Veteran Peer-Assisted Computerized Cognitive Behavioral Therapy for Depression

NCT02057042

September 4, 2019

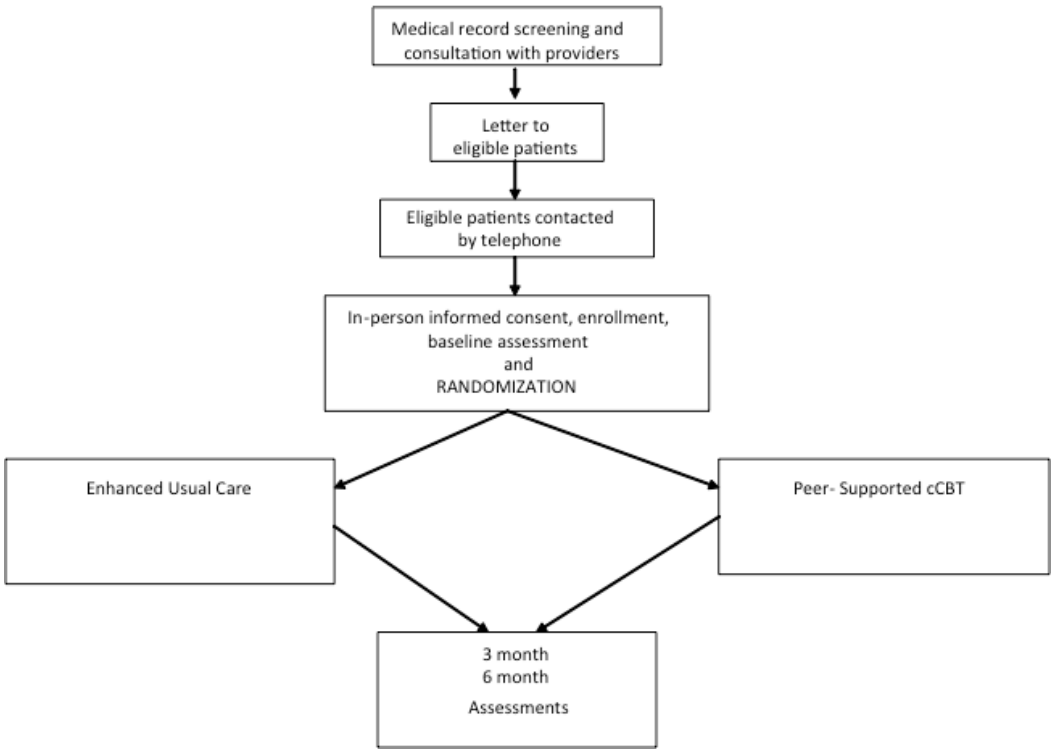
E. RESEARCH APPROACH/METHODS

E.1 Study Design This will be a Hybrid I randomized controlled trial (RCT) of peer-supported cCBT (PS-cCBT) compared to enhanced usual care (EUC) among Veterans with new diagnoses of depression in primary care. Patient assessments will occur at baseline, 12 and 24 weeks following enrollment.

(Study flow of the RCT is shown in Figure 2.)

Concurrent with the RCT, we will collect administrative and qualitative data that will allow us to better understand the context and process of the PS-cCBT implementation including barriers/facilitators to patient recruitment, integration of the peer specialist into the Primary Care-Mental Health Integration team, challenges and successes in maintaining contact with patients, and patient perspectives of peer specialist calls and cCBT content and helpfulness.

Figure 2: Overall Study Flow



E.2 Study Sites and Patient Population

We have chosen our study sites, Ann Arbor, Battle Creek, Detroit), to ensure adequate numbers for the study (estimated at 330 patients, see below), patient diversity and inclusion of rural and urban areas.

All study VA medical centers have a full range of services, including primary care clinics and comprehensive (inpatient and outpatient) mental health services. These three medical centers also have a total of 9 associated Community Based Outpatient Clinics (CBOCs). The John D. Dingell VA Medical Center in Detroit is located in a highly urban area and serves a large number of African American Veterans; whereas, many of the CBOCs from Battle Creek serve rural areas.

During FY 2010, the three study sites (Ann Arbor, Battle Creek, and Detroit) and their associated CBOCs served 6,283 patients who met criteria for a new depressive episode, of which 3,312 were diagnosed with new episode of depression in primary care. Approximately, 11% of these patients were women, 25% were aged 44 or younger, 53% were ages 45-64, and 22% were ages 65 or older. Of patients with known race, 27% were African American. In prior RCTs conducted in several of these study sites, we were successful in recruiting 17% African Americans and 20% women. Thus, we have been quite successful in recruiting women and have also recruited African Americans in proportion to their percentage nationally (18%) of the VA patient population with depression diagnoses.(11)

E.3 Patient Eligibility Criteria

We have deliberately made our inclusion criteria for this study broad and our exclusion criteria narrow to increase the generalizability of our findings to VA primary care patients with new depressive episodes.

Patients will be eligible for the study if they: 1) have been diagnosed with a new episode of depression in primary care at any of three VA study sites or associated CBOCs; 2) have a current PHQ-9 score $\geq$ 10; 3) are not receiving mental health care outside of VHA; 4) have broadband internet access at home or confirm

willingness, ability, and a plan to go to their VA or library to complete cCBT modules; 5) have familiarity with email and internet use (see below); and 6) have stable access to and ability to communicate by telephone.

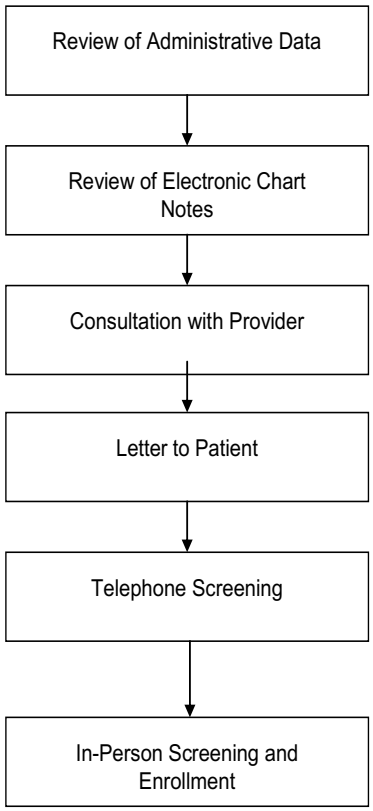
We will assess patients' familiarity and self assessed comfort with the internet with questions such as "How frequently do you use the internet?" and "How often do you email?". Our threshold for being computer familiar will be relatively low, requiring only that individuals have an existing email account that they access at least once per week. In our pilot work, we found patients who met these criteria had a higher likelihood of completing the cCBT modules.

We will **include patients who have suicidal ideation** that is not immediately threatening. Suicidal ideation is common among patients in treatment for depression. Approximately 30-50% of patients in depression treatment endorse some level of suicidal ideation, although only 2-3% are a current suicide risk.(56) Peer specialists will follow the protocol used within their facility mental health services when patients confide suicidal thoughts. These protocols are clearly outlined for all staff at each of these facilities, and will be reviewed with study peer specialists during their training. The protocol for research staff when patients divulge suicidal thoughts upon screening is outlined below.

We will also **include patients in the study who are starting an antidepressant medication** as this is the de facto treatment nationally in VA primary care settings for depression and also for our three study sites, with 70% of VA patients with new episodes of depression filling at least one antidepressant prescription. (See section E.6.a.) Prior studies of Beating the Blues (BTB) indicate there is no interaction between cCBT program use and either antidepressant treatment or depression severity. Benefits from the BTB and antidepressant medication have been additive. (35) However, we will consider whether a patient has filled an antidepressant prescription in our randomization scheme.

Exclusion criteria for the study will be narrow and include: 1) a diagnosis of schizophrenia, schizoaffective disorder, MDD with psychotic features, or Bipolar I in the past 12 months; 2) a positive screen for moderate or severe substance use in the past 6 months (per DSM 5); or 3) an immediate risk of suicide, requiring hospitalization or urgent evaluation (as evidenced by suicidal plan or intent).

Figure 3: Patient Identification and Screening



E.4 Patient Recruitment

Pharmacy data, patient diagnoses and CPT codes from outpatient visits are updated nightly from VISTA to the Corporate Data Warehouse (CDW), and study analysts have extensive experience in using these data. We will use these administrative data for preliminary identification of patients who may have new diagnoses of depression made in primary care. As in our pilot work, at this preliminary stage we will identify patients who may have new episodes of depression in primary care as those with at least two diagnoses of depression or one depression diagnosis accompanied by an antidepressant fill within 120 days of the diagnosis and *no prior depression diagnoses or antidepressant fills within 120 days* of the index date of their depression diagnosis. Patients must also have no diagnoses of schizophrenia, schizoaffective disorders, Bipolar I disorder, or major depression with psychosis in the prior year.

We will use the ICD-9 codes for depressive disorders that are used in the National Depression Registry to identify potentially eligible patients.(11) Patients will be identified in all of the study facilities' primary care clinics, not just PC-MHI clinics, as only a minority of primary care patients with depression are currently seen in PC-MHI. Patients who are not seen in PC-MHI are also less likely to be offered any psychotherapy option.

After identification of potentially eligible patients via administrative data, we will review patients' electronic medical records to assess whether they meet additional study eligibility criteria (e.g. no mention of use of mental health care outside of the VHA in charts, no exclusionary diagnoses in chart notes, etc.)

Our study team has had extensive experience in conducting chart reviews for purposes of eligibility screening. As in several of our past studies, chart reviews will be assisted through the use of EMERSE, a

"Google-like" system for the electronic medical record, developed by David A. Hanauer MD. We have used EMERSE in several HSR&D studies to rapidly screen patients for study enrollment. EMERSE maintains an audit trail and has an easy to use, intuitive search engine for free-text documents. Use of EMERSE speeds chart searches markedly and provides a more consistent, accurate and objective method of abstracting.(57)(58)

After identifying potentially eligible patients, we will briefly consult with patients' primary care clinicians to confirm that there are no clinical contraindications to study participation. *(*Our co-investigators at each site will assist in educating clinicians about the study and advocate for cooperation and assistance in recruiting patients.)

Letters will then be sent to potentially eligible patients, informing them about the study. Patients will be given a phone number which they can use to contact study staff and either indicate their interest in the study or their wish to "opt out" of further contact. If patients have not contacted study staff within7 days of the mailing, staff will telephone patients to further describe the study, answer questions, and assess patients' interest in participating. Research personnel will make several attempts to contact patients, calling at different times of the day.

Patients who are interested in the study will be screened for current severity of depression symptoms using the nine-item Patient Health Questionnaire (PHQ-9). The PHQ-9 has high levels of sensitivity and specificity for major depressive disorder, can be used over the telephone, and quantifies depression severity.(59)(60) Patients with PHQ-9 scores $\geq$ 10, who are not receiving mental health services outside of the VA and who have broadband internet access will be eligible for the study.

Patients who endorse suicidal ideation on the PHQ-9 will be asked additional questions from a structured screener assessing suicidal history and current intent or plan. For patients who meet predetermined criteria on this screener, appropriate action plans are specified. (See suicide screener and action plans in Appendix A.) A similar telephone screener has been in place and successfully used in team members' prior RCTs. When staff who are screening identify patients deemed at higher risk for suicide, study clinicians or the patient's personal clinicians have been able to contact the patients in a timely manner for further evaluation and assistance.

Patients who remain eligible after telephone screening will be invited to an in-person interview at their local VA facility or CBOC. At this appointment, potential enrollees will learn more about the study and complete the informed consent process. Those patients agreeing to study participation and providing written informed consent will be randomized to either PS-cCBT or EUC. Patients will also complete their baseline assessments at this time, using Qualtrics, to familiarize them with use of this online data collection platform as their follow up-assessments will be conducted using this platform. (See section G.3.)

If the patient is randomized to PS-cCBT, the peer specialist will attend part of this interview to be introduced. If this is not logistically possible, research staff will introduce the peer specialist via video-conference on a secure internet connection.

Based on our work in the DIAL-UP reciprocal peer support study, we expect to be able to recruit approximately 1-2 patients at each site per week (3-6 per week total) for the PS-cCBT study.

At the time of our first in-person patient contact, we will begin our efforts to *retain* enrolled patients. During the initial assessment, patients will be asked to supply the names, phone numbers, and addresses of at least two family members, friends, or acquaintances—and give consent for staff to contact these individuals should we lose touch with the patient. As noted below, for the first 12 weeks, patients in the control condition will be receiving bi-weekly mailings giving depression self-management tips and patients in the PS-cCBT condition will be receiving peer specialist calls. These regular contacts will help maintain patients' connection to the study. We will also send an additional mailing with study updates and logos to all patients at 18 weeks to help maintain a connection to the study and increase willingness to complete the final assessment. When needed, research staff will also check patient appointments and admissions to meet directly with patients near their scheduled assessment times.

We note that with similar procedures, we have been able to maintain a follow rate of $\geq$85% in prior RCTs even over longer time frames.

E.5 Patient Randomization

Eligible patients will be randomized to either enhanced PS-cCBT or to EUC. Random assignment will be coordinated and completed centrally at the study coordinating site to ensure that the RAs and clinical staff will not able to determine the likely treatment assignment for the next enrollee. Randomization will be stratified by study sites, and to increase balance in prognostic factors between groups, minimization will be used for

randomization within each site. Factors to be included in minimization will include: 1) age group (≥55 vs. <55), 2) gender, 3) antidepressant medication fill in prior 90 days vs. not, and 4) depression severity (PHQ-9 ≥ 15 vs. <15) at time of baseline measures. Minimization method allows balancing on multiple factors, and we will utilize MinimPy, a free open-source, desktop minimization randomization program in this study.(61)(62)(63)

E.6 Study Groups and Intervention Description

The PS-cCBT intervention and enhanced usual care (EUC) will be delivered over 12 weeks. The Beating The Blues (BTB) program consists of 8 interactive modules and recommends completing one module per week. However, we will provide 12 weeks of peer specialist support for completion of these 8 modules. Table 3 lists the components that will be delivered in each of the study treatment arms.

Table 3: Components of Treatment Arms

Enhanced Usual Care	PS-cCBT Intervention
• Usual depression care • Patient education regarding treatment options, including antidepressants and evidence-based psychotherapies • Bi-weekly mailings with depression self management tips and local resources • Notification to the primary care clinician at 12 and 24 weeks if patient shows significant clinical worsening	• Usual depression care • Access to cCBT program—Beating the Blues • Veteran peer specialist assigned • Peer specialist contacts at least once per week for 12 weeks (in-person or by telephone) to provide support and encourage cCBT participation and completion • Notification to the primary care clinician at 12 and 24 weeks if patient shows significant clinical worsening

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E. 6.a Enhanced Usual Care:

As outlined above, in 2010, primary care patients newly diagnosed with depression in the study primary care settings (AA, DET, and BC and associated CBOCs) received the following treatments. Approximately 70% received an antidepressant fill, and 51% of these patients (36% overall) had an adequate trial of antidepressant (84 or days supply of antidepressant in the 114 days after first AD fill). Approximately 22% of patients had one psychotherapy visit within 14 weeks of their depression diagnosis and 3% had 8 or more psychotherapy visits within the 14 weeks following their depression diagnosis.

We assume that usual care delivered to our EUC patients will be similar to that outlined above, although our enhancements to usual care may increase treatment use slightly. (We provide these enhancements to increase the credibility and acceptability of usual care for patients randomized to this arm, please see Section E.7.)

Patients randomized to EUC will receive the following enhancements: 1) patient education regarding the symptoms of depression and evidence-based depression treatments, 2) a copy of the Depression Helpbook by Wayne Katon and colleagues which provides basic information on depressive disorders, self-management strategies, and effective communications, 3) information about how to access local VA mental health depression treatment resources (groups, individual psychotherapy, etc), and 4) bi-weekly study mailings with depression management tips.

E.6.b Peer-Supported cCBT:

Patients in the PS-cCBT intervention will receive usual depression care described above and will also receive access to Beating the Blues (BTB), the cCBT program that currently has the most research support and is recommended by the UK National Institute for Health and Care Excellence (NICE). The 8-module BTB program will be supported by the peer specialists for 12 weeks. **(The peer support component for PS-cCBT is described below.)**

cCBT Program: Beating the Blues (BTB) program includes eight interactive therapy modules, each of which is approximately 50 minutes in duration. Patients are advised to complete one module per week. The program teaches both cognitive and behavioral strategies over the eight modules and is tailored to the patient's reported problems. Videos are used to elucidate presented concepts and homework is assigned and easily printed for reference and completion. The Beating the Blues program allows patients to flexibly stop and start modules. However, each module is designed to build upon the content in the preceding modules.

The program modules are: 1) Getting Started, 2) Goal Setting and Automatic Thoughts, 3) Common Thinking Distortions in Anxiety and Depression, 4) Changing Unhelpful Thinking, 5) Inner Beliefs, 6) Inner Beliefs (continued) and Attributional Style and 7) Attributional Style (continued), and 8) Conclusion and Coping with Setbacks.

The "Getting Started" module introduces the patient to the program and establishes the structure of all program modules. Patients learn about the symptoms of anxiety and depression and the Cognitive Behavioral Therapy model is explained. Video vignettes elucidate CBT principles. The patient is assisted in identifying his/her symptoms (which are input into the program) and targeting the problems on which they would like to work in the subsequent modules.

The second module, "Goal Setting and Automatic Thoughts", orients the user to the ABC (Antecedent-Behavior- Consequence) model and the concept of "automatic thoughts." Patients learn how to catch and record their automatic thoughts in an attempt to gain greater control over their intensity, duration, and impact. They also start to work on behavioral strategies such as activity scheduling. In the third module, "Common Thinking Distortions in Anxiety and Depression", patients learn about common thinking errors and how to recognize the type of errors that they most commonly make. They are also taught to use controlled breathing techniques to manage more intense emotions and are encouraged to work on their behavioral activation strategy.

The fourth module, "Changing Unhelpful Thinking", begins with a review of the previous session's assigned homework. Patients are then introduced to four techniques to challenge their negative thoughts. These techniques are then modeled in video vignettes. Patients are again encouraged to continue using the behavioral strategies they learned in session two.

The fifth module, "Inner Beliefs", orients the patient to "inner," or "core beliefs". They are encouraged to use their own experience as evidence against negative, inaccurate core beliefs. They are also coached again on earlier behavioral strategies. The sixth module, "Inner Beliefs and Attributional Style", continues to provide the patient with strategies for gathering evidence that does not support their maladaptive inner beliefs and to replace it with more helpful ones. They also learn about attributional style and its impact on affect. Finally, patients are provided a choice of three new behavioral strategies on which to work (i.e., Sleep Management, Graded Exposure, and Task Breakdown).

The seventh module, "Attributional Style, continued" teaches strategies for modifying one's attributional style. Patients also continue to work on the new behavioral strategy they chose in Module Six.

The final module, "Conclusion and Coping with Setbacks", completes the program by providing a review of the materials and concepts in the first seven modules. Progress towards the patient's goals that were recorded at the beginning of program are reviewed. Patients are also helped to develop an action plan that incorporates the new strategies and techniques they have learned from the program. They are encouraged to think about and prepare for setbacks and to repeat previous cCBT modules if desired or needed.

Other BTB Functions: Besides providing interactive CBT content, the Beating the Blues program provides a variety of tracking, assessment, notification and reminder functions. **For patients**, the program provides feedback on modules that have been completed, provides selective tailoring of modules based on patient input, and sends e-mails reminders to patients when the next BTB session is due.

BTB also allows the **supervising clinician and/or program administrator** to embed selected questionnaires in the 8 interactive modules for clinical purposes. The administrator can determine the frequency with which the selected questionnaires are presented to patients (e.g., every module, every other module, etc.) and the juncture within the module at which questionnaires will be presented (pre- or post-module CBT content). **Please note that these questionnaires are used for clinical purposes to allow patients to self-monitor and to allow the overseeing clinicians to monitor patient progress and contact individuals who are not responding or engaging in the program.** We will likely embed the PHQ-9 and GAD-7 in every other module for these clinical purposes.

(We note that study assessments will be completed on-line separately using the Qualtrics platform at baseline, 12, and 24 weeks following enrollment. Patients will receive incentives for completing study assessments on Qualtrics but will not receive incentives for completing program questionnaires which are part of the clinical cCBT program.)

The Beating the Blues program also allows for queries about whether the user has had any suicidal or homicidal thoughts, and if so, the seriousness of their intent on a 0 through 8 scale. The administrator can determine the level of severity that would prompt immediate notification. The BTB program also allows information to be presented regarding local crisis services and emergency phone numbers to further assist

users who might be in crisis. In this study, we will include phone numbers for the relevant local VHA clinical services, clinically trained research staff, and for the VA Crisis Line.

Peer Specialist Support of BTB: Peer specialists will assist patients in initially accessing the BTB program. They will also call patients weekly for the first 12 weeks following enrollment to support completion of the 8-module cCBT program. In all patient interactions, the peer specialists will be supportive, encouraging cCBT participation while respecting patient autonomy and not focusing solely on cCBT completion. Participants will be also be able to contact their assigned peer specialist between "check-in" calls if they would like additional peer support or assistance.

Training: As in our pilot study, part of the VA peer specialists' training will include completing the BTB program themselves under the supervision of VA study psychologists. Peer specialists will review the modules in real time with the psychologists and complete homework assignments with feedback. They will also review the sections of the VA peer specialist manual that are most relevant to supporting patients in their recovery journey in addition to the protocol for serving as a supporter of cCBT. Peer specialists will receive additional training on identifying situations in which study staff or health care providers should be contacted, including emerging risk factors for suicide. Peers will also review with study psychologists their facility's specific protocol for dealing with suicidal crises, including use of the Veterans Crisis Line.

Ongoing Peer-Specialist Activity and Supervision: Similar to a prior study examining the efficacy of technician support for an internet cCBT program for depression,(38) peer specialists will be given a guide to the topics covered in each BTB program module and a list of the goals and homework that each patient has generated as part of the program.(38) **The peer specialist will not provide clinical advice** but may talk about their own experience with BTB and how s/he handled homework in similar areas (i.e., identifying their own cognitive errors). If patients have more specific questions regarding CBT content, peer specialists will refer patients to the appropriate place in the cCBT modules where more information can be found or refer the patients' questions to their supervising psychologist. (Depending upon the circumstances, the psychologist may call the patient directly to answer questions or provide a written answer that can be delivered via email or through the peer specialist.) The peer specialists will also inform the supervising clinician of any perceived urgent issues in cCBT participants' mental health. They will complete templated notes in CPRS after their contacts with patients. These templates will include checklists for important elements covered during the calls (i.e, general social support, shared my recovery story, discussed cCBT program, technical issues, discussed Veteran's experience with cCBT module/or home practice, etc.) For further detail, please see draft template for progress notes in the PS-cCBT manual, Appendix B.) Peer specialist notes will all be countersigned by the their supervising clinician, at which point, the patient's primary care clinician may also be added as a co-signer.

Interactions with the PC-MHI Team: Peer specialists will be part of the Primary Care-Mental Health Integration (PC-MHI) team during the trial and will attend PC-MHI team meetings. At least one of their supervisors will come from the PC-MHI team.

We note that patients for this study will be recruited from primary care more generally rather than only from PC-MHI-- as only 9% of patients nationally and 12% of patients at the three study sites receive new diagnosis of depression in PC-MHI. However, once patients are enrolled into the study and randomized to the PS-cCBT program, they will be considered to be receiving PC-MHI services and "taken back" to the PC-MHI team. Peer specialists will discuss their interactions with the PS-cCBT patients with their PC-MHI supervisor, who will work in concert with Drs. Abraham and Nelson , who will oversee all peer specialist training and supervision across sites.

E.7 Alternatives, Methodological Issues and Rationale for Study Design Choices

Recognizing that there will always be limitations arising from RCT design,(64) several study design issues were considered as we formulated this proposal. Below, we outline why we made several key design choices, recognize other choices that might have been made, and discuss the trade-offs involved in our design decisions.

E.7.a Choice of Control Arm: We have chosen to use an **enhanced usual care (EUC) control group**. The level of support offered in the EUC offers credibility to this control condition, addressing potential issues with patient expectancy. However, it does not include an equivalent amount of "attention". We do not feel the lack of a full **attention control** raises issues in study interpretability because offering additional attention and monitoring in the form of supportive, low cost, peer specialist interactions is an inherent part of the intervention. We note that we will assess potential mediators that are specific to peer specialists interactions (i.e. reduction in self-stigma) rather than applicable to general non-specific attention.

We also could have compared PC-cCBT or cCBT alone to **traditional in-person therapy**; however, other comparisons were of more pragmatic interest. Even if traditional in-person therapy has larger effect sizes, it is expensive and logistically complex to deliver. Also, despite enormous efforts to bolster the capacity to deliver traditional in-person therapy, a small minority of Veterans with depression currently complete an adequate treatment trial. Thus, we were more interested in comparing a highly flexible treatment option (PS-cCBT) to usual care. PS-cCBT includes both basic psychotherapeutic content and a supportive relationship, and it may address issues that are currently barriers to completing in-person evidence-based psychotherapies, including therapist supply, travel difficulties, and patient time constraints.

Finally, we chose **not to restrict treatment options in usual care**, for example, by prohibiting antidepressant treatment, care management, or other psychotherapy. This decision was based on the ethical consideration of not depriving patients of any effective treatments that they might receive under naturalistic conditions. (Antidepressant medication is the default treatment in VA primary care, with 70% of patients with new diagnoses of depression receiving an antidepressant fill.) As prior studies of cCBT have shown no interactive effect of antidepressant treatment on cCBT effectiveness, study findings are likely to remain easily interpretable. We note that we deliberately consider antidepressant use in our randomization/minimization scheme. We also note that few individuals with new diagnoses of depression in primary care currently receive any definitive trial of psychotherapy.

As recommended when using enhanced usual care as a control group, we will carefully track and describe all care that patients receive during the study period.

E.7.b Choice of intervention arm: We chose the PS-cCBT as the intervention arm for several reasons. First, this intervention has synergies with ongoing operational initiatives within the VHA, providing evidence-based treatments for depression AND providing recovery-oriented services. cCBT is currently widely disseminated in the UK as an evidence-based option for depression care but needs to be supported to be most effective. Peer specialists, who constitute a rapidly growing workforce in mental health within the VHA, are ideal candidates to support this effort for reasons elucidated through out this proposal. Combining these initiatives allows us to examine, for the first time, a low cost, flexible and evidence-based treatment option (cCBT) supported in a manner that is likely to increase its effectiveness and promote patient recovery.

E.7.c Choice of location: Finally, although cCBT has been successfully piloted in specialty mental health settings and we included VA patients from specialty mental health in our pilot, we decided to focus on providing PS-cCBT for primary care patients. The body of work supporting cCBT's effectiveness for primary care patients is more robust than the literature on cCBT in specialty mental health settings. Also in our pilot, although patients in primary care showed similar reductions in depressive symptoms as patients recruited from specialty mental health, they rated the PS-cCBT intervention as more useful, relevant, and easier to use. Patients in primary care are also likely to receive fewer intensive psychotherapy services than patients treated in specialty mental health.

E.8 Patient Safety and Confidentiality Issues

E.8.a Patient safety: Threats to patient safety will consist primarily of lack of treatment response or worsening of depressive symptoms and the emergence of suicidal ideation or behaviors. We note that these threats can occur for all VA patients in depression treatment, including patients in both PS-cCBT and EUC. Patients enrolled in in either arm of this study will have all the access to depression care that is usually provided to VA patients plus additional safety precautions and monitoring. **Importantly, all study patients will continue to receive usual care from their treating clinicians and have full access to these clinicians throughout the study.**

Threats to safety of patients in this study may also arise from the study interventions. Specifically, patients in the PS-cCBT arm may become more distressed or symptomatic through working with the cCBT modules or through their interactions with peer specialists. To mitigate this possibility, all peer specialists will be supervised by clinicians who are part of the PC-MHI team, who in turn, will work in concert with Drs. Nelson and Abraham who will oversee peer specialists' training and activity across study sites.

Patients' clinical status will also be systematically followed in the BTB program through the use of standardized scales (an inherent part of this clinical intervention) so that clinical worsening will be readily identified. This level of symptom monitoring is as intensive as that provided in proactive care management. If patients' symptoms are increasing significantly over time (i.e. depression scores increase >25% from baseline at more than one follow up clinical assessment point), then the supervising clinician will contact the patient and discuss their treatment progress, treatment preferences, and options for increasing the intensity of treatment.

Also, at the end of PS-cCBT participation, patients who continue with problematic symptoms will be encouraged to progress on to more intensive treatments. Please note that, PS-cCBT is not designed to "replace" more intensive and proven interventions, such as face-to-face individual CBT, but to serve as a first intervention that may provide sufficient benefit but could also serve as a "stepping-stone" to more intensive care if needed.

Potentially, patients in the study may develop suicidal ideation. Again, this will be monitored as part of the cCBT program as often as in proactive care management. The cCBT program will include information about local emergency resources as well as the Veterans Crisis Line which can provide immediate assistance. Research staff will also be available in a timely fashion and will further assess the seriousness of any emerging suicidal ideation or behaviors within 48 hours. Patients' clinicians will also be informed and asked to follow up.

Study staff will have less frequent contact with EUC patients; however, if they become aware of significant suicidal ideation during the 12 week or 24 week assessments (follow-up assessments on the Qualtrics platform will be reviewed within 48 hours of receipt), study clinicians will again contact the patients for further evaluation and assistance and their usual care clinicians will be informed. The Qualtrics platform will also have information about local emergency resources and the VA Crisis Line. (Please see further detail in the Human Participants section.)

E.8.b Confidentiality: Throughout the study, IRB and HIPAA guidelines will be followed to ensure the privacy of patient data. The BTB program takes extensive precautions to guard patient data security. Likewise, the Qualtrics platform that will be used to collect study assessment data, has transport layer security (TLS) encryption, HTTP referrer checking, and is hosted by data centers that are SSAE-16 SOC II certified. As soon as patients consent to study participation, they will be assigned a unique study ID number. A file linking patients' identifying information and their study ID will be stored in a password protected file on a secure server, with study data stored in a *separate* electronic file with only the study ID. At the study's conclusion, the electronic file linking study IDs with patient identifiers will be destroyed. All research data will be presented in aggregate form only.

We note that as a VA multi-site randomized trial, this project will be overseen by the VA HSR&D Data Safety and Monitoring Board. We will report all serious adverse events within 14 days as well as summary data on all outcomes semi-annually or annually to the DSMB. (Please see further detail in the Human Participants section.)

E.9 Study Measures

The primary predictor of interest will be PS-cCBT intervention versus enhanced usual care (EUC).

Below, we describe study measures in each domain of interest (symptoms, functioning, and recovery constructs such as coping self efficacy and hope). We designate the measures that will serve as primary and secondary outcomes. **We note that some measures may serve as outcome measures when addressing one aim and as potential mediators when addressing another aim**.

E.9.a Primary Outcome Measures

Inventory of Depression Symptoms – Self Report (IDS-SR) is a 31-item self-report instrument for measuring the severity of depression symptoms among adults. Each item is rate on a four-point scale (0-3), and aggregate scores range from 0-84. The IDS-SR has been shown to be reliable, with Cronbach's α's in the range of 0.92-0.94 (Rush et al., 1996).

Veterans RAND 12-Item Health Survey (VR-12) is a measure of functional status adapted from the Medical Outcomes Study Short Form-36 for use among Veterans. The measure assesses physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), energy/vitality (V), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). The VR-36 has somewhat greater precision at the lower end of the health status continuum than the SF-36. The VR-12 has been used in quality management systems in the VHS (Kazis et al., 2006).

The Quality of Life Enjoyment and Satisfaction Questionnaire Short Form (Q-LES-Q-SF) is a valid proxy for the longer Q-LES form. It consists of 14 items that patients rate on a 5-point scale to indicate their satisfaction with a variety of life domains, including physical health, mood, work, household activities, social relationships, etc.(69) The *Q-LES-Q-SF* has been shown to have high levels of reliability and has been used in numerous studies of depression, including the NIMH funded STAR*D study.(69)(70)(71)

Recovery Assessment Scale - Short Form (RAS-SF): This 20-item scale is a shorter version of the RAS(72) and has four factors: personal confidence and hope, willingness to ask for help, reliance on others, and no domination by symptoms. The RAS-SF shows evidence for both convergent and discriminate validity when compared to quality of life, social support, and symptomatic scales. (73)

Alcohol Use will be assessed using the *Alcohol Use Disorders Identification Test (AUDIT-C)* which assesses average alcohol consumption (quantity and frequency) and binge drinking (6 or more) over the past 3-months.(84) Recent literature support the internal consistency, test-retest reliability, and accuracy of the AUDIT-C in identifying at-risk alcohol use.

E.9.b Secondary Outcomes

Cognitive-Behavioral Therapy Skills Questionnaire (CBTSQ) is a 16-item scale consisting of two factors, Behavioral Activation and Cognitive Restructuring. The scale shows construct validity, appears sensitive to change among patients undergoing CBT treatment, and predicts reduction in depressive symptoms.(76)

Adherence with Antidepressant Medications: Team members have extensive experience using VA pharmacy data to assess adherence. We will construct medication possession ratios for antidepressants prescribed for the 3 months following enrollment and for 3-6 months following enrollment. In addition to pharmacy data, *The 8-item Morisky Medical Adherence Scale (MMAS)* will also be used to assess adherence and may be particularly helpful if patients receive some antidepressant medication fills outside of the VA. The MMAS-8 has been shown to be reliable (Cronbach's alpha = .83) and to be significantly correlated with the validated 4-item MMAS (Pearson correlation: 0.64, $p<.05$) (Moriskey et al., 2008).

Receipt of VA and non-VA Traditional In-Person Psychotherapy: We will review enrolled patients' VA medical record notes to determine their receipt of any traditional in-person psychotherapy and their completion of 8 in-person psychotherapy visits within 12 and 24 weeks following enrollment. We will also assess whether the Veteran received psychotherapy that was depression focused and evidence-based, assessing the presence of key phrases in notes that denote CBT, ACT, or IPT treatment. We will also determine non-VA psychotherapy use, using the Cornell Services Index, as patients may have started non-VA psychotherapy after enrollment. Finally, we will construct variables that indicate if the Veteran received any in-person psychotherapy (y/n), completed an adequate trial of any psychotherapy (y/n), received any evidence-based VA psychotherapy (y/n), and completed a trial of evidence-based VA psychotherapy (y/n).

Generalized Anxiety Disorder 7 item scale (GAD-7). The GAD-7 total score ranges from 0 to 21, with "cut scores" for mild, moderate and severe anxiety. Although originally developed for generalized anxiety disorder symptoms, the GAD-7 has good operating characteristics for detection and severity ratings of panic disorder and social anxiety disorder.(117)

The *Columbia-Suicide Severity Rating Scale (C-SSRS)* is an assessment tool that evaluates suicidal ideation and behavior. The C-SSRS has good validity with other scales of suicidal ideation and behavior, and sensitivity to clinical change (Posner et al., 2011).

State Hope Scale is an internally consistent 6-item measure that asks respondents to select a number between 1 (Definitely False) and 8 (Definitely True) that represents how they think about themselves at the time of the assessment. The SHS total score ranges from 6 to 48 with higher scores being indicative of greater levels of hope. The scale has demonstrated good internal consistency and validity.(81) Variations of this scale have been used in studies of peer-led interventions for persons with mental health conditions and have shown positive change.(82) Positive change on this scale was also found in our pilot work.

Treatment Stigma is a 4-item Likert scale measure derived from the *Self-Stigma of Depression Scale (SSDS),* which consists of 16 items and four subscales (Shame, Self-Blame, Help-Seeking Inhibition, and Social Inadequacy) and has been shown to have high internal consistency (Cronbach's alpha = 0.87) (Barney et al., 2010).

Working Alliance with Peer is an 8-item Likert scale measure developed for this study in order to assess participants' therapeutic alliance with their peer mentor.

E.9.c Potential Mediating Variables : Below, we note potential mediating variables for the impact of PS-cCBT on patient outcomes, including depressive symptoms and functional status. Some of these proposed mechanisms may result from the cCBT core content (for example, CBTSQ) while others may result primarily from supportive contact with the peer specialists (ISMI) or from both components of the intervention (PAM-MH). However, in this study, we will not attempt to separate the impact of the two components of PS-cCBT.

E.9.d Other Covariates

Demographics: Patients age, gender, reported race/ethnicity, educational level, and marital status will be obtained in the study-specific questionnaire.

Primary Care Provider Mental Health Activity: Primary care clinicians may differ in their interest in and their level of activity in treating depression among their patients. Patients who are treated by primary care clinicians who actively diagnose and treat depression might receive more active depression management (more monitoring, referrals, and more medication starts and changes) than patients who are treated with clinicians who are less active in depression care. Therefore, we will construct a measure of primary care clinician depression care activity and include this measure as a covariate in study analyses. Using provider code, we will determine primary care provider antidepressant prescribing patterns (calculated as the number of antidepressant fills written by PC clinician divided by the number of patients seen by the clinician in the prior FY). We will also construct a variable for PC clinician diagnostic patterns (calculated as the number of patients who have a psychiatric diagnosis noted in an encounter by the clinician divided by the number of patients seen by the clinician in the prior FY).

Receipt of Other Health Services: We will also use VA administrative data to assess the numbers of VA primary care outpatient visits, VA specialty medical or surgical visits, emergency department visits, VA medical or surgical hospitalizations, and VA psychiatric hospitalizations. Our team has had considerable experience using administrative data to assess all of these types of health services use, and careful description of all care received is necessary when an intervention is added to usual care and a EUC control is used.(64)

Out of VA health care use will be assessed with the Cornell Service Index (CSI). The CSI was developed to assess the frequency and duration of use of a range of health services over the past three months. (85)The CSI has good inter-rater reliability with ICC for the global indices ranging between 0.97 to 1.0. Test-retest data generated Pearson correlation coefficients of 0.93 for psychiatric outpatient care and 0.83 for all visits combined.(85)

Psychiatric and Substance Use Comorbidities. Psychiatric comorbidities may have implications for the success of the PS-cCBT intervention. We will include dichotomous indicators for the presence/absence of PTSD, another comorbid anxiety disorder, Bipolar II, or a comorbid personality disorders in study analyses. These comorbidities will be ascertained from medical records for the 12 months prior to enrollment. Although patients with severe substance use disorder will not be included in the study, we will assess potential hazardous alcohol use and non-dependent substance use.

General Medical Burden will be measured using a modified version of the Charlson Co-morbidity Index, constructed from medical record review.

The Interpersonal Support Evaluation List (ISEL)-12 is a shorter 12 item version of the ISEL, including the subscales of “appraisal”, “belonging”, and “tangible” support. Each item is rated on a four point Likert-type scale in which the subject indicates whether statements about social activities are definitely true, probably true, probably false, or probably true. The “tangible” subscale assesses the perceived availability of material aid; the “appraisal” subscale examines emotional support; and “belonging” subscale assess opportunities for shared activities. Various versions of the ISEL have demonstrated excellent reliability, validity, and internal consistency in both general and psychiatric populations. (86)

Distance to the VA service site: Distance/travel barriers may make affect the uptake and use of formal mental health services for depression. (87) We will assess the number of miles from a patient's residence to their nearest VA source of care.

Computer Literacy: Computer literacy may serve as a barrier to use of a computerized CBT program; therefore, a study-specific, 8-item measure of computer literacy will be collected to assess participants’ comfort level with using a computer and internet applications, as well as how frequently they use these tools.

E.10 Schedule and Content of Study Assessments

We have attempted to keep the burden of study assessments within reason, deliberately choosing some shorter measures of important constructs, if possible. (For example, we use the GAD-7 rather than the BAI for measurement of anxiety because of its shorter length.) The estimated times for study assessments is approximately 50-60 minutes, based on published questionnaire administration times and the use of the general rule of 5 closed-ended questions or 2 open-ended questions per minute.

The Interpersonal Support Evaluation List (ISEL) will only be administered at baseline and several covariates will be assessed using chart and administrative data, reducing patient burden.

Study Measures for Patient Completion	Screening	Baseline	12 weeks	24 weeks
Screening Measures				
Patient Health Questionnaire (PHQ-9)	X			
Computer Literacy (study specific questions)	X			
Primary Outcome Measures				
Inventory of Depression Symptoms – Self Report (IDS-SR)		X	X	X
Veterans RAND 12-Item Health Survey (VR-12)		X	X	X
Quality of Life Enjoyment and Satisfaction Questionnaire		X	X	X
Recovery Assessment Scale (RAS)		X	X	X
Secondary Outcome Measures*/ Many also Mediators				
Depression Coping Self-Efficacy Scale (DCSES)		X	X	X
Cognitive-Behavioral Therapy Skills Questionnaire (CBTSQ)		X	X	X
Adherence with Antidepressant Medications (MPR* and BMQ)		X	X	X
Receipt of Traditional In-Person Psychotherapy		X	X	X
State Hope Scale (SHS)		X	X	X
Patient Activation Measure		X	X	X
Internalized Stigma of Mental Illness (ISMI)		X	X	X
Working Alliance with Peer Specialist (study specific questions)			X	X
Generalized Anxiety Disorder -7 (GAD-7)		X	X	X
Beck Scale for Suicidal Ideation (BSS)		X	X	X
Other Covariates				
Demographics		X		
Alcohol use (AUDIT-C)		X	X	X
Primary care provider mental health activity*		X		
Concurrent health services use (VA administrative data* and CSI)		X	X	X
Mental health and substance use comorbidities*		X		
General medical burden*		X		
Baseline social support (ISEL)		X		
Distance to VA facility (calculated by staff)*		X		

*calculated by staff, no burden on patient

E.11 Study Analyses

E.11.a Analyses of Success of Randomization**:** We will first determine the success of the randomization process for potential prognostic factors that may affect the primary outcomes of severity of depressive symptoms and functional status, but were not considered in minimization scheme. These factors include variables such as prior hospitalization or baseline severity of anxiety symptoms. Potential differences between groups will be determined through the use of t-tests or chi-square analyses, as appropriate. When there are significant differences in the distribution of these variables, they will be included as covariates in multivariable analyses. The interpretations of final results will also be made carefully in the presence of significant baseline differences.

E.11.b Analyses Relevant to Primary Aims**:** Primary study analyses will determine the effectiveness of the PS-cCBT intervention in decreasing depressive symptoms (IDS-SR), improving functioning and quality of life (VR-12, Q-LESQ-SF), and increasing recovery focus (RAS) at 24 weeks post-enrollment. We will also examine the impact of the intervention on depression coping efficacy and skills, antidepressant adherence, and initiation and completion of traditional in-person psychotherapy (contingent on symptoms).

Analyses will be of two broad types, those that assess intervention effects at each assessment point (12 weeks and 24 weeks), and those that determine effects over time. Primary analysis will be based on “intent to treat” principle, with all randomized patients included in the originally randomized group, regardless of whether they have subsequently dropped from their assigned treatment group.

Univariate Analyses: In the first phase of analysis (data verification), we will examine the distribution of all study variables to assess extreme values, missing data, variances, possible coding errors, skewness and whether or how to categorize skewed data. We will then describe means (±SD) for the continuous *IDS-SR, VR-12*, *Q-LES-Q-SF, and RAS* measures by study group for each assessment time for the entire sample and

for each of the study sites, separately.

Bivariate/Multivariate Analyses: We will evaluate bivariate associations between patients' treatment condition (PS-cCBT versus EUC) and the study outcomes to determine unadjusted measures of effect. We will also examine bivariate relationships between each of the potential covariates and the outcomes, and between each of the potential covariates and intervention group to assess possible confounders. Bivariate relationships between potential covariates will also be assessed for any collinearity in subsequent analyses.

Independent (Predictor) Variables	**Dependent (Outcome) Variables**
Treatment Group PS-cCBT vs Usual Care **Potential Covariates** Demographics Baseline measures of outcome variables Psychiatric comorbidities Study Site Social Support Prior to Enrollment General Primary Care Clinician Level of Depression Treatment Activity Distance to nearest VA facility	**Primary Outcome Variables** IDS-SR VR-12 Q-LES-Q-SF RAS **Secondary Outcomes *** Depression Coping skills (DCSES, CBTSQ) Antidepressant adherence Traditional psychotherapy use (contingent on symptoms) Hope Patient activation Anxiety Suicidal Ideation ***** please note some secondary outcomes may be considered mediators in other study analyses

Effects At Each Assessment Time: Comparison at 24 weeks post-enrollment will be our primary comparison, but we will also assess patient outcomes to acute effects of the PS-cCBT intervention at 12 weeks. We will first obtain unadjusted differences in the outcomes between the two study groups with its associated 95% confidence interval. Comparisons of primary outcomes (IDS-SR, VR-12, Q-LES-Q-SF, RAS) between treatment groups at each assessment time will be accomplished using multiple regression models. Multiple regression models for each outcome variables will include the baseline values of the outcome variable as covariates to adjust for baseline differences, making the model analogous to analysis of covariance. We will also include two dummy variables for three sites and adjust for additional baseline covariates that show baseline imbalances in bivariate analyses.

Effects over time: We will next compare the effects of the PS-cCBT intervention versus EUC *over time.* This second set of analyses will use linear mixed-effects model with outcomes at all three assessment times as the response variable. The mixed-effects model will include patient as random intercepts to take into account the correlation of data within person over time. The model will allow the full use of all observed data despite missing outcomes at one or two assessment times and will give unbiased estimates as long as the missingness does not depend on the unobserved missing data (missing at random).

Using this model, we will be able to estimate the time-averaged effect of the intervention if the response to the intervention is immediate and lasting, or compare the rates of changes in the outcomes between the two groups if the outcomes show different trends between the study groups. Whether we compare the time-averaged effects or the rates between two groups, we will be guided by careful graphical exploration of the longitudinal data over time between the two groups. For example, if we find scores from IDS-SR to slowly decrease over time in the intervention group, but to slightly increase in the enhanced usual care group, we will model this by including a continuous time indicator (e.g., month since randomization) and a time by intervention group term in the model. The coefficient from the interaction term will estimate the difference in rates of change in outcomes between the two study groups.

E.11.c Secondary Outcomes: Analyses of secondary outcome of Depression Coping Skills and antidepressant medication adherence will proceed as outlined above for the primary outcome variables. For analyses of receipt of VA and non-VA traditional in-person psychotherapy, we will compare the percent

initiating traditional psychotherapy between 12 to 24 weeks in patients in PS-cCBT versus EUC who have continued significant depressive symptoms at 12 weeks, defined as IDS-SR >16. The likelihood of initiation of traditional psychotherapy by 24 weeks will be compared using logistic regression model. As patients in need of continuing treatment at 12 weeks from the two groups are likely to differ, the model will be adjusted for variables that show meaningful differences between groups at 12 weeks. Although completion of a traditional therapy trial will be of interest, our primary interest here will be to see whether PS-cCBT increases the likelihood that Veterans would initiate a traditional therapy.

E.11.d Secondary Aim: Mediation of Intervention Effects on Symptoms, Functioning, QoL: We will examine whether any improvements in the primary outcomes of depressive symptoms, quality of life, functional status, or recovery focus are mediated through increased medication adherence or increased depression coping skills. To test whether a variable might be a mediator, we will first test the associations between the intervention and the mediator, and then the mediator and the outcome of interest using bivariate analyses. A variable will be considered a potential mediator if the variable is associated with both the intervention and the outcome in these analyses (i.e., as determined by a significance level of P<.10), and changes in the mediating variable occur prior to changes in outcomes.

Finally, for primary outcomes, such depressive symptoms at 24 weeks, we will additionally include the change in depression coping score from baseline to 24 weeks and/or change in antidepressant adherence from baseline to 24 weeks. If, as hypothesized, the intervention's effects on the primary outcomes are mediated through changes in depression coping or increased antidepressant adherence, the variance in 24 week symptoms explained by the intervention group will be less once the depression coping scores and antidepressant adherence are taken into account. We will also consider change in depression coping score from baseline to 12 weeks and/or antidepressant adherence at 12 weeks as potential mediators as the early effect of intervention on these variables may have affected the 24 week outcome.

E.11.e Planned Exploratory Subgroup Analyses**:** In addition to our primary comparisons of quality of life, and functional status, we will explore whether the peer-support intervention is differentially effective in specific, identifiable subgroups of patients, including those with more or less severe depression and those who have the primary care clinician with higher versus lower level of general activity in the management of their depressed patients.

We hypothesize that: a) Benefit from PS-cCBT will not be associated with initial severity of depressive symptoms and b) Patients will benefit more from PS-cCBT than usual care if their primary care physician is less active in depression treatment.

Univariate Analyses: We will describe the frequencies of patients reporting mild, moderate, or severe depressive symptoms. We will also describe either the frequencies of patients who have primary care physicians who are more rather than less active in depression care or the mean and standard deviation of the primary care provider depression care activity measure based on the number of antidepressant fills written by the primary care provider divided by the number of patients seen in the prior FY by the provider.

Bivariate/Multivariable Analyses: To explore the differential effectiveness of the PS-cCBT intervention among these patient subgroups, we will extend the model to include potential moderators of the intervention effect. For example, in addition to treatment group and other covariates, we will now stratify the analysis by the categories of baseline depressive symptom severity. If there is an observed differential effect (e.g., intervention effects are larger for patients with moderate or higher levels of depression symptoms than those with mild symptoms), then the differential effect of the PS-cCBT for these subgroups will be more formally assessed by adding in the main and interaction effects of the moderator (e.g., depressive symptom categories) and the intervention group. Assessment of whether the effects of PS-cCBT depend on the primary care provider's level of depression management activity will be carried out in similar fashion. Because subgroups are being considered, we may have limited power to detect differential effects of the intervention unless the interaction is large, and at the same time, due to the limited power, we may find that benefit from PS-cCBT does not depend on baseline severity of depressive symptoms. Therefore, these analyses will be exploratory and focused more on identifying trends rather than inferential testing.

E.12 Approach to Missing Data: Our initial analyses will only use observed data. We will check if missingness depends on covariates and will include those covariates in the models described above. However, we will conduct a second analysis that imputes missing data. Specifically, we will impute missing data using the method described by Lavori, Dawson, and Shera.(83) In brief, we will use logistic regression to model patients' likelihood of having specific outcome data and define strata within which outcome values are missing

at random. We will then stratify patients according to these propensities and randomly sample from the observed outcome distribution and impute values for missing data within each stratum. When data are missing for items within scales, we will use recommended imputation procedures rather than deleting patients list-wise from the analysis.

E.13 Power Analysis

We propose to enroll 330 patients in total (165 per group). The sample size was calculated to provide 90% power to detect a difference in levels of depressive symptoms at the primary end-point of 24 weeks, conservatively assuming a mean effect size of 0.4 SD with a two-tailed alpha of .05 and 20% dropout. We expect that this effect size is conservative based on the meta-analysis completed by Spek et. al. The meta analysis of cCBT interventions for depression and anxiety found that RCTs of cCBTs for depression and anxiety with therapist support had a mean effect size of 1.00 SD, while unsupported cCBT had a mean effect size of 0.26 SD. This suggests that we can reasonably expect our peer-supported cCBT to have an effect size in the range of 0.4 to 0.6 SD compared with enhanced usual care. In another study, Titov et al, reported an effect size of 1.1 from a technician supported cCBT for depression. In our pilot work, congruent with reported effect sizes in the literature in other populations, we found that depressive symptoms among Veterans with depression enrolled in BTB were reduced by 27%, with a mean BDI-II of 21.9 (SD=11.1) at baseline and 16 (SD=13.5) at 8 weeks. Although the pilot study did not have a control group and the endpoint was at 8 weeks, the effect size estimated based on changes from baseline to 8 weeks can be considered to range from 0.43 SD (with an assumed SD of 13.5) to 0.53 SD (an assumed SD of 11.1). Thus, based on the meta-analyses and our pilot data, we consider a between-group difference of 0.4 SD a clinically meaningful and detectable effect size for the proposed intervention. We also note that for the analysis using longitudinally measured data, the power will also depend on the within-person correlation. The proposed sample size, however, will likely give greater power than 90% if 0.4 SD is the time-averaged between-group difference.

For the secondary outcome of rate of initiation of a traditional psychotherapy, assuming that at 12 weeks, 50% and 65% of patients in the PS-cCBT and the enhanced usual care groups, respectively, could benefit from more intensive intervention and further conservatively assuming that 20% will drop out by 12 weeks, we expect the proposed number of enrollees with less than full response will be approximately 66 in the PS-cCBT group and 86 in enhanced usual care group. With these expected numbers of patients in need of more intensive treatment at 12 weeks, we will have 63% power to detect the difference of 55% initiating a traditional therapy in PS-cCBT group vs. 35% initiating a traditional therapy in the enhanced usual care group, and 80% power to detect the difference of 59% initiating a traditional therapy in PS-cCBT group vs. 35% base rate.

F. DISSEMINATION/IMPLEMENTATION

We will disseminate the results of this project through usual channels such as journal publication and presentations at conferences. Dr. Valenstein has regular contact with members of the VA Mental Health QUERI and both Drs. Valenstein and Pfeiffer are part of the QUERI Recovery – Peer Support working group. Drs. Valenstein and Pfeiffer regularly apprise this group of team progress in peer related research. One of the operational letters of support comes from Mr. Dan O'Brien-Mazza, the National Director of Peer Support Services. He also regularly attends the QUERI-Peer Support working group calls and will receive regular updates throughout the course of the trial.

Dr. Valenstein and Pfeiffer have offices that are co-located with the Primary Care-Mental Health Integration (PC-MHI) implementation and the PC-MHI evaluation team. Thus, they have regular contact with Drs. Post and McCarthy who lead and evaluate efforts to improve integration of mental health services into primary care settings, respectively. This proposal has been discussed with Dr. Edward Post who wrote an operational letter of support and gave several suggestions regarding how to make this proposal relevant to primary care services in the VHA.

Team members also regularly communicate with both the VHA Office of Mental Health Operations and VHA Office of Mental Health Services. If we find that the intervention leads to improved outcomes, we will seek partnerships to explore how the intervention can be more widely implemented throughout the VA.

If the trial is positive, we have discussed with Dr. Dan O'Brien-Mazza the option of adding an appendix to the existing VA peer-specialist manual that describes the structure of PS-cCBT intervention and outlines the protocol for peer specialist involvement as supporters of this treatment option.

G. Data Management

Study assessment will be administered online through Qualtrics, a University of Michigan research partner that meets HIPAA privacy standards. The Qualtrics website is password protected and hosted on a secure server. Participants will be referred to Qualtrics terms and conditions of use during the informed consent process and upon opening each of the study assessment batteries. Participants who have provided consent will enter their own personal information and no VA data will be transmitted to Qualtrics.com. Each participant will be given a code number. The link between the names and code numbers will be encrypted and stored behind the VA firewall. All patient consent forms will be kept in a locked cabinet. The administration of all study assessments will be conducted and monitored by the study staff through a password-protected Qualtrics.com account. Research data collected through the survey will be stored on the Qualtrics.com server and will be purged weekly and uploaded to a secure VA-maintained data file. Confidentiality will be protected by restricting access to the research data to authorized study personnel only. In particular, data will be stored on dedicated servers and in study folders that can only be accessed by specified study personnel. Qualtrics has been used in several VA Center for Clinical Management research projects without incident.