IIR03-315 Effectiveness and Implementation of Brief Cognitive Behavioral Therapy in CBOCs

Funding Agency: Office of Research and Development

Principal Investigator: Jeffrey A. Cully, PhD

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Abstract

Provide a summary of the study (recommended length: less than 500 words).

Depression is a serious health condition that places tremendous burden on patients and healthcare systems and is especially prevalent among Veterans. The delivery of complex evidence-based psychotherapy depression care is challenging, especially in settings such as primary care and community-based clinics. Within the Veterans Health Administration (VHA), efforts are needed to assist community-based outpatient clinic (CBOC) clinicians to deliver evidence-based psychotherapy for depression. The proposed 4-year multi-site trial seeks to train and assist (facilitate) CBOC clinicians in the use of a brief cognitive behavioral therapy (bCBT) and to subsequently monitor the effectiveness of this treatment on Veteran outcomes using a direct-referral versus enhanced usual care patient randomized trial design. Aim 1 will develop a series of strategies to train and assist CBOC clinicians in the use of bCBT at 16 CBOC sites connected to the Houston and Oklahoma City VA Medical Centers. Initial development of these strategies will involve CBOC clinician feedback in an iterative fashion that refines and enhances the training and support offered. Collectively, the development and assessment of these strategies will occur through a formal “formative evaluation” process. Formative evaluation will include a needs assessment as well as modifications to the clinical (bCBT) and implementation (clinician training and support) approaches. Following Aim 1, Aim 2 will seek to determine whether depression outcomes for Veterans differ as a function of the intervention (direct referral to bCBT provided by CBOC clinicians vs. enhanced usual care) at post-treatment (4-month), and 8- and 12-month follow-up. A total of 232 Veterans with clinically elevated symptoms of depression will be recruited from CBOC clinics associated with the Houston and Oklahoma City VA medical centers (8 CBOCs per station). Eligible Veterans will be randomized to either 1) a direct referral to a CBOC bCBT trained VA provider or 2) an Enhanced Usual Care (EUC) arm where participants will receive depression information and a depression tool kit as well as a note placed in their electronic medical record. EUC participants will be asked to talk to their primary care provider about additional depression treatment options. No participants in either the bCBT or EUC groups will be restricted in any way from the receipt of VHA services. Rather, the study will use VHA databases and chart review procedures to document and control for health care use during the study period.

Data from this project will help providers, managers, and policy makers to understand the potential impact, challenges, and benefits of using bCBT in VA CBOC settings. The implications of this study are multifaceted and will provide: 1) training and clinical support to existing CBOC clinicians who currently struggle to incorporate evidence-based psychotherapies into their clinical practice; 2) data on the impact of an implementation strategy (clinician support program) to aid CBOC clinicians in the use of a structured bCBT; and 3) clinical data on the effectiveness of bCBT for Veterans in CBOC settings as delivered by CBOC frontline clinicians.

List of abbreviations:

bCBT – brief Cognitive Behavioral Therapy

CBT - Cognitive behavioral therapy

CBOC – Community-Based Outpatient Clinic

Co I – Co-Investigator

EBT – Evidence Based Treatment

EUC – Enhanced Usual Care

HSR&D – Health Services Research & Development

HSR&D IIR

IQuEST - Center for Innovations in Quality, Effectiveness and Safety

LAC – Local Advisory Council

NAC – National Advisory Council

ORCA – Organizational Readiness to Change Assessment

PARiHS - Promoting Action on Research Implementation in Health Services

RE-AIM – Reach Effectiveness Adoption Implementation Maintenance

VHA – Veterans Health Administration

PHQ-9 (Patient Health Questionnaire)

PFE - Progress-Focused Evaluation

NIMH – National Institute of Mental Health

PI – Principal Investigator

RA – Research Assistant

SC MIRECC – South Central Mental Illness Research, Education and Clinical Centers

SF-12 – Short Form Health Survey Veteran Version

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1.0 Study Personnel

Principal Investigator/Study Chair:

Jeffrey A. Cully, PhD
Clinical Psychologist
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-794-8526 (office)
Jeffrey.cully@va.gov

Co-Investigators:

Natalie Hundt, PhD
MIRECC Post-Doctoral Fellow
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-440-4450
Natalie.hundt@va.gov

Michael Kauth, PhD
Co-Director and Associate Director for Education, South Central MIRECC
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-440-4460
Michael.Kauth@va.gov

Mark Kunik, MD, MPH
Director of South Central MIRECC
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-794-8639
KUNIK.MARKE@va.gov

Lindsey Martin, PhD.
Health Science Specialist
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-440-4452
Lindsey.Martin3@va.gov

Nancy Petersen, PhD.
Senior Biostatistician
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston

713-440-4443
Petersen.nancyj@va.gov

Shubhada Sansgiry, PhD.
Programmer
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-440-4455
Shubhada.Sansgiry@va.gov

Kristen Sorocco, PhD.
Clinical Psychologist
Oklahoma City VAMC, 635
405-456-1454
Kristen.Sorocco@va.gov

Melinda Stanley, PhD.
Clinical Psychologist
MEDVAMC, 580
VA HSR&D Center for Innovations in Quality, Effectiveness and Safety (IQuESt), Houston
713-794-8841
Melinda.Stanley@va.gov

Collaborators:

Geoffrey Curran, PhD.
Research Health Scientist
Arkansas Department of Veterans Affairs
501-255-1701 (office)
Curran.geoffreym@va.gov

Consultants

JoAnn Kirchner, MD
Director Mental Health QUERI
Little Rock VAMC
501-257-1719
JoAnn.Kirchner@va.gov

Lisa Kearney, PhD
Senior Consultant Mental Health
VA Central Office
210-694-6222
Lisa.Kearney3@va.gov

Andrew Pomerantz, MD
National Mental Health Director, Integrated Services
VA Central Office
802-625-2040
Andrew.Pmerantz@va.gov

John Rader, MSW
VISN 16 Mental Health Product Line Manager
Little Rock VAMC
501-228-8303
John.Rader@va.gov

Anna Teague, MD
Associate Chief of Staff for CBOCs
MEDVAMC, 580
713-791-1414 ext. 28792
Anna.B.Teague@va.gov

2.0 Introduction

Depression is a serious health condition that places tremendous burden on patients and healthcare systems and is especially prevalent in Veterans.[1] In 2008, the VHA released the Uniform Mental Health Services Handbook (Handbook 1160.01) in an effort to expand services for Veterans with depression, including those in primary care and CBOC settings.

Cognitive behavioral therapy (CBT) has strong empirical support and is effective for depression.[2-4] Full-course CBT (12-16 sessions) is recognized as an evidence-based treatment (EBT) by VHA.[5] However, the provision of full course CBT outside traditional mental health settings is complicated by a host of patient and system factors.[6, 7] Briefer versions of CBT have been explored to increase access and efficiency of care while reducing barriers, especially in non-specialty mental health settings such as primary care.[8, 9] Preliminary data suggest that bCBT (e.g., 4-6 sessions) is moderately effective. [10-12]

Although CBT improves patient outcomes, it is infrequently used in integrated healthcare settings.[13,14] Within the VA, Cully et al.[15] found that only 22% of urban and 15% of rural Veterans received at least 1 session of psychotherapy in the year following a depression diagnosis. Exposure was also limited, with 5.6% of urban and 2.4% of rural Veterans receiving 8 or more sessions.[15] In 2008 the VA launched the Uniform Mental Health Services Handbook, which mandates that hospitals and larger CBOCs provide mental health services within the primary care setting and make available evidence-based psychotherapies for all Veterans with depression. These policies may be a step ahead of the current scientific literature, as studies are needed to document the real-world effectiveness of these treatments, especially for CBOCs, which face unique barriers to the delivery of mental health treatments.

Clinical trials on bCBT are especially needed in care settings such as CBOCs where the provision of full course psychotherapy is under-utilized. CBOCs often have fewer mental health clinicians, limited access to mental health specialists and other referral networks, diverse patient needs, and logistical and patient attitudinal barriers.[16,17] Data suggest that CBOCs are increasing access to mental health care but have limited follow-up services for depression.[15,18,19] A recent VA survey of 4,200 providers found that psychotherapies are often not available in CBOCs (see Appendix 1, VA memorandum). Further, CBOC clinicians feel significantly less knowledgeable and confident than urban providers in treating depression.[20] Ultimately, research is needed to document the effectiveness and implementation potential of bCBT for VA CBOC settings.

The proposed 4-year multi-site trial seeks to use an effectiveness-implementation design to examine a brief cognitive behavioral therapy (bCBT) intervention for Veterans with depression as delivered by existing mental health providers in VA CBOC clinics. Effectiveness-implementation designs seek to simultaneously test: 1) strategies to improve care practices (e.g. clinician support programs) and 2) examine patient outcomes associated with the clinician program being implemented. For the current study, aim 1 will use a formal formative evaluation

process to better understand the contextual factors related to bCBT delivery including feasibility, adoption, and implementation (use in the clinical care setting). The study team will work with CBOC providers to train and assist them to more regularly use bCBT in their practice. Aim 2 will seek to determine whether depression outcomes differ as a function of the intervention (bCBT provided by CBOC clinicians vs. enhanced usual care) at post-treatment (4-month), and 8- and 12-month follow-up. Veteran participants will be randomized to either a direct bCBT referral or to an enhanced usual care arm.

The current investigation will examine whether existing VA CBOC mental health clinicians, with training and support, can effectively administer a structured bCBT intervention for Veterans with clinically elevated symptoms of depression. The project was designed to help providers, managers, and policy makers to understand the potential impact, challenges and benefits to using bCBT in VA CBOC settings. The implications of this study are multifaceted and will provide: 1) training and clinical support to existing CBOC clinicians who currently struggle to incorporate evidence-based psychotherapies into their clinical practice; 2) provide data on the impact of an implementation strategy (clinician support program) to aid CBOC clinicians in the use of a structured bCBT; and 3) clinical (patient) data on the effectiveness of bCBT for Veterans in CBOC settings.

Clinician Participants

All mental health clinicians at Houston and Oklahoma City CBOCs will be targeted for participation. CBOC clinicians whose scope of practice includes the delivery of psychotherapy will be invited to participate in this study.

Veteran Participants

The project will target all depressed Veterans treated at CBOCs in the Houston and Oklahoma City VAMC parent facility catchment area. Inclusion criteria will include: clinically elevated symptoms of depression using the PHQ-9 (Patient Health Questionnaire) and the participant must have a primary care clinician at one of the above listed CBOCs. Exclusions will be limited to traditional criteria used in randomized psychotherapy trials. **Exclusion criteria were kept to a minimum and only include factors that would make provision of a brief psychotherapeutic treatment inappropriate.** Although psychotherapy may be appropriate for a wider patient population, brief psychotherapies (as proposed here) are believed to be of limited benefit to patients with more severe mental health difficulties. As such, exclusion criteria will include presence of cognitive impairment, bipolar, psychotic or substance-abuse disorders. Veterans currently receiving psychotherapy will also be excluded to avoid overlapping or competing services. Those receiving general mental health services including antidepressant medications will not be excluded. The study will not restrict the participant sample in any other manner.

3.0 Objectives

The proposed 4-year, multisite, randomized effectiveness-implementation trial will focus on the real-world application of bCBT for Veterans with depression, as applied by frontline CBOC practitioners. Effectiveness-implementation designs seek to simultaneously test: 1) strategies to improve care practices (e.g. clinician support programs) and 2) examine patient outcomes associated with the clinician program being implemented. The current project will invite mental health clinicians at the Houston and Oklahoma City CBOCs (16 sites) to participate. As part of study participation, providers will receive bCBT training and support from the study. Once trained, these CBOC clinicians will be asked to provide care to a Veteran patient population identified by the study team. Veteran participants from each respective CBOC, identified by study-based screening, will be randomized to a bCBT direct referral arm or to an Enhanced Usual Care (EUC) condition. Direct referral participants will be assigned to a CBOC provider trained by the study team in the use of bCBT. The study will pair providers and patients at each CBOC facility. EUC participants will not receive a direct referral. Rather, these participants will receive depression education materials, a note placed in their medical record indicating the presence of depression, and encouragement to seek services from their existing providers.

Aim 1 – Implementation (training and assisted use of bCBT by frontline CBOC clinicians): The study will use a formal evaluation procedure to capture information on the clinical and implementation efforts as delivered by CBOC providers. Data will be used to modify the clinical training and support program. Known as a formative evaluation, the study will include a developmental assessment to collect data on clinician adoption, intervention fidelity, and individual interviews with stakeholders to obtain a deeper understanding of implementation challenges associated with using bCBT in the CBOC setting.

Aim 2 – Clinical Effectiveness (patient outcomes): To determine whether depression (PHQ-9 and Beck Depression Inventory) and quality- of-life (SF-12) differ as a function of bCBT referral (vs. EUC) at 4-, 8- and 12-month follow-ups.

Exploratory Aims: A) To predict bCBT treatment response, using patient, treatment, and clinician variables. B) To explore patient and provider reactions to variable-length treatment options, using outcome data, patient and provider surveys, and qualitative interviews. C) To assess stakeholder (Veterans, clinicians, clinic managers/directors, as well as regional and national VA mental health leaders) perceptions of potential for wider implementation and maintenance of bCBT poststudy, using qualitative interviews and focus groups.

4.0 Resources and Personnel

The primary site for study coordination will be the Houston VAMC. Houston VAMC personnel will be responsible for obtaining database information and will conduct all recruitment of Veteran participants and local site (HOU) provider participants. Houston personnel will also be responsible for allocation (randomization) of Veteran participants to study arms and will coordinate care activities at the Houston CBOCs. Houston personnel will also conduct all baseline and follow-up evaluations with consented participants (by telephone). Houston personnel will also lead all clinician training efforts but will work collaboratively with Oklahoma City study personnel to implement the CBOC clinician training and facilitation efforts at the Oklahoma City CBOC locations. Oklahoma City study personnel will be responsible for recruitment of local site provider participants and Local Advisory Council (LAC) members.

The PI (Cully) will assume overall responsibility for Veteran recruitment. Dr. Cully will work with Mr. Zeno and Mr. Robinson (see listing in personnel description below). Mr. Zeno and Mr. Robinson will be the primary study personnel responsible for sending out participant recruitment letters and conducting follow-up participant calls. They will also oversee a comprehensive training program for our "to be named" research personnel including additional research assistants and independent evaluators. Study personnel (Zeno, Robinson, and a "to be named" research assistant) will complete patient consent procedures and conduct baseline interviews with consented participants. Follow-up telephone survey (data collection) will be completed by independent evaluators (to be named) who will remain blind to participant randomization and other study procedures (e.g. clinical treatment information).

All data and databases will be kept at the Houston VAMC behind the VA firewall. All study staff are VA employees and no data sharing agreements will be needed for this project. Transcription of audio recording will occur with a VA contractor and will occur via sharing of data behind the VA firewall. All data and database procedures will be overseen by Drs. Petersen and Sansgiry (see below).

<u>HOUSTON, TX – PERSONNEL</u>:

Jeffrey A. Cully, PhD (Principal Investigator). Dr. Cully will have overall responsibility for clinical and scientific aspects of the project. In this role, he will train and supervise research personnel, conduct project meetings, and be responsible for the scientific progress of the research including manuscripts and reporting of study results. He will also be responsible for the overall bCBT training program and lead the bCBT training team including Co-I's Stanley, Hundt, and Sorocco. He will also work closely with Dr. Martin on all aspects related to the qualitative inquiry of the project. Dr. Cully is a past VA HSR&D Career Development and HSR&D Merit Review Awardee. He is a clinical psychologist (with a clinical appointment at the Michael E. DeBakey VA Medical Center) and health services researcher (with an appointment with the Houston HSR&D Center of Excellence). No salary is requested for his effort.

Melinda A. Stanley, PhD (Co-Investigator). Dr. Stanley is a clinical psychologist and NIMH-funded researcher with specific expertise in the development and implementation of psychosocial interventions, including interventions for older adults in primary-care settings. Dr. Stanley is a core member of this research team which also includes close working relationships with Drs. Kunik and Kauth. Dr. Stanley has served as Co-I on the PI's ongoing HSR&D IIR and previously served as a secondary mentor for Dr. Cully on his VA Career Development Award. As with the current IIR grant, Stanley will aid in the final development and implementation of the study intervention and training materials and will serve as a bCBT mentor and expert rater of CBOC clinician audio taped sessions. Dr. Stanley will also serve as a co-author and co-investigator on manuscripts and future grant applications.

Mark E. Kunik, MD, MPH (Co-Investigator). Dr. Kunik is a psychiatrist and health services researcher with specific experiences and expertise in researching issues related to psychiatric conditions in medically ill patient populations. He will primarily serve as a senior consultant and guide for participant recruitment, intervention implementation, manuscript development, and future grant planning. Dr. Kunik has served as a senior consultant on the PI's ongoing IIR and previously as Dr. Cully's primary mentor during his VA Career Development Award. In his role as co-investigator and mentor, Dr. Kunik will attend project meetings, as well as provide weekly one-on-one mentoring meetings to address the project and career development needs of the PI. Dr. Kunik is a VA staff psychiatrist and, therefore, no salary support is requested for his effort.

Michael Kauth, PhD (Co-Investigator). Dr. Kauth is a clinical psychologist and staff psychologist with specific expertise in VA psychology training, VA implementation, and national VA mental health programming. Dr. Kauth is an active teacher, administrator, and researcher within the SC MIRECC and currently serves as a Co-I on Dr. Cully's ongoing HSR&D IIR. He has a long history of collaborating and mentoring Dr. Cully in the areas of VA mental health planning and implementation theory and practice. For this project, Dr. Kauth, along with the other co-investigators, will serve in an advisory capacity and will be actively involved in the study training and implementation procedures. Given his expertise he will be relied upon to guide the consultation and facilitation aspects of the training initiatives. Dr. Kauth will attend staff meetings and will serve as co-author and co-investigator on manuscripts and future grant applications. No salary support is requested for his effort.

Natalie Hundt, PhD (Co-Investigator). Dr. Hundt is a clinical psychologist with an emerging research agenda to incorporate peer support programming to support psychotherapy practices for Veterans with PTSD and depression. Dr. Hundt is submitting a first version of her VA HSR&D Career Development Award (June 2013) where Dr. Stanley (project Co-I) and Dr. Cully (project PI) are serving as her primary and secondary mentors respectively. For the current project, Dr. Hundt will serve as Co-I and will work directly with Dr. Stanley as a clinician mentor and bCBT expert. Given Dr. Hundt's clinical appointment at the MEDVAMC, no salary support is requested for her effort.

Lindsey Martin, PhD (Co-Investigator) Dr. Martin is a medical ethnographer and qualitative methodologist. Dr. Martin will work closely with the PI and collaborator Curran to implement the

project's comprehensive formative evaluation. Dr. Martin will lead the effort needed to conduct qualitative interviews and analyze/code the qualitative data.

Nancy Petersen, PhD (Co-Investigator). Dr. Petersen is a biostatistician and senior methodologist at the Houston HSR&D CoE. Dr. Petersen has a longstanding relationship with the current study team and will serve as the senior statistical methodologist on the project. She has already served as a methodological consultant to the grant application and will continue to be actively involved in the planning of statistical analyses and will assist in writing manuscripts. She will actively work with the study programmer (Sansgiry) and oversee the development of programming for data entry and ensure the accuracy and consistency of data collection. Dr. Petersen's effort will decrease in year 2 due to reduced emphasis of statistical and programming issues and then increase during years 3 and 4 to allow adequate time for data procedures related to preliminary and final papers and reports.

Shubhada Sansgiry, PhD (Co-Investigator). Dr. Sansgiry is a data analyst at the Houston HSR&D CoE. Dr. Sansgiry is currently serving as a data analyst on the PI's ongoing HSR&D IIR and will continue to serve in that role for the current project. She will extract patient information from VA databases and assist the senior statistician (Petersen) in the construction and maintenance of the study database.

Darrell Zeno, MS (Project Coordinator). Mr. Zeno will serve as the project coordinator and will assume day-to-day responsibility for project management, including study recruitment, coordination of all clinician referrals and independent evaluator sessions, and coordination of data collection, entry, and verification. Mr. Zeno has worked with the PI for over 7 years and brings a wealth of knowledge and expertise related to the management of large VA studies. He currently serves as the project coordinator on the PI's ongoing HSR&D IIR. The use of a project coordinator at the GS 11/1 level will provide invaluable project support at a master's level in order to perform higher-order database construction and management tasks. The project coordinator will attend all project meetings and assist in preparing scientific reports.

Andy Robinson, MS (Research Assistant). Mr. Robinson will conduct day-to-day recruitment of patients and assist with coordination of clinician referrals and independent evaluator session, and data collection / entry. Mr. Robinson will attend all project meetings.

Research Assistant (RA) – Houston: To be named. The RA will also conduct day-to-day recruitment of patients and assist with coordination of clinician referrals and independent evaluator sessions and data collection/entry. The second RA will also attend all project meetings.

Suzette Stine BS (Research Assurance Coordinator). The cost of a research compliance coordinator is shared by all investigators at the Houston HSR&D CoE (CoE). The coordinator directs, coordinates, and supervises the administrative functions of research compliance at the CoE. The coordinator audits and monitors all CoE research, and aids in the reporting of

compliance issues. The coordinator also provides education to investigators and staff regarding regulations, policies, and other VA and federal requirements related to research compliance.

Alex Chau, BS (Study Data Management Specialist). Mr. Chau will perform dataset maintenance and upgrades. He will provide support and training for study personnel on project-related software programs. He will ensure data privacy standards are maintained. He will process Data Use Agreements and PKI for study personnel. These functions are critical part of our data-management security plan to ensure compliance and the safety of all encrypted veteran data.

OKLAHOMA CITY, OK – PERSONNEL:

Kristen Sorocco, PhD (Co-Investigator). Dr. Sorocco is a clinical psychologist and researcher with the South Central MIRECC. Dr. Sorocco currently serves as the site PI on Dr. Cully's current multisite HSR&D clinical trial (IIR 09-088). For the current project, Dr. Sorocco will assume site PI responsibilities including regulatory oversight at the site level (IRB, Human Subjects, R&D Approvals, etc). She will also direct the RA at Oklahoma City which will include training and supervision. Dr. Sorocco has been and will continue to be an active member of this project team and will attend all full team meetings (by telephone) and use study data to publish first and secondary authorship manuscripts. Dr. Sorocco is a VA paid clinician and no salary support is requested.

Research Assistant (RA) – Oklahoma City: To be named. This RA will be hired to facilitate “on the ground efforts” at the Oklahoma City site. This RA will be asked to support Dr. Kristen Sorroco (OKC bCBT expert) in regard to clinician training and consultation and other CBOC clinician facilitation efforts. The RA will also be asked to facilitate administrative duties related to data collection at the OKC site, including data from therapists and patients (where needed).

LITTLE ROCK, AR – PERSONNEL:

Geoffrey Curran, PhD (Collaborator). Dr. Curran is a medical sociologist and a qualitative and implementation science expert. Dr. Curran is also the Associate Director for the Mental Health QUERI. Dr. Curran will serve as a methodological consultant to the project. His role will focus on the development and refinement of the formative evaluation and implementation strategy of the project. No research activities will occur in Arkansas.

CONSULTANTS:

The consultants consist of regional and national leadership. The study team has formed a national advisory council with the consultants. We will meet with them annually to guide the project. The advisory council will provide feedback on project implementation and will serve as a critical link to aid in interpreting and disseminating study findings, thus ensuring the study is closely aligned with VA clinical and policy initiatives.

5.0 Study Procedures

5.1 Study Design

The proposed 4-year, multisite trial seeks to use an effectiveness-implementation design[21] to examine a bCBT intervention for Veterans with depression, delivered by existing mental healthcare providers in CBOC settings. Effectiveness-implementation designs seek to simultaneously test: 1) strategies to improve care practices (e.g. clinician support programs) and 2) examine patient outcomes associated with the clinician program being implemented. Initial steps of this trial will refine a clinician training and facilitation process to increase the availability of frontline providers to deliver these evidence-based practices in CBOCs. The study will evaluate a series of provider and system-level strategies (STUDY AIM #1) designed to increase the use (adoption and fidelity) of bCBT by CBOC clinicians. Proposed strategies, developed from our prior work, will be modified using formative evaluation (FE) procedures with input from local and national stakeholders. Anticipated strategies include the use of standardized treatment materials, online clinician training, audit and feedback, and group and individual facilitation to reduce practice barriers and enhance successful delivery of bCBT.

Clinical effectiveness will focus on the use of a bCBT intervention for depression adapted for use in the CBOC setting (STUDY AIM #2).[9, 12, 21] The proposed bCBT intervention has been shown to be feasible and acceptable to patients and providers[12, 22] and will be offered using in-person and/or telephone sessions. Final treatment intensity (number of sessions) and duration (time in treatment) will be informed by real-time depression symptom response and ultimately decided by patients and clinicians but not to exceed 4 months.[23] A total of 232 CBOC Veterans with clinically elevated symptoms of depression will be recruited from 16 Houston and Oklahoma City CBOCs. Eligible Veterans will be randomized to a direct referral arm and offered a course of bCBT to be provided by existing VA CBOC providers or to Enhanced Usual Care (EUC; patient education) group where they will be provided with depression information, and the recommendation to seek additional depression care options through their primary care providers.

All randomized participants will also receive a note added to their charts. The note will provide information about the patient's level of depressive symptoms, the presence or absence of suicidal ideation reported, and any actions being taken by the research team. Notes will provide information about the assessment process, including information conveyed to the subject about the VA crisis hotline and encouragement provided to the patient to seek additional services through their existing care providers. The note will also indicate that the patient should continue to receive care as usual regardless of their study group assignment. Participants randomized to bCBT will receive a note, similar to the EUC group, with the exception being that the note will also indicate the patient was referred to a local CBOC provider for bCBT care. For subjects that enter the trial with depression but without suicidal ideation, the study team intends to provide a

detailed note for the chart but will NOT require an additional signature or co-signature from the PCP.

The primary outcome, depression symptoms, will be evaluated at 4-, 8- and 12-month follow-ups.

Study Aim #1: Implementation (Training and Assistance Program) of bCBT by CBOC clinicians

The bCBT intervention will be delivered by VA CBOC clinicians at the Houston and Oklahoma City affiliated CBOCs. All mental health clinicians at the 16 CBOC sites will be approached for inclusion in the study. We anticipate that a minimum of 12 clinicians will be enrolled, with a realistic estimate to approach 15 or more enrolled clinicians before the end of the trial, given staff turnover and program expansion efforts. Clinicians will receive online bCBT training with an emphasis on care for Veterans in the CBOC setting. Clinicians will be invited to participate by referral from clinic directors and/or VISN 16 mental health leadership. The study team will follow-up with the clinician and his/her supervisor to verify that study participation is appropriate. CBOC clinicians will receive advocacy (when needed) from the study staff and VISN leadership (see Appendix 2, letters of support) to resolve barriers to participation. Clinicians will not be restricted based on discipline or prior CBT experiences, but will be expected to have an interest in obtaining training and willingness to use bCBT in their practice. As seen in our ongoing trial, we anticipate that nurses, social workers, psychologists, counselors, and physician assistants will participate. The study team will try to work with clinicians to receive workload credit, but will not guarantee.

All enrolled clinicians will receive a series of training and facilitation tools to assist their use of bCBT in their VA care settings. The proposed implementation strategy (training and facilitation tools) will be based on our prior work as outlined by Mignogna,et al. 2014.[22] The proposed implementation strategy will initially include a series of techniques but will be modified with input from CBOC stakeholders during the development and refinement process. The initial strategy will include the following facets:

bCBT Training and Certification:-[24] Based on our prior work, bCBT training will be offered at 2 levels –novice and experienced – to provide an individualized and efficient training experience. Tailored training is believed to be superior to a “1-size-fits-all” approach, which often is inefficient, reduces motivation, and increases frustration. Novice clinicians will have limited or no CBT experience, whereas experienced clinicians will have significant prior psychotherapy and CBT experiences. Clinicians’ experience will be collected through surveys, and the training team (Cully, Sorocco, Stanley, and Hundt) will determine a recommended training level. Clinicians will review the bCBT clinician manual and patient workbook prior to the introductory session. Novice therapists will be asked to complete an online training program modeled after our current work.[22, 25] This 6 to 8- hour program is broken down into 30- to 45-minute modules. Each module contains didactic information, as well as audio vignettes to "model" intervention procedures. Following completion of the online training, novice therapists will be “certified” for

bCBT patient care. Initial "certification" will be viewed as an intermediate implementation outcome. However, the study team will provide additional training opportunities (e.g., audit and feedback, facilitation, clinic support) to aid bCBT use over time.

bCBT Mentoring and Facilitation:[24, 26] Each CBOC provider will be paired with a "mentor." Mentors, members of the study team, will serve as bCBT experts, as well as practice facilitators to enhance adoption. Clinicians will be introduced to mentors at study enrollment, and monthly meetings will be scheduled for the first 6 months (every 3-4 months thereafter) to discuss successes and challenges associated with using bCBT. Facilitation will be a "mediating intervention" that enables and supports the larger bCBT intervention.[27]

Facilitation will use a variety of techniques to help therapists put their bCBT knowledge into practice (QUERI facilitation guide).[28] The study team will also coordinate monthly group calls with clinicians to share experiences across settings and to provide clinicians the chance to interact with one another (e.g., practice community). Group calls will address how to apply bCBT in a complex patient population (e.g., advanced bCBT training) and within a competing-demands CBOC environment (e.g., managing a psychotherapy practice).

Intervention Fidelity and bCBT Feedback: Ratings of adherence and competence will be assessed, using a previously developed measure.[8, 29] BCBT ratings will be assigned, using audio taped sessions and the standardized rating measure, with scores ranging from 0-8, where 6 is considered "good." [8, 29] It is anticipated that some participants may decline to be recorded. In these instances participants will be included in the larger study but will not be audio recorded. Audio recordings will be uploaded to a VA shared drive and will not leave the VA server). All sessions for each clinician's first bCBT patient will be reviewed by a bCBT expert. Feedback will be provided by mentors (Stanley and Hundt) to the clinician after sessions 2 and 6 (or at the end of treatment). Following the initial patient, bCBT experts will review 2 randomly selected recordings and will provide feedback to clinicians every 3-4 months. Ongoing monitoring of therapists will identify "developmental areas," defined as scores of 5 or less on any skill.

Therapists, regardless of ratings, will not be removed from the trial but will receive feedback to address needs. This training model closely resembles training initiatives within the VA. Measurement and analyses of fidelity ratings will also provide data for the project's implementation and progress-focused formative evaluation.

Study Aim #2: Clinical Effectiveness / Patient-Participant Randomized Arms

ARM #1: Referral to Brief CBT (bCBT)

Participants randomized to the bCBT referral intervention[9, 12, 30] will be assigned directly to a study trained CBOC provider who will deliver bCBT as part of their established clinic procedures. The bCBT will use a flexible, patient-centered approach to increase engagement and adherence while addressing the mental and physical health needs of depressed Veterans. Emphasis was placed on maximizing intervention potency and minimizing intensity and duration

to improve implementation value. A bCBT therapist manual and patient workbook provide structure and increase patient participation. The patient workbook includes intervention session information and worksheets, along with homework assignments to facilitate between-session patient activities. Importantly, the patient workbook provides the structure needed to conduct telephone sessions.

The proposed bCBT intervention uses 6 active-treatment sessions, each lasting 30 to 40 minutes, and the option to include 3 more sessions if the participant and clinician deem necessary (see Table 1). All participants receive an initial (core) session when participants work with their study clinician to set goals that are not restricted to "emotional health" (e.g., depression) but may also address "physical health" concerns (e.g., diet, exercise, managing a chronic condition). This flexible, patient-centered approach allows clinicians and patients to target broader factors that may impact mood and depression. Following the core session, clinicians provide participants with a series of module choices, from which they select skills that match their most pressing needs. Skill modules use psychosocial techniques established in our prior trials[8, 9, 12, 30, 31] and flexibly apply these skills to improve mental and physical health. Each module focuses on a CBT technique (e.g., behavioral activation, changing thoughts), introduced and customized to the patient's immediate goals, regardless of the focus (physical or mental health).

Table 1. bCBT Intervention Overview

Session	Module	Content / Description
1 Core	bCBT Introduction; Overlap of Emotional/Physical Health	Treatment rationale; emotional and physical health overlap; quality of life; patient strengths/concerns; treatment options/modules; setting initial goals (action plan)
2-5 Skill Modules	Managing Physical Health	Self-management skills: exercise, nutrition, managing medications, sleep
	The Power of Thoughts	Understanding how thoughts affect mood/functioning; adaptive statements
	Increasing Pleasant Activities	Understanding how behaviors affect mood/functioning; identifying/ planning activities
	Learning How to Relax	Controlling emotional/physical sensations via relaxation – breathing/guided imagery
6	Wrap-up Session*	Review of progress/ skills, maintaining changes, addressing barriers

**Note: Treatment may extend up to 9 sessions. Therefore, wrap-up could occur at session 7, 8, or 9*

Participants randomized to the bCBT direct referral arm will have information obtained from the assessment (e.g. responses from the PHQ-9, level of physical pain experiencing, any comorbid psychiatric diagnoses, and their contact information forwarded to a study-consented CBOC provider (via encrypted email), who will schedule the patient for an initial treatment session. The assessment information is provided to inform the clinician on areas of difficulty the patient may be experiencing to aid in recommendation of treatment modules. Participants and clinicians will work collaboratively to determine the modality of treatment – telephone, face-to-face, or a mixture. All bCBT sessions are deliverable by telephone but clinicians and patients may opt to have face-to-face meetings. Data on telephone and face-to-face meetings will be collected and examined in treatment analyses. Clinicians will be encouraged to offer 6 weekly treatment sessions but may alter the intensity or "dose" of treatment, based on Veteran depression response scores and/or provider/patient decision to discontinue treatment. For completers, the final treatment "dose" may include between 3 and 9 sessions over a course of up to 4 months. Clinicians will be asked to complete the PHQ-9 during treatment sessions to assess treatment

response. Regular PHQ-9 administration is consistent with bCBT and measurement-based care. Data on treatment sessions will be documented using template CPRS clinician notes to facilitate clinician documentation, allowing the study team to monitor and extract important treatment information during and after the trial.

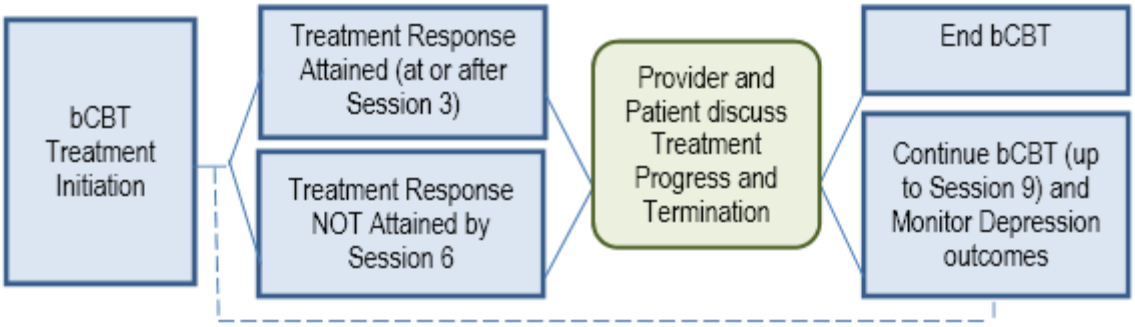
Variable Length of Treatment (see Figure 1): Clinicians will provide bCBT with a flexible treatment intensity and duration, based on an innovative model described by Galovski et al.[23] In the current study each Veteran's depressive symptoms will be assessed, using an a priori PHQ-9 outcome benchmark of 50% reduction in baseline symptoms[33-35] to determine treatment response and to provide guidance to clinicians and patients about the potential for treatment discontinuation. Clinicians are encouraged to talk about discontinuation prior to treatment completion to 1) ensure that patients continue to see value in the treatment and wish to continue the treatment 2) explore additional or alternative treatment options that may be more in line with patient needs and/or expectations. Ideally, patients will continue with the bCBT intervention but some may elect to explore other treatment options.

PHQ-9 data will inform treatment progress but will not dictate treatment discontinuation. Rather, clinicians and patients will decide on the final length of treatment (up to the maximum 9 sessions in 4 months). A response of 50% reduction in depressive symptoms was chosen, based on prior work and evidence from other studies.[33-35] This response criterion also appropriately classifies responders with variable depression levels. A decrease in symptoms by 50% for an initial PHQ-9 of 10 (the lowest possible entry score) would require a 5-point change (the minimally clinically important difference for the PHQ-9).[36]

During active treatment, clinicians will be asked to discuss depressive symptoms and response with participants as part of the treatment process. Providers will be encouraged to deliver bCBT as long as it remains appropriate for any given patient. If a patient is discovered to have additional needs that make the use of bCBT inappropriate, the clinician can opt to seek additional or alternative care for the patient. The presence of severe depression, substance abuse, and comorbid PTSD or anxiety disorders could all require the clinician to change or add treatments. At the end of the 4 month treatment period, clinicians will be encouraged but not required to discontinue treatment. For patients who reach the response criterion, clinicians will introduce the potential for treatment discontinuation. For patients who do not reach the targeted depression goal by the final session (6th session), clinicians will work with the patient to determine whether additional sessions would be helpful. The provider will have the option to continue care or refer the patient to other therapies that are not a part of the research study based on their clinical judgment.

“Rapid” responders will be asked to stay in treatment for a minimum of 3 sessions. For nonresponders, treatment may be extended up to a maximum of 9 sessions.

Figure 1. Response to bCBT Treatment and Determination of Treatment Ending



ARM #2: Enhanced Usual Care

Following randomization, EUC participants will receive feedback and educational materials about managing depression[37] and a letter encouraging them to discuss treatment options with their VA primary care provider (see Appendix 9, Patient Educational Brochure and Appendix 11, Usual Care Letter). The EUC arm represents a modest enhancement to the ongoing CBOC practices in that it will add routine, comprehensive screenings for all consenting patients, identification of depressive symptoms, encouragement to address depression using print-based materials, and notification of the patient's primary care provider. EUC participants will be given the same reimbursement as bCBT participants and will be asked to complete the same assessments at 4-, 8-, and 12-month follow-ups. Following each assessment, findings will be documented within each patient's electronic medical record. Because depression identification and treatment are a priority within VA, we fully expect that enrolled participants may receive depression treatment (e.g., antidepressants or depression care management). Although medications are a first line of care for depression, data suggest that antidepressant medication use remains modest.[38]

NOTE: Participants in EUC will NOT be restricted from any mental health services. To address the possible confounding effects of co-occurring mental health treatments, we will measure health services utilized, with particular emphasis on use of psychotropic medications, psychotherapy, and other specialty mental health care.

Minimization of Risk

Provider Participants: Prior to any provider recruitment efforts, union representatives at the Houston and Oklahoma City VAMCs will be notified of the study proposal. Potential therapists will be referred by their clinic director and/or VISN mental health leadership and subsequently screened for appropriateness by the study investigators. The study team will be careful to ensure that VISN leadership or clinic directors do not require clinicians to engage in this work. Any clinician who does not wish to participate will be excluded. Clinician participants final decision to participate or not will not be made known to their supervisor or VISN leadership. Clinicians who wish to participate (receive the training and provide care) will be enrolled. Therapist information related to performance and feedback will be coded within the study so that no therapist specific information will be identifiable outside of the study itself.

Veteran Participants: To maximize confidentiality, participants will receive a unique study number that is attached to study related data. Data will be kept in locked file cabinet housed in a data storage room that has a security keypad as entry. All electronic data files will be maintained within the VA setting and behind the VA firewall. In addition, all electronic data files will be password protected for additional security.

Local Advisory Council Participants: Prior to any provider recruitment efforts, union representatives at the Houston and Oklahoma City VAMCs will be notified of the study proposal. Potential LAC members will be referred by their clinic director and/or VISN mental health leadership and subsequently screened for appropriateness by the study investigators. The study team will be careful to ensure that VISN leadership or clinic directors do not require employees to participate in the LAC. Any employee who does not wish to participate will be excluded.

No participants will be identified in any reports that may be published. Intervention participants are not required to take any study medication or undergo any invasive procedures; therefore, we do not foresee any study related adverse events.

In the event of a participant who reports suicidal ideation during the assessment or treatment process, a specific protocol will be used to triage the participant to the appropriate source of VA care. As part of all baseline and follow-up assessments, study staff will closely monitor and explore all indications of suicidal thinking. The PHQ-9 item #9 asks for responses about thoughts of being “better off dead or hurting yourself in some way”. Study staff will follow up on any positive response to this item using a structured crisis assessment protocol. The structured assessment will distinguish between passive vs. active suicidal thinking, identify any intent or plans for self-harm, and inquire into family, health care, or community supports (see Appendix 3 for detailed listing of the structured assessment). Participants who express suicidal ideation will be immediately forwarded to a study investigator who will triage and refer for care as appropriate. If it is an emergent situation the research assistant will page an on-call licensed practitioner (study PI or co-investigator). The PI, and other study staff (Drs. Kunik, Kauth, Stanley, and Sorocco) are all licensed mental health practitioners and will serve as the on-call staff.

We will also monitor changes in depression symptoms over time and initiate contact with participants who report an increase of 5 points or more on the PHQ-9 from baseline or between any two study assessments. Reports will be run by the study team on a weekly basis to identify participants with increased depressive symptoms.

Potential Benefits

Provider Participants: All clinicians will receive expert bCBT training and ongoing consultation to learn how to apply bCBT in their daily practice. The risk-benefit ratio of the study suggests that the proposal is reasonable given the potential direct benefits to participants and providers via the intervention and education provided.

Veteran Participants: Participants randomized to the direct referral arm will be provided with bCBT treatment while participants randomized to the enhanced usual care arm will receive educational products designed to increase their ability to manage their emotional health issues. Additionally, EUC participants will be encouraged to seek services for their depressive symptoms. Participants may feel less depression, worry, and associated symptoms and may experience an improved ability to perform normal activities of daily life.

Local Advisory Council Participants: LAC members are expected to experience few direct benefits as a result of participating in the developmental evaluation. The benefits are largely scientific in nature and will facilitate the integration of the research program into existing workplace procedures. Having an opportunity to provide feedback on this process may be a rewarding experience for some participants, and the information gathered may improve the quality of care of future patients.

The risk-benefit ratio of the study suggests that the proposal is reasonable given the potential direct benefits to participants via the intervention and education provided as well as the potential for this research to benefit other Veterans and the larger research and clinical community by providing detailed information on the use of brief cognitive-behavioral therapy for Veterans in rural health care settings.

The potential benefits of the study are numerous, with many involving the provision of care to participants but also including information related to how the VA can improve its ability to train and implement psychotherapies in the primary care setting. Data to be obtained from this study will provide important information on the use of brief cognitive-behavioral therapy for Veterans with depression as provided by frontline VA practitioners. Should the intervention prove effective, the study team will target clinical and research initiatives designed to further increase the implementation of these procedures within VA. Risks of the study are minimal and many research participants will be provided with care that may not be available within existing care settings.

Description of study population

Clinician Participants: The bCBT intervention will be delivered by VA CBOC clinicians at the Houston and Oklahoma City affiliated CBOCs. All mental health clinicians at the 16 CBOC sites will be approached for inclusion in the study. Clinicians will not be restricted based on discipline or prior CBT experiences, but will be expected to have an interest in obtaining training and willingness to use bCBT in their practice. As seen in our ongoing trial, we anticipate that nurses,

social workers, psychologists, counselors, and physician assistants will participate. Clinicians may receive workload credits for bCBT delivery since these practices will be delivered as part of their clinic duties. The study team will work with the clinician to receive workload credit, but will not guarantee that workload credit can be obtained.

Veteran Participants: Recruitment efforts will utilize VA databases, opt- out recruitment letters, and follow-up phone calls. Participants randomized to the intervention arm will receive treatment from one of the 16 CBOC sites within the Houston and Oklahoma City regions and who screen positive for depression on the PHQ-8. A total of 232 Veteran participants will be randomized.

Local Advisory Council Participants:

The LAC will consist of VA employees working at CBOC facilities. CBOC clinicians already consented as study clinicians, administrative staff, and facility leadership at the 16 CBOCs are eligible for participation. No contract CBOCs or contract employees will be approached.

Added protections for vulnerable populations

No vulnerable populations will be targeted for enrollment, except for VA employees who provide mental health treatment to Veterans. No added protections are planned outside those described above.

5.2 Recruitment Methods

Clinician Participants

Clinicians will be VA employees working as mental health clinicians at CBOC facilities. All VA mental health clinicians at the 16 CBOC sites will be approached for inclusion in the study. No contract CBOCs or contract mental health providers will be approached. We anticipate that a minimum of 12 clinicians will be enrolled, with a realistic estimate, given staff turnover and program expansion efforts, to approach 15 or more enrolled clinicians before the end of the trial. Clinicians will be invited to participate by referral from clinic directors and/or VISN 16 mental health leadership (see Appendix 4, Clinician Recruitment Letter). The study team will follow-up with the clinician and his/her supervisor to verify that study participation is appropriate. Study staff will follow up with the clinician via email to confirm interest. If there is no response to the email a follow up phone call will be placed. CBOC clinicians will receive advocacy (when needed) from the study staff and VISN leadership (see letters of support) to resolve barriers to participation. Clinicians will not be restricted based on discipline or prior CBT experiences but will be expected to have an interest in obtaining training and willingness to use bCBT in their practice.

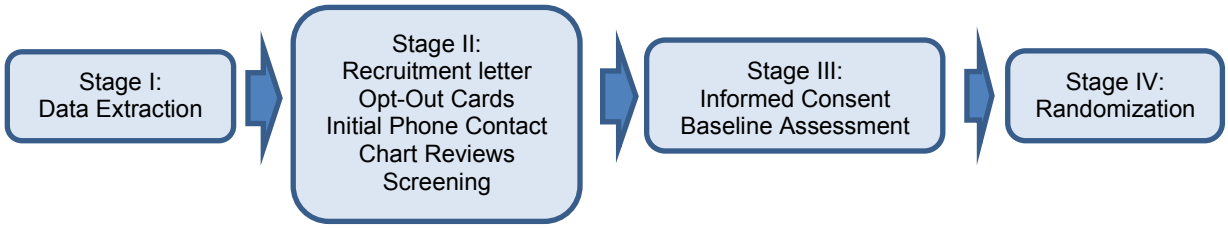
Veteran Participants

Based upon sample-size calculations (including attrition over time), the total sample to be randomized is 232. Participants are not randomized until after conformation of depression after the baseline. Because final determination of study inclusion cannot be determined until the baseline appointment, we anticipate needing to provide consent to approximately 300 Veterans total. Approaching Veterans who are not necessarily treatment seeking is a critical component of the project and allows for increased reach to Veterans who might otherwise go unrecognized by the healthcare system. The recruitment procedures comprise four stages designed to maximize reach while minimizing participant burden and confusion about study procedures.

Local Advisory Council Participants

The LAC will consist of VA employees working at CBOC facilities. CBOC clinicians already consented as study clinicians, administrative staff, and facility leadership at the 16 CBOC are eligible for participation. No contract CBOCs or contract employees will be approached. We anticipate recruiting 4 clinicians, 2 administrative personnel, and 2 Parent Facility leaders for the LAC. Employees will be invited to participate by referral from clinic directors and/or VISN 16 mental health leadership. Study staff will follow up with the clinician via email to confirm interest (see Appendix 4C, LAC Recruitment Letter). If there is no response to the email a follow up phone call will be placed.

Figure 2. Veteran Recruitment Flow Chart



Stage I:

The first stage will consist of a data extraction from national VA databases to identify the pool of potential study participants. This data extraction will target patients who received care at the Houston and Oklahoma City CBOCs. CBOC/Facility categorization will be based on the location of the patient's current primary care provider. Initial database extraction will only be used to identify Veterans who receive care at one of the 16 CBOCs in the HOU and OKC regions. The study will not target any specific patient populations – rather the study will request information on all Veterans treated at each of the respective CBOCs.

The following participant recruitment strategies were designed to ensure that enlisted participants would be clinically appropriate for treatment of depression using bCBT in the CBOC setting.

Stage II:

In stage two, study personnel at the Houston VAMC will mail potential participants an opt-out letter, and an opt-out card (self-addressed and stamped) to their home address as listed in CPRS. The letter will state that study staff will call within two weeks unless the patient requests not to be contacted. The patient may make a no-contact request via a telephone number listed in the letter or by mailing back the enclosed opt-out card. During the initial phone contact, a research assistant will administer the screening questions. The RA will follow a script for the telephone contact that includes assent procedures for the screening questions (see Appendix 5 for screening telephone script and Appendix 6 for screening assessments). Participants will be asked questions to screen for depression (PHQ-8), cognitive functioning (6 –item Cognitive Screen), presence of bipolar and psychotic disorders, substance use (MINI), and alcohol use (AUDIT-C). Eligible participants (those who screen positive for depression on the PHQ-8 and are not excluded for more severe mental health issues) will progress to the final recruitment procedures. After screening eligible, a chart review will be conducted to confirm the participant is not currently receiving any other psychotherapy treatment. Current treatment will be defined as patients that have received a psychotherapy appointment within the last 3 months. Chart reviews will be conducted by staff in Houston and Oklahoma City. Staff in Houston will utilize the Compensation and Pension Record Interchange (CAPRI) to review the charts of Oklahoma City participants.

Stage III:

A full baseline assessment will be scheduled within 1-2 weeks of the telephone screening. The independent evaluator assigned to complete the baseline assessment will complete the informed consent process with the participant before beginning the assessment.

Stage IV:

Participants still eligible based upon a second positive response to the PHQ-9 will be randomized to the direct referral or EUC groups.

Participants identified to be at the upper limits of depressive symptoms will not be restricted from participation. We plan to offer the treatment to severely depressed patients, knowing they may require additional services beyond the study, either as an augmentation of or alternative to the bCBT.

Only Veteran participants will be compensated in the study. Study clinicians are not eligible for compensation given their VA appointment. Veteran participants can receive a total of $110 if they complete all study assessments ($20 baseline, $30 for 4-, 8-, and 12-month assessments). Payment will be in the form of a debit card that will be mailed to their address. If a participant has electronic funds transfer set up with the VA then they will be eligible to have the money deposited directly into their account. The debit card process can take up to 8 weeks to be received and an electronic fund transfer takes approximately 10 days to appear in the account.

A subset of Veterans randomized to the direct referral arm will be asked to complete a one-time qualitative interview regarding their previous experience with emotional health services and experiences in the brief CBT program. We will approach equal numbers of Veterans who have completed a) 4 or more sessions, b) 1 – 3 sessions, or c) no sessions, for a total of 9-12 Veterans. The interview will last 30-45 minutes, and Veterans will be compensated $30 for their time completing the interview.

5.3 Informed Consent Procedures

The consent process will occur before administration of the baseline assessment for Veterans and before training for clinicians. LAC members will be consented during the first month of the active phase of the project. The informed consent process will be completed by the local Site RA or the Project Coordinator. This study does not involve subjects with impaired decision-making ability or who have legally authorized representatives.

Clinician Participants

Clinicians will be recruited from all 16 CBOCs and included as study participants. Local union representatives will be informed of the study. Currently, there are 24 mental health clinicians who provide care to the 16 identified CBOCs.

The study is requesting a waiver of documentation of informed consent for clinician participants. Potential therapists will be referred by their clinic director and/or VISN mental health leadership and subsequently screened for appropriateness by the study investigators. Clinicians identified as interested will be contacted via email by study staff to confirm interest. A follow up call will be made if there is no email response from the clinician. When interest is confirmed, a time will be set up to review the informational document (see Appendix 4E) with the clinician by phone. The informational document will be emailed to clinicians prior to the meeting. During the meeting, the study team member will review the document and explain all procedures requested of a participating clinician and address any questions posed. In some instances, the consent process will take place during the initial phone call confirming interest if the clinician is available at that time. If so, a copy of the informational document will be emailed at that time. Once a clinician gives their consent, their name will be added to the master list of enrolled participants.

Veteran Participants

The study is requesting a waiver of documentation of informed consent, as well as a waiver of HIPAA authorization for veteran participants. The study requests a waiver of informed consent and HIPPA authorization for recruitment stages 1 and 2 which occur prior to the formal consent process (Stage 3). All participants will be mailed a study introductory letter informing of the opportunity to participate (see Appendix 5F Recruitment Letter). An opt-out card will also be included with the recruitment letter (see Appendix 5B, Opt-out card). Participants will be able to opt-out either by using the provided telephone number or by mailing back the opt-out card. Any one that does not opt-out within two weeks from the date of the mailing will be called and provided with an explanation of the study. A telephone script will include assent procedures (see

Appendix 5C, Script for Screening Phone Contact). This initial phone contact will begin with reference to the recruitment letter and will explain the purpose of the research and inquire about participants' interest. Potential participants will also be provided with a number they can use to verify that the project is VA research. After assent, interested participants will be asked a series of survey-based screening questions that will take approximately 10-15 minutes. Eligible participants (those who screen positive for depression on the PHQ-8 and are not excluded for more severe mental health issues) will be scheduled for a baseline assessment to occur 2 weeks after the telephone screening.

Participants' informed consent will be obtained at the baseline appointment. Prior to the initiation of the baseline, a telephone script (see Appendix 5D) will be utilized by the RA. As part of the script the RA will review the Detailed Patient Information sheet (see Appendix 5E). The information sheet will describe the procedures involved in the project as well as their rights as a participant in a research study. Participants will also be informed a select sample of assessments (5%) will be audio recorded for data integrity checks and training purposes of Independent Evaluators (IE). Before initiating the assessment, selected participants will be asked to be recorded. In addition, eligible participants randomized to the bCBT direct referral group, will be asked to have their session audio recorded by their clinician. Audio consent will be explained as an optional matter and not a requirement for participation. Potential participants will be provided an opportunity to ask questions. After questions have been answered to their satisfaction, they will be asked if they give their verbal consent to proceed with the assessment questions. Once the RA obtains verbal consent from the participant their name will be added to a master list (see Appendices 5B5E for a complete listing of patient recruitment materials).

Participants that decline being audio recorded will have a note placed in the research master record indicating as such. Providers will be notified via encrypted email of participants randomized to the direct referral group that declined being audio recorded.

Qualitative Interview

Participants randomized to the treatment group will be asked to complete a one-time qualitative interview. The study will target participants that fall into 3 categories: a) completed 4 or more sessions; b) completed 1 – 3 sessions; and c) completed 0 sessions. A total of 12 participants (4 from each category) will be approached to complete the interview. Participants will be contacted at the 4 month time period or immediately following their decision to end treatment. Veterans will be contacted to determine their interest in completing the qualitative interview. Veterans that agree to complete the interview will be scheduled for a phone meeting and a copy of the qualitative interview informational document (see Appendix 5H) will be mailed to them at that time. The informational document will explain the procedures for the interview and the participant's rights as a research participant and will be reviewed during the telephone meeting. The participant will have an opportunity to ask any questions. After the questions have been answered to the participant's satisfaction, their verbal consent will be obtained to proceed with the interview.

The waivers of documentation of informed consent and HIPAA are requested because the intervention has a specific focus on increasing rural Veterans' access to mental health services via strategies such as telephone-based assessments and treatment alternatives. Determining the effectiveness of these strategies requires a sample of Veterans that represents the Veteran community at-large and does not include only highly selected, motivated, or resourceful individuals. The proposed recruitment strategies represent the study team's attempt to reduce the research burden on our Veteran participants and to reach a wider audience of Veterans, many of whom do not get the care they need. The requirement for written HIPAA authorization would increase the research burden on these Veterans and preclude their participation.

Local Advisory Council Participants

LAC participants will be recruited from all 16 CBOCs and included as study participants. Local union representatives will be informed of the study and all enrolled employees will sign written informed consent (see Appendix 4D).

All project staff is required to undergo significant training on the protection of human subjects, research methods, and the importance of integrity in the research process. Study team members who are authorized to recruit participants and/or obtain informed consent will be trained on specific study consent procedures by the study PI (Cully), the Project Coordinator (Zeno), or the main site RA (Robinson). Each person will be required to administer a mock consent where they will receive hands on experience on possible questions and proper ways to address. Local site (OKC) study personnel will recruit and consent provider participants and LAC members. The LSI (Sorocco) will be trained in the consent and enrollment process to ensure familiarity with study procedures. Ongoing, weekly team meetings will be conducted in-person or via conference calls with local site study team members together with the main site project team to ensure study protocols continue to be followed consistently throughout the study

5.4 Inclusion/Exclusion Criteria

Provider Criteria

All mental health clinicians at the 16 CBOC sites will be approached for inclusion in the study. Clinicians will not be restricted based on discipline or prior CBT experiences but will be expected to have an interest in obtaining training and willingness to use bCBT in their practice. As seen in our ongoing trial, we anticipate that nurses, social workers, psychologists, counselors, and physician assistants will participate. The only exclusion criteria for clinicians will be for those clinicians who are not appropriately authorized to provide psychotherapy as part of their scope of practice at the VA.

Veteran Participant Criteria

Veterans with clinically significant symptoms of depression will be included after multiple "baselines" to ensure consistency of depressive symptoms (score of 8 or greater as reported on the PHQ-8 during the telephone screen and 10 or greater PHQ-9 during the baseline appointment). The PHQ-9 is the instrument of choice for the VA PC-MHI initiative (consistency of current practice) and is ideal for use as a monitoring measure for depression over time.

The single inclusion criterion is that Veteran participants be current recipients of services at CBOCs associated with the Houston or Oklahoma City VAMCs. To increase generalizability, participants will be excluded only for factors that would render bCBT inappropriate for the CBOC setting, including: 1) cognitive impairment; 2) presence of bipolar, psychotic or substance-abuse disorders. 3) Veterans currently receiving psychotherapy WILL be excluded. Those receiving general mental health services, including antidepressant medications, WILL NOT be excluded.

Local Advisory Council Participant Criteria

Consented clinicians serving as providers of the bCBT intervention, administrative staff, and facility leadership at the 16 Houston and Oklahoma City CBOCs will be eligible for participation. CBOC clinicians who have declined to participate in the bCBT training program will not be invited. No contract CBOCs or contract employees will be approached.

5.5 Study Evaluations

Implementation Measures and Data Collection Schedule (Study Aim 1): *A mixed-method formative evaluation* (FE) will be utilized to assess the adoption potential of the bCBT clinical intervention and implementation strategy. As informed by Stetler et al.,[39] FE will progress strategically through four phases over the course of the project as follows: 1) a developmental evaluation to adapt the proposed implementation strategy for CBOCs, 2) an implementation-focused evaluation to refine the implementation strategy based on lessons learned from early adopters, 3) a progress-focused evaluation to assess implementation outcomes, and 4) an interpretative evaluation to engage key stakeholders to better understand the impact of the implementation strategy. FE will assess adoption, effectiveness, and implementation (fidelity), and will pay close attention to the processes, challenges/barriers, and patient, provider, and clinic needs related to the use of bCBT in the CBOC setting. Table 2 lists the formative evaluation phases, timelines, and methods.

Quantitative Implementation Data: Adoption will be defined as the number of enrolled CBOC clinicians relative to the number of providers able to provide bCBT within their scope of practice. Adoption will include the number of CBOC clinicians who are approached, complete training, and engage in implementation facets. We will also examine the average number of sessions clinicians provide per patient. *Clinician Adherence and Competence* will be assessed using fidelity scores and summarized as descriptive data. Scores will be used to identify clinician strengths and weaknesses and will provide the basis for feedback provided to clinicians through

the bCBT mentors. Data will also be used to determine whether bCBT was implemented as intended. *Clinician bCBT Training and Utilization*: Clinician bCBT utilization will be collected using chart reviews as well as a series of clinician-based self-report measures. Chart reviews will be conducted for all bCBT-randomized Veterans. Clinicians will be provided with a note template to standardize documentation and improve data extraction. Chart review data will include treatment initiation, number of sessions, type of session (in-person or telephone), content of session (module selected), as well as other quality indicators of care such as timeliness of initial session and duration of time between sessions. Chart review data will be supplemented with clinician surveys to document the frequency of use of various bCBT procedures and techniques (*in development*; modeled after our prior bCBT training study[24, 26]).

Qualitative Implementation Data Collection and Outcomes: Qualitative data collection will occur in the form of focus groups and individual interviews with CBOC and national stakeholders. Interviews and focus groups will seek to understand the perspectives of clinicians, administrators, patients, and national leaders about the process and experience of providing bCBT in the CBOC setting and to further understand the challenges and opportunities for using such treatments in the future. The guiding domains for the interviews and focus groups are based on the PARiHS and RE-AIM frameworks. Guides were created for each interview type (individual or group), formative evaluation stage, and stakeholder group (patient, clinician, administrator, leadership; see Appendix 7 for a detailed listing of the interview guides). All qualitative data will be collected by experienced qualitative researchers. Interviews and focus groups will be conducted by telephone. Although the developmental evaluation will include the PI (Cully) and qualitative methodologist (Martin) – all other qualitative data will be collected by Dr. Martin and a research assistant who will remain independent of the main study project to maintain data integrity and privacy. Thus stakeholders will likely have no prior professional interactions with the interviewer. All qualitative data will be audio recorded and transcribed, and interviewers will maintain field notes to document tone or affect that may not be apparent from the written transcript. It is anticipated that individual interviews will last between 30-45 minutes with some groups (clerks/staff and leadership) lasting 20-30 minutes. Focus groups are expected to take 1-1.5 hours.

Developmental Evaluation: The aim of this evaluation is threefold: 1) to asses CBOC needs, barriers, and facilitators related to bCBT use 2) to refine the clinical and implementation approach for CBOCs and 3) to increase local and national stakeholder engagement. It is anticipated that CBOC leadership will be critical throughout the project. The team will use the developmental evaluations as a foundation for future relationship building and engagement of CBOC leadership. During months 1-6, the project team will develop a local advisory council (LAC) consisting of CBOC clinicians, administrators/clerks, and CBOC/Parent Facility leadership to assist with understanding the current needs of CBOCs in the use and delivery of psychotherapy. The LAC will react to and refine the bCBT clinical intervention and implementation strategies proposed by the study team to help ensure these methods are consistent with practice needs at the CBOC level. LAC members will be asked to participate in up to 3 45-minute telephone-based focus groups to provide insight into process improvements. These individual interviews will occur during months 2 (needs assessment), 4 (reaction and

suggested changes to the bCBT and implementation strategies), and 6 (final refinement of strategies for initial role out). The total time commitment for LAC members will be 135 minutes and over the course of 6 months. Also, during months 1-6, the project team will engage the national advisory council (NAC; see Table 2). Although NAC members will be available for individual consultation, the project team will host a telephone conference call (e.g. Live Meeting) during month 5 where members will be asked to react and comment on the proposed bCBT intervention and implementation strategies as refined by the LAC. The NAC will be asked to specifically comment on the implementation potential and consistency of the strategies with national VA initiatives. Feedback from the NAC will be fed forward to the LAC for the final LAC meeting at month 6. Focus groups and interviews will be audio recorded and facilitated by the study qualitative methodologists. Given the aims of this phase, qualitative analyses will identify important concepts using transcript summaries rather than a full coding strategy (defined by Curran et al).[40] Summary data will be distilled after each focus group, and study team will use these data to refine the intervention and implementation materials. At the conclusion of the developmental evaluation, the clinical and implementation approaches will have been modified for initial use within the CBOC setting.

Implementation-Focused Evaluation: The aim of this evaluation is twofold: 1) to collect initial data and feedback on the clinical and implementation approaches from initial adopters (e.g., clinicians and clinics) and 2) modify the implementation strategy to enhance bCBT use. The study will also engage incoming CBOC clinicians regarding their perceptions of organizational readiness to support the implementation of bCBT using the Organizational Readiness to Change Assessment (ORCA).[41] After initial role out of the clinical and implementation interventions, the team will conduct an evaluation during months 12-15 to obtain preliminary data from local stakeholders (clinicians, administrative staff, leadership, and Veterans) about their reactions to the bCBT programming. The ultimate goal of this aspect of the formative evaluation is to discover any barriers that were not identified during the developmental evaluation. Should additional barriers be identified, the study team will work with stakeholders to modify the implementation approach. Quantitative data will be collected including: 1) clinician adoption rates, 2) clinician fidelity ratings, and 3) patient bCBT use (treatment engagement, completion, and number of total sessions attended). Qualitative data will be collected from bCBT clinicians (n = 3-4) and clinic administrators/leadership (n = 2) in the form of individual telephone interviews. Dr. Martin (qualitative methodologist) will lead all study interviews for this phase. In addition, a purposeful sample of Veterans (3-4) who received bCBT will be interviewed to elicit feedback on feasibility, acceptability, and meaning /impact. We will purposefully select Veterans based on engagement / completion rates to ensure diversity. Interviews will be audio recorded and transcribed into summaries (rather than full coding).

Progress-Focused Evaluation (PFE): will 1) explore the impact of the bCBT clinical and implementation approaches; 2) assess factors related to using the implementation approach; and 3) produce a project summary document to be used during the interpretive evaluation phase. The PFE will occur at the beginning of year 3 when the majority of CBOC clinicians and clinics will have been recruited for the trial. PFE will differ from the implementation-focused evaluation in that it will involve a larger number of CBOC clinicians and will occur after the

implementation strategy has been refined. The project will continue to use the ORCA with all incoming CBOC clinicians during this phase to enhance our understanding of organizational culture and needs. Quantitative data will include clinician and clinic adoption rates, clinician fidelity ratings, and bCBT utilization statistics. Qualitative methods will focus on bCBT implementation with particular emphasis on barriers, facilitators, and reaction to the implementation strategy provided by the study team. Individual interviews will be conducted with CBOC clinicians (n = 12-15), CBOC administrative staff (n = 4-5), and CBOC leadership (n = 4-5). We will also conduct individual interviews with Veterans (n = 9-12) who were randomized to the bCBT intervention. Veterans will be purposefully sampled according to bCBT exposure (no engagement, 1-3 sessions, and 4 or more sessions/completers). The study team will begin all interviews from a phenomenological perspective asking participants a broad, open-ended question about their lived experiences with bCBT, probing the salient factors and processes identified. Interviews will transition into a semi-structured format to allow for the use of probes, as suggested by Patton [42,43] and informed by PARHIS and RE-AIM. Unlike the first two phases of formative evaluation, data collected from the PFE will be subjected to rigorous qualitative data coding and analyses. The study qualitative methodologists will then work with the larger study team to create a summary document for use during the interpretive evaluation. Interpretive Evaluation will occur during months 39-42 of the project and will seek to: 1) use a project data summary document to inform stakeholders (NAC and LAC) about preliminary study outcomes and 2) obtain stakeholder reflections on importance, meaning, and the potential for wider use of bCBT in CBOCs. To accomplish these goals, focus groups will be conducted with the NAC and LAC. Stakeholders will receive the project data summary document two weeks prior to their focus group. Focus groups will seek stakeholders' reactions to the project data using open ended questions. Follow up questions will engage stakeholders in future-oriented inquiries about implementation and dissemination potential of bCBT in CBOC settings and will attempt to obtain consensus on next steps. Focus groups will be conducted by Dr. Martin and audio recorded. Analyses will use transcript summaries rather than full coding. Focus group data will be reviewed by the full team and used to inform dissemination of project materials, manuscripts, and grant planning.

Table 2. Formative Evaluation (FE) Data Collection Timeline, Methods, Expected Outcomes

FE Type	***Methods / Expected Outcomes***
Developmental *(months 1-6)*	*- Local advisory council - focus groups at months 2, 4, and 6; National advisory council focus group - month 5* ***Expected outcomes****: Data will be used to modify clinical and implementation strategies prior to use (month 7).*
Implementation-Focused *(months 12-15)*	*Qualitative Data: Individual interviews with local stakeholders (early adopters – clinicians, clinics, Veterans) Quantitative Data: Clinician / clinic adoption, fidelity, Veteran bCBT engagement and completion rates.* ***Expected outcomes****: Data will be used to explore initial successes and challenges of the implementation approach. The full study team will modify the implementation strategy to be deployed in month 16.*
Progress-Focused *(months 24-27)*	*Qualitative Data: Individual Interviews with CBOC clinicians (N=12-15); CBOC administrative staff (N=4-5); CBOC leadership (N=4-5); and Veterans (N=9-12). Interviews will assess meaning and impact of the bCBT intervention, as well as a focused exploration of bCBT use - needs, successes, and barriers (PARHIS). Quantitative Data*: Clinician / clinic adoption and fidelity; Veteran engagement, completion, and bCBT session attendance. *limited/partial data due to ongoing nature of study* ***Expected outcomes****: Implementation data will augment the project's clinical outcome data on depression and quality of life. A project data summary document will be developed to inform the interpretive evaluation.*
Interpretive *(months 39-42)*	*- Focus groups 1) local advisory council 2) national leadership council – reaction to data summary document* ***Expected outcomes****: Summary data will be vetted with the full study team and used to inform final dissemination of project materials, manuscripts, and future grant planning.*

Effectiveness Measures (Study Aim 2): Measures were selected for their strong psychometric properties, ability to detect patient-centered change, and feasibility for adoption/implementation within VA (see Appendix 8 for a complete listing of all Effectiveness measures).

*Depression: D*epression will be assessed using the Patient Health Questionnaire – 9 (PHQ-9) and the Beck Depression Inventory – Second Edition (BDI-II). Treatment response will be defined by a 50% reduction in depressive symptoms on both the PHQ-9 and BDI-II. [33-35] The PHQ-9 consists of the depression module from the larger, self-administered version of the PRIME-MD[44] and is particularly versatile in its ability to assess both symptoms as well as each of the nine *DSM-V* depression criteria.[36] For this study, a PHQ-9 cutoff score of 10 or greater will be used for inclusion criteria. Note: The PHQ-9 will be administered by study RAs and independent evaluators as part of all "study-based assessments" and will also be used by bCBT clinicians as part of their regular course of treatment with bCBT participants. The BDI-II, a 21-item self-report instrument, will be used as a second measure of depressive symptoms. The BDI-II is psychometrically strong[45] and is reliable, internally consistent, and valid for use in the primary care setting.[46] The BDI-II will serve as a second measure of depression and, unlike the PHQ-9, will be administered exclusively by study staff.

Quality of Life and Functional Status: Quality of life will be assessed using the 12-Item Short Form Health Survey for Veterans (SF-12V),[47] an instrument adopted by VHA as a performance measure of functional status. The SF-12V is comprised of 12 items from the SF-36. The SF-12 consists of two scores, physical (PCS) and mental (MCS) functioning. Covariates: Demographic data will include age, gender, ethnicity, income, marital status, education, employment, and distance from the VA and/or CBOC. *Diagnoses of Anxiety and Depressive* Disorders will be assessed using the MINI depression and anxiety modules. Coding of these variables will be dichotomized for each type of depressive and anxiety disorder assessed. *PTSD* will be assessed using the PTSD Checklist- Civilian Version (PCL-5), a standardized self-report rating scale that corresponds to *DSM-IV* symptoms of PTSD and possess strong psychometric properties.[50,51] *Comorbid Medical Conditions/Medical Complexity* will be calculated using the Charlson Comorbidity Index (CCI) as defined by VA database extractions for the 12 months prior to the baseline date. The Charlson score has been widely used in the literature for assessing morbidity and mortality in a wide range of patients.[52] The ICD-9 codes constituting each condition will be based on those identified in Deyo's adaptation.[53] *Co-existent Use of Psychotropic Medications* will be collected to control for possible effects of ongoing pharmacologic treatment. VA databases and participant surveys will be used to assess for the presence of mental health medications. The study team has experience evaluating the impact of psychotropic medications in psychotherapy trials and has also conducted several VA database studies looking at the impact of antidepressant medications on depression care quality.[8, 54] Dr. Kunik (psychiatrist and Co-I) will lead efforts related to psychotropic medication tracking which will include information on start date of medication, dose, and days' supply. Medication use will be coded for presence or absence, changes to type or dosage, as well as medication possession ratios (days of medication relative to time frame of medication

treatment). Antidepressant medications will be evaluated in both the treatment and usual care groups at all assessment time points, affording the study an opportunity to evaluate whether assignment to the treatment group impacted receipt of medications. Participant self-report data will allow for global estimates of non-VA medication use. *Health Service Use*: Health-service-use will be collected for each participant to control for non-study encounters and healthcare services. Service use will be collected from VA medical records as well as a patient self-reported non-VA service-use questionnaire. Health service information will be collected via VHA national and regional databases. The study team will obtain all relevant approvals (e.g. DART) prior to data extraction. Data will be collected on the frequency and type of inpatient hospitalizations and outpatient medical and mental health encounters. Outpatient mental health care use will be monitored and used as a covariate.

Treatment Variables Intensity/dose of bCBT will be defined as the total number of sessions attended. Session (telephone/in-person) and module type will be collected to examine for impact on outcomes. These data will be collected via note templates and chart review procedures using CAPRI. *Treatment Expectancy* will be assessed using the Expectancy Rating Scale (ERS).[55] The ERS includes 4 items that assess how logical treatment seems, the patient's confidence undergoing treatment and recommending it to others, and expectations for treatment's success. *Therapist Rating of Patient Engagement and Adherence* will be collected following the last session of treatment.

Therapists will be asked to rate the overall level of patient engagement and adherence (2 items), using a 10- point Likert-style format, ranging from not at all engaged/adherent to fully engaged/adherent. *Working Alliance* will be assessed using patient and therapist report forms of the Working Alliance Inventory - Short Form (WAI-S). The WAI-S consists of 12 items and yields an overall score and 3 subscale scores, has adequate internal consistency, good overall validity, and is predictive of reduction in depressive symptoms.

Secondary Measures: To better understand factors that may contribute to participant treatment response, the protocol has been expanded to include brief assessments for the following: insomnia, pain, illness intrusiveness, CBT skill acquisition, personality, social support, attachment style, life purpose, and Veterans perceptions. Careful consideration has been taken into selection of the measures, as not to add any undue burden on participants.

Effectiveness Data-Collection Schedule: Data will be collected over 12 months posttreatment to examine long-term effects/decay of the intervention (see Table 3). An initial telephone assessment will screen for exclusion criteria, with final eligibility determined at the baseline appointment. Four-, eight-, and twelve-month follow-up assessments will be conducted by blinded independent evaluators. A 90 minute time limit has been established for all assessment interviews in order to reduce burden on Veteran participants. For participants that do not complete all study measures during the 90 minute assessment period, participants will be

reminded that they have completed their participation. They will be provided with the option to end the call or continue the interview – not to exceed 120 minutes in total time.

Table 3. Assessment Schedule – Effectiveness Data

Aim 1 Effectiveness

	Screen	Baseline	1 mo (bCBT only)	4 mo (post-tx)	8 mo F/ U	12 mo F/U
Chart Review, Initial PHQ-8, MINI, Cognitive Screen	P-IE or RA					
Demographics		P-IE or RA				
Charlson Index (medical comorbidities)		D				
MINI – depression, anxiety, and PTSD modules		P-IE or RA				P-IE
PHQ-9		P-IE or RA		P-IE	P-IE	P-IE
BDI-II		P-IE or RA		P-IE	P-IE	P-IE
SF-12		P-IE or RA		P-IE	P-IE	P-IE
PCL-5		P-IE or RA		P-IE	P-IE	P-IE
GAD-7		P-IE or RA		P-IE	P-IE	P-IE
Insomnia Severity Index (ISI)		P-IE or RA		P-IE	P-IE	P-IE
Illness Intrusiveness Ratings (Medical Issues)		P-IE or RA		P-IE	P-IE	P-IE
Working Alliance Inventory (Patient)				P-RA*		
Working Alliance Inventory (Clinician)				C-RA		
Cognitive-Behavioral Therapy Skills Questionnaire (CBTSQ)		P-IE or RA	P-RA*	P-RA*		
Ten Item Personality Inventory (TIPI)		P-IE or RA				
Social Support		P-IE or RA		P-IE or RA	P-IE or RA	P-IE or RA
Purpose of Life (PiL)		P-IE or RA		P-IE or RA	P-IE or RA	P-IE or RA
Attachment		P-IE or RA				
VA Perceptions		P-IE or RA		P-IE or RA		
Expectancy Rating Scale (ERS)			P-RA*			
Pain – 2 questions		P-IE or RA		P-IE	P-IE	P-IE
Medication and Health Service Use Database Extraction						D

P-IE = Participant via Independent Evaluator
P-RA = Participant/Research Assistant
D = Database Extraction
C-RA = Clinician/Research Assistant
P-RA* = Participant/Research Assistant - bCBT group only (no usual care)

5.6 Data Analysis

Sample Size and Power Calculations:

Provider Sample (Implementation Data; Aim 1)

No formal sample size calculations were used for the implementation-focused elements of this project. Rather, the team will invite all CBOC providers at all sites within the HOU and OKC VAMCs to participate and subsequently evaluate how many providers opted to engage in the bCBT project. These procedures are common for implementation-focused trials that often have a smaller pool of "subjects". Designs of this nature often look less at statistical significance and

instead focus more on descriptive quantitative data and depth interviewing and qualitative analyses to determine impact and “lessons learned”.

Veteran Sample (Effectiveness Data; Aim 2)

Sample-size calculations indicate that 232 patients will need to be randomized to address the primary hypothesis for aim 2. Based upon our current project, we will need to recruit 300 Veterans. Approximately 30% of recruited participants were screened ineligible due to subthreshold anxiety and/or depression scores.

We will use unequal randomization to reduce unnecessary recruitment, resulting in 138 patients for bCBT and 94 for EUC. In determining the sample size, we first determined the number of participants needed to have 80% power to detect significant differences in the primary outcomes between our groups. We then inflated this to account for intraclass correlations among patients and for attrition and loss to follow-up. A sample size of 70 patients in both the bCBT and EUC groups (140 total) is needed to detect a difference in the means of the primary outcome that reflects a small effect size of .30, using a 2-sided *t*-test with 80% power at the .05 significance level, adjusted for repeated measures.[56] The small effect size was chosen to ensure an adequate sample size to address multiple study aims and outcomes. The bCBT sample size was then inflated by [1 + (m - 1) c] to account for the intraclass correlation due to clustering of patients within bCBT clinicians.[57] Based on the sample size of 70 bCBT patients, an average of 5.8 patients per therapist, and an assumed correlation, c, among patients of .10,[57] our inflation factor is 1.48 (70 x 1.48 = 104). A clustering inflation factor was not used for the EUC group. Both the bCBT and EUC groups are inflated to account for attrition rate at 12 months of 25%.

Unequal numbers of patients per group offers the advantage of reduction in unnecessary recruitment. We will have 80% power to detect a clinically important difference in means on the PHQ-9 between the intervention and usual care groups that is as small as 1.83, based on a small effect size of .30 and estimates of the pooled standard deviation of 6.1.[58] Lowe concluded that differences in PHQ-9 scores of 5 or greater reflect a clinically relevant difference. Similarly, we can detect differences in the means of the BDI between the treatment and EUC arms as small as 3.6 units, assuming a standard deviation of approximately 12 as seen in Kunik et al. 2008.[31] Assuming mean baseline BDI values of 20 or higher,[31] we will have more than 80% power to detect a 50% reduction in BDI. For quality of life as measured by SF-12, a difference of one-half standard deviation (i.e., 5 points) is considered clinically significant.[48] On the basis of the standard deviation of the Mental Component Summary score (MCS) from Kunik et al.[31] of 14.7 and from Hendrick et al of 11.5, we will have 80% power to detect a difference in MCS scores as small as 3.45. For the SF-12 Physical Component Summary score, assuming standard deviations of 11 and 12 we can detect a difference in means as small as 3.3 points. Therefore, we will have more than 80% power to find clinically significant differences in quality of life.

Patient Availability: CBOCs in Houston and Oklahoma City care for a large (n = 50,000+) and diverse Veteran population. We estimate a sample of 7,500 assuming a 15% rate of elevated depressive symptoms.

Minimization of Attrition: Improved engagement and retention of participants may be challenging for Veterans cared for in CBOC settings but our experiences using telephone-based recruitment procedures in prior trials have been highly successful. A 25% attrition rate was used for study-power calculations, which is slightly above our current trial's attrition rate of 22%. Dropouts will include any participants who indicate a desire to withdraw from the study following random assignment. Reasons for study discontinuation will be recorded for subsequent analyses; and overall attrition rates will be examined as a primary study aim. The current proposal employs a flexible intervention approach, using individual sessions and telephone encounters to decrease attrition and improve participant engagement and adherence to treatment. We will also minimize attrition by reducing our "research presence" by using telephone assessments and limited research contact following randomization, and modestly compensating participants for their time. Additionally, Veterans that become difficult to contact via telephone will be mailed an unable to reach letter to encourage them to contact the study (see Appendix 10). The letter will explain the team's efforts in trying to contact them and ask the Veteran to follow up with study staff to schedule an appointment.

Note: bCBT patients who drop out of treatment will be allowed to continue with research follow-up assessments.

Analyses:

Aim 1 analyses will use data from the mixed-method formative evaluation described above.

Quantitative analyses will use descriptive data related to clinician adoption, fidelity ratings, and bCBT utilization (participant engagement, treatment completion, and total session exposure). Data will be compared to our prior work to explore if differences exist between VA hospitals (HOU and OKC) and the CBOCs engaged in the current proposal. We will also use VA databases to explore the use of psychotherapy services pre- and post- implementation using depression ICD-9 and psychotherapy CPT codes as used by the PI in prior work.[15,59] Qualitative data for aim 2 will use a combined inductive and deductive analytic approach given our desire to understand the firsthand accounts of stakeholders (inductive) while incorporating a priori codes using elements from our implementation frameworks (deductive). The analytic approach will examine interview and field-note data from patients, providers, clinic leaders, and leadership. This entails examining the textual data from the insider's perspective to uncover patterns in the experiences under investigation.[43, 60-62] The result is the description of a deeper structure, a synthesis of the data into one explanatory framework.[62] Field notes and transcripts will be read and re-read, and key terms coded. Initial coding will identify significant statements, sentences, or quotes that provide an understanding of how the participants experienced/used bCBT. Study coders will develop clusters of meaning or themes to produce a written description of the contextual elements. Coding will culminate in a codebook that includes a narrative of the central

themes with illustrative quotes, along with a visual portrayal of the data including the factors and outcomes related to the central phenomenon.

The above listed coding methods will be used during the progress-focused formative evaluation. A briefer coding method will be used during other formative evaluation phases. These less rigorous coding strategies, informed by Curran et al, fit well with the focused aims of the formative evaluation phases and are seen as critical to ensure project feasibility. Coding will be conducted by a qualitative investigator at the Houston HSR&D CoE (Martin). Dr. Martin, a medical anthropologist, will lead the qualitative inquiry. She will collaborate with Dr. Curran (senior consultant and co-I) and coordinate coding procedures with the study team.

Aim 2 will determine whether depression and quality of life outcomes differ as a function of the intervention at posttreatment, and at 8- and 12-month follow-ups. All analyses will be done on an intention-to- treat basis. Following the recommendation of the CONSORT group, we will not test for differences in baseline characteristics or adjust subsequent analyses for any variables we did not decide a priori to include in the regression models.[63] To compare changes between the 2 groups over time, we will use a longitudinal, mixed- model analysis containing terms for the intercept, treatment, time period and interaction between time and treatment. Separate models will be run for each outcome (PHQ-9, BDI, SF-12 PCS and MCS) and for the combined outcome of whether or not the patient responded to treatment as measured by both a 50% reduction in PHQ-9 and BDI-II. Linear regression will be run for the continuous outcomes and logistic regression will be used for the combined depression outcome. We will include the use of antidepressant medications, receipt of outpatient mental health care, the modality of treatment (e.g., telephone, in-person, combination), and the stratification variable, site, in the analyses to control for any possible differences that might exist between the treatment arms that might impact our outcomes. The interaction between time and treatment will indicate whether there is a difference over time between the 2 groups. We will conduct sensitivity analyses to evaluate whether the reasons for loss to follow-up at the various time periods are related to the observed values of the outcome variable, using tests for missing completely at random and tests for nonrandom missingness.[56]

Analyses for Aim 2 will occur exclusively at the Houston HSR&D CoE under the direction of the PI (Cully), study statistician (Co-I Petersen), and study data analyst (Sansgiry).

Other analyses: Prediction of bCBT Treatment Response: We will use multivariate analyses to predict treatment response in the bCBT group, defined as 50% or greater reduction in PHQ-9 and BDI scores from baseline to posttreatment. Variables will include patient demographic and clinical characteristics (e.g., baseline depression severity, mental health comorbidities, treatment expectancy), as well as treatment (number of sessions attended, therapeutic alliance, patient engagement) and clinician factors (e.g., clinician adherence/skillfulness). Depression Treatment Intensity: Within the bCBT treatment group, the study team will evaluate the associations between depression-symptom response and treatment intensity (number of sessions).We will explore potential patient demographic and clinical characteristics associated with treatment response and intensity. Further, we will use surveys and qualitative interviews

with clinicians and bCBT participants to more fully understand whether the treatment intensity received was the treatment believed to be ideal. Perspectives from both patients and providers will be needed to fully understand this construct.

All exploratory analyses will occur exclusively at the Houston HSR&D CoE under the direction of the PI (Cully), study statistician (Co-I Petersen), and study data analyst (Sansgiry).

5.7 Withdrawal of Subjects

There is no foreseeable circumstance for which research participants will be withdrawn from the study without their consent. If a participant chooses to withdraw from the study, there will be no consequences. The subject will not lose any rights or permissions s/he currently receives. To withdraw from the study, an individual will be asked to contact the study staff to inform of the decision and remove their participation status in the project databases.

6.0 Reporting

All unanticipated serious adverse events (U-SAEs) and unanticipated serious problems (UAPs) will be reported to the VA Central IRB within five business days. U-SAEs will be reported to VA Central IRB regardless of their relationship to the research. All protocol deviations, violations, and/or noncompliance will be reported to the VA Central IRB within five business days of the reporting individual becoming aware of the occurrence.

Safety information, including SAEs/UAPs, that will be collected:

Safety information will be monitored for all participants over the course of the study. Participants demonstrating increased depression symptoms as reported on the PHQ-9 (a 5-point increase) from baseline will be evaluated and referred for additional assessment and intervention as needed. Participants in need of immediate treatment (e.g., active psychosis or suicidal intent) will be referred for appropriate services with VA upon identification. Study staff will follow up on any positive responses to items involving suicidal thinking, using a structured crisis-assessment protocol (see Appendix 3). Participants who express suicidal ideation will be forwarded to a study investigator who will triage and refer for care as appropriate.

All occurrences of events resulting in a participants' death, life threatening experience, hospitalization, prolonged hospitalization, or persistent or significant disability will be documented. Any occurrence of an event that results in the need for medical or other interventions to prevent any of the above listed outcomes will be documented as well. As such, any participants identified as having an immediate mental or physical health issue will be referred to care as appropriate.

Frequency/methods of safety-related data collection:

Collection of safety information will commence when the first participant is enrolled in the study; this is anticipated to occur during March 2015. Safety information may be collected either 1) during baseline and follow up assessments, 2) during bCBT sessions, or 3) during telephone contacts with participants made for purposes of scheduling assessments and/or treatment sessions. All participants will complete comprehensive assessments via telephone at baseline and at 4-, 8-, and 12-month follow-ups. Symptoms of depression and suicidal ideation will be assessed at these time points. Secondly, those participants assigned to the bCBT group will complete measures of depression during each session with their study clinician; these sessions will occur either in person or over the telephone depending on patient preference. Third, the Research Coordinator or RA will periodically contact patients to schedule study-related appointments. The participants or other informants may report information related to their safety at those times.

Conditions that would trigger an immediate suspension of the research:

This intervention will compare a brief, structured cognitive-behavioral intervention with usual care practices in VA CBOCs. The active treatment, bCBT, utilizes well-established psychotherapeutic techniques to enhance patients' self-management of mood and physical functioning. No medications, invasive procedures, or untested techniques will be used. As such, this protocol is judged to be of low risk. We do not anticipate the occurrence of events that would necessitate the immediate suspension of research because of 1) the low probability of adverse events from the intervention in either arm of the study, 2) all participants will continue to receive usual care services within the VA, and 3) treatment for depression will not be withheld from any participants.

Specify procedures to determine when and how to notify individual participants or their health care providers of findings that may affect the participant's health or welfare:

The decision to contact a patient and/or their health care provider regarding patient welfare can be made in two ways. First, the Project Coordinator, RA, or independent evaluators will conduct routine checks on participants' safety and well-being, including an assessment of suicidal ideation, during baseline and follow up assessments. These study personnel will notify the patient and/or their healthcare provider as necessary.

Second, data and safety monitoring is expected to be conducted at both the local and national levels. At the local level, the study PI (Cully), site PI (Sorocco), co-investigators (Stanley, Kunik, Kauth) will work with the study programmer and statistician to review data and safety issues regularly during monthly investigator meetings or more immediately as needed. Data and safety monitoring will occur for any identified adverse events as well as including a regular monitoring schedule of participant longitudinal data. Any participants identified as having an immediate mental or physical health issue will be referred to care as appropriate. Participants will also be monitored for increases in symptoms of depression. All participants, regardless of treatment,

with a 20% increase in symptoms (relative to baseline) will be called to ensure safety and encourage the participant to obtain care if desired.

At the national level, the study has been approved by the VA's Data and Safety Monitoring Board (DSMB). We will continue to provide the national DSMB with comprehensive annual and semi-annual reports for formal independent review of study safety and recruitment practices.

7.0 Privacy and Confidentiality

Protected health information (PHI) obtained from patient participants will include: name, age, date of birth, home address, contact phone number, last 4 digits of their social security number (which allows us access to their medical record). PHI requested from enrolled clinicians will be restricted to their name. Information obtained about participants (veteran and clinician) will be kept strictly confidential and not disclosed.

Each participant (veteran and clinician) in the study will receive a unique ID number to increase confidentiality. Data obtained from participants will be maintained in a password protected electronic database. Data and audio recordings will be limited to the study team and stored on VA computers (behind the VA firewall) under Drive:M. As another level of security, access to study folders will be restricted to study team members listed on the delegation of authority. In addition, all electronic data files will be password protected for additional security. To maintain privacy, assessments and interviews will be conducted in one of several private interview rooms available or in the study staffs' office. Private interview rooms will be scheduled for use at the time the assessment is scheduled. Clinician consent forms will be kept in a locked cabinet, housed in a data storage room that has a security keypad as entry. All electronic data files will be maintained within the VA setting and behind the VA firewall. The file cabinet is in room (212) located in the John P. McGovern Campus (Nabisco building), Suite 01Y. Access to research records will be restricted to the PI and his project staff.

All project staff are required to have undergone focused training on privacy, the protection of human subjects, research methods and the importance of integrity in the research process. Houston VA HSR&D IQuESt Computing Center also requires all project staff to review the Data Secutrity Compliance Agreement which describes the center's data security protocol. Each project staff member must sign an acknowledgement that they have reviewed the policy and agree to follow the policy before accessing data. The Houston VA HSR&D IQuESt Computing Center data security policy conforms with current VA policies and has been reviewed and approved by the MEDVAMC Chief Information Officer, Information Security Officer, and Privacy Officer.

8.0 Communication Plan

Plan for engaged facilities:

- Upon approval of the PI/SC application Form 108, each local site will submit VA Central IRB Form 104 (Local Site Investigator Application), which must be signed by the Local Site Investigator, his/her supervisor, and the local site ACOS/R&D or Chief of Staff.
- Upon VA Central IRB approval of the Form 104 Local Site Investigator Application, the local site R&D Committee must provide written approval for the research to be conducted at the local site before the research begins.
- The Project Coordinator will maintain copies of the local site R&D Committee approvals in the main site regulatory binder.
- Local site Investigators or their designated study team member Research Assistants (RAs) will maintain copies of the main site approval, as well as the local site R&D Committee approvals in their respective local site regulatory binders

Plan for non-engaged facilities:

This research study will not take place at any facility not engaged in the research (i.e., without a Local Site Investigator Project Application approval).

Plan for notifying and obtaining local site approval of amendments and other administrative changes:

- Upon VA Central IRB approval of all PI/SC Amendments and Local Site Amendments (including modifications to the protocol, the procedures for verbal informed consent and HIPAA authorization, and any administrative change approvals), the Project Coordinator will send an electronic copy of the approval and all attachments via email to the Local Site Investigator to submit to the local site R&D Committee for approval (when required by the local site RDC).
- The Project Coordinator will maintain copies of all approval documents, including local site R&D Committee approvals (when required by the local RDC) in the main site study binder.
- The local site Investigator or local site RA will maintain copies of all PI/SC Amendments and Local Site Amendments (including modifications to the protocol, the procedures for verbal informed consent and HIPAA authorization, and any administrative change approvals) that pertain to their respective site in the local site regulatory study binders.
- The local site Investigator or local site RA will maintain copies of their respective local site R&D Committee approvals (when required by the local site RDC) in their local site study binder.
- When the local site R&D Committee requires approval of amendments and/or administrative changes, no change will be implemented prior to receiving documentation of the approval of the local site R&D Committee.

***Plan for keeping all engaged sites informed of changes to the protocol, informed consent, and HIPAA authorization*:**

A. Regular meetings and conference calls: The PI will lead regular conference calls and meetings that will include discussions of changes to the protocol, informed consent process and the HIPAA authorization. Study team members will be notified through these conference calls and meetings of upcoming changes, as well as when the PI receives notification from the VA Central IRB of final approval of such changes.

- The PI will lead weekly meetings to discuss the study status with the study leadership team (select co-Investigators, Project Coordinator, and other study team members)
- The PI will lead weekly conference call discussions with the Local Site Investigator and her study team.
- The PI will lead monthly meetings in person and via conference calls to provide status update/discussions with all co-Investigators, Local Site Investigator, and all local site study team members

B. Shared drive: The Project Coordinator will maintain a shared drive on the Houston VA HSR&D IQuESt secure server (that resides behind the VA firewall) that is accessible to local site study team members**.** The Project Coordinator will maintain the most current version of all IRB approved documents on this shared drive.

- When new or revised documents are submitted for approval, the Project Coordinator will notify the Local Site Investigator and her study team that changes have been submitted for approval and are under review by the VA Central IRB.
- Upon VA Central IRB approval of a new or revised form, the Project Coordinator will notify the Local Site Investigator and her study team that the new form has been approved. The PI or the Project Coordinator will provide training on newly approved procedures to all local site study team members.
- All local site personnel will be asked to do the following:
    - File a printed copy of the VA Central IRB approval, and all newly approved documents, in the local site study binder.
    - Destroy all blank supply copies of previously approved versions of any newly approved study forms.
    - Begin using the new form, or applying the newly approved procedure, immediately.

***Plan for informing local sites of any Serious Adverse Events, Unanticipated Problems, or interim results that may impact conduct of the study*:**

- The Project Coordinator will notify all participating sites immediately of any SAEs, Unanticipated problems, or interim results that have the potential to affect implementation of the study. A copy of the SAE report or Protocol Deviation report that is

submitted to the VA Central IRB will be sent to the Local Site Investigator, as well as their local site study team members via encrypted email. Additional copies will be sent to the local site R&D Committees.
- The PI will discuss SAEs, Unanticipated Problems, Protocol Deviations, and interim results that may affect the conduct of the study during the weekly and monthly, meetings.

***Plan for ensuring the study is conducted according to the IRB-approved protocol*:**

- The importance of conducting the study according to the IRB-approved protocol is emphasized by the PI to all study team members on a regular basis. In particular, all research team members are required to read the IRB-approved protocol (and any subsequent amendments), and research staff will receive specific training from the PI or Project Coordinator regarding protocol elements relevant to their study role before their involvement in the study begins. This study-specific training is over and above the mandatory trainings that all research staff receives.
- During weekly and monthly meetings, the PI will follow-up with the LSI to ensure that she continues to adhere to the protocol and to standard research compliance procedures as required by the VA.
- The PI will require the LSI to hold weekly or bi-weekly meetings with their respective local site study teams

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

- The PI will notify the LSIs when the study reaches the point at which it no longer requires engagement of the local facility.
- The LSIs will submit Form 117b Local Site Project Participation Closure Report to the PI, who will submit the signed form to the VA Central IRB.
- The LSI will notify their respective local site Facility Director and R&D Committee that their facility will no longer be engaged in the research.

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