Enhancing Access to Insomnia Care (EASI Care): Implementing Brief Behavioral Treatment for Insomnia in Primary Care Mental Health Integration Clinics

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Study Protocol and Statistical Analysis Plan

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Funding Agency: Health Services Research & Development

Principal Investigator: Adam D. Bramoweth, PhD

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Abstract

Chronic insomnia, one of the most common health problems among Veterans, significantly impacts health, function, and quality of life. Cognitive Behavioral Therapy for Insomnia (CBT-I) is the first line treatment; however, despite efforts to train hundreds of VA clinicians to deliver CBT-I, there are still significant barriers to providing adequate access to insomnia care. Up to 44% of Veterans seen in Primary Care report insomnia, making it an optimal clinical setting for improving access to insomnia care. Furthermore, a briefer, more flexible therapy that is more suitable for the Primary Care setting, Brief Behavioral Treatment for Insomnia (BBTI), has been shown to be similarly effective in reducing insomnia symptoms.

BBTI is easily delivered by Primary Care Mental Health Integration (PCMHI) clinicians; yet simply training PCMHI clinicians to deliver it is not enough. Implementation strategies are needed for successful uptake, adoption, and sustainable delivery of care. Thus, Aim 1 of this study is to compare the impact of PCMHI clinicians trained to deliver BBTI vs. the impact of BBTI training plus 12-months of access to an implementation strategy bundle (BBTI+IS); supplementing training with recommended implementation strategies is expected to result in more Veterans accessing insomnia care in the Primary Care setting. Aim 2 of the study is to use qualitative interviews and surveys with clinical stakeholders at each study site to identify strategies within this bundle that promote successful implementation of BBTI in PCMHI.

This stepped-wedge, hybrid III implementation-effectiveness trial involves four VA Medical Centers/Health Care Systems: Baltimore, Durham, Minneapolis, and Philadelphia. The hybrid design allows for testing of *implementation* and treatment *effectiveness*, guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.

Retrospective data collected from VA electronic health records will be used to obtain variables of interest related to Veteran treatment outcomes and data related to how PCMHI clinicians deliver BBTI.

By showing how these clinicians can deliver BBTI sustainably within Primary Care, this study will increase Veterans' access to evidence-based insomnia therapy. Using a cross-cutting health services research methodology, implementation science, it has the potential to significantly impact, and improve, how insomnia care is delivered in VA.

List of Abbreviations

BBTI	Brief Behavioral Treatment for Insomnia
BBTI-CDA	Brief Behavioral Treatment for Insomnia - Career Development Award
BBTI-CRS	Brief Behavioral Treatment for Insomnia - Competency Rating Scale
BBTI-MV	Brief Behavioral Treatment for Insomnia - Military and Veterans
CBOC	Community Based Outpatient Clinic
CBT-I	Cognitive Behavioral Therapy for Insomnia
CBT-I-VA	Cognitive Behavioral Therapy for Insomnia - Veterans Affairs
CDA	Career Development Award
CDW	Corporate Data Warehouse
CFIR	Consolidated Framework for Implementation Research
CHERP	Center for Health Equity Research and Promotion
COIN	Center of Innovation
CPRS	Computerized Patient Record System
EBP	Evidence-Based Psychotherapy
ERIC	Expert Recommendations for Implementing Change
FTEE	Full Time Employee Equivalent
HSR&D	Health Services Research and Development
IIR	Investigator Initiated Research
IS	Implementation Support
ISI	Insomnia Severity Index
MIRECC	Mental Illness Research, Education and Clinical Center
NIH	National Institutes of Health
OMHSP	Office of Mental Health and Suicide Prevention
ORD	Office of Research and Development
PCMHI	Primary Care Mental Health Integration
PCP	Primary Care Provider
PHQ-9	Patient Health Questionnaire
PI	Principal Investigator
RE-AIM	Reach, Effectiveness, Adoption, Implementation, and Maintenance
RR&D	Rehabilitation Research and Development
SME	Subject Matter Expert
VA	Department of Veterans Affairs
VAB	Veterans' Advisory Board
VACO	VA Central Office
VAMC	Veterans Affairs Medical Center
VAPHS	VA Pittsburgh Healthcare System
VHA	Veterans Health Administration

Contents

1.0 Study Personnel

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There are 5 VAMCs/Healthcare Systems involved in this study. Pittsburgh is the coordinating/hub site. The participating sites are Baltimore, Durham, Minneapolis, and Philadelphia. This is a stepped-wedge trial. Training in BBTI will occur at approximately the same time for all sites, the third month of the study. However, sites' access to implementation strategies and support will be staggered (see Figure 2).

2.1 Introduction

Chronic insomnia is one of the most common health problems among Veterans with significant impact on health, function, and quality of life. Insomnia impacts over 50% of Veterans[1,2] with even higher prevalence of insomnia and other sleep disturbances in Veterans with posttraumatic stress disorder (70-87%)[3] and those who served in the Vietnam War era (94%).[4] Insomnia also significantly contributes to the exacerbation of symptoms and increased risk of depression, anxiety, substance use, chronic pain, cardiometabolic disorders, and even suicide behaviors.[5–7] Healthcare utilization and costs, annually, are also significantly greater for those with chronic insomnia vs. good sleepers ($5010 vs. $421)[8] with an estimated annual economic impact over $100 billion, increasing the burden on both the Veteran and the VA system.[9–11]

The state-of-the-science specifies that Cognitive Behavioral Therapy for Insomnia (CBT-I) is the first line treatment.[12,13] Through studies conducted within and outside the VA, CBT-I significantly improves insomnia symptoms experienced by Veterans, their nighttime sleep quality, and their daytime function.[14–16] A recent VA study, with nearly 700 Veterans, found that 60% who completed treatment achieved a treatment response (i.e., insomnia severity reductions ≥8 points per the Insomnia Severity Index [ISI]). These Veterans had a mean ISI change of 20.7 to 10.9, a large effect size (pre- to post-treatment Cohen's d = 2.3; see CBT-I-VA in Figure 1).[15] In terms of long-term treatment gains, a recent literature review found that 50% of patients responded to CBT-I and maintained treatment effects for 4-10 years.[17]

Brief Behavioral Treatment for Insomnia (BBTI) is effective, developed for delivery outside of specialty care settings, and easier to deliver than CBT-I. BBTI, a briefer and more flexible treatment adapted from CBT-I, has been established as an effective intervention for insomnia.[18–25] Clinical trials have found similar reduction of insomnia symptoms with similar effect sizes as CBT-I trials, including the VA CBT-I rollout studies.[14–16] BBTI was specifically developed for delivery outside of mental health settings to increase access to care[26]—it shortens and simplifies treatment compared to the longer and more complex CBT-I. It is also one of the recommended treatments for chronic insomnia, along with CBT-I, per the 2020 VA/DOD Clinical Practice Guidelines.[27] Key elements that make BBTI advantageous for Primary Care are: (1) fewer sessions (BBTI, 2 in-person + 2 phone; CBT-I, 5-8 in-person) and (2) shorter session duration (BBTI, in-person 30-45 min, phone <20-30 min; CBT-I, in-person 30-45 min). It is important to note that while BBTI is packaged differently than CBT-I, it is a more focused treatment that emphasizes the two key behavioral components in multicomponent CBT-I, stimulus control and sleep restriction. Also, iterations of BBTI and/or brief CBT-I have been tested in VA[18,22] and are already delivered as part of routine care within VA, usually in PCMHI settings. However, these brief insomnia treatments lack the saturation of CBT-I, the more established treatment with the support of the VA EBP program. Increasing saturation (increased uptake,

Figure 1. Pre- to post-treatment ISI and effect sizes.

adoption, and sustainability) and the methods that support saturation are the foci of this proposal. Further adding to the support of BBTI, a non-inferiority trial recently completed by the Principal Investigator (PI), Dr. Bramoweth, as part of his HSR&D CDA, directly compared BBTI and CBT-I, as delivered by PCMHI clinicians, and found no significant differences between the two groups.[28] As shown in Figure 1, BBTI outcomes for the ISI, pre- to post-treatment (BBTI-CDA[24]), were significant and similar to the VA CBT-I outcomes (CBT-I-VA[15]) and a prior BBTI clinical trial with Military Service Members and Veterans (BBTI-MV[21]); all three studies also had large pre- to post-treatment effect sizes (CBT-I-VA and BBTI-MV, Cohen's d; BBTI-CDA, Glass' Δ). Also, data from the large VA CBT-I trials[14,15] found a more rapid decrease of insomnia symptoms during the early, behaviorally focused sessions of CBT-I, which are the core components of BBTI (i.e., stimulus control and sleep restriction). This is consistent with early studies of brief insomnia treatment that found that 4 sessions outperformed 8 sessions of treatment.[19]

BBTI delivered within Primary Care would help increase access to evidence-based care for Veterans, helping to overcome barriers related to accessing CBT-I. Insomnia is highly prevalent in Primary Care, the most common setting where insomnia is initially reported.[29–31] Since the VA is the leader in PCMHI, delivering BBTI in PCMHI would greatly increase access and efficiency of care. This would also significantly reduce the barriers to insomnia care commonly associated with CBT-I. CBT-I remains primarily delivered in specialty settings like Mental Health, which still carries stigma for many Veterans, and Sleep Medicine, which is not available at all VAMCs.[32] Although relatively brief, the 5-8 CBT-I sessions, usually in-person, can limit some Veterans from engaging in care due to their inability to take time off work, travel barriers, and/or arranging for caregiving. There is also a dearth of clinicians despite the VA's efforts to train ~800 clinicians in CBT-I, with more trained each year. However, this is still not enough to meet the needs of Veterans with insomnia. By training PCMHI clinicians, whose role is to deliver brief, solution-focused treatments, the number of insomnia-treating providers would greatly increase as will access to insomnia care. Furthermore, as PCMHI emphasizes same-day access, Veterans would get care fast and avoid an unnecessary referral out of Primary Care.

Simply training clinicians to deliver an EBP is rarely enough.[33,34] Implementation strategies are needed for successful uptake, adoption, and sustainable delivery of care.[35] CBT-I has substantial evidence for treatment effectiveness and the VA continues to train more providers. However, it remains challenging to sustainably deliver CBT-I, contributing to the gap between the high prevalence of insomnia and the number of providers necessary for optimal access. This is a common pattern for behavioral interventions that often require substantial training to deliver care while accounting for patient-, provider, and system-level barriers. Implementation science, the application of strategies targeting contextually-based barriers, can help narrow that gap.[33,34] However, specific strategies are needed to bring the EBP into regular practice and maintain sustainable delivery. The focus of this proposal is how effective are a bundle of implementation strategies, and which ones work best compared to BBTI training alone (the most common dissemination approach)?

3.1 Objectives

Insomnia disorder impacts as much as 54% of military personnel and Veterans, and it has significant negative impact on physical and mental health, and overall quality of life and functioning.[36] Cognitive Behavioral Therapy for Insomnia (CBT-I) is the recommended, first line intervention by the National Institutes of Health[12] and the American College of Physicians.[13] However, despite significant efforts to train VA clinicians in CBT-I, barriers remain regarding the ability of VA to provide adequate access to care.[1,2] Key barriers include: (1) a continued shortage of trained clinicians, especially outside of urban VA Medical Centers (VAMCs); (2) CBT-I mainly delivered in mental health clinics, which remains stigmatizing for many Veterans; (3) CBT-I can be inflexible to meet the needs of many Veterans due to the number, frequency, and duration of sessions (e.g., 5-8 in-person sessions, 30-45 minutes); (4) insomnia is often considered a symptom of other disorders resulting in poor diagnosis and treatment,[37] and if treated at all is typically done so with prescription sedative-hypnotics.[38]

The goal of this proposal is to develop and test a model for providing evidence-based insomnia care more efficiently to address this critical, unmet need. An optimal setting to treat insomnia where it is reported at high rates, up to 44%,[39] in Primary Care. VA is also a leader and champion for delivering mental health in Primary Care (Primary Care Mental Health Integration [PCMHI]). A candidate treatment for delivery in PCMHI is Brief Behavioral Treatment for Insomnia (BBTI), an evidence-based intervention[18–25,40] adapted from CBT-I as a briefer, more flexible treatment (only 4 sessions with combined in-person and telehealth sessions).[26] PCMHI

clinicians are promising candidates to deliver BBTI as they are specifically trained to deliver brief, solution-focused treatments to ensure efficient access to care. However, simply training PCMHI clinicians is rarely enough.[33,34] This is especially true of evidence-based psychotherapies (EBPs) that often require accounting for patient-, provider, and systemic-level barriers in addition to substantial training to deliver care with fidelity. Implementation science has shown that an integrated set, or bundle, of interventions and strategies are needed to enhance the likelihood of successful uptake, adoption, and sustainable delivery of EBPs.[33,41]

Implementation science also states it is critical to match known barriers to specific implementation strategies. Barriers to delivering behavioral insomnia treatment in Primary Care, informed by the PI's Career Development Award (CDA), were matched to Expert Recommendations for Implementing Change (ERIC) strategies[42,43] to create a bundle of strategies. This study, a stepped-wedge, hybrid III implementation-effectiveness trial, will test the implementation strategy bundle (e.g., implementation blueprint, provider education, audit and feedback) in how well it improves and supports the uptake and sustainable delivery of BBTI in PCMHI at four VAMCs (Baltimore, Durham, Minneapolis, and Philadelphia). The stepped-wedge is advantageous vs. a non-stepped trial as fewer sites are needed to achieve adequate power and all sites are exposed to the intervention in a sequential fashion. The hybrid design tests for level of *implementation* in real-world settings and Veteran-level treatment *effectiveness* of BBTI, both necessary for uptake, adoption, and sustainable delivery. Furthermore, taking a multi-method approach with implementation outcomes guided by the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework,[44] qualitative interviews, and surveys will provide valuable information about specific strategies that are effective given site-specific context.

Aim 1. To compare the impact of training PCMHI clinicians to deliver BBTI (BBTI) vs. the impact of BBTI training plus 12-months of access to an implementation strategy bundle (BBTI+IS). Sites will be measured across three study phases: BBTI (pre-implementation), BBTI+IS (implementation), and maintenance (post-implementation). During the implementation phase, sites will have internal and external support from insomnia and implementation experts to enhance their implementation efforts. We hypothesize that BBTI+IS will result in more Veterans obtaining insomnia-related care in PCMHI (R [primary outcome]), better treatment outcomes (E), greater uptake of BBTI by clinicians (A), improved treatment fidelity (I), and result in sustained BBTI delivery without implementation support (M). RE-AIM outcomes will allow for the evaluation and refinement of specific implementation strategies to use in future efforts to improve access to evidence-based insomnia care.

Aim 2. To identify specific strategies that help promote the implementation of BBTI in PCMHI. Using qualitative interviews, we will evaluate site PI and PCMHI clinician perspectives on BBTI training, and the impact of implementation strategies and barriers that continue to impede progress. Using surveys, completed by site PIs, we will identify specific strategies that help, or hinder, the implementation of BBTI in PCMHI. Strategies identified as helping to implement BBTI in PCMHI will help further adapt strategies to enhance implementation.

This proposal is responsive to VA ORD priorities of expanding access to Veterans for high quality clinical trials (e.g., a stepped-wedge, hybrid trial) and increasing the real-world impact of VA research. It also targets HSR&D research, and ORD clinical, priority areas of access to care, mental health, primary care practice, and virtual care and telehealth, within the framework of implementation science, a prioritized cross-cutting method.

Significance to the VA Mission

Insomnia is a highly prevalent disorder, that without treatment, remains chronic and contributes to significant decreases in quality of life and exacerbates health problems. It often takes longer than 10 years before patients with chronic insomnia seek help.[45] More efficient access to care is needed (e.g., BBTI in PCMHI) to reduce time-to-treatment for Veterans with insomnia. Having adequate access to insomnia care will help more Veterans reduce their insomnia, improve their quality of life and function, and reduce their risk of developing and/or exacerbating comorbid disorders.[6,7,14,15,21,24] Primary Care is a prime target for implementing BBTI to increase access to care as it is the most common clinical setting where insomnia is first reported, diagnosed, and treated. As noted by the National Mental Health Director for Integrated Services at VA OMHSP, Dr. Andrew Pomerantz, there is an "importance and value of implementing and integrating treatments such as BBTI into Primary Care. Integrating interventions such as BBTI are vital to meeting the needs and preferences of Veterans" (see letter of support).

Another benefit of implementing BBTI in Primary Care is the potential for time and cost savings passed on to the Veteran. Shorter treatment duration, briefer in-person sessions, and the use of telehealth (e.g., phone calls, video) means less time in clinic for Veterans, less time travelling to the VA, and less time away from work,

school, or family and friends. These benefits of BBTI are shared by clinicians who can deliver an evidence-based treatment more quickly, allowing more time available for other Veterans in PCMHI. In sum, BBTI is easier to participate in for Veterans, advantageous to deliver for PCMHI clinicians, and has treatment outcomes similar to the more intensive CBT-I.[18–25,40] As VA is the leader in providing mental health care within the Primary Care setting, implementing BBTI in PCMHI will increase access to care for Veterans with insomnia.

The proposed study has potential to significantly impact, and improve, how VA delivers insomnia care. The VA has invested, and continues to invest, significant resources into the treatment of insomnia primarily through the ongoing dissemination of training in CBT-I as part of the EBP Program. However, training more mental health providers to deliver care is not enough to truly meet the needs of Veterans with insomnia. This is especially true as the awareness of insomnia as an important aspect of health increases.[38,46,47] Most clinicians trained to deliver CBT-I do so through specialty Mental Health settings, which is appropriate as many Veterans with psychiatric disorders have comorbid insomnia. Yet the most common clinic in which insomnia is initially reported is Primary Care.[39,48,49] This presents an opportunity to treat Veterans where they are instead of routing them to a potentially new clinic and one that still carries stigma for many Veterans. Delivery of BBTI in PCMHI is not a replacement of CBT-I in specialty clinics, and not all Veterans who present in Primary Care with an insomnia complaint are appropriate for BBTI in PCMHI. However, the ability to initially assess and treat, or triage, insomnia in PCMHI, especially during a same day visit, creates a unique clinical situation that can increase access to evidence-based care in an efficient manner for both Veterans and providers. As PCMHI is a VA-wide initiative, successful implementation of BBTI in PCMHI and a better understanding of context-specific strategies for implementation can promote sustainable delivery of brief, Primary Care-friendly insomnia care.

This proposal is responsive to specific HSR&D priorities. Insomnia, by its nature, is highly comorbid with most mental health conditions as well as serving as an independent risk factor for depression, anxiety, substance use, and suicidal behaviors.[5–7] There is preliminary evidence that by treating insomnia, symptoms of comorbid psychiatric disorders may be reduced.[50–53] However, this proposal most directly addresses the priorities of access to care and primary care practice. The impetus of delivering BBTI in *Primary Care* is to increase *access to care* in the setting where insomnia is most common. BBTI in PCMHI gives Veterans access to insomnia care everywhere PCMHI is practiced (urban and rural VAMCs, Community Based Outpatient Clinics [CBOCs]) when it might otherwise only be available in a specialty care setting or potentially not at all. BBTI also has built-in telehealth—two of its sessions are intended to be delivered by telephone with the potential for all sessions to be delivered using clinical video telehealth and VA Video Connect, tailored to meet Veterans' needs and preferences. Health equity may also by addressed as BBTI in PCMHI can increase access using multiple delivery modalities that can help Veterans who may be traditionally underserved access care they need, such as rural, minority, low income, and disabled Veterans.

4.1 Resources and Personnel

Name: Lisa Lederer, MA, MPH
Location: VA Pittsburgh Healthcare System, Pittsburgh, PA
Role: Study Coordinator
Affiliations: Center for Health Equity Research and Promotion

Ms. Lederer will coordinate the day-to-day activities of the project. She will develop standard operating procedures, develop Institutional Review Board and other regulatory documents, and develop informed consent documents and data collection tools. She will also contribute to the development of project products including presentations, reports, and manuscripts, conducting literature reviews and syntheses. The Study Coordinator will be responsible for coordinating meetings, communications, and dissemination of findings. She will also be involved in the informed consent process and administering surveys and qualitative interviews. Ms. Lederer may also conduct qualitative interviews, as needed, and may also serve as a secondary coder, meeting with the qualitative staff members to verify inter-rater reliability of the co-coded transcripts.

Name: Monique Kelly, PhD
Location: VA Pittsburgh Healthcare System, Pittsburgh, PA
Role: Data Manager/Programmer Analyst/Honest Broker

Affiliations: VA Pittsburgh Healthcare System, Research and Development StatCore

Dr. Kelly is an epidemiologist by training who provides epidemiological, data programming, and statistical support to researchers, clinicians, and leadership within the VAPHS' Research Office's StatCore. She has expertise in programming within the VA Informatics and Computing Infrastructure environment (VINCI), SQL Server to extract and define data elements from the Corporate Data Warehouse (CDW) from within the VINCI environment, and analyze data utilizing the available software in VINCI, specifically SAS and R. Her role in this project will be the development of data extraction programs for the study outcomes, through VINCI from the CDW, as well as provide staff support and training for CDW data extraction for Ms. Kim.

Name: Nadejda Kim, MA
Location: VA Pittsburgh Healthcare System, Pittsburgh, PA
Role: Data Manager/Programmer Analyst
Affiliations: Center for Health Equity Research and Promotion

Ms. Kim is a member of the CHERP Bioinformatics Core who will work on data extraction, data management, programming, statistical analysis, and documentation tasks described above. Ms. Kim will participate in study meetings and will work under the direction of Drs. Bramoweth, Kelly, and Youk.

Name: Gloria Klima, MA
Location: VA Pittsburgh Healthcare System, Pittsburgh, PA
Role: Qualitative Staff
Affiliations: Center for Health Equity Research and Promotion

Ms. Klima is a Research Health Science Specialist and member of the CHERP Qualitative Methods Core. She will work under the direction of Drs. Bramoweth and Rodriguez as the primary qualitative coder for the project and contribute to codebook development. She will also assist with informed consent, qualitative interviews, and verbatim denaturalized transcription of all interviews. Ms. Klima will attend regular meetings of the study team to gain insights for codebook development. She will also meet regularly with Dr. Rodriguez and Ms. Beyer to verify interrater reliability of the co-coded transcripts.

Name: Nicole Beyer, MA
Location: VA Pittsburgh Healthcare System, Pittsburgh, PA
Role: Qualitative Staff
Affiliations: Center for Health Equity Research and Promotion

Ms. Beyer will conduct qualitative interviews and work with other staff members (e.g., Ms. Klima and Dr. Rodriguez) to verify all interviews and to serve as a secondary coder. She will attend regular study meetings to gain insights for codebook development. She will also meet regularly with Dr. Rodriguez and Ms. Klima to verify interrater reliability of the co-coded transcripts.

Name: Jenny Zervakis
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Affiliations: Center of Innovation to Accelerate Discovery and Practice Transformation

Name: TBN
Location: Philadelphia VA Medical Center, Philadelphia, PA
Role: Research Assistant
Affiliations: Center for Health Equity Research and Promotion

Name: Kirsten Poston
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Affiliations: Mental Illness Research, Education and Clinical Center

Name: Alexandra Gowdy-Jaehnig
Location: Minneapolis VA Health Care System, Minneapolis, MN
Role: Research Assistant
Affiliations: Center for Care Delivery and Outcomes Research

A research assistant will be assigned to assist with regulatory tasks (e.g., IRB) and help the site PI at Baltimore, Durham, Minneapolis, and Philadelphia manage study procedures locally and help to coordinate with VAPHS, the study coordinating site (note: all Research Assistants share the same basic duties).

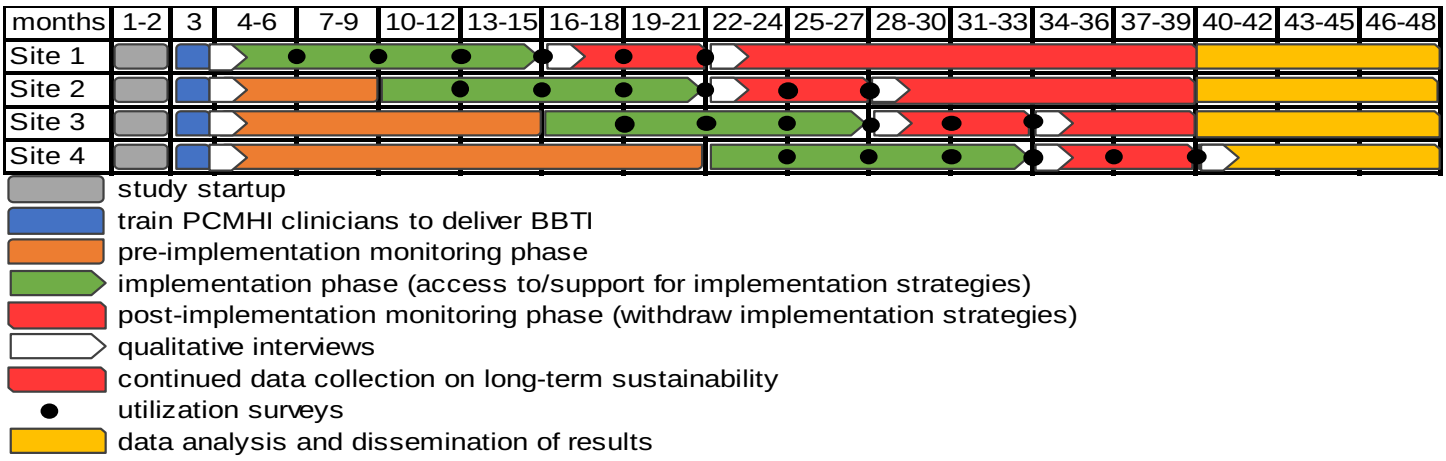
5.1 Study Procedures

5.1 Study Design

Overview of Experimental Design and Timeline. This is a four-year, stepped-wedge, hybrid III implementation-effectiveness trial comparing two conditions: training PCMHI clinicians to deliver BBTI (BBTI) vs. training clinicians to deliver BBTI augmented by access to, and support for, a bundle of expert-consensus implementation strategies (BBTI+IS). The goal of this trial is to determine if a bundle of implementation strategies can improve the uptake and sustainable delivery, and treatment outcomes, of BBTI in VA PCMHI settings. Three approaches will be used to measure outcomes: (1) RE-AIM framework; (2) CFIR-guided qualitative interviews, with site PIs and PCMHI clinicians, to identify barriers and facilitators related to implementation outcomes; and (3) surveys, completed by site PIs and PCMHI clinicians, to identify utilization of specific implementation strategies. Four sites were invited to participate (Baltimore, Durham, Minneapolis, and Philadelphia) with Pittsburgh serving as the coordinating site, responsible for: (1) oversight of all study activities, (2) development and conduct of BBTI training, (3) providing support for the implementation strategies, and (4) directing data collection and analysis efforts.

As depicted in Figure 2, after study start-up procedures, the first step will involve training PCMHI clinicians in BBTI at all sites. After BBTI training, site 1 (randomly selected) will have immediate access to, and support for, the bundle of implementation strategies for 12-months; this is the implementation phase of the trial. Sites 2, 3, and 4 will enter the pre-implementation monitoring phase for 6-, 12-, and 18-months, respectively, followed by their own 12-month implementation phase (random order). After each site has completed their 12-month implementation phase, access to the implementation strategies will be removed and each site will begin a 6-month post-implementation monitoring phase; however, for sites 1-3 we will continue to collect data to evaluate long-term sustainability through study month 39. Data collection will occur through all phases of the trial.

Figure 1. Study timeline.



Site Selection and Study Sample. Sites were selected based on their combination of a strong PCMHI program and presence of a local clinician-investigator with expertise in insomnia who could also serve as an insomnia SME and champion the delivery of BBTI in PCMHI. Table 1 provides a summary of each site, the affiliated PCMHI clinics, and number of PCMHI clinicians.

Table 1. Participating sites, number of PCMHI clinicians, and location of PCMHI clinics.

Site	Clinicians	PCMHI Clinics
Baltimore	14	VA Maryland Health Care System (Baltimore, Perry Point, and Loch Raven VAMCs; Fort Meade and Glen Burnie CBOCs)
Durham	9	Durham VA Health Care System (Durham VAMC; Raleigh I/III and Hillandale Road I/II CBOC).
Minneapolis	19	Minneapolis VA Health Care System (Primary Care clinic)
Philadelphia	18	Cpl. Michael J. Crescenz VAMC (Primary Care clinic; Behavioral Health Lab)

As is typical in hybrid III and implementation trials, the focus will be on clinician- and site-level findings. PCMHI clinicians who volunteer to receive BBTI training will be invited to participate in the trial; PCMHI clinicians can receive BBTI training and not participate in the trial. Participation, from site PIs and PCMHI clinicians, will involve (1) access to, and support for, the bundle of implementation strategies, (2) participating in qualitative interviews to identify barriers and facilitators related to implementation of BBTI, and (3) completion of surveys regarding implementation strategies utilized. Retrospective data collection from the electronic health records will be used to obtain variables of interest related to Veteran treatment outcomes and variables related to PCMHI clinician delivery of BBTI. These data will allow for evaluation of implementation outcomes guided by RE-AIM (e.g., BBTI effectiveness, clinician adoption, sustainable delivery of care) outside the context a clinical trial; this will improve the study's pragmatism and generalizability of findings.

Brief Behavioral Treatment for Insomnia. BBTI[26] has been used in several clinical trials[20,21,54] and like CBT-I is based on the rationale that modifying behaviors impacts the homeostatic and circadian drives. The homeostatic drive is the physiological mechanism that increased wakefulness leads to increased propensity for sleep. The circadian drive is the biological process that promotes or inhibits the propensity to remain alert or fall asleep throughout the 24-hour cycle. BBTI modifies behaviors to increase and regulate wakefulness, which can increase the homeostatic sleep drive, and restructures and optimizes sleep and wake times to reinforce the circadian drive.

BBTI is delivered in four sessions, typically within four to five weeks. BBTI is delivered using both in-person and phone calls, or other telehealth mechanisms, and is flexible and adaptable to meet the needs of the Veteran: all in-person; 2 in-person (session 1 and 3) and 2 phone/video calls (session 2 and 4); or even all telehealth using combined phone/video calls. Session 1 is recommended to be in-person or to use video telehealth as this is where the majority of psychoeducation takes place, the initial sleep schedule is established, and is the longest session, which may be more challenging by phone.

Session 1 (~45 minutes). Education about healthy sleep and sleep regulation, and the principles of stimulus control, sleep restriction, and sleep hygiene. Baseline sleep diaries, from the initial evaluation, will help to determine the new structure sleep schedule. Lastly, the four "rules" to improving sleep are introduced.

1. *Reduce your time in bed*. Reducing time in bed and increasing time awake (out of bed) helps to increase the homeostatic sleep drive, leading to falling asleep more quickly, deeper sleep (fewer awakenings with less time awake at night), and higher quality sleep.
2. *Do not go to bed unless sleepy.* By waiting until the homeostatic sleep drive is at its peak, the likelihood of falling asleep quickly is increased. It is important to distinguish between sleepiness and fatigue/tiredness. Going to bed when not sleepy can lead to frustration and lying awake in bed. Bedtime is not when the Veteran "should" go to sleep but rather when actually sleepy, but only after the prescribed bedtime.
3. *Do not stay in bed unless asleep.* By saving the bed for sleep (and sexual activity), the association between bed and sleep is strengthened. Staying in bed when awake perpetuates the cycle of wakefulness → frustration → arousal → wakefulness. Break the cycle by staying out of bed if awake—get out of bed if awake longer than 15-20 minutes (self-estimation), or when realizing sleep will not come quickly. It is also important to plan in advance the activities to do when out of bed (applies for #2 as well).

4. *Wake up at the same time every day*. A consistent wake time is the most important cue for setting the biological clock, regulates exposure to morning light (an important cue for the biological clock), and helps to increase the homeostatic sleep drive and decrease wakefulness at night. Even if sleep is poor, getting up at the same time helps you sleep better the next night by increasing the sleep drive.

Session 2 (<20 minutes). A check-in session. The clinician and Veteran will discuss the sleep diary, new sleep/ wake behaviors, following the "rules," and problem-solve any adherence issues.

Session 3 (<30 minutes). The Veteran and clinician will review sleep diaries and adjust the sleep/wake schedule as needed. If time to fall asleep and time awake at night are <30 minutes most nights since session 1, the Veteran can extend their sleep schedule by 15 minutes, advancing the bedtime or delaying the wake time. If time to fall asleep and time awake at night are >30 minutes most nights, the sleep schedule is restricted/reduced by 15 minutes. Adherence to treatment recommendations is reinforced.

Session 4 (<20 minutes). The final session addresses treatment difficulties, reviews progress made and treatment gains, and relapse-prevention techniques are discussed. The four rules are emphasized, as is the process of measuring and titrating sleep in the future.

Clinician BBTI Training. Each site, in month 3 (see Figure 2), will have a group training led by the site-PI (face-to-face) and joined by Dr. Bramoweth and/or Drs. Bramoweth and Germain by video or phone. Topics covered will include: (1) normal vs. abnormal sleep, sleep stages, (2) the two-process model (homeostatic + circadian processes), (3) the etiology of insomnia (e.g., 3P model), and (4) assessment and diagnosis. Training will cover use of the PCMHI 5A functional assessment (see Table 2). Training will also cover triaging complex cases as not all Veterans who present to Primary Care with an insomnia complaint are appropriate for PCMHI. A referral to a higher level of care (e.g., specialty mental health, sleep medicine) is an option as part of the shared decision-making process. Triaging a Veteran with complex insomnia is similar to triaging a Veteran with complex psychiatric symptoms, which is a standard procedure for PCMHI clinicians.

The VA CBT-I intake, per the EBP training, can serve as a model for a PCMHI insomnia intake, which will be modified to fit the PCMHI 5A evaluation: assess, advise, agree, assist, and arrange (see Table 2).[55] Adaptation of BBTI will also be covered, including multi-modal delivery of care (e.g., in-person, phone, video) and how to integrate additional therapeutic techniques that may enhance treatment adherence and outcomes (e.g., behavioral activation, motivational interviewing). Treatment documentation and the utility of the BBTI templated note will be discussed as will the value and importance of involving Veterans in care and learning from them on how to improve delivery of insomnia treatment in the Primary Care setting.

After BBTI training, and enrolling in the study, PCMHI clinicians will undergo individual mock sessions with their site PI to ensure competency, as rated using the BBTI Competency Rating Scale (BBTI-CRS [see appendix]; adapted from the Cognitive Therapy Rating Scale[56]). A score ≥50% (or ≥2 for each item) is passing and if <50%, PCMHI clinicians can review materials and work with their site PI until they pass.

Table 2. PCMHI 5A functional assessment for insomnia.

5As	Definition and Application to Insomnia
Assess	• Introduce role of PCMHI clinician (1-2 minutes) • Identify/clarify problem (10-60 seconds) – ensure insomnia is the key complaint • Functional analysis of problem (12-15 minutes) – assess for insomnia diagnostic criteria, impact on function and quality of life, administer self-report measures (e.g., ISI, PHQ-9, etc.), brief history of prior or current treatment efforts (e.g., sedative-hypnotics) • Summarize understanding of problem (1-2 minutes) – re-affirm functional analysis
Advise	• Discuss treatment options (1-2 minutes) – explain BBTI and other options (e.g., insomnia workbook, online treatment) or referral to specialty care (e.g., sleep medicine, mental health)
Agree	• Shared decision making about treatment plan (1-2 minutes) – collaboratively select treatment options based on Veteran's goals, interest, and willingness to engage (e.g., BBTI vs. CBT-I).
Assist	• Start a change plan (5-10 minutes) – if treating in PCMHI, introduce and explain sleep diaries

Arrange	• Specify plan (5-10 minutes) – schedule follow-up appointments; make referrals as needed

Bundled Implementation Strategies. Implementing EBPs can be a complex process and a primary goal of implementation research is to identify the *strategies* that enable the uptake and sustainable delivery of EBPs.[41] These strategies are the applied methods, approaches, and/or techniques used to enable successful implementation of a clinical practice or program.[57] Furthermore, implementation science aims to match these strategies to the unique conditions of local settings.[58] We considered the consensus recommendations from an expert panel of implementation scientists used to link specific implementation strategies developed through the ERIC Project[59] to specific implementation barriers identified by CFIR. Using an online tool,[43] the ERIC strategies below were selected to facilitate implementation, although the use of any of the below strategies, or other strategies, will depend on the unique context of each site.

Table 3. ERIC implementation strategies addressing CFIR barriers.

1. *ERIC*: Develop a formal implementation blueprint/checklist	Prior to the implementation phase at each site, Drs. Bramoweth and Chinman will work with site PIs to develop an implementation blueprint/checklist, which will then be used to guide BBTI delivery during the implementation phase. This will include which Implementation Strategies the site will use (expressed as specific and actionable items), the time frame to accomplish each task, and who is responsible at the local site.:
CFIR: Planning	*Example*: All clinicians practicing BBTI, or who are interested in practicing it in the future, will attend weekly meetings on Wednesdays at 2pm to reflect on the implementation effort, troubleshoot, share lessons learned, and support one another's learning
2. *ERIC*: Conduct educational meetings; Develop & distribute educational materials	At the beginning of each site's implementation phase, Dr. Bramoweth will assist site PIs and local PCMHI clinicians to plan educational meetings with their Primary Care and/or other clinical teams to inform them about the benefits of delivering BBTI in PCMHI and their availability for same-day access related to insomnia. Educational materials (e.g., fact sheets) will also be made accessible to Primary Care staff and to Veterans. After the initial session, education will vary based on needs of each site. For example, education can occur regularly (e.g., quarterly), as needed upon request by Primary Care staff, or individual consultation with insomnia SMEs.
CFIR: Access to knowledge & information; Knowledge & beliefs about the intervention	*Example*: Site PIs and PCMHI clinicians will attend quarterly Primary Care meetings to provide a 10-15-minute overview of BBTI and how to access care, answer questions, and provide contact info in case of follow-up questions and concerns from Primary Care staff. Site PIs and PCMHI clinicians will also place Veteran-centric educational materials in Primary Care clinics informing Veterans of the availability in PCMHI and to talk to their PCP to learn more.
3. *ERIC*: Organize implementation meetings	Regular communication and engagement between the coordinating site and the participating sites is key to implementation success. Meetings, through calls and emails, aim to support sites in their implementation efforts (e.g., education, audit and feedback, marketing]) and help build relationships and refine the implementation plan that can dictate success. These meetings can also be used to review aspects of BBTI training or to discuss new approaches to enhancing collaborations with Primary Care staff. Bi-weekly calls are planned with more frequent communication as needed.
CFIR: Networks & communications	*Example*: Dr. Bramoweth will lead bi-weekly phone calls with each site during the implementation phase, reviewing progress, assisting in identifying roadblocks, and working collaboratively with sites to problem solve implementation barriers.
4. *ERIC*: Audit and provide feedback	Audit and feedback are valuable tools to help improve implementation. It involves the measurement and summary of clinical performance (e.g., number BBTI initiations) over a specific period (e.g., past month), which can help assess and adjust performance.

CFIR: Goals & feedback; Reflecting & evaluating	*Example*: The coordinating site will query electronic health records of all Veterans treated for insomnia to measure RE-AIM outcomes (e.g., weekly data queries). This will include Veterans in PCMHI treated with BBTI as well as CBT-I in order to capture the full spectrum of insomnia treatment within PCMHI. The PI can provide this information as a summary report to sites during their implementation phase, as part of monthly conference calls, to keep PCMHI clinicians informed of their progress and to also serve as a discussion point on how to improve and/or maintain progress.
5. *ERIC*: Facilitation *CFIR*: Learning climate	Facilitation helps to enable and support PCMHI clinicians in their efforts to implement BBTI in PCMHI. Facilitation will involve interactive problem solving and support, within a site and between the coordinating-site and participating VAMCs, adapted to the unique contexts of each site.[59,60] Drs. Bramoweth and Chinman will serve as the primary external facilitators, providing implementation facilitation and support from the coordinating site and assisting the site PIs who will serve as internal facilitators for local BBTI implementation efforts. *Example*: Site PIs will meet regularly with their local PCMHI clinicians (e.g., monthly by phone) to discuss implementation efforts, both successes and setbacks. They will also engage with local clinical stakeholders (i.e., Primary Care teams). Also, during scheduled and ad hoc calls, external facilitators at the coordinating site will provide guidance regarding barriers towards implementation and work with site PIs to reinforce successful strategies with their local PCMHI clinicians.
6. *ERIC*: Increase demand with marketing to patients *CFIR*: Peer pressure	Marketing to Veterans can increase awareness, referrals, and same-day access of BBTI in PCMHI. Potential methods to be used: (1) letters mailed directly to Veterans prior to upcoming Primary Care appointments; and (2) signs, brochures, and other educational information in Primary Care clinics regarding BBTI services and encouraging Veterans to discuss sleep issues with their Primary Care team; (3) digital educational products (e.g., short video) that can be shown to Veterans by providers and/or posted on VA websites (e.g., Facebook, YouTube). The process of identifying Veterans prior to appointments, and the creation of marketing materials, will be managed by the coordinating site and executed locally by site PIs. *Example*: The coordinating site will identify Veterans with an insomnia diagnosis and/ or prescription for a sedative-hypnotic medication who have a Primary Care appointment in the next month. This information will be forwarded to site PIs, who can then mail information to these Veterans about BBTI in Primary Care and encourage them to discuss sleep-related problems with their PCP.
7. *ERIC*: Promote adaptability *CFIR*: Adaptability	It is important that BBTI is delivered with fidelity to maximize treatment effectiveness; however, adaptability is vital to ensure that treatment delivery meets the needs and preferences of the Veteran and clinician. BBTI was developed with a few core elements (e.g., four rules) yet delivery can be adapted (e.g., all in-person vs. combined in-person and telehealth) and therapeutic techniques integrated to meet the Veterans' needs (e.g., motivational interviewing, behavioral activation). BBTI is an adaptable treatment and this advantageous feature will be emphasized during BBTI training and highlighted at planned education efforts with local Primary Care teams. *Example*: PCMHI clinicians, during the PCMHI intake may identify insomnia with mild depression. Treatment planning, through shared decision making, may include initiation of BBTI plus behavioral activation to assist with staying out of bed during the day (stimulus control) and engaging in pleasant activities (a way to avoid naps).
8. *ERIC*: Involve patients and family; Use their feedback; Prepare them to be	Behavioral interventions require active patient involvement to achieve optimal outcomes. As part of BBTI training, PCMHI clinicians will be taught to encourage and reinforce Veterans to actively participate in care to maximize positive change. Also, PCMHI clinicians will be encouraged to speak with Veterans about the referral and treatment process to identify ways to improve their care experience. Lastly, PCMHI clinicians will be encouraged to discuss involving Veteran's family and/or support

active participants	system to participate in the Veterans' care, when deemed clinically appropriate.
CFIR: Patient Needs & Resources	*Example*: A PCMHI clinician learns a Veteran's wife disapproved of the Veteran's new bed/wake time as it does not coincide with hers. With encouragement from the clinician, the Veteran invites his wife to attend the next session to learn more about the treatment process and have a better understanding of why a new bed/wake time is necessary.

Cost-Benefit Analysis. The potential risks involved in this study are minimal. For VA staff participants, site PIs and PCMHI clinicians, there is potential risk of emotional or psychological discomfort related to speaking and sharing information with study staff during the qualitative interviews. There is also a minimal risk of breach of confidentiality. Appropriate measures will be taken to ensure that the identity of participants remain confidential (e.g., identified with unique ID numbers).

For Veterans receiving care in PCMHI, data will be collected retrospectively from the electronic health records. The data are generated as part of a Veteran's receipt of care in PCMHI and engagement in an evidence-based treatment that is part of usual care within PCMHI (e.g., BBTI, CBT-I) and the resulting progress note from their treating clinicians. There is minimal risk of breach of confidentiality. All Veteran data collected will be managed by the study data managers; they will ensure all PHI are removed prior to data review and analysis. In sum, the risks for Veterans are not considered to be different than risks associated with other research that utilizes retrospective collection of Veteran data.

There are no expected direct benefits for site PIs and PCMHI clinicians from participating in the qualitative interviews and/or utilization surveys. However, there is potential benefit for PCMHI clinicians to undergo training in BBTI, as this will provide them with an expanded skillset that directly applies to the improvement of Veteran care. The primary benefit will be the ability of PCMHI clinicians to provide evidence-based care (BBTI) to Veterans for a highly prevalent disorder, insomnia. There is also potential benefit for Veterans and VA broadly, as reduction of symptoms and dysfunction related to chronic insomnia can potentially improve overall Veteran health and reduce utilization of VA health care services.

Veterans who engage in treatment, BBTI (or CBT-I) in PCMHI, have the potential for a reduction of symptoms that may result in a treatment response or even remission from insomnia symptoms. BBTI is an evidence-based psychotherapy and there is strong support that participation in BBTI can result in a reduction of symptom severity. Secondary benefits may include the reduction of symptom severity of comorbid psychiatric disorders, such as depression and posttraumatic stress disorder. The long-term objective of this proposal is to help increase access to insomnia care for Veterans in the Primary Care setting. Therefore, this study also has the potential to benefit Veterans with insomnia who may prefer to seek treatment in Primary Care and can apply to non-Veterans and non-VA settings as well.

5.2 Recruitment Methods

Site PIs will invite (e.g., in-person, email, service line notification, phone) local PCMHI clinicians to participate in BBTI training. PCMHI clinicians who agree to attend training, upon completion will be invited to participate in the study. The goal is to recruit at least 2 PCMHI clinicians from each site. See Appendix 10.1 for phone and email recruitment scripts. PCMHI clinicians at local sites may also become aware of the opportunity to participate through participating colleagues and/or through the BBTI training available through TMS. They may then contact their local Site PI/coordinator or coordinating study PI/coordinator to express interest in participating.

Veterans will not be recruited. Retrospective data collection from Veterans' electronic health records (e.g., CPRS, CDW) will be used to obtain variables of interest related to Veteran treatment outcomes and variables related to PCMHI clinician delivery of BBTI (or CBT-I). Our goal is to obtain retrospective data from at least n=329 Veterans, which would represent approximately 0.75% of unique Primary Care patients with insomnia across all four participating sites; this would result in 90% power for the Reach variable in RE-AIM (see Table 5 for full power analysis [section 5.6]).

There will be no participant payments.

5.3 Informed Consent Procedures

VA employee participants—site PIs and PCMHI clinicians—will be invited to participate in this trial (see section 5.4). Those who volunteer to participate will complete a verbal informed consent by phone, administered by study staff at the hub site in Pittsburgh. See Appendix 10.2 for the study information sheet that will be provided to all potential participants prior to consent. We are requesting a waiver of documentation of informed consent to conduct the consent process by phone. VA employee participants will be informed that audio-recorded interviews are involved and consent for audio-recording will be documented along with their consent to participate in the study. During the interviews, immediately after recording begins, study staff will ask all participants if they agree to being recorded. If not agreeable with recording, the recording will stop, but the interview will still proceed. This agreement/disagreement will be documented by study staff and stored in the study network drive where audio-recordings are stored. Other than their name, no other PHI will be collected from VA employee participants.

We will collect retrospective data, from the electronic medical records, for Veterans who receive BBTI from PCMHI clinicians at the participating sites. No information will be collected directly from Veterans; a waiver of informed consent and a waiver of HIPAA will be requested. Veterans will be receiving usual care (BBTI), thus, the risk to Veterans is minimal and limited to breach of confidentiality from the retrospectively collected data.

Study staff at the hub site and participating sites will complete and stay up to date on the required trainings for the conduct of human subjects research.

5.4 Inclusion/Exclusion Criteria

Site PIs and PCMHI clinicians are the focus of this study with retrospective data collection for Veterans who receive BBTI (or CBT-I) delivered by PCMHI clinicians at the participating sites. Each participating site PI will be invited to participate in this study. PCMHI clinicians at each participating site will be invited, by their site PI, to attend a training for BBTI. Those who attend and complete BBTI training will be invited to participate in this study. PCMHI clinicians who have been previously training in CBT-I will not be required to take the BBTI training as BBTI is adapted from CBT-I and there is significant overlap. Women and minorities will be included in this study.

There will be retrospective data collection from electronic health records and databases for Veterans who receive care in PCMHI and engage in BBTI (or CBT-I) from a PCMHI clinician.

5.5 Study Evaluations

Data Collection and Outcomes by Specific Aim. Data collection will be accomplished through three mechanisms: (1) Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) outcomes will be retrospective, based on custom queries of electronic health record data through the VA Corporate Data Warehouse (CDW); (2) CFIR-guided qualitative interviews, conducted with site PIs and PCMHI clinicians, to assess their perspectives on BBTI training and the implementation process; and (3) surveys, completed by site PIs and PCMHI clinicians, on utilization of implementation strategies.

Specific Aim 1: To test the impact of BBTI+IS to improve RE-AIM outcomes and the sustainable delivery of BBTI without implementation support.

RE-AIM Implementation Outcomes. These outcomes will be measured with data from electronic health records through custom queries of tables in the CDW. Extracting information from Veterans' progress notes, including a custom BBTI templated note (see Appendix), will allow for data collection and organization to calculate RE-AIM outcomes, operationally defined below. The data query will be regularly conducted (e.g., weekly) to allow for frequent updates of the outcomes. Data queries that extract variables of interest from progress notes, such as the ISI scores, have been successfully tested as part of the PI's pilot project on characterizing insomnia care in the VA.[61] Variables necessary to calculate RE-AIM will be measured during all phases (pre, implementation, and post). This data organization will help facilitate analyses and comparisons across sites at

similar phases and across sites for similar phase comparisons. It will also allow for within site comparisons to evaluate the impact from pre- to implementation, from implementation to post-implementation, as well as the evaluation of long-term sustainability (>6-months post-implementation). SQL Server queries will be utilized to automatically update the data reported in the study's Microsoft Access database. The Access database front-end will be comprised of a form with buttons for on-demand updates to results from the existing queries (e.g., ISI scores from progress notes). Also, we will closely monitor the ongoing electronic health record update to Cerner. While the Cerner integration is not expected to impact this study, if participating sites do integrate Cerner during the study period, we will adapt our automated data query methods or utilize a standardized chart review form to collect data from individual Veteran records.

Reach, the primary outcome, will calculate the number of Veterans in PCMHI who receive insomnia-related care. This may include (1) Veterans in Primary Care/PCMHI clinics who receive an insomnia diagnostic code and/or a sedative hypnotic medication (see Table 4); (2) Veterans in Primary Care/PCMHI clinics who initiate BBTI or CBT-I (indicated by a relevant progress note/encounter); (3) the proportion of Veterans in Primary Care/PCMHI clinics who initiate BBTI/CBT-I relative to the Veterans in Primary Care/PCMHI clinics who are eligible to initiate BBTI/CBT-I. Data collection will begin 1/1/2020 in order to compare to data during the study period (beginning 1/1/2021) and evaluate change. While the focus is on BBTI, initiation and engagement in CBT-I is also relevant as it will be important to evaluate different insomnia services delivered in Primary Care/PCMHI (e.g., diagnoses, medications, BBTI, CBT-I).

Tracking these insomnia-related variables will allow us to measure trends in treatment initiation, diagnosis, and prescribing practices at different stages of the study (and prior to the study). However, this will still likely represent an underestimate of potential Reach since there will be Veterans with insomnia who turn down a PCMHI visit, do not receive an insomnia diagnosis, and decline a sedative-hypnotic.

Table 4. Insomnia diagnoses and prescription sedative-hypnotics eligible for Reach denominator.

Diagnoses	ICD-10:	F51.0, F51.01, F51.02, F51.03, F51.04, F51.05, F51.09, G47.00, G47.01, G47.09
	ICD-9:	307.41, 307.42, 780.50, 780.51, 780.52
Sedative-hypnotics	On label:	diphenhydramine, doxepin, eszopiclone, prazosin, ramelteon, suvorexant, temazepam, triazolam, zaleplon, zolpidem
	Off label:	hydroxyzine, melatonin, trazodone, others specifically indicated for sleep

Effectiveness will be measured as the change on the ISI[62] from the initial score obtained (e.g., PCMHI initial evaluation, BBTI/CBT-I session 1) to the last BBTI/CBT-I session. The ISI is commonly used within the VA and is easily accessible within VA electronic health records through the Mental Health Assistant toolbox as well as Behavioral Health Lab software, which was developed for use in PCMHI. ISI data may also be extracted from CPRS progress notes (e.g., BBTI progress notes). The ISI has well-established psychometrics with good reliability and validity. It is standard practice as part of insomnia-related treatment (i.e., BBTI and CBT-I) and PCMHI treatment (e.g., depression, anxiety, pain) to use measurement-based care (e.g., ISI, PHQ-9) and include outcome measures in progress notes to inform care and track treatment progress. For Effectiveness to be calculated, ISI scores from each BBTI/CBT-I session (e.g., entered in a BBTI progress note or CBT-I templated note) by PCMHI clinicians will be extracted through the automated CDW queries to calculate outcomes for each Veteran. Rates of treatment response and remission will also be calculated. Response is a reduction of ≥8 points on the ISI from pre- to post-treatment. Remission is achieving a post-treatment response *and* an ISI <8. Previous BBTI trials found treatment response rates of 42-77% and remission rates of 28-53%.[20,21,24]

Adoption will be measured in two ways: (1) the number of PCMHI clinicians who undergo training in BBTI relative to the number of PCMHI clinicians eligible for training; and (2) the number of PCMHI clinicians who treat at least one Veteran with BBTI relative to the total number of PCMHI clinicians trained.

Implementation, or treatment fidelity, will be measured by rating mock treatment sessions with enrolled PCMHI clinicians; ratings will be completed by site PIs using the BBTI-CRS. All enrolled PCMHI clinicians will be rated following BBTI training, and then quarterly thereafter. They will receive clinical feedback by their site PI, as needed, and, if they score below the competency cutoff (<50% or <2 per item; 2=satisfactory), any necessary re-training from their site PI. If PCMHI clinicians pass three consecutive mock sessions, they have the option of

discontinuing the mock sessions until mock session ratings at the end of the implementation phase and the end of the post-implementation phase. The BBTI-CRS scores will be used to develop an "implementation score" for each site—the average ratings across each site's enrolled PCMHI clinicians.

As a secondary measure of Implementation, all enrolled PCMHI clinicians will have a random selection of BBTI progress notes reviewed, by their site PI, to assess BBTI elements being utilized (10% or at least 1 per month of eligible notes). Clinicians who neglect important BBTI elements (e.g., discuss 4 rules, assess with ISI, titrate TIB) will receive clinical feedback from their site PI. Each site's secondary "implementation score" will be the average number of important elements across enrolled PCMHI clinicians reviewed progress notes. Though previous trials of BBTI have used audio-recorded sessions to measure Implementation, feedback from clinicians (current and prior studies) has suggested that audio-recording sessions were considered intrusive to delivering clinical care and limited rapport building with Veterans.

While not recording sessions is a less precise measure of Implementation/treatment fidelity, recorded sessions from the PI's CDA found that clinicians consistently delivered treatment with competency (cutoff >50%; session 1 M=78% [SD=13%]; session 3 M=94% [SD=5%]) and only one rated session for a single clinician was below the 50% cutoff (47.5%).

Maintenance will measure the sustainability of Reach, Effectiveness, Adoption, and Implementation during the 6-month post-implementation phase as well as during the long-term sustainability period (>6-months). The outcomes from the sustainability periods will then be compared to the outcomes during the pre- and implementation phases. The same operational definitions as described above will be used for Reach, Effectiveness, and Implementation. For Adoption, comparisons will be based on the rate a clinician delivers BBTI over time within each study phase. For example, the number months a PCMHI clinician Adopts BBTI (i.e., delivers BBTI to a Veteran) relative to the number of months [n=6] in the post-implementation phase.

Specific Aim 2: To identify specific strategies that help promote the implementation of BBTI in PCMHI using qualitative interviews and utilization surveys.

Qualitative and Survey Outcomes. CFIR-guided interviews will be conducted with site PIs and 2-3 PCMHI clinicians per site (n=9-12/site; n=36-48 across all sites) at three time points: after BBTI training (study month 3); at the end of the 12-month implementation phase; and at the end of the 6-month post-implementation phase. Interviews will be recorded (if the participant is willing) utilizing any of the VA-approved recording options available during the study period (i.e., VA phone, Phillips recorder, and Microsoft Teams [approved methods at time of this submission]). Interviews will be guided by CFIR[63] but will not follow a script verbatim; rather, the interview guide (see Appendix) will be treated as a loose structure to assist the interviewer, , a masters- and/or doctoral-level qualitative staff member at the coordinating site who is not involved the implementation process. This will help ensure confidentiality of the data for the site PIs and PCMHI clinicians who engage in the qualitative interviews. The first interview will focus on the BBTI training experience and anticipated barriers and facilitators that may impact implementation efforts. The second will focus on site PI and PCMHI clinician experiences during the implementation phase and how the access to, and support for, the bundle of strategies influenced their ability to deliver BBTI in PCMHI, specific strategies that were helpful (or not), and barriers that may continue to impede implementation efforts. The final interview will focus on issues of sustainability and experiences delivering BBTI during the post-implementation phase. Interviews will help to provide context for the implementation process and to better differentiate sites on strategies that worked (or not).

During the implementation and post-implementation phases, site PIs and enrolled PCMHI clinicians will complete a quarterly survey (n≥12 surveys/site, n≥48 surveys across all sites) about strategies from the bundle proposed (e.g., "Did providers use X strategy to promote delivery of BBTI?").[64] These surveys will assess the uptake of strategies, longitudinally, across study phases. Site PIs and PCMHI clinicians will also be asked to rate each strategy on its importance during the last three months (i.e., how vital a strategy was to improving implementation) and its feasibility during that time (i.e., how possible a strategy was to implement).[64,65] The surveys will be managed through Microsoft Forms by the study coordinator at the coordinating site .

Each enrolled site PI and PCMHI clinicians will also be asked to complete a demographics form through Microsoft Forms after verbal consent.

5.6 Data Analysis

Specific Aim 1: To test the impact of BBTI+IS to improve RE-AIM outcomes and the sustainable delivery of BBTI without implementation support.

Analyses. Power estimates were based on Reach and were conducted for an incomplete stepped-wedge design with four steps (four participating sites) with site randomization every six months. An incomplete design was used since the implementation phase stops after 12-months rather than continuing until study completion. Using VA 2018 data from Primary Care and PCMHI dashboards as estimates,[66,67] all Primary Care patients at the four sites, n=99,572, are considered the potential sample (denominator). The pre-implementation phase sample are Veterans seen for same-day PCMHI care across the four sites, n=4,778 (numerator). Considering the prevalence of insomnia is estimated as 44% of Primary Care patients,[39] n=43,812, and there is minimal insomnia care being conducted in PCMHI currently, we expect to increase overall PCMHI care even if only a fraction of Veterans with insomnia can be reached through the implementation intervention (BBTI+IS). If 0.75% of the estimated 44% with insomnia are seen in PCMHI (n=329, n≈82/site, 1-2 new Veterans per week/site) we have 90% power to detect a significant increase of 6.88% in PCMHI care (4,778 to 5,107) from pre- to implementation phase. See Table 5 for power estimates at different levels of Reach.

Table 5. Power estimates for Reach.

	% of unique Primary Care patients with insomnia (n=43,812)						
	2%	1.5%	1.25%	1%	0.75%	0.5%	Baseline
New PCMHI patients	876	657	548	438	329	219	--
Current same-day access	5,654	5,435	5,326	5,216	5,107	4,997	4,778
Current PC patients	99,572	99,572	99,572	99,572	99,572	99,572	99,572
Same day/PC patients (%)	5.69	5.46	5.35	5.24	5.13	5.02	4.80
Power (%)	100	100	99.96	99.02	90.03	59.25	--

Descriptive statistics will be used to characterize the participating sites, PCMHI clinicians who are trained in BBTI (enrolled and not enrolled), and Veterans who received insomnia-related care in Primary Care/PCMHI (e.g., BBTI, CBT-I). Key enrolled clinician variables (self-report) will include socio-demographics, training, and work experience (e.g., degree, prior insomnia experience, duration working in PCMHI). For Veterans, variables of interest, from CPRS/CDW, include socio-demographics, vitals, service connection, combat history, and medical and psychiatric disorders, prescription medications, healthcare utilization, and information from progress notes (e.g., ISI scores). For Reach, Adoption, Implementation, and Maintenance outcomes, generalized linear mixed models will be used to compare the impact of the implementation strategy bundle across the three study phases for each site. These models will include a fixed main effect for study phase (pre, implementation, post) and random effects for clinician (nesting of Veterans within clinicians) and site (nesting of Veterans and clinicians within site); the primary comparison will be pre-implementation vs. implementation, with the secondary comparison implementation vs. post-implementation and long-term sustainability. Also, a we will conduct a comparison of outcomes from the study phases vs. a historical period prior to the study (1/1/20 – 12/31/20). While we did not power the study to assess interactions, to the extent possible, a fixed effect for site and the interaction between site and phase, will be introduced to assess differences between sites at the same study phase and differences between sites for the primary and secondary comparisons (e.g., differences from pre-implementation to implementation and from implementation to post-implementation, site 2 vs. site 3).

For treatment Effectiveness, using an intent-to-treat approach, we will fit a linear mixed model that tests for BBTI effectiveness (reduction of ISI score over the course of treatment) that includes a main effect of time (evaluation to last treatment session) and includes random effects for Veteran (multiple measurements per Veteran during treatment), clinician (nesting of Veterans within clinicians) and site (nesting of Veterans and clinicians within site). We will also attempt to control for clinician experience on treatment outcomes as well as mode of delivery of BBTI (e.g., in-person, phone, video) and other adaptations, such as integrating other

therapeutic techniques as indicated per the progress notes and extracted as part of the data query process (e.g., behavioral activation, motivational interviewing). Rates of response and remission from treatment will be calculated as will treatment effect sizes.

Specific Aim 2: To identify specific strategies that help promote the implementation of BBTI in PCMHI using qualitative interviews and utilization surveys.

Analyses. The interviews will be semi-structured with broad, open-ended questions to assess general impressions without leading the PIs or PCMHI clinicians toward specific CFIR factors or implementation strategies. Interviews will be transcribed verbatim and coded by two independent staff in an inductive fashion to identify specific CFIR factors and other factors related to implementation of BBTI in PCMHI.[68,69] The initial codebook will be developed by trained qualitative staff followed by a group consensus review involving the PI and experienced implementation and qualitative Co-Investigators, Drs. Chinman and Rodriguez; this method was used by the PI in his pilot work and CDA.[54,70] Discrepancies will be discussed until consensus is reached. After coding is complete, the identified CFIR factors will be aggregated and summarized using memos, and rated on their valence (positive [+1,+2] or negative [-1,-2] influence on implementation) and strength (strong [+1,+2] or weak [-1,-2] influence on implementation).[69] Valence is determined by the influence the coded data has on the implementation process (i.e., factors that facilitate/hinder implementation) and strength by factors like level of participant agreement, strength of language, and concrete examples. Similar to initial coding, qualitative staff will complete CFIR ratings with discrepancies discussed as a group until consensus is reached.

Results of these quarterly surveys will be used as a preliminary descriptive analysis of the most/least commonly utilized strategies as well as the overall number of strategies utilized by each site. We will also evaluate the strategies by quadrant, the combination of rated importance and feasibility,[64,65] which will help to provide context as to why a strategy may or may not have been utilized and how it may impact RE-AIM outcomes. Quadrant categories are: high importance/high feasibility (quadrant 1), low importance/high feasibility (quadrant 2), low importance/low feasibility (quadrant 3), and high importance/low feasibility (quadrant 4).[65] Identifying the strategies utilized most frequently during the implementation and post-implementation period and those strategies rated as highly important and/or highly feasible will help inform future implementation efforts and which strategies to emphasize.

Quantitative analyses will be led by Dr. Youk (Co-I/statistician) and qualitative analyses will be led by Dr. Rodriguez (Co-I). Both will be completed in collaboration with study PI and other Co-Investigators/Consultants. Analyses are planned to be completed at the hub site, VAPHS.

5.7 Withdrawal of Subjects

Participation by VA staff (site PIs and PCMHI clinicians) is voluntary. After informed consent is completed and the VA staff participants are enrolled, they can withdraw at any time. To do so, the participant will inform their site's research assistant and/or PI, who will then inform the study PI; alternatively, the participant can inform the study coordinator and/or study PI.

An anticipated circumstance for withdrawal of a PCMHI clinician would be if the participant changed positions and no longer delivered care in PCMHI and/or stopped working at the participating VAMC. If this were to occur, similar procedures as above can be followed to inform study leadership.

There are not follow-up phases to participate in if a participant withdraws. As a minimal risk study, there are not anticipated safety concerns that would require follow-up after withdrawal.

6.1 Reporting

This is a minimal risk study. Any unanticipated problems, serious adverse events, and/or deviations will be reported according to the "Table of Reporting Requirements to the VA Central IRB." Any reportable events that occur at the participating sites will be reported by the site PI to the study PI, who will then submit the

information to the Central IRB. Reportable events that occur at the hub site will be reported to the Central IRB by the study PI immediately.

There is no Data Monitoring Committee for this study.

7.1 Privacy and Confidentiality

This study will collect PHI but will not disclose PHI. All data collected and obtained during the study will be confidential. Data collection and management will be conducted in strict accordance with the policies and procedures set forth by the VA Office of Research and Development.

Data Management

Dr. Bramoweth (PI) will oversee all aspects of the study and data management. The VAPHS Center for Health Equity Research and Promotion (CHERP) Biostatistics and Informatics Core (BIC) will provide data management and statistical support. The PI and study team will standardize all staff training and procedures. Any databases and necessary data entry forms will be developed by BIC personnel and/or study staff and stored on a VA server maintained by OI&T in a study-specific network drive with access limited to the research team. All participants, site PIs and PCMHI clinicians, will be identified with unique study IDs that do not include PHI. Unique study IDs will also be used for the retrospective data collected for Veterans from the electronic health records. The PI, project coordinator, data manger, and other relevant study staff will ensure that study protocols and procedures are followed, that data integrity and confidentiality are maintained, and that incorrect and missing data are minimized.

Data Security

All data, for site PIs and PCMHI clinicians (from qualitative interviews and surveys) and for the retrospective data collected for Veterans (from VA CDW), will be identified with unique study IDs. Any hard copy study documents will be kept in a locked file cabinet within locked offices of the study staff (VAPHS, University Drive C, Research Office Building, Building #30, 1st floor, cube 1-14). The study data managers/programmer analysts will be responsible for removing PHI prior to any data review or analysis by members of the study team. Electronic data will be stored on a secure study network drive with limited access to the study team. Coded interview data will be manually entered by study staff into a database that will be stored on a secure study network drive located behind the VA secure firewall.

Windows integrated security will be used for all computer access. At the VA, all PCs, laptops, workstations and remote devices are set to lock and are secured after being left unattended for 5 minutes or more, or by logging-off when the equipment will be unattended for an extended period. User and role permissions will be defined at the computer-, directory-, and server-level. Source documents with private information (e.g., consent document, payment form, etc.) will be stored in a locked file cabinet within the locked office of study staff. Research records may be released or disclosed if required by federal law. Participants will not be specifically identified in any publication of research results. Records will be stored and maintained per current VA regulations.

Data and Safety Monitoring

A data and safety monitoring plan will be implemented to ensure that there are no changes in the benefit/risk ratio during this project and that confidentiality of research data is maintained. The entire study team will be responsible for data safety and monitoring. As mentioned previously, all electronic data will be stored and maintained on a VA secure study network drive, on a VA server maintained by OI&T. Only approved study staff will have access to the data Regular meetings between the PI and study staff will include a discussion of issues pertaining to the assurance of data security, patient confidentiality, and any needed changes will be instituted immediately to assure optimal data security and patient protection. Breaches of confidentiality will be brought to the attention of the appropriate persons immediately (e.g., VA CIRB), as will any proposed changes to the data safety and monitoring plan.

Data Banking

Data collected from this study, both provider and Veteran data may be retained for future use. If retained, it will be stored and managed in a data repository at VAPHS. If data is retained, it will be banked in the following repository:

Name: VAPHS Research Repository (MIRECC)

Location: \\r04pthnas.v04.med.va.gov\PTH_Groups\Research Registry Repository

8.1 Communication Plan

Communication between the PI and all site-PIs will occur regularly (e.g., bi-weekly) to review overall study progress, regulatory issues, and important findings to report, with regularly scheduled individual phone calls between the PI and site PIs (e.g., bi-weekly to monthly) with ad hoc phone calls/communication as needed.

The PI will meet with the study coordinator regularly (e.g., weekly) to review study progress. The study coordinator will maintain open lines of communication with all site PIs and site research assistants to inform them of study progress, interim results, and reportable events (e.g., significant Serious Adverse Events, Unanticipated Problems).

No research will be conducted at any site prior to the approval/authorization of both the VA Central IRB and each participating site's IRB. Each participating site PI will be responsible for keeping approval documents on site and up-to-date in the appropriate network study drive. The study PI will be responsible for keeping approval documents for all participating sites and the overall study up-to-date and in the appropriate network study drive.

There will be regular communication between the study PI and the site PIs, including study-specific communication as well as regulatory communication. Each site PI will be informed of any changes to the protocol, the informed consent and HIPAA authorization process, and any other changes to the study.

Site PIs will be informed of any serious adverse events, unanticipated problems, or interim results that may impact study conduct within the required timelines.

Communication between the hub site and the participating sites may include but is not limited to: phone, email, Skype for business/Microsoft Teams, and in-person when feasible.

Once a site has completed their post-implementation phase and all surveys and qualitative interviews with VA staff participants have been completed, the site PI will be notified. There will be continued retrospective data collection, but this will not involve any direct involvement with PCMHI clinician participants or site PIs (see Figure 2). The site PIs and site study staff may still be involved data analysis and dissemination of results.

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10.0 Appendix

10.1 Recruitment Scripts

Phone Script

Site PI will call PCMHI clinician

Answer? No – leave a voicemail requesting a call back

Yes – proceed with information about the BBTI training

"We are planning to have a training on an evidence-based behavioral insomnia intervention to be delivered in PCMHI. Additionally, after the training you will have the opportunity to learn more about participating in a VA Health Services Research & Development research study. Are you interested in hearing more?"

No – thank you for time

Yes – describe training and study (see below)

"As you are aware, insomnia is a common disorder among our Veterans seen in Primary Care. For many of them, it may be appropriate and beneficial to treat them within PCMHI rather than referring them out to specialty care.

Brief Behavioral Treatment for Insomnia (BBTI) is consistent with other behavioral health and behavioral medicine interventions delivered in PCMHI. It consists of 4 core sessions and can be delivered in-person, through telehealth, or a combination. Sessions can also be completed within 30 minutes. BBTI is adapted from Cognitive Behavioral Therapy for Insomnia, which has a significant evidence base and has been widely disseminated across VHA. BBTI is based on the core behavioral concepts of CBT-I—stimulus control and sleep restriction.

Training in BBTI will be available to any PCMHI clinician who delivers therapy/behavioral interventions. Training is expected to last approximately 2-3 hours and will be delivered by [local site PI] (Dr. Klingaman/Koffel/O'Brien/Ulmer) and joined remotely by Dr. Bramoweth (VA Pittsburgh Healthcare System). However, if you have already been trained to deliver CBT-I, you can participate in the study without the BBTI training. If you have already been trained in CBT-I, let us know and we'll provide more information about the research study.

Following the training, clinicians will have the option of partaking in a VA Health Services Research & Development funded study (PI: Adam Bramoweth, PhD). This study will focus on testing the impact of additional resources and strategies that may help PCMHI clinicians deliver BBTI more sustainably in PCMHI.

Participating in the training and the research is voluntary. You can only participate in the research if you complete the BBTI training (or have been previously trained in CBT-I). More information about the study will be available following the training."

Are you interested in participating in the BBTI training?

No – thank you for your time

Yes – great, let's discuss your availability (provide date and time options)

I'm CBT-I trained – great, let's discuss the study in more detail if you are interested

No – thank you for your time

Yes – provide additional study details

Email Script

Dear PCMHI team:

I am writing to inform you about a PCMHI training opportunity to learn an evidence-based behavioral insomnia intervention. As you are aware, insomnia is a common disorder among our Veterans seen in Primary Care. For many of them, it may be appropriate and beneficial to treat them within PCMHI rather than referring them out to specialty care.

Brief Behavioral Treatment for Insomnia (BBTI) is consistent with other behavioral health and behavioral medicine interventions delivered in PCMHI. It consists of 4 core sessions and can be delivered in-person, through telehealth, or a combination. Sessions can also be completed within 30 minutes. BBTI is adapted from Cognitive Behavioral Therapy for Insomnia, which has a significant evidence base and has been widely disseminated across VHA. BBTI is based on the core behavioral concepts of CBT-I—stimulus control and sleep restriction.

Training in BBTI will be available to any PCMHI clinician who delivers therapy/behavioral interventions. Training is expected to last approximately 2-3 hours and will be delivered by [local site PI] (Klingaman/Koffel/O'Brien-Veara/Ulmer) and joined remotely by Dr. Bramoweth (VA Pittsburgh Healthcare System).

Following the training, clinicians will have the option of partaking in a VA Health Services Research & Development funded study (PI: Adam Bramoweth, PhD). This study will focus on testing the impact of additional resources and strategies that may help PCMHI clinicians deliver BBTI more sustainably in PCMHI.

Participating in the training and the research is voluntary. You can only participate in the research if you complete the BBTI training. However, if you have already been trained to deliver CBT-I, you are not required to participate in the BBTI training; please reach out to Dr. Klingaman/Koffel/O'Brien-Veara/Ulmer for more information. More information about the study will be available following the training.

If interested in participating in the BBTI training, and potentially the research study, please respond to this email for additional information.

Sincerely,

[signature]
First Name Last Name, Degree
Signature Block
[indicate PCMHI supervisor status]

[signature]
First Name Last Name, Degree
Signature Block
[indicate Site PI status]

10.2 Study Information Sheet

INFORMATION SHEET FOR: *Enhancing Access to Insomnia Care (EASI Care): Implementing Brief Behavioral Treatment for Insomnia in Primary Care Mental Health Integration Clinics*

You are being asked to participate in a study funded by VA HSR&D and conducted by Adam Bramoweth, PhD at the VA Pittsburgh Healthcare System. This study will test if certain strategies improve the sustainable delivery of an evidence-based brief behavioral treatment for insomnia (BBTI) in Primary Care Mental Health Integration (PCMHI) Clinics. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

We are conducting this study to compare the impact of training PCMHI providers to deliver BBTI (BBTI) vs. the impact of BBTI training plus 12-months of access to implementation strategies and support (BBTI+IS). During BBTI+IS, sites will have internal and external support from insomnia and implementation experts to enhance their efforts delivering BBTI.

Our goal is to identify specific strategies that help promote the implementation of BBTI in PCMHI. Through qualitative interviews, we will seek your perspectives on BBTI training, the impact (positive and negative) of the strategies, and barriers that continue to impede progress. Brief surveys will help us identify specific strategies that help, or hinder, the implementation of BBTI in PCMHI.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

As a PCMHI provider you will be asked to complete three activities over the course of the study, across various phases (pre-implementation, implementation, post-implementation). If enrolled, your participation may last 18-36 months.

First, complete brief surveys about your utilization of implementation strategies. These surveys take approximately 5 minutes to complete, will be administered quarterly during the implementation phase (4x over 12-months) and the post-implementation phase (2x over 6-months).

Second, participate in audio-recorded qualitative interviews. These will occur at three time points: after BBTI training; after the implementation phase; and after the post-implementation phase. Interviews will focus on your experiences, successes, and challenges with the training and implementation process. Your responses will help provide context about the strategies that worked (or didn't). The interviews will vary in time but may take up to 30-45-minutes.

Third, engage in quarterly mock BBTI sessions during all three phases of the study. These will be conducted with your site PI and should take no more than 30-minutes and serve as fidelity checks for your delivery of BBTI. As a secondary fidelity check, site PIs will review a random sample of your BBTI sessions. You will only get feedback on these fidelity checks during the implementation phase; however, if you are determined to be delivering care below the fidelity threshold, your site PI may offer you additional training in BBTI.

As a site PI you will be asked to complete the brief surveys and qualitative interviews, similar to the PCMHI providers (see above); however, your focus will be about your site broadly, rather than as an individual. Also, you will be asked to conduct the mock BBTI sessions to rate the PCMHI provider's fidelity of BBTI delivery. Finally, you will be asked to conduct chart reviews (i.e., 10% or at least 1 per month) of PCMHI provider's BBTI sessions as a secondary fidelity check. Chart reviews are not expected to take longer than 30-minutes.

Participating is voluntary. You may choose not to participate and can withdraw at any time. You are not required to answer all questions from the surveys and interviews. If you withdraw, collected data will be retained by the study team. There is no expectation you will receive study results, although you may as determined by the study team.

ARE THERE ANY RISKS OR DISCOMFORTS?

None are expected. Although this is a minimal risk study, there is always potential risk of experiencing emotional or psychological discomfort when engaged in research (e.g., sharing information during the interviews). There is also a minimal risk of breach of participant confidentiality. Appropriate measures will be taken to ensure that your identity remains confidential (e.g., study materials identified with unique ID numbers,

data stored on secure network drive). Your VA supervisor will not have access to your data—interviews or brief surveys.

ARE THERE ANY BENEFITS?

You will not benefit directly from being in this study. Your participation may benefit others, both VA employees and Veterans, in the future by contributing to the researchers understanding of implementation strategies that improve the sustainable delivery of behavioral insomnia treatments in PCMHI.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

The information collected for this study will be kept confidential. Appropriate measures will be taken to ensure that your identity remains confidential (e.g., identified with unique ID numbers; data transferred from participating sites to the coordinating sites via encrypted email; use of encrypted audio-recorders). Identifiers will be removed from any identifiable information. Your data may be used in future research by other investigators; if so, it will be stored on a secure network drive at VAPHS and only accessible by approved study staff and investigators. Data will be stored on a restricted VA shared network drive or in locked filing cabinets at VAPHS. Only approved study staff will have access to research data. Also, we will include information about your study participation in your medical record (i.e., CPRS).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

No, you will not receive payment for your participation.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with study procedures. Please immediately contact your site PI and overall study PI, Dr. Adam Bramoweth, at 412-360-2806. If you have any other questions, comments or concerns about the research, please contact Study Coordinator, Lisa Lederer, MA, MPH at 412-360-2364.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.

10.3 Demographics Questionnaire

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Demographics

ID: _____ **Site ID:** _____ **Date:** ___ ___ / ___ ___ / ___ ___ ___ ___

Please answer the following demographic questions. Place an ✕ or ✓ next to your answer.

AGE	# years	_____
GENDER	0	FEMALE _____
	1	MALE _____
	2	OTHER _____
RACE	1	CAUCASIAN _____
	2	BLACK/AFRICAN AMERICAN _____
	3	ASIAN _____
	4	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER _____
	5	AMERICAN INDIAN OR ALASKA NATIVE _____
	6	OTHER _____
		IF OTHER, EXPLAIN _____
ETHNICITY	0	NOT HISPANIC/LATINO_____
	1	HISPANIC/LATINO_____
MARITAL STATUS	1	MARRIED _____
	2	DIVORCED/SEPARATED _____
	3	WIDOWED _____
	4	SINGLE/NEVER MARRIED _____
	5	OTHER _____
		IF OTHER, EXPLAIN_____

VA ROLE/TITLE		_____
PROFESSIONAL DEGREE	1	PHD_____
	2	PSYD_____
	3	OTHER_____
		SPECIFY_____
YEAR OF DEGREE	Date	_____
YEARS AT VA	# years	_____
YEARS IN PCMHI	# years	_____
% EFFORT IN PCMHI	%	_____
% EFFORT ELSEWHERE	%	_____
		SPECIFY WHERE
PRIOR INSOMNIA TRAINING	0	NO_____
	1	YES_____
		IF YES, PLEASE DESCRIBE WHEN AND WHERE_____
		_____
		_____

10.4 BBTI-CRS

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BBTI Competency Rating Scale (BBTI-CRS)

ID: _____ Rater: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Mock Session # (1, 2, 3, 4, 5, 6, etc.): _____

Directions: Assess the clinician's skill level on a scale of 0-4 and record the score on the line next to the item number. The rating descriptors are provided for even number points. If the clinician falls between two descriptors choose the intervening odd scale (below). For example, if rating item 2 you thought the clinician's presentation (or review) of the Four Rules was barely adequate, enter a "1" on the line. Please do not leave any item blank.

0	**1**	**2**	**3**	**4**
Poor	Barely Adequate	Satisfactory	Good	Excellent

___ **1.** Clinician's review of patient's progress through the sleep diary (noting changes in sleep based on sleep diary data from week to week, accuracy/inconsistencies of sleep data, and completion of sleep diary).

0 Clinician did not discuss the sleep diary data with the patient. Or, if the patient did not complete the diary, the clinician did not review the importance of doing so.

2 Clinician reviewed sleep diary data and provided some feedback on completion and content but did not fully address accuracy/inconsistencies. If the patient did not complete the diary, the clinician emphasized the importance of doing so, but did not fully discuss obstacles/motivation issues.

4 Clinician skillfully reviewed sleep diary information: provided feedback on accuracy/inconsistencies in the diary, provided positive reinforcement and demonstrated the use of sleep diary data in treatment (if applicable). If the patient did not bring the diary, the clinician emphasized the importance of doing so and discussed obstacles/motivation issues.

___ **2.** Clinician's presentation (or review) of the Four Rules: All elements need to be present during initial presentation; only relevant elements need to be discussed in subsequent sessions.

0 No attempt to present (review) elements of the Four Rules.

2 Clinician presented (or reviewed) the Four Rules (1. Reduce time in bed; 2. Don't go to bed unless you are sleepy; 3. Don't stay in bed unless you are asleep; 4. Get up at same time every day). Clinician presented or reviewed correct rationale for each element, integrating relevant psychoeducation (e.g., process S/C, 3P model, etc.), discussed the difference between sleepiness versus fatigue, discussed activities to do when awake/while out of bed, and established a new tailored time in bed window. However, the clinician failed to do two of the following: a) assess patient's understanding of concepts, b) discuss obstacles to adherence and solutions to these obstacles, c) assess and support patient's motivation to adhere to the Four Rules, d) appropriately discuss recommended activities before bedtime and when applicable in the middle of the night (e.g., non-sedentary activities to help stay awake to a later than habitual bedtime or sedentary activities to help unwind before bedtime), and e) tailor a recommended time in bed window considering chronotype and daytime schedule obligations.

4 Clinician skillfully implemented the Four Rules as above. In addition, the clinician did all the following: a) assess patient's understanding of concepts, b) discuss obstacles to adherence and solutions to these obstacles, c) assess and support patient's motivation to adhere to the Four Rules, d) appropriately discuss recommended activities before bedtime and when applicable in the middle of the night (e.g., non-sedentary activities to help stay awake to a later than habitual bedtime or sedentary activities to help unwind before bedtime), and e) tailor a recommended time in bed window considering chronotype and

daytime schedule obligations.

___ **3.** Clinician's attention to adherence issues

0 Clinician did not address adherence issues.

2 Clinician identified the reasons for non-adherence and worked on identifying solutions or supported the patient's level of motivation as appropriate. However, clinician did not fully ascertain patient's commitment to adherence, or failed to address a key obstacle to adherence.

4 Clinician skillfully attended to and problem-solved adherence issues that arose and adequately addressed patient's needs, supported patient's level of motivation as appropriate and reviewed commitment to adherence.

___ **4.** Homework (i.e. TIB, sleep diary, behavioral experiments, etc…)

0 Clinician did not incorporate relevant homework to the treatment.

2 Clinician assigned relevant homework and provided sufficient rationale for homework. However, the clinician failed to address adherence/motivation issues or failed to provide adequate feedback on homework assigned during the previous session.

4 Clinician skillfully incorporated relevant homework and provided rationale and feedback and addressed motivation and obstacles to adherence.

___ **5.** Interpersonal effectiveness

0 Clinician had confrontational style, seemed impatient or otherwise demonstrated poor interpersonal skills.

2 Clinician had effective interpersonal style; however, at times the clinician seemed to have difficulty maintaining rapport OR did not convey competence or confidence.

4 Clinician had an effective interpersonal style conveying confidence and competence and maintained rapport and addressed rapport issues as needed.

___**6.** Collaboration

0 Clinician did not collaborate with patient.

2 Clinician did attempt to collaborate with patient; however, the clinician was occasionally overly directive.

4 Clinician collaborated with patient and elicited patient participation in modifying treatment components such as selecting TIB, TIB extension.

___ **7.** Feedback

0 Clinician did not provide feedback or elicit information regarding patient's understanding of treatment.

2 Clinician adequately used feedback; however, the clinician did not use enough questioning to ensure patient understood rationale or line of reasoning during the session OR did not elicit or provide summary of the main points of the session.

4 Clinician skillfully provided feedback and regularly employed questioning to obtain information regarding patient's understanding during the session and elicited or provided summary of the main points of the session.

___ **8.** Case conceptualization grounded in sleep knowledge including consideration of: factors that weaken the sleep drive, factors that impact the circadian clock, manifestations of hyperarousal, unhealthy sleep behaviors, comorbidity that affects the patient's presentation, medications that impact sleep/sleepiness, and any other relevant predisposing, precipitating, or maintaining factors.

0 Clinician failed to consider important case conceptualization issues entirely or failed to consider critical issues such factors affecting safety of intervention strategies.

2 Clinician was guided by case conceptualization informed by knowledge of sleep regulation and provided a clear treatment plan. The clinician may have failed to consider one or two of the relevant case conceptualization factors listed in the question stem above. However, this oversight did not result in significant harm to overall treatment effectiveness.

4 Clinician skillfully implemented behavioral and cognitive components of treatment based on sound case conceptualization grounded in knowledge of sleep regulation, well-tailored to the patient's unique needs and circumstances.

Overall Rating of Clinician

9. Overall, what is your rating of the clinician providing BBTI in this session?

0	**1**	**2**	**3**	**4**
Poor	Barely Adequate	Satisfactory	Good	Excellent

Scoring and Minimal Competency

For items 1 and 2, a score of ≥2 on each item at least once across all rated sessions.

Total score = 9 x (sum of scores on all scored items/number of items scored).

Score of ≥18 on at least one rated session.

Comments / Feedback / Suggestions for clinician's improvement:

10.5 Qualitative Interviews

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Qualitative Interview Guide #1

ID: _____ Site ID: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Phase: pre-implementation / implementation

This conversation will be audio recorded and kept confidential, and study results will be kept under lock and key. Your participation is voluntary, and you may withdraw from this project at any time. The interview will take approximately 30-60 minutes. Do you have any questions before we begin? **[Answer questions then turn on audio-recorder]**

This is [**INTERVIEWER NAME**] with [**PARTICIPANT ID#, SITE ID#**] and today is [**DATE**].

Interview #1

Question	Probe(s)
You recently completed training for BBTI. I'm going to ask you some questions about the training and insomnia broadly. First, I'd like to get a little information about you.	
What is your role/position here at VAPHS? How long have you been at this VA? In this clinic?	Where were you previously? What was your role/position there?
Tell me how often you encounter patients with sleeping issues and/or insomnia?	Has this changed during COVID compared to pre-COVID?
What is your typical approach to treating Veterans with insomnia (prior to this training)? Did anything change since BBTI training? What are some of the challenges to providing behavioral insomnia therapy in PCMHI?	How do you manage/treat insomnia? Multi-visit or single visit? What kind of behavioral interventions have you used for insomnia (prior to the BBTI training)? Any other approaches/interventions for sleep? • Education/sleep hygiene • CBT-I • Cognitive therapy • Relaxation strategies • Motivational interviewing What do you do differently if the patient is medically complex? What referrals do you make with your patients with insomnia? Have you received any patient feedback?
Tell me what you knew (prior to the training) about assessing and treating insomnia? More specifically, tell me what you know about behaviorally based interventions for insomnia?	What kind of training have you received? (CBT-I?) Where did you receive these trainings?

Do you feel prepared to deliver BBTI?	Do you have the right information? Are the right people involved? Do you have the right resources? [If NOT trained in CBT-I: Is the Clinician Toolkit folder sufficient, or would you have benefitted from a treatment manual?]
Was there any pressure, or expectations, to treat Veterans with insomnia in PCMHI? If so, where is the pressure/expectation coming from? Was there any pressure *not* to treat insomnia in PCMHI (e.g., to refer out)?	Pressure for behavioral treatments in PCMHI vs. referring out? Primary Care vs. Behavioral Health?
Tell me your thoughts about the BBTI training? Prior to completing training in BBTI, did you think delivery of insomnia care was a good fit for PCMHI? [If trained in CBT-I: how does the fit with BBTI compare to the fit with CBT-I?] Has training changed this view? Who else could deliver this treatment? What types of providers?	What did you like? What did you dislike? What would you change to improve the training? Why or why not (e.g., limited time, space, personnel)? If not PCMHI, where is the better fit? What are your thoughts about nurses (RNs or LPNs) or social workers delivering BBTI?
Is BBTI the best option to treat insomnia in PCMHI?	What else would be a better option or effective alternative?
Is there anything you would change about how BBTI is organized or delivered?	What/how/why?
Is BBTI adaptable? Does it fit the needs of your therapeutic approach?	What could be changed or improved? Specifically, do the following aspects of BBTI fit with your PCMHI practice (if you don't remember from the training, please just say so): • General content of the intervention • Patient-centeredness (ability and flexibility to meet the unique needs of your patients) • Session length (<30 min) • Session frequency (~4) • Overall treatment duration • Use of telehealth sessions
How does BBTI fit within the overall mission of the PCMHI clinic, or the VA in general?	

What gets in the way of patients accessing insomnia care in PCMHI? How could access to insomnia care for Veterans be improved?	What do you need? What do Veterans need?
What may prevent you from successfully delivering BBTI in PCMHI? What may prevent BBTI from becoming a sustainably delivered treatment in PCMHI?	How could you overcome these barriers?
What is needed, in the clinic/system, to prepare or be ready to successfully implement BBTI in PCMHI?	What do you need to know? Who needs to be involved? What resources do you need?
Anything else to add about the training to deliver BBTI? Anything else to add about what you think is required to successfully implement BBTI in PCMHI?	

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Qualitative Interview Guide #2

ID: _____ Site ID: _____ Date: ___ ___ / ___ ___ / ___ ___ ___ ___

Phase: implementation

This conversation will be audio recorded and kept confidential, and study results will be kept under lock and key. Your participation is voluntary, and you may withdraw from this project at any time. The interview will take approximately 30-60 minutes. Do you have any questions before we begin? **[Answer questions then turn on audio-recorder]**

This is [**INTERVIEWER NAME**] with [**PARTICIPANT ID#, SITE ID#**] and today is [**DATE**].

Interview #2

Question	Probe(s)
You've had access to numerous implementation strategies and support for a year, let's talk about what's happened.	
What's the past year been like delivering BBTI in PCMHI?	What's gone well? What hasn't? Specifically, how well did these fit with your PCMHI practice: • General content of the intervention • Patient-centeredness (ability and flexibility to meet the unique needs of your patients) • Session length (<30 min) • Session frequency (~4) • Overall treatment duration • Telehealth sessions
Were you prepared for the implementation of BBTI in PCMHI?	Did you have the right information? Were the right people involved? Did you have the right resources? [If NOT trained in CBT-I: Was the Clinician Toolkit folder sufficient, or would you have benefitted from a treatment manual? If trained in CBT-I: How much did you rely on your CBT-I training/manual?]
Did BBTI in PCMHI meet the needs of Veterans in Primary Care?	
Did BBTI in PCMHI meet the needs of the PCMHI/Primary Care team?	
Tell me about any specific implementation strategies? What resources/tools did you use?	Those that you utilized the most? The least?

	[can name specific strategies, as a prompt, if necessary]

Who played a role in helping you implement BBTI in PCMHI? Or, who needed to be involved to assist with implementation?	Who else could have made valuable contributions towards success? Locally? Externally?
What was it like to work with the coordinating site (Pittsburgh)?	How did they help? Did they help overcome any barriers you were experiencing? • What activities or support provided by the facilitator(s) were most helpful in supporting your local implementation efforts? • What was least helpful about the facilitation strategy? • How could the facilitation strategy be improved or enhanced to support implementation of this intervention at sites like yours?
Was communication/consultation with the coordinating site effective?	Bi-weekly calls? As needed consultation?
Did things go according to plan?	What changed/adapted?
What could have been done differently to improve implementation?	What did you need that you didn't have? What did you need more of, that you did have? What did you need less of, that you did have?
When the support and resources are removed, what do you expect will happen?	How can you ensure sustainability? What is needed?
Anything else to add about the process of implementing BBTI in PCMHI the past year? Anything else you think is necessary to successfully deliver BBTI in PCMHI?	

EASI Care

Qualitative Interview Guide #3

ID: _____ **Site ID:** _____ **Date:** ___ ___ / ___ ___ / ___ ___ ___ ___

Phase: post-implementation

This conversation will be audio recorded and kept confidential, and study results will be kept under lock and key. Your participation is voluntary, and you may withdraw from this project at any time. The interview will take approximately 30-60 minutes. Do you have any questions before we begin? **[Answer questions then turn on audio-recorder]**

This is [**INTERVIEWER NAME**] with [**PARTICIPANT ID#, SITE ID#**] and today is [**DATE**].

Interview #3

Question	**Probe(s)**
It's been 6 months since access to, and support for, the implementation strategies has been removed. How have things been going delivering BBTI in PCMHI?	What's gone well? What hasn't?
Tell me about any implementation strategies you continue to utilize?	What resources do you use? What additional support/resources would help with sustainability?
Who needs to be involved more?	Why? Who doesn't need to be involved?
Is BBTI still a good fit with PCMHI here?	If not, why?
Will you continue to deliver BBTI in PCMHI?	How?
Anything else to add about how BBTI in PCMHI was sustained? Anything else you think is necessary to sustainably deliver BBTI in PCMHI?	
Some sites we anticipate working with in the future may not be as well-resourced or motivated to implement this intervention as your site has been. • What thoughts do you have about how we may need to improve or adapt our facilitation strategy to better support sites like that? • Are there additional tools or resources that you would suggest we develop to better support implementation of this intervention at sites like that? [If yes, ask]: What tools or resources would you suggest?	

10.6 Strategy Utilization Survey

V4 2021-03-05

EASI Care

Strategy Utilization Survey

ID: _____ **Site ID:** _____ **Date:** ___ ___ / ___ ___ / ___ ___ ___ ___

Survey #: 1 2 3 4 5 6

In Column 1, indicate whether your PCMHI clinic engaged in activities (even if only briefly) that could be described as the Implementation Strategy *in the last 3 months.* **In Column 2, rate on a scale of 1-5 how important it was, or would have been, for your PCMHI clinic to use the Implementation Strategy to help implement BBTI *in the last 3 months*.** **(1 = not at all important, 5 = very important)** **In Column 3, rate on a scale of 1-5 how feasible it was, or would have been, for your PCMHI clinic to use the Implementation Strategy to help implement BBTI *in the last 3 months.*** **(1 = not at all feasible, 5 = very feasible)** **(Please note: The 3 ratings in columns 2 and 3 might be different. "The innovation" refers to BBTI.)**	**Strategy Followed? (Yes/No/ Unknown)**	**Feasibility (1-5)**	**Importance (1-5)**
Example: **Deliver behavioral insomnia treatment to patients** **Work with patients with the ultimate aim of treating their insomnia using behaviorally based interventions.** **Example: PCMHI clinician delivers BBTI to Veterans.**	Yes	4	5
Develop a formal implementation blueprint **Develop a formal implementation blueprint that includes all goals and strategies. The blueprint should include: 1) aim/purpose of the implementation; 2) scope of the change (e.g., what organizational units are affected); 3) timeframe and milestones; and 4) appropriate performance/progress measures. Use and update this plan to guide the implementation effort over time.** **Example: An implementation blueprint was developed and is available for PCMHI clinicians to review and, as needed, the blueprint is updated with the implementation team.**			

	Strategy Followed? (Yes/	Feasibility (1-5)	Importance (1-5)
<u>Conduct educational meetings</u> **Hold meetings targeting different stakeholder groups (e.g., clinicians, administrators, other organizational stakeholders, and community, patient/consumer, and family stakeholders) to teach them about the clinical innovation (BBTI).** **Example: A member of the PCMHI team delivers a presentation about the advantages of delivering BBTI in PCMHI to PCPs at a Primary Care team meeting.**			
<u>Develop educational materials</u> **Develop and format manuals, toolkits, and other supporting materials in ways that make it easier for stakeholders to learn about the innovation and for clinicians to learn how to deliver the clinical innovation.** **Example: A clinician who practices BBTI creates a new patient handout for use by PCMHI clinicians at your site.**			
<u>Distribute educational materials</u> **Distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically.** **Example: A PCMHI clinician emails a BBTI information sheet to all PCPs at their VAMC and affiliated CBOCs to inform clinicians about BBTI services available in PCMHI.**			
<u>Organize clinician implementation team meetings</u> **Develop and support teams of clinicians who are implementing BBTI and give them protected time to reflect on the implementation effort, share lessons learned, and support one another's learning.** **Example: Clinicians who deliver BBTI in PCMHI meet on Teams every other week to discuss related experiences.**			
<u>Audit and provide feedback</u> **Collect and summarize clinical performance data over a specified time period to provide feedback to clinicians and administrators to monitor, evaluate, and modify clinician behavior.** **Example: The Implementation team in Pittsburgh sends monthly reports including # of new BBTI cases for each trained clinician.**			

	Strategy Followed? (Yes/	Feasibility (1-5)	Importance (1-5)
Develop or implement tools for quality monitoring **Develop, test, or introduce quality-monitoring systems—the appropriate language, protocols, algorithms, standards, and measures (of processes, patient/consumer outcomes, and implementation outcomes) that are often specific to the innovation being implemented.** **Example: Clinicians delivering BBTI are assessed on their ability to deliver BBTI with competency by participating in mock sessions that are rated using a standardized rating scale; scores above a cutoff indicate comptency.**			
Facilitation **A process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship.** **Example: The Pittsburgh Implementation Team works with PCMHI clinicians to enhance the delivery of BBTI, through the identification of barriers and facilitators at each site and supporting the implementation of strategies.**			
Increase demand **Attempt to influence the market to increase demand for BBTI.** **Example: Brochures about BBTI in PCMHI are strategically placed in primary care waiting rooms, encouraging Veterans to talk with their PCPs about sleep problems.**			
Obtain and/or use patients/consumers and family feedback **Develop strategies to increase patient/consumer and family feedback on the implementation effort.** **Example: Veterans who initiate BBTI are asked to provide feedback about their experience and/or sent a survey on their experience.**			
Prepare patients/consumers to be active participants **Prepare patients/consumers to be active in their care, to ask questions, and specifically to inquire about care guidelines, the evidence behind clinical decisions, or about available evidence-supported treatments.** **Example: During BBTI, clinicians encourage Veterans to be active participants in care, including inquiring about BBTI, its effectiveness, how it compares to other treatments, and why it is being delivered in PCMHI.**			

	Strategy Followed?	**Feasibility (1-5)**	**Importance (1-5)**
<u>Identify and/or prepare champions</u> **Identify and/or prepare individuals (e.g., clinicians, administrators) who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organization.** **Example: PCMHI clinicians who show great enthusiasm for BBTI are asked to remind their colleagues of its importance and actively promote the delivery of BBTI in PCMHI with relevant stakeholders.**			
<u>Obtain formal commitments</u> **Obtain written commitments from key partners that state what they will do to implement the innovation.** **Example: Primary Care leadership formally commits to improving referrals of Veterans with insomnia to PCMHI clinicians to evaluate for insomnia and treatment with BBTI. Commitment includes ensuring PCPs are familiar with insomnia symptoms and referral process.**			
<u>Conduct ongoing training</u> **Plan for and conduct training in the clinical innovation in an ongoing way.** **Example: Annual BBTI training is made available for new PCMHI clinicians and as a refresher for already trained clinicians.**			
<u>Develop academic partnerships</u> **Partner with a university or academic unit for the purposes of shared training and bringing research skills to an implementation project.** **Example: If available, develop relationships with investigators within VA and/or Academia to integrate research and evaluation of your BBTI implementation efforts to further improve patient-, clinician-, and system-level outcomes.**			

	Strategy Followed?	Feasibility (1-5)	Importance (1-5)
<u>Remind clinicians</u> **Develop reminder systems designed to help clinicians to recall information and/or prompt them to use the clinical innovation.** **Example: Primary Care Provider meetings include a tally of referrals made to PCMHI for BBTI or a reminder is placed in the electronic medical records to assess for insomnia annually and if present, refer to PCMHI for BBTI.**			
<u>Conduct local needs assessment</u> **Collect and analyze data related to the need for the innovation.** **Example: A survey is distributed to Veterans in Primary Care waiting rooms asking about insomnia symptoms and treatment preferences.**			
<u>Conduct cyclical small tests of change</u> **Implement changes in a cyclical fashion using small tests of change before taking changes system-wide (e.g., plan-do-study-act). Tests of change benefit from systematic measurement, and results of the tests of change are studied for insights on how to do better. This process continues serially over time, and refinement is added with each cycle.** **Example: No-show rates are compared before and after Veterans are sent different types of reminders (e.g., phone, secure message, Annie app, etc.).**			