or psychosis.

Patients will be recruited one of two ways. First, MH CBOC providers participating in Aim 1 will provide each patient with a study information sheet inviting them to participate. This information sheet will contain research team contact information. Veterans who express an interest in participating and/or learning more about the study will be encouraged to contact the study team for more information or the veteran may provide contact information and a preferred day/time to their provider and the provider will give the information to the study team. The mental health providers will not be recruiting participants but rather providing information about the study and study team contact information. Only the research team will be involved in the recruitment of eligible Veterans. Veterans, who give their permission, will be contacted by a study team member (qualified research personnel) who will answer any questions about the study, and if interested, conduct the informed consent via the telephone and enroll the veteran into the study. Second, we will obtain a list of Veterans with diagnosis of anxiety or depression for each of the participating CBOC MH providers (through the use of VA administrative records). Veterans with diagnosis of depression, PTSD or anxiety disorders **under the care of the Mental Health provider participant** and for whom their Mental Health provider has made a clinical determination that CBT is an indicated treatment will be presented to the participating Mental Health Provider for review and confirmation that veteran meets eligibility criteria. After the MHP participant has confirmed the veteran is under their care and a good candidate, the study team will send the veteran an opt-out letter inviting them to participate. Veterans interested in participating in the study will be asked to contact study staff and if the veterans do not opt-out; the research staff will contact the veterans within 10 days of mailing the opt-out letter. If veteran meets inclusion criteria and agrees to participate, informed consent will be obtained via telephone by trained study staff. Both recruitment methods are needed to ensure we can meet recruitment goals. Veterans will be compensated $25 for the first assessment, $25 for the 3-month assessment, and $30 for the 6-month assessment (for a total possible of $80).

Aim 1: Screening Veterans for eligibility

In Aim 1, we have requested a waiver of informed consent for recruitment purposes to allow research staff to review potential participants' electronic medical record to determine eligibility prior to contacting participant and/or mailing opt-out letters. Screening will consist of reviewing (1) whether they currently have a diagnosis of depression, PTSD, or other anxiety disorder, (2)

review to identify if they have received CBT in the past (3) and/or does their MHP recommend CBT.
Patients will be considered ineligible if they (1) have evidence of significant cognitive impairment, are in crisis (e.g., suicidal plus current intent to harm oneself), (2) have previously completed a course of CBT or CPT treatment (patients who have previously had only one or two sessions of CBT or CPT will be allowed), or (3) have a comorbid diagnosis of schizophrenia or psychosis

Aim 2: CBOC directors

All MH providers who participated in the implementation trial will be invited to take part in a focus group at the end of the trial. In addition, we will recruit f 8-10 CBOC directors from those sites whose Mental Health providers participated in the trial and invite them to participate in a brief telephone interview (up to 15 minutes). CBOC directors will be identified via VA Mental Health Leadership, and invited to participate in Aim 2 via email and follow up phone call. We will also attend a CBOC director monthly call to discuss the project and invite directors to participate.

5.3 Informed Consent Procedures

Aim 1: provider and Veteran participants:
Mental Health Providers who express interest in this project will be contacted by study staff and after confirming eligibility and obtaining verbal consent to discuss this project, the study coordinator will describe the study purpose and interventions with the potential participant. Informed consent will be obtained verbally via telephone. We have requested a waiver of documentation of informed consent for this purpose. Likewise, Veterans who express interest in this project and meet eligibility requirements will be contacted by the study coordinator and (or the veteran may contact the study staff). Some potential participants will be referred to the Study Coordinator from their CBOC provider while some potential participants may be responding to an opt-out letter. We will access the veteran EMR via CPRS / CAPRI to screen for eligibility, the study staff will obtain verbal permission to discuss this project; the study coordinator (SC) will describe the study purpose and interventions with the potential participant. Again, we are requesting a waiver of documentation of informed consent as trained study staff will conduct the informed consent process via telephone.
Informed consent will be obtained before data collection occurs for either participant group. Patients with evidence of psychosis, dementia, and/or terminal illness will be ineligible to participate.

Aim 2: provider participants:
CBOC directors who express interest in participating in the interview will be provided an additional informed consent information sheet and informed consent will be obtained via telephone with qualified study staff. We are requesting a waiver of documentation of informed consent for the CBOC directors as we will not be conducting informed consent in person.

5.4 Inclusion/Exclusion Criteria

Patients will be considered **eligible** if they: (1) are a veteran, (2) their Mental Health provider is a participant in this study; (3) their Mental Health provider has made a clinical determination that CBT is an indicated treatment; (4) the patients plan to continue to receive mental health care at the CBOC or have a computer with a reliable internet connection, with a video camera,

microphone and speakers, (5) have depression, PTSD, or other anxiety disorder (PD, GAD, SAD), (6) are willing to receive CBT specifically, () are willing and able to participate in clinical assessments (baseline, 3, and 6 months) by phone. Patients will be considered **ineligible** if they (1) have significant cognitive impairment, are in crisis (e.g., suicidal), (2) are dependent on alcohol or drugs (substance abuse is allowed or (3) have a comorbid diagnosis of schizophrenia or psychosis.

All MH CBOC providers within VISN 16 will be invited to participate. All directors of CBOC sites with a MH provider participant will be eligible to participate.

5.5 Study Evaluations

Aim 1: Veteran participants will be asked to complete following questionnaires at each of three assessment points; Baseline, 3 month and 6 months:

Table 1 – Veteran completed research assessments (see Appendix C)

Instrument	Construct
Socio-Demographics	18 items that measure socio-economic and military characteristics
Readiness Ruler	3 items that assess perceived readiness to seek treatment
SF-12 Patient Questionnaire	12 items addressing overall physical and mental health functioning
BAM	Brief Addiction Monitor (BAM)
PHQ9	9 item inventory that yields a continuous and dichotomous assessment of depression
GAD7	7 item inventory that yields a continuous and dichotomous assessment of generalized anxiety disorder
APA_DSM5	Severity Measure for Panic Disorder
PCL-5	17 item inventory that yields a continuous and dichotomous assessment of PTSD
*Perceived Access Inventory**	Perceived access instrument developed by CREATE Project 1
BSI 18	18 items gather patient-reported data used to measure psychological distress and psychiatric disorders

The Veteran assessments will be conducted via telephone; however, for those Veterans who are hard to reach for the follow up assessments we will send the follow up questionnaires via US mail and ask them to return via US mail. We will provide the Veterans postage paid envelopes with instruction to complete the survey and not include their name or any identifying information on the assessment form or the postage-paid envelope.

Aim 1: Fidelity Assessments: Implementation fidelity of CBT is our primary outcome**.** Consistent with the recommendations of Sharpless and Barber (2009),[24] a multidimensional approach to measuring fidelity is taken. We will use the fidelity rating scales employed in the CALM study 49 in which fidelity is rated on a 1 to 7 scale using multiple items spanning three domains: protocol adherence, protocol competence, and global competence. Although separate ratings will be completed for each of these three domains, they will ultimately be combined to create a single measure of fidelity. We will add a fourth domain (non-adherence) developed just for this study. We felt this additional measure would be useful in identifying incidents of serious non-adherence to the model. This measure will be analyzed separately as a possible covariate for patient outcomes (see Appendix D).

Rater Selection, Training, and Procedures. Raters will be doctoral level CBT experts who either attend or review an audio recording of the training workshop for study therapists (to be named). They will also be provided with the treatment manual. To establish initial inter-rater reliability each of two raters will independently rate an audiotape of a session and share their item-by-item ratings to determine a consensus rating for each item when discrepancies are found. This procedure will be repeated for a minimum of two sessions and until a percentage agreement on items ≥80% for achieved.

Ratings. Fidelity assessments will focus on therapy sessions delivered early and late in the project. Fidelity for the first patient (of 3) will be assessed and used to control for initial group differences in multivariate analyses. We expect each patient to complete up to 8 sessions. Fidelity will be assessed only for patients who have attended at least four sessions. The first and last two patients receiving at least four treatment sessions from each provider will be selected to have all of their treatment sessions rated for fidelity. Fidelity for the last 2 (of 3) patients for each provider is our primary outcome measure. A single overall fidelity rating will be completed for each of these patients' last 3 sessions. A minimum of 5% of the total sessions being analyzed will be randomly selected to be rated by both raters to characterize inter-rater reliability. Average absolute agreement will be established using 2-way, mixed model intraclass correlation coefficients (ICC) on individual items and summary (i.e., mean) scores. Inter-rater reliability for the non-adherence items will be calculated separately.

Aim 2: All MH providers who participated in the randomized implementation trial will be invited to take part in a focus group at the end of the trial. In addition, we will invite a total of 8-10 CBOC directors from those sites who participated in the trial to participate in a brief telephone interviewSee draft interview guide.

5.6 Data Analysis

Aim 1: Analysis Plan

Analysis plan for hypothesis 1a. MH providers will be the unit of the intent-to-treat analysis for hypothesis 1a. The dependent variable will be the composite fidelity score from each provider's last three patients. The composite score will be calculated as the mean of the three scores. A dummy variable representing treatment group assignment will be specified as the explanatory variable of interest. An alpha significance level of 0.05 will be used to reject/accept the null hypothesis. The hypotheses will be tested using a standard logistic regression model. Three covariates will be specified to control for differences across providers. To choose the covariates, we will first examine differences in the characteristics of providers across the intervention and control group and include those characteristics that differed with a $p<0.2$. If no group differences are observed in the characteristics of the providers, we will control for: 1) previous CBT experience and 2) length of time in clinical practice.

Power Calculation: The power calculation takes into consideration analyses involving comparisons of means and proportions. In making these power calculations we assume that 2 providers in each group (4 total) will either "drop out" of the project, change jobs, or leave VA employment, leaving us with a sample size of 30. With a sample size of n=30 providers, we will have an 84% power to detect a large effect size (Cohen's *d*=1.0) in mean treatment fidelity based on all sessions from each provider's last three patients. This calculation assumed a 1.2 point difference in mean fidelity between the intervention and control groups, a pooled standard deviation of 1.2, alpha=0.5, and a two-tailed test of significance. This calculation assumed a conservative (i.e., lower) estimate of fidelity for the intervention group (5.2 of 7) compared to previous data [27], places the mean of the control group at the minimally adequate rating of 4, and assumes larger standard deviations in the fidelity of providers not using the computer-based fidelity assistant (s.d. = 2.0 versus 1.0). With a sample size of n=30 providers, we will also have 88% power to detect a 35% difference (85% versus 50%) in the proportion of providers maintaining minimally acceptable treatment fidelity (≥4) between the intervention and control groups based on all sessions from each provider's last three patients. This calculation assumed 0% attrition rate, alpha=0.05, and a two-tailed test of significance.

Analysis plan for hypothesis 2b. Veterans will be the unit of intent-to-treat analysis for hypothesis 2b. The primary outcomes will be the continuously measured BSI and SF12V scores at baseline, 3, and 6 months. These are generic measures that are appropriate for all participants.

Primary outcome analyses. A dummy variable representing treatment group assignment will be specified as the explanatory variable of interest. An alpha significance level of 0.05 will be used to reject/accept the null hypothesis. We will use mixed models and included data from all completed research assessments.[25] Casemix variables will be selected using the method of purposeful selection.[26, 27] Casemix variables with missing values were imputed using the PROC MI procedure in SAS9.3. PROC GLIMMIX will be used with the PROC MIANALYZE procedure to model the continuous outcomes measures (i.e., BSI and SF12V MCS). Time will be included as a fixed effect with baseline specified as the reference group. The model specifications will include main effects for group and time (with the control group assigned as the reference group), and interaction effects for group by time. The group by time interaction effects will be used to test the hypotheses that the rate of improvement differed across the two groups. Because there will be multiple group by time interaction terms, an omnibus test will be used to determine whether these variables collectively explained a significant amount of the variance in the dependent variable.[28] If the omnibus test is significant at the conservative alpha <0.10 level, we will report group differences and significance tests for each time period. Otherwise, we will report group differences averaged across the time periods and one significance test. The

clustering of patients within providers may require that the regression error term be correlated across patients within the same cluster. Significant intra-class correlation violates the independence assumption of standard regression models and may cause underestimation of coefficient standard errors, possibly leading to incorrect inferences concerning the rejection of the null hypotheses. Therefore, the first step of the statistical analysis will be to test for lack of independence among observations within clusters using intra-class correlation coefficients at provider level. Specifically, using a likelihood ratio test, we will compare the -2log likelihoods for an unrestricted model to a model that restricts the intra-class correlation to be zero. Raudenbush recommends that unconditional models (i.e. without explanatory variables) should be estimated prior to considering conditional models (i.e., with explanatory variables).[29] If it turns out that the -2log likelihoods are not significantly different, the mixed models will be specified to account for nesting at the provider level. The variance-covariance matrix will be specified to be unstructured.

Power Calculation for primary outcome analysis: It will not be necessary for patients to complete a full course (8 sessions) of CBT in order to be included in the study so we expect minimal “drop out” of patients. The power calculation must take into account the clustering of patients with providers. Prior psychotherapy RCTs have found intraclass correlation coefficients (ICC) to vary widely (range 0 to 0.73) with a mean of about 0.08.[30] We based our power analysis on a slightly conservative ICC of 0.10. With a sample size of n=300, we will have 85% power to detect a medium effect size (Cohen's *d*=0.5) for our primary outcome (BSI).[31] This calculation assumed a 5-point difference in MCS scores between the two groups, a pooled standard deviation of 10, 15% attrition rate, ICC=0.10, alpha=0.05, and a two-tailed test of significance.

Aim 2: Data Analysis plan

Data Analysis: The focus groups will be audio-taped, transcribed, and co-analyzed by Drs. Curran, Cucciare and Abraham using "traditional content analysis" techniques which are largely inductive.[32]Drs. Curran, Cucciare and Abraham will code the qualitative data together. Coding is analogous to developing a book index, with coders linking blocks of text to a code or group of codes.[33, 34] In general, we will note patterns that seem salient due to their recurring nature (both within and across interviews) or the extent of responses devoted to them. We will divide the data-coding process into 4 steps:

1. Data Management: We will enter verbatim interview transcripts into a qualitative data analysis software package (MAXQDA) that enables researchers to mark blocks of text with thematic codes and explore relationships among codes and between codes/participant groups.

2. Open Coding: Drs. Curran, Cucciare and Abraham will review the interview guides and transcripts line-by-line and begin to identify key emerging themes. This open-coding approach allows us to discover themes that appear regularly, leading to development of initial “top-level” codes.[35]

3. Top-Level Coding: After coming to consensus on the top-level codes (key themes/categories); the investigators will then apply these codes to the focus group and interview transcripts (2-3 transcripts each depending on the number of focus groups completed). To ensure coding reliability and consistency, Drs. Curran and Abraham will review one another’s work and discuss and resolve differences.

4. Subcoding: After completing top-level coding, Drs. Curran, Cucciare and Abraham will subcode those top-level codes that are “grounded” (i.e., associated with repeated quotations/discussions), using the same methods described above for top-level coding. Subcoding entails further refinement of the broad constructs represented by the top-level codes into subcategories.

5.7 Withdrawal of Subjects

Although we do not foresee any circumstances under which subjects with be withdrawn from the research without their consent, there is a possibility that participant may be deemed cognitively impaired, at which point we will withdraw them from the study. Withdrawing from the study at any point in time will not impact care or treatment at the VA.

6.0 Reporting

The PI or designee will be responsible for evaluating any adverse events or serious adverse events and submitting the appropriate reports to the CIRB within 5 working days after being made aware of the occurrence. The PI will evaluate whether a participant in the study should be discontinued from further participation in the study, for safety reasons. The PI and study staff will respond immediately to all directives from the CIRB or VA concerning the protocol and the continuation of the study.

We will consider unanticipated problems or events that place participants at a greater risk of harm or discomfort than was previously known or recognized as adverse events. Stable, chronic conditions that are present prior to the study and do not worsen will not be considered. Given the nature of the study, the following adverse events are possible: discomfort or distress during primary data collection and breaches of confidentiality for data collected from participants and from databases. Should such adverse events be observed by or reported to members of the study team, research staff will take appropriate action, reporting the events to Dr. Cucciare, who will then report to the VA CIRB and CAVHS R&D Committee according to VHA policies.

If a participant experiences any distress during data collection, study staff will inform the participant that they can take their time, ignore questions they do not wish to answer, and that data collection can be stopped at any time. Breaches of confidentiality are not anticipated given the commitment and experience of the PI and study staff/investigators; however, if this occurs the PI will follow VHA, federal and institutional requirements for reporting. All reports will be submitted to the VACIRB.

Primary responsibility for regulatory compliance and monitoring adherence to the protocol resides with the Principal Investigator, Dr. Michael Cucciare. He will ensure that all members of the research team involved in human subjects research have successfully completed mandatory VA human subjects protection, good clinical practice and privacy policy training and understand their responsibility for reporting 1) adverse events or unanticipated problems to the PI immediately and 2) any incident involving the potential for lost, stolen or compromised research data to the PI and to CAVHS’s Information Security Officer/Privacy Officer within one hour after the incident has been identified.

Data and Safety Monitoring Plan
The PI will be responsible for assuring that all elements of the DSMP are followed. He will also be responsible for notifying HSR&D should the Central IRB suspend the study for any reason or length of time. During regularly scheduled weekly meetings, project personnel will discuss study progress, including recruitment; conduct of interviews; protocol adherence problems, if any; and any adverse events that may occur.

Safety of participants: Veterans who receive the baseline, 3-month and 6-month assessments will complete a 20-40-minute individual telephone interview. For those hard to reach Veterans, we will send the Veteran Assessments via US mail using only their Study ID on the actual assessment forms. For Veteran participants, the intervention activities pose little, if any, risk to participants, as described above. All interviews will be conducted via telephone. If participants feel tired during the interview, they can take a break or discontinue study participation at any time. We will take every precaution to ensure Veteran participant confidentiality and especially, to avoid disclosing Veterans' identity as individuals who have used VA mental health services.

Accuracy and integrity of the data:
MHP/CBOC participant qualitative interviews: All interviews will be audio-recorded. Hard copies of documents will be stored in a locked file cabinet in a locked location at CAVHS HSR&D offices. Digital recordings will be uploaded to a restricted-access folder on the password-protected CAVHS HSR&D server. Before erasing the interview from the digital recorder, Dr. Abraham will confirm the completeness and integrity of the saved audio-recording. The audio-recordings for each interview will be transcribed verbatim. Dr. Abraham will systematically review the transcript for completeness and accuracy. She will correct any errors or omissions in the transcript before it is entered into the qualitative data management system.

Veteran Quantitative data collection: Data will be collected using a Microsoft ACCESS database. Direct data entry via Microsoft Access and inclusion of "not applicable/doesn't know" and "refused to answer" response categories will minimize the likelihood of unintentional missing data. Site RAs will collect interviewer-administered questionnaire data using these programs on a desktop computer connected to the VA network.

The Data Safety and Monitoring Plan will capture Serious Adverse Events (SAEs), i.e., death, hospitalization. It will also capture Adverse Events (AEs), i.e., suicidal or homicidal ideation, expression of severe distress, other serious psychiatric or medical symptoms. The Data Safety and Monitoring Plan will utilize the following categories in determining the severity of an event:

A. Classification of Event Severity: Events will be labeled according to severity which is based on their impact on the patient. An Event will be termed 'mild' if it does not have a major impact on the patient, 'moderate' if it causes the patient some minor inconvenience and 'severe' if it causes a substantial disruption to the patient's well-being.

B. Event Attribution Scale: Events will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled either probably, possibly, or unrelated to the study intervention.

C. Expected Risks: This study includes no invasive procedures or medications. All changes to patients' treatment will be known to their MH care team.

(1) Breach of confidentiality associated with reporting suicidal or homicidal intent to appropriate authorities or health personnel

(2) Severe distress as indicated by: (a) an increase of more than one standard deviation from their mean score on the PHQ-9 during follow-up assessments, (b) patient verbal report of a serious psychiatric distress at follow-up, (c) patients reporting significant distress due to the content of the self-report measures, or (d) patients reporting significant distress due to the content of CBT. In each case, the research personnel will consult with the PI to determine whether the participant's distress is significant enough to warrant an AE.

(3) Suicidal ideation will be indicated by: (a) self-report of significant suicidal ideation on the PHQ-9, or (b) verbal report of thoughts of suicide. Even for those who report suicidal ideation on the PHQ-9, determination of suicidality will be based on a combination of the self-report information and the interaction between the research personnel and the participant. The research personnel will be trained to identify and address suicidal ideation in patients. If the patient articulates thoughts of death or suicidal ideation, the study team member will ask the patient to elaborate on recent suicidal thoughts/behavior (e.g., does the patient have a suicide plan). The situation will be based on the patient's responses and whether the study team member perceives that the patient is in immediate danger (e.g., an active plan verbalized). Study personnel will follow established safety protocols and contact local licensed clinical staff when appropriate. Also, the study PI Dr. Cucciare is well-suited to manage clinical situations involving the expression of intent to harm oneself as he is a licensed clinical psychologist in the State of Arkansas.

(4) Homicidal ideation will be indicated by verbal report of thoughts of hurting others in general or harming a specific individual. The study does not directly ask about homicidal ideation but this information may be provided by a participant during an interaction with study team members. This protocol will be similar to that for suicidal ideation. Specifically, the research personnel will be trained to identify and address homicidal ideation in patients. If the patient articulates thoughts of hurting others, the study team member will ask the patient to elaborate on his/her thoughts/behaviors (e.g., does the patient have a plan or specific target?). The situation will be based on the patient's responses and whether the study team member perceives that the patient or someone else is in immediate danger. Study personnel will follow established safety protocols and contact local licensed clinical staff when appropriate. Also, the study PI Dr. Cucciare is well-suited to manage clinical situations involving the expression of intent to harm another person as he is a licensed clinical psychologist in the State of Arkansas.

(5) Given the study population, it is possible that participants will report other serious psychiatric or medical symptoms. Research staff will be trained to monitor significant abnormal behavior and/or report that the patient perceives him/herself to be in imminent need of medical treatment. If it is determined that the patient requires immediate care, the research staff will coordinate access to appropriate services.

Triggers to action will be the participant's expression of severe distress, suicidal or homicidal ideation, and/or other serious psychiatric or medical symptoms. Research staff will be trained and prepared for situations in which a participant expresses severe distress. Specifically, all project staff will have been trained on VA's suicide risk assessment and response guidelines, including the capability of directly connecting suicidal participants to the 24-hour VA suicide hotline, as well as arranging with local psychiatry crisis management staff to assess and potentially hospitalize the patient. Subsequent to any participant's expression of severe distress, ideation, or other serious symptoms, project staff will make all reasonable attempts to re-contact the participant to monitor his or her well-being until the acute situation is resolved.

Research staff will also be trained and prepared for situations in which a participant not currently in addiction treatment reports severe alcohol misuse, e.g., A blackout, delirium tremens, alcohol-related injury). Such individuals will be protected by having research staff provide a referral to substance use disorder treatment at the VA closest to where they are residing. If the VA is rejected by the participant for any reason, project staff will utilize SAMHSA's (the federal agency within HHS that funds most non-VA substance use disorder treatment) online substance abuse treatment facility locator to provide a referral.

7.0 Privacy and Confidentiality

We will use Protected Health Information (PHI) for this study. PHI will not be disclosed to anyone outside of the PI and study Co-I's and research team members involved with data collection and management.
Digital Voice recordings, Mental Health Providers will audiotape their sessions with veteran participants with a digital recorder and upload these recordings directly to a secure folder on the HSR&D drive located in Little Rock. This drive is behind the VA firewall. Upon verification of a successful upload, the recording will be erased from the recorder. We will use only government issued, ISO approved devices that are FIPS compliant per VHA policy.

All PHI and final data collected for this study will be managed and housed at the Center for Mental Healthcare and Outcomes Research (CeMHOR), located at CAVHS in North Little Rock. CeMHOR has a centralized server and mass data storage device that is fire-walled, encrypted, and backed-up daily; two information technology specialists to ensure data security and integrity; networked personal computers for all personnel; and statistical, publishing and database software for data management and analysis. Relevant to data storage and safety, access to local Windows Active Directory Domain Controllers, a UNIX NIS Server and Network Appliance storage facilities are available. These resources allow large amounts of research data to be stored and analyzed within a secure environment, while still connected to VA computing resources. Network infrastructure and connectivity are maintained by the Shared Computer and Resources Facility (SCARF) that serves CeMHOR.
All source documents and hard copy records will be kept in a locked cabinet in a locked room in building 58. Only authorized research staff will have the key to the locked cabinet. All electronic records will be kept on maintained, encrypted VA servers housed in building 58. All files and folders will be password protected. Research Investigator files will be destroyed six years after the end of the fiscal year when the research project has been completed per Records Schedule

DAA-0015-2015-004. The ISO/PO will be notified within one hour if data loss or misuse is discovered.

Ethics:

The protocol and all related documents shall be approved by the IRB and R&D Committee prior to enrollment of any subjects. The informed consent process shall be conducted only by appropriately qualified study personnel. Subject privacy and confidentiality shall be respected by all study personnel.

8.0 Communication Plan

The research team will regularly meet to discuss the study's progress and address any adverse events or unanticipated issues. The study coordinators will be in continuous communication as they coordinate screening, data collection and management. The Study coordinators will be in direct communication with the PI, Dr. Michael Cucciare, to remain up to date on the study protocol and to ensure that any serious adverse events or unanticipated problems are reviewed and reported appropriately.

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