Project Description
Last Update: 28 May 2019

Implementing and Evaluating Computer-Based Interventions for Mental Health: Testing an Implementation Strategy for VA Outpatient Care

NCT03151083

1. **Purpose:** The purpose of this study is to evaluate the preliminary (1) effectiveness of an implementation strategy for Internet-based Self-help Interventions and (2) clinical outcomes of a specific Internet-based self-help program for insomnia, SHUTi™, in VACT outpatient primary care. Internet-based self-help programs are personalized, self-guided interventions delivered over a computer, mobile device, or other Internet platform and focused on improving knowledge, awareness, or behavior change for a mental or physical health problem.[1] Through our previous and current work at VACT (protocol EH0002), we are developing a general strategy for implementing Internet-based Self-help programs in VA primary care, specifically among Patient Aligned Care Teams (PACT) and Primary Care Mental Health Integration (PCMHI) teams. An implementation strategy is defined as a systematic intervention to integrate evidence-based health innovations into usual care.[2] The strategy we propose to test consists of four core components: (1) a clinical intermediary for patient support, (2) provider/staff facilitation and education, (3) patient education, and (4) stepped-care for those requiring additional treatment. Our currently approved protocol (EH0002) involves interviewing VA providers, administrators, and staff in order to expand and modify the components of this strategy. In the proposed study, we will compare this strategy to an enhanced usual care (control) strategy with respect to the implementation related outcomes of patent engagement, provider adoption through referral to the program, and patient completion, over a eight-month active implementation period. There are evidence-based Internet-based self-help programs for many mental and behavioral health problems common in primary care such as depression, anxiety, problematic alcohol use, etc. We will target insomnia and use the SHUTi™ program, a 6-week self-guided program utilizing standard cognitive-behavioral therapy (CBT) techniques for the treatment of chronic insomnia. The program has been shown to improve insomnia severity and other sleep related outcomes in multiple randomized controlled trials.[3-5] The clinical effectiveness of SHUTi™ will be evaluated using clinical insomnia outcomes obtained on all patients enrolled over the two 8-month active implementation periods.

2. Background

Insomnia Treatment: A Prototypical Gap in Access to Quality Mental Healthcare

Insomnia is one of the most common mental health disorders among Veterans and is likely under-diagnosed in routine care.[6] Most Veterans receive treatment for insomnia (and other common mental health conditions) in primary care, where psychotropic medications such as sedative-hypnotics are the primary treatment.[7,8] unfortunately, sedative-hypnotic medications have risks such as accidents, falls, and abuse potential. Medications are also of limited efficacy for the extended treatment of insomnia.[9] Several non-pharmacologic evidence-based practices (EBPs), including CBT for insomnia, have equal or better effectiveness and far fewer risks.[10,11] EBPs are generally underutilized, and engagement in and completion of EBP-driven treatments are limited within VA.

VA Patient Aligned Care Teams and Primary Care Mental Health Integration

One method to improve the deployment of EBPs is to leverage the use of Internet-based self-help interventions within VA PACT in cooperation with PCMHI providers. PACT/PCMHI teams distribute mental healthcare activities across a range of providers, including physicians, psychologists, nurses, care managers, and health technicians, who use a collaborative care model to treat a range of mental health conditions, most commonly mild to moderate depression, anxiety, and insomnia.

Internet-Based Self-Help Interventions

Internet-based interventions are personalized, self-guided programs delivered over a computer, mobile or other Internet access device and are focused on improving knowledge, awareness, or behavior change.[1] Most Internet-based interventions are based on CBT principles and focused on fostering behavior change for a range of problems. Such programs present

standardized yet individualized material in rich and varying formats, including audio, video, text, standardized symptom assessments, and graphical presentation of treatment response. Because patient interaction with these programs is relatively standardized through their format, Internet-based interventions provide a high degree of fidelity to psychotherapeutic EBP models. Many programs also include measurement tools, providing the opportunity to collect and monitor relevant outcome data. Most are designed around a "self-help" format and are accessed at a pace and in a setting chosen by the user, but are also available with varying levels of professional support.

The potential health services benefits of Internet-based self-help interventions are extensive. They can (1) reduce travel barriers, providing treatment for individuals who cannot visit a clinic during business hours, (2) reduce barriers associated with the stigma of seeking mental health care and increase self-care, (3) increase clinic productivity, and (4) reduce costs associated with provider time.[12-14] As a result, Congress mandated that VA implement Internet-based interventions through the *Veterans' Mental Health and Other Care Improvements Act of 2008*.[15] Evidence from systematic reviews indicates that Internet-based self-help programs on the whole are efficacious for a range of mental health conditions, and when compared with face-to-face therapy some programs may provide similar, yet more cost-effective care.[16-19]

During the development of this project, VACT PACT/PCMHI leaders and providers indicated that they would like to target insomnia, one of the most common conditions encountered in primary care, for intervention via Internet-based self-help. Multiple Internet-based self-help programs for the treatment of insomnia have shown efficacy in randomized controlled trials. We will use the SHUTi™ program, based on its effectiveness in trials involving over 1500 individuals, in which it showed improvements in insomnia severity ratings, depression severity ratings, and sleep indices up to six months following program engagement.[3-5]

Implementing Internet-based Self-help in VA Primary Care

The development and testing of effective strategies to support the implementation of empirically supported Internet-based self-help programs in current outpatient treatment models is a novel area of research. The objective of this proposal is to evaluate the preliminary effectiveness of an implementation strategy for Internet-based self-help Interventions in VA Primary care using a specific Internet-based self-help program for insomnia. An implementation strategy is defined as a systematic intervention to integrate evidence-based health innovations into usual care.[2] This strategy will provide guidance for the implementation of this novel intervention platform in a specific context, outpatient care in VA PACT/PCMHI.

Past Pilot Study of Internet-based Self-Help At VACT

In 2014, we completed a pilot feasibility study implementing Internet-based self-help in VA outpatient care.[20] In this study an evidence-based program for insomnia (RESTORE™) was implemented in the VACT substance abuse clinic using provider and patient education sessions, on-site Internet access, and clinician telephone support. The feasibility of this strategy was evaluated by assessing engagement/completion rates, participant reported acceptability, and clinical outcomes. Please see the abstract from the published article in the appendix of this proposal for the results of this study. These findings demonstrate the ability of our team to perform research on the implementation of Internet-based self-help in VA clinical care, as well as the feasibility of the strategy we propose in this study.

3. Significance

The proposed project has major innovations:

1. The development of a general strategy for the implementation of evidence-based Internet-based self-help programs in VA primary care, independent of the target condition, specific program, or treatment site is a **novel** undertaking.
2. The testing of an implementation strategy for such interventions compared to an enhanced usual care strategy has not been attempted. Specific aspects of our proposed strategy have

been tested, but none have codified core components into a defined strategy as they pertain to Internet-based self-help implementation.

Positive benefits for Veterans and VA care include:

1. Better access to effective mental health care, especially among Veterans from more recent conflicts who may find Internet-based self-help a more attractive treatment modality.
2. Provision of mental health treatment earlier in the course of illness.
3. Intervention-related improvements in health outcomes (insomnia severity).
4. Greater self-care associated with the use of self-help programs.
5. The ability to access care 24/7.
6. Improved clinic productivity.
7. Potentially reduced the risks associated with long-term use of sedative-hypnotic medications, such as benzodiazepines.

In addition to providing a safer alternative for treating insomnia, the insights gained from developing and testing this implementation strategy will be transferable to other common mental health disorders for which other evidence-based self-help programs are currently available, such as depression, generalized anxiety, problematic alcohol use, smoking cessation, chronic pain, diabetes management, etc.

4. Research Plan

A. Study Design and Procedures

Table 1. Timeline of Research Activities

	Year 1				Year 2				Year 3			
	1	2	3	4	1	2	3	4	1	2	3	4
Implement Program Using Enhanced Usual Care	X	X										
Finalization of Experimental Implementation Strategy			X									
Identification and Training of Support Clinician			X									
Provider/Staff Training for Experimental Strategy			X									
Piloting in two individuals			X	X								
Implement SHUTi Using phase 1 Exp. Strategy				X	X							
Implement SHUTi using Phase 2 Exp. Strategy						X	X					
Analysis of Data from active Implementations						X	X	X	X			

As described by Curran et al. (2012), we will employ a hybrid type 3 implementation-effectiveness study design through which we will primarily test the effectiveness of the experimental implementation strategy we are developing and secondarily evaluate the clinical effectiveness of SHUTi™.[21] We will use a quasi-experimental pre-/post-cohort design whereby the program will initially be implemented using an enhanced usual care (control) strategy, followed by implementation using experimental implementation strategies. The program's association with clinical response will be evaluated in an uncontrolled pre-/post-format. The timeline of events for this study is described in Table 1.

SHUTi™ will initially be implemented using an enhanced usual care (control) strategy (described in detail below), over a eight-month period. For this strategy, VACT PACT/PCMHI providers will be given a 30-min education session on how to refer to and use SHUTi™ in clinical practice. This education will be followed by a eight-month period in which VACT PACT/PCMHI patients will be recruited to use SHUTi™ using this strategy. PACT/PCMHI providers will identify patients with insomnia who are appropriate for SHUTi™, and recruit

them through the normal course of clinical interactions. During recruitment, patients will be given a pamphlet with information about the SHUTi™ program including: educational information about insomnia and CBT treatment for insomnia, information about the content of the program, as well as website, login, privacy and provider contact information. Individuals will then meet with the research assistant for the application of final inclusion/exclusion criteria and research consent. Individuals who do not meet the inclusion/exclusion criteria will be referred back to the PACT/PCMHI provider. The research assistant will also provide a de-identified user name for login, password resets, and will collect paper and pencil baseline measures. Subjects will then engage in the program at their own convenience. The research assistant will not provide program education or support directly to patients. Patients will be explicitly instructed on how to use regular PACT/PCMHI follow-up channels or the Veteran's crisis line in the case of emergency, as they would do in the course of typical PACT/PCMHI treatment. Patients will be contacted by the research assistant after 10 weeks for the purpose of follow-up measure completion, which will take place either face-to-face or over the phone. Subjects will be compensated $10.00 for participation in each of two visits with the research team. See Table 2 for a full list and description of visits for individuals involved in the study.

Table 2. Schedule of Subject Visits

Phase	Visit	Visit description	Context	Location	Duration (Min)	Payment
Enhance Usual Care (Control)	Provider Initial Contact	1. Identification of Insomnia 2. Discussion of program with patient 3. Provider gives pamphlet 4. Provider/Patient Contacts Research Staff	As part of regular treatment encounter	VACT PACT Offices	5-15	None
	Baseline Visit with Research Personnel	1. Application of Inclusion/Exclusion criteria 2. Informed Consent 3. Baseline measures 4. Issue userID and temporary password	Individual contacted by research assistant to coordinate in-person visit	VACT PACT Offices	10-25	$10
	Provider Follow-up	As need support contacts to address issues that arise, coordinated by provider/patient	Provider: In-person or phone	Phone or PACT Offices	As needed	None
	Research Follow-up	Complete final follow-up measures 10-weeks after baseline visit	Research Assistant: In-person or phone	Phone or PACT Offices	5-15	$10
Experimental Strategy (Phases 1&2)	Provider Initial Contact	1. Identification of Insomnia 2. Discussion of program with patient 3. Provider/patient contacts support clinician	As part of regular treatment encounter	VACT PACT Offices	10-20	None
	Support clinician Initial Contact	1. Education session 2. Initial tour of program 3. Issue userID and temporary password	Initial in-person education session	VACT PACT Offices	30-45	None
	Baseline Visit, Research Personnel	1. Application of Inclusion/Exclusion criteria 2. Informed Consent 3. Baseline measures	Research assistant contacted by support clinician. Visit takes place prior to support clinician visit	VACT PACT Offices	10-20	$10
	Support Clinician Follow-up	Scheduled and as needed support contacts to address issues that arise. Coordinated by support clinician and patient	Support clinician: In-person or phone	Phone or PACT Offices	As needed	none
	Research Follow-up	Complete final Follow-up measures 10-weeks after baseline visit.	Research assistant: In-person or phone	Phone or PACT Offices	10-15	$10

After the initial 8-month testing period, referrals to SHUTi™ in VACT PACT/PCMHI will stop for three to four months. During this critical period, several activities will take place:

(1) Focus groups consisting if VACT PACT/PCMHI staff will take place, as described in our other protocol (EH0002).
(2) Final specific modifications to the experimental implementation strategy using information from interviews with VA-wide providers and administrators as well as the focus groups. (A final description of the implementation strategy will be supplied to the VACT HSC via a protocol amendment during this period.)
(3) Identification and training of the support clinician (described in the experimental implementation strategy below).
(4) Provider education for the experimental strategy (described in the experimental implementation strategy below).
(5) Pre-piloting of the SHUTi™ program with one-two individuals using this strategy.

After this period, patients will be recruited to participate in SHUTi™ using the experimental implementation strategy over a period of eight months. The experimental implementation strategy is described at length in the intervention section below. First, a provider education session will take place. Then over a 8-month period, providers will identify and recruit PACT/PCMHI patients to participate in the program. Providers will refer patients they recruit to the support clinician for an initial education session. The support clinician will also provide patients with user names, password resets, and privacy information. As part of this initial session, research staff will meet with the patient and apply final inclusion/exclusion criteria, consent individuals, and complete baseline measures. Subjects will then engage in the program at their own convenience with support from the support clinician. The research assistant will not provide program education or support directly to the patient. Patients will be instructed on how to use the support clinician, regular PACT/PCMHI follow-up channels, or the Veteran's crisis line in the case of emergency or with any questions about the program. Patients will be contacted by the support clinician over the telephone at regular intervals for check in. Patients will be contacted by the research assistant after 10 weeks for the purpose of follow up measure completion which will happen either face-to-face or over the phone. Subjects will be compensated $10.00 for participation in each of two visits with the research team. See Table 2 for a full list and description of visits for individuals involved in the study.

After the first experimental implementation period, patients will be recruited to participate in SHUTi™ using a modified experimental implementation strategy over another period of 8 months, the phase 2 experimental strategy. No changes to the core components of the experimental implementation strategy will be made (table 2), only to the individuals who will provide the clinical support, who will be psychologists, nurses, and peers in the West Haven VA PCMHI clinic. Providers will continue to identify and recruit PACT/PCMHI patients to participate in the program and refer patients they recruit to the support clinician for an initial education session. Referrals will be made through a modification to the PCMHI consult request form in CPRS. Research staff will still apply the same final inclusion/exclusion criteria, review project information documents, and complete baseline measures. Subjects will engage in the program at their own convenience with support from the support clinician. As in the other phases, subjects will be instructed on how to use the support clinician, regular PACT/PCMHI follow-up channels, or the Veteran's crisis line in the case of emergency or with any questions about the program. Patients will still be contacted by the support clinician over the telephone at regular intervals for check in. Patients will be contacted by the research assistant after 10 weeks for the purpose of follow up measure completion which will happen either face-to-face or over the phone. Subjects will be compensated $10.00 for participation in each of two visits with the research team.

B. Subjects. Participants will include individuals from **three** different groups: West Haven VACT PACT/PCMHI providers and staff, a clinical intermediary for patient support who will be a VACT PACT/PCMHI staff member, and West Haven VACT PACT/PCMHI patients. Please

see the appendix and Initial review application for a description of the Subject sample, roles, recruitment, inclusion/exclusion criteria, and consent procedures. Roles, recruitment, inclusion/exclusion criteria, and consent procedures will remain the same for the additional phase 2 experimental implementation strategy.

C. Interventions

The Experimental Implementation Strategy. Components of the experimental implementation strategy consists of (1) a clinical intermediary for patient support, (2) provider/staff facilitation and education to empower adoption, (3) patient education to facilitate engagement and completion, and (4) a process of stepped-care to identify and refer individuals requiring a higher level of care. The components of this strategy, especially the educational content, will be expanded and modified using results from our ongoing work in protocol EH0002.

1. Clinical Intermediary for Participant Support (Support Clinician)

The support clinician will accept provider referrals to the program and provide support to patients as they engage in the Internet-based self-help program. This position is consistent with research showing that engagement and completion with Internet-based self-help programs is higher when such programs are supported,[16,17,19,22] the well-known impact of collaborative care models on the treatment of mental health disorders in primary care,[23] as well as implementation research recognizing the need for "Technical Assistance" and "Program Champions" who can provide direct support.[24]

The support clinician will have six duties: (1) interacting with providers to facilitate referrals, (2) performing face-to-face introductory patient education sessions, (3) encouraging program engagement and completion, (4) resolving technical problems such as log-on issues and password loss, (5) resolving clinical questions associated with insomnia treatment, and (6) identifying individuals who require elevated levels of care. In our prior work, 96% of support contacts were for encouragement, 3% for technical issues, and 1% for insomnia treatment-related questions, with no emergent clinical issues identified.[25] Support will be provided during initial contact, by phone at regular intervals, as well as through as needed phone and face-to-face contact. All patient interaction will be logged, using de-identified research numbers, in the treatment log kept by the support clinician and documented in the medical record. The training and facilitation provided to the support clinician is described below, and fidelity to support plans will be monitored as described below.

For this study, a current PACT/PCMHI staff member, such as a nurse, case manager, tele-case-management clinician, health-technician, or peer support individual will be identified in the 3-4 month period prior to implementation using the experimental strategy through focus groups described in the current VACT HSC protocol (EH0002) and discussion with VACT PACT/PCMHI and case management leadership. Such leaders (Drs. Chris Ruser, Kirsten Wilkins, and Donna Vogel) have already agreed to carve out four hours per week in this person's schedule to support this work (see support letter). When selected, this person will be identified to the VACT HSC through an amendment to this protocol.

For the second phase of the experimental implementation strategy, Mr. Battagliotti will no longer be providing clinical support duties. We have identified individuals in the PCMHI clinical group as being willing to perform SHUTi clinical support tasks. We had previously identified a peer support specialist within PCMHI, Mr. Greg Dante, to share "internal champion" duties with Mr. Battagliotti. Both Anne Klee and Nicole Campbell, leasers of the Peer Support program at West Haven, and Lisa Osborne, Mr. Dante's supervisor, have agreed to allow him to take part. Lisa Osborne will continue to supervise his clinical duties

while he acts as internal champion for approximately one hour per week. Additional members of the PCMHI team, psychologists, psychiatrists, and the nurse care manager within PCMHI have agreed to take on these duties as well.

These specific activities are as follows:

A. Provide academic detailing: PCMHI personnel will liaise with providers in individual meetings, team meetings, and larger meetings to educate them on program content and the referral process.
B. Patient education: PCMHI personnel will discuss the availability of the program with patients during the normal course of his clinical duties. Referrals to the program will come from providers as per the original project description. Once patients are referred, PRMHI personnel will discuss the content of the program with them and answer questions. Per the original project description, the research team will provide informed consent and access codes to the program.
C. Patient motivational enhancement and educational support for engagement and completion: After subjects have been consented, PCMHI personnel will provide follow-up phone (and as needed face-to-face) contact. He will encourage patients to engage in the program and answer program related questions that are within his skill level. Clinical questions or safety concerns during these contacts which are beyond his skill level will be referred to the appropriate clinician, in accordance with current clinic protocol.
D. Using VA clinical quality improvement databases to identify patients who may be appropriate for the program: The VA Central Office, Offices of Academic Detailing and the Psychotropic Drug Safety Initiative have developed informatics dashboards which identify patients who are treated with recurrent prescriptions of sedative-hypnotics (https://vaww.portal2.va.gov/sites/ad/SitePages/Chronic%20Insomnia.aspx). The dashboards can be searched by facility, clinic, team and provider to identify patients who may be appropriate for evidence-based non-pharmacologic treatment of insomnia (such as the SHUTiTM program). VACT academic detailing and PCMHI personnel will use this dashboard to identify patients who may benefit from non-pharmacologic treatment of insomnia. Patients identified through these dashboards will be mailed a letter describing the reason they are being contacted, the potential benefits of behavioral treatment for insomnia, and the treatment options (either face-to-face or online versions of this treatment). The letter will include the name and contact information of the peer support specialist, Greg Dante, who will be able to describe behavioral treatment for insomnia, answer questions, and mediate referrals to treatment through providers, if the patient is interested. The SHUTi information brochure, will be included with the letter. This brochure has information about insomnia, behavioral treatment, and the SHUTi program, as well as Greg Dante's contact information.
E. Audit and feedback to support provider champions within the clinic. We will identify the WHVA primary care providers who have made the most referrals to the program since it began and identify the outcomes of the patients these providers referred. Three providers will be identified in Firms A and B, respectively, and one in the Woman's clinic. The following outcomes will be identified: (a) the number of referrals they have made to the program, (b) the number of those referred who went on to engage, (c) the number of those referred who completed the program, and (d) the change in insomnia level and sedative hypnotic use after using the program in those who engaged and

completed the program. This information will be given to the respective providers in a deidentified and pooled format in the form of an encrypted email (using the WHVA outlook encryption system) and face to face discussions. No patient personally identifying information will be shared with the provider. The aim will be to recruit providers to become program champions, communicating the success they have seen with the program to other providers in order to get more patients referred.

As an additional point of clarification, the above activities are clinical activities related to the care of patients within the primary care clinic in West Haven. Research activities will remain the same as described in the original project description.

A. The research team will educate the PCMHI team as to aspects of the SHUTiTM program allowing them to perform the provider academic detailing, patient education, and patient support contacts.
B. The research team will continue to perform informed consent on those referred to the program as described in the original project description.
C. The research team will educate the PCMHI team as to aspects of the VACO insomnia dashboard in order to allow him to identify WHVA primary care patients with insomnia.
D. The research team will have weekly meetings with the PCMHI team to provide coaching, answer questions, and track activities.

2. Provider/Staff Facilitation and Education

PACT/PCMHI providers will be given a 30-minute educational session by study personnel, which will include a discussion of (1) insomnia prevalence, diagnosis, and treatment options; (2) efficacy and content of CBT for insomnia and specifically the SHUTi™ program; (3) program referral; and (4) the role of the support clinician and the shared responsibility for identifying those who require a step-up in care. The use of this program as part of a menu of treatment options for insomnia and as a potential alternative to long-term sedative-hypnotic use will also be emphasized. These sessions will take place during regularly scheduled PACT/PCMHI meetings. The support clinician will receive two separate hour-long educational sessions focusing on training for the key duties described above. The content of these sessions will be developed in collaboration with Dr. DeViva and influenced by findings from our ongoing qualitative work (HSC EH0002). To facilitate implementation during the experimental period, research staff will be available during regularly scheduled PACT/PCMHI meetings and day-to-day (in person or by telephone) to answer questions and troubleshoot problems. The support clinician will meet with research staff bi-weekly to review progress and troubleshoot.

3. Patient Education and Facilitation

Patients enrolled in the program during the experimental implementation phase will be provided an initial short education session with the support clinician in the experimental phases. This session will allow for relationship development and is hypothesized to be essential to support patient engagement. The session will include information on: (1) CBT concepts; (2) SHUTi™ program content and components; (3) program access (website, username, passwords, privacy, etc.); and (4) access to clinical support for the program

during participation. The content of these sessions will be developed in collaboration with Dr. DeViva and influenced by findings from ongoing work (EH0002).

4. Stepped-Care

Stepped-care refers to adjusting the intensity of treatment in stages according to factors such as changes in symptomatology or lack of engagement or efficacy. In short, patients who fail a less intense level of treatment should be offer progressively more intense treatment services. This approach is derived from the extensive literature available on the efficacy of collaborative care approaches for mental health treatment in primary care, which forms the basis of the PACT/PCMHI teams and has been used for the implementation of Internet-based self-help interventions within the U.K.'s National Health Service.[66-68]

From our initial feasibility work[25] and our continued work as part of HSC protocol EH0002, we have noted three general categories of clinical issues during the course of Internet-based self-help program participation that would trigger a change in care: (1) consideration of dropping out related to a lack of efficacy, dissatisfaction, or competing demands; (2) new psychiatric and/or medical problem interfering with participation; and (3) a clinical question related to participation in Internet-based self-help such as how to manage specific stimulus control or sleep timing issues. The support clinician will monitor participants for these issues as part of phone contact with participants and will refer participants accordingly. Referrals may include time-limited consultation with PCMHI providers (psychologists) to address a low-intensity problem or referral back to PACT/PCMHI providers after treatment failure, drop out, or identification of additional clinical concerns. These processes will be further developed in our current study (EH0002) and consultation with Dr. DeViva, an expert in CBT for insomnia.

Enhanced Usual Care (Control) Implementation Strategy. Currently, Internet-based self-help interventions are not widely utilized in U.S. healthcare organizations, including VACT. This fact prohibits a "treatment as usual" competitor developed from the literature. Therefore, we developed a "low-intensity" enhanced usual care strategy, which minimizes aspects of the four core components of the experimental strategy, to serve as a control strategy. This strategy can also be thought of as "enhanced usual care," because it represents the process by which Internet-based self-help programs can be implemented using a method with the lowest logistical impact on the current PACT/PCMHI treatment process.

The enhanced usual care strategy will consist of (1) a 30-minute introductory session with providers to explain the SHUTi™ program and how it will be used; (2) provider use of a referral pamphlet that includes website, login, and clinic contact information for patients; and (3) clinical support provided by PACT/PCMHI providers. Research staff will consent patients, provide log-in information/password resets, and collect measures only. They will not provide program education or support. Patients will be explicitly instructed on how to use regular PACT/PCMHI follow-up channels or the Veteran's crisis line in the case of emergency, as they would do in the course of typical PACT/PCMHI treatment.

Internet-based Self-help Insomnia Intervention. We will use the program, SHUTi™ for the treatment of insomnia. SHUTi™ was developed by Drs. Lee Ritterband, Francis Thorndike, and Charles Morin. It is currently openly available for a fee as a self-help program at http://www.myshuti.com/ and marketed for healthcare delivery by BeHealth Solutions, LLC. The intervention is a CBT-based 6-week, self-administered course accessed via the Internet on mobile, desk-top, and other devices. The program is split into six modules, completed weekly, which include instruction on psycho-education, stimulus control, relaxation training,

sleep restriction, medication tapering, and addressing cognitive distortions. The content is delivered via text, video vignettes, case histories, interactive learning tools, interactive skills assessments, symptom assessments, and a sleep log. Homework is assigned after each module. Providers and support staff can follow treatment progress via access to a dashboard of patient information collected by the program. Such information includes progress through the modules, date of last engagement, symptom assessment outcomes, and sleep log data abstracted into commonly used sleep indices such as sleep onset latency and sleep efficiency.

SHUTi™ has been empirically validated across four randomized and controlled trials. In addition to the specific trials listed below, there are four other ongoing International trials involving the program.

(1) *NIH-R34 Pilot*. This project studied 45 adults with chronic insomnia. After 8 weeks and again at eight months following the intervention, SHUTi™ users demonstrated statistically significant sleep improvements (insomnia severity, sleep efficiency, and wake after sleep onset) compared to wait-list controls.[26]
(2) *Study of Cancer Survivors*. This project studied 28 adult cancer survivors with chronic insomnia. After 8 weeks, SHUTi™ users demonstrated statistically significant improvements in insomnia severity, sleep onset latency, and sleep efficiency compared to wait-list controls.[4]
(3) *Australian Study Evaluating Depression Prevention*. This project studied 1149 Australians with depression and insomnia recruited over the Internet. Compared to an Internet-based information control group, SHUTi™ users demonstrated lowered depression symptoms on the PHQ-9 and improved insomnia severity at 6 weeks and 6 months compared with the control group.[5]
(4) *NIH ROI Study (Currently Under Review*). This project is studying 303 adults with chronic insomnia randomly assigned to either SHUTi™ or an Internet-based education control. Recent discussion with investigators from this study indicated that SHUTi™ users demonstrated improved insomnia severity, sleep onset latency, and wake time after sleep onset at 6 weeks and one year after participation. Within group effect sizes show that the magnitude of the improvements from baseline to post assessment were medium to large for the SHUTi™ group. This study is currently under review for publication.

Although SHUTi™ is a commercial product, the program is similar to programs for insomnia currently under development by the VA. We have extensive experience using a different but similar Internet-based self-help program for insomnia, RESTORE™, in our pilot study.[25] We have chosen SHUTi™ for this study because its superior evidence base as well as functionality and content. In the execution of our pilot project and the development of this proposal, we have been in contact with Dr. Carolyn Greene, VA National Program Manager for Web Services, regarding the status of VA sponsored Internet-based self-help programs for insomnia. Currently, a program is being efficacy-tested while funds for the development of another are still waiting to be allocated. As VA-developed Internet-based self-help programs become available and show efficacy, the implementation strategy described here will easily apply to these VA-developed products.

We currently have a verbal agreement with the CEO of BeHealth Solutions, LLC to provide the SHUTi program for the purposes of this study. BeHealth Solutions, LLC has also agreed to supply de-identified data which participants will input during their interaction with the program. We will sign a letter of agreement with the CEO of BeHealth Solutions, LLC which documents this agreement once the VA Connecticut IRB has reviewed this protocol.

D. Outcomes. This is a hybrid implementation-effectiveness study. Therefore, summative implementation, clinical, and implementation process outcomes will be evaluated. Please see the appendix to this application for a full description of the outcomes that will be assessed.

a. *Summative Implementation Outcomes*. For the two 8-month control and experimental strategy implementation periods, data will be collected by a research assistant who will not play a role in intervention delivery.
   i. Program Engagement (Primary Outcome). Engagement will be defined in two ways in order to encompass the breadth of the construct: (1) completion of the first module of the SHUTi™ program (binary) and (2) the number of modules completed (counts).
   ii. Program Completion (Secondary Outcome). Completion of all six modules of the program will serve as a secondary outcome (binary).
   iii. Provider Adoption (Secondary Outcome). This measure will be operationalized as a PACT/PCMHI provider referring a patient with insomnia to the program. In the enhanced usual care (control) implementation condition, the referral will be to the research assistant for the purposes of informed consent and assessments. In the experimental implementation strategy condition, referral will be to the support clinician. The support clinician will then perform the education session and involve the research assistant to obtain written informed consent and assessments. Referral will be logged by the research assistant in the enhanced usual care condition. The support clinician in the experimental condition will capture this outcome.
   iv. Exploratory Implementation Outcomes. SHUTi™ also allows the tracking of homework completion and para-data (screens viewed, log-in frequency, etc.). This data will be used to explore the level of interaction with the program and whether there are associations between program interaction and clinical outcomes.

b. *Insomnia Treatment Outcomes*. Clinical outcomes will be collected by the research assistant via structured assessments at baseline (following informed consent) and at follow-up (10-weeks after baseline) during the two eight-month implementation periods. Follow-up measures will be completed during face-to-face meetings by all participants, including those who do not engage or drop out prior to completion.
   i. The Insomnia Severity Index (ISI). The ISI will be the primary clinical outcome and is a self-report seven-item measure that targets the subjective symptoms and functional consequences of insomnia.[27,28]
   ii. Beck Depression Inventory (BDI). The BDI II is a self-report measure of depression.[29,30]
   iii. Sedative-Hypnotic Medication Use. The use of sedative-hypnotics will be measured by self-report of the type and dose of specific medications used in the last week.
   iv. Sleep Indices. Change in sleep indices (total sleep time, sleep onset latency, sleep efficiency, wake time after sleep onset, and nocturnal awakenings) will be measured in sleep logs, which are integral to the SHUTi™ program. Such measures can only be completed by those who engage in the program and, therefore, cannot be used as the primary clinical outcome.

c. *Implementation Process Outcomes*. Implementation process outcomes will have two functions: (1) to identify mediators of summative outcomes and (2) to evaluate fidelity to the experimental implementation strategy. The measures used in this project are developed from validated measures of technology acceptance and use, derived from the Unified Theory or the Use and Acceptance of Technology (UTAUT).[31]
   i. Patients. Patients will complete implementation process outcomes during the control and experimental implementation conditions at the pre- and post-intervention assessment time points.
   ii. Providers and staff. Providers will complete process measures (1) prior to the initial enhanced usual care implementation phase, (2) following the enhanced usual care implementation phase, and (3) following the experimental implementation.
   iii. Support Clinician. The support clinician's fidelity to the experimental implementation strategy will be measured during the 8-month experimental implementation period by data obtained from the support clinician's clinical log. This log will track interactions the support clinician has with PACT/PCMHI patients referred to the program. This log will

track patients via user name and will not contain PHI. Information tracked will include: date of referral, date of education session, date of support contacts, date of completion, date patient indicated he or she were dropping out, last module and date completed, and whether the individual required a step-up in care. Specific measures developed from this log will include: (a) The proportion of individuals referred who attend the initial education session with the support clinician, (b) The proportion of individuals referred who receive weekly phone calls during their participation, (c) The number and content of clinical and technical help sessions with the support clinician during participation.

E. Data Analysis. Please see the appendix for a full discussion of the statistical analysis plan.
   a. *Summative Implementation Outcomes*. For the three active 8-month implementation periods, four separate but related dependent variables representing both the patient and provider levels of implementation will be analyzed. Summative implementation outcomes will be analyzed by comparing the two experimental implementation periods with the enhanced usual control period. Co-primary outcomes will include: (1) the proportion of participants engaging in the program (completing at least one module) among the unique Veterans treated in VACT primary care over the respective time periods; (2) the mean number of modules completed among all participants enrolled (Poisson mean as the distribution is expected to be non-normal, heavy skewing with large numbers of zeroes and ones).Secondary outcomes will include: (1) The proportion of individuals completing all six modules among all individuals enrolled. (2) The proportion referred to the program (whether they engaged or not) among all unique Veterans treated in VACT primary care over the respective time periods.
   b. *Clinical Outcomes*. Pre- and post-intervention total ISI scores obtained for all participants in each implementation period will be calculated and treated as a continuous variable for the primary dependent variable of the clinical outcome. A 7-point change pre-post will be considered clinically meaningful. A secondary dependent variable representing sedative-hypnotic use will be calculated as the mean number of total weekly sedative-hypnotic doses. Exploratory continuous variables representing sleep indices developed from sleep logs internal to the SHUTi™ program will also be analyzed, but only in participants who engage in the program. In exploratory analyses, clinical outcome data will be evaluated by clinical and demographic data extracted from the just, such as medical and mental health diagnoses as well as prescribed medications.
   c. *Implementation Process-Level Outcomes*
      i. Patients. Process-level outcomes will be analyzed as ordinal variables in frequencies and proportions based on Likert responses. Responses will be compared between the enhanced usual care and the two experimental conditions using chi-square tests. The association between process-level and primary summative implementation outcomes will be analyzed using chi-square tests and multivariable
      ii. Providers. Process-level outcomes at the provider level will be analyzed as ordinal variables in frequencies and proportions based on Likert responses. For providers, the change in responses over three periods (prior to the enhanced usual care implementation, following the control phase, and following the 8-month active facilitation of the experimental Implementation) will be analyzed using Cochran-Mantel-Haenszel and GEE marginal models. The association between changes in process-level provider outcomes and provider referral will be analyzed using chi-square.
      iii. Support Clinician. Fidelity of the support clinician to the experimental implementation strategy will be analyzed as the proportion of patients (1) who attend the initial education session among those referred, and (2) who receive weekly phone calls during the experimental implementation phase among enrollees. Bivariate associations between these proportions and key patient level outcomes as well as baseline characteristics will be analyzed.

5. Other Information

A. Study Location. This study will be conducted in the VACT (West Haven) PACT/PCMHI clinics. The intervention will be accessed via the Internet using a computer or other device of the participant's choosing at a time and in a location of their choosing. Research records will be located in the PI's office. The PI's office is located in the New England MIRECC offices located in Building 35, lower level.

B. Payment. Subjects who are VACT PACT/PCMHI patients will be paid $10.00 for their participation in each baseline and follow up meeting with research personnel, but not for their interactions with PACT/PCMHI providers or staff such as the support clinician (See Table 2). PACT/PCMHI providers and the support clinician will not be compensated for their participation.

C. Funding Source. VA Office of Research and Development, HSR&D, via a carrier development award to the PI, Eric Hermes, MD, as well as New England Mental Illness Research, Education, and Clinical Center (MIRECC) and/or funds from the VACREF.

D. Duration. The expected duration is 5 years.

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