Enhancing daily function in veterans with chronic obstructive pulmonary disease through internet-based cognitive-behavioral treatment for insomnia

NCT04700098

03/14/2025

VA Pittsburgh Healthcare System

ProSPECT - Protocol Submission Portal and Electronic Communication Tracker

Date: Wednesday, June 30, 2021 4:16:18 PM
ID: Pro00003666 View: 0.0 Type of Submission Entry

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate forms needed to complete your submissions.

1.0 * **Study Name:**
Enhancing daily function in veterans with chronic obstructive pulmonary disease through internet-based cognitive-behavioral treatment for insomnia

2.0 * **Brief Description (using layman's terms) - 500 words or less:**
Veterans with chronic obstructive pulmonary disease (COPD) are a vulnerable group for developing insomnia, with about 37% having comorbid insomnia. Insomnia is associated with limitations in activities of daily living (ADL), lower physical activity levels, poor quality of life, greater COPD symptom severity, and reduced exercise performance. Fatigue associated with insomnia can impede engagement in daily activities. Therefore, targeted treatments that effectively improve insomnia could improve quality of life and exercise capacity and enhance active living. We propose a randomized clinical trial to compare the effects of Internet-based cognitive-behavioral therapy for insomnia versus online insomnia patient education on sleep and health-related functioning.

3.0 * **Is this research study a Greater than Minimal Risk Clinical Trial?** ○ Yes ◉ **No**

4.0 * **Is this study a Greater than Minimal Risk Comparative Effectiveness research?** ○ Yes ◉ **No**

7.0 **Type of Submission:**

	Description
◉	**This is a new study. This has not previously been submitted to the IRB.**
○	This is a new paper conversion. This study has been previously approved by the IRB.

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

Study Identification Information (Continued)

1.0

*** Do you certify that all research staff administering informed consent are knowledgeable about the study?**

yes

2.0

*** To the best of your knowledge do you, or any member of your research staff, have any potential, actual or perceived conflict of interest of a professional or personal nature that may affect any aspect of the research, including, but not limited to, the review and/or conduct of this study?**

○ Yes ◉ **No**

If yes, provide a description, including name of study team member with conflict:

3.0 *** Qualifications of the Investigators:**

Patrick Strollo, MD is Vice Chairman of Medicine for Veteran Affairs at the VA Pittsburgh Healthcare System and Professor of Medicine at the University of Pittsburgh School of Medicine. He is an experienced investigator in pulmonary sleep disorders and has extensive expertise in the diagnosis and management of sleep disordered breathing. Hhe will be responsible for overseeing all phases of the project, including project design, implementation, and analyses and for manuscript writing.

Tony Macedonia, MD, is a staff physician at the VA Pittsburgh Healthcare System. Dr. Macedonia's clinical interest is focused on critical care outcomes and deployment related lung disease. He will advise on study design and data interpretation, preparation of manuscripts for publication, and manage COPD or treatment-related medical issues should they arise.

Daniel Forman, MD is the Director of Cardiac Rehabilitation, GeroFit wellness program, and the Veteran Health Enhancement Activity Research Testing Center at VAPHS and is Professor in the University of Pittsburgh School of Medicine. He has extensive expertise in the impact of exercise training on functional outcomes, particularly among older adults, and clinical and research implementation of home-based cardiac rehabilitation. Dr. Forman will contribute both content and methodological expertise in functional assessment including walk tests and home-based exercise and will assist with manuscript preparation.

Monique Boudreaux-Kelly, PhD is a statistician in the VA StatCore and has extensive experience with use of SQL, predictive modeling, and statistical analysis. She will provide statistical support for the entire project.

Lynn Baniak, PhD, RN, is Associate Chief Nurse for Research at VA Pittsburgh Healthcare System and an adjunct faculty member at the University of Pittsburgh School of Nursing. Dr. Baniak's program of research targets comorbid sleep disorders and their impact on health outcomes in adults with chronic medical conditions but doing this from a patient-centered standpoint focusing on quality of life, functional status, and patient safety. Her research interests include sleep behavior and circadian science as well as treatment-focused research. Dr. Baniak will advise on interpretation

of study results.

ID: Pro00003666 View: 1.2 VA Involvement

VA Involvement

1.0 **Does the proposed research involve any of the following?:**

	Name
☑	**VA Funding**
☑	**VA Personnel Funded Effort**
☑	**VA Patients or their Private Health Information**
☐	Other VA Resources: Central IRB
☑	**Other VA Resources: VA Equipment**
☑	**Other VA Resources: VA Property (Including space leased to, or used by VA)**
☐	Other VA Resources: VA Databases
☐	None of the Above apply to this research

ID: Pro00003666 View: 1.3 Study Funding Information

Study Funding Information

1.0 * **Funding Sources:**

	Funding Source	(Other)	Code
View	Merit Review (CC 103)		9003

2.0 **Upload Grant Application, if applicable (If NIH, VA, voluntary agency, must upload):**

Name	Modified Date
VA Merit Award	11/6/2020 2:48 PM

ID: Pro00003666 View: 1.4 Resources

1.0

* **Do you currently have adequate resources (e.g., staff, physical space, information technology, etc.) to protect the safety of participants, staff, and the confidentiality of subjects' data during the conduct of this study?**

◉ **Yes** ○ No

If yes, include a listing of the VAPHS resources that will be used for this study and are necessary to protect participants.

Resources to be utilized in the VA include study personnel, the time of the Principal Investigator, the co-investigators and consultant. Space utilized will be those areas in the MIRECC that are available to the PI and her staff. The study will also utilize Exam Room 4 of the Research Office Building for

study assessment. We will use an available portable spirometer for spirometry. Activity monitors have been budgeted for and will be purchased through grant funding.

If no, please describe the resources that will be needed and explain how the resources will be obtained before the study is initiated:

2.0 * **VAPHS requires that either the PI or co-PI have a *physical presence* at VAPHS. Please describe the role the PI and/or co-PI have at VAPHS with respect to clinical responsibilities or in relation to other research activities.**
Dr. Patick Strollo has a 8/8th VA appointment.

3.0 * **Will off-site ancillary service facilities (e.g., radiology services, central labs, non VA space, etc) be used for this study?**

○ Yes ◉ **No**

If yes, please provide the location and a brief description of the project activities to be conducted at the off-site ancillary facilities:

4.0 * **Will a firm be contracted to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects' research?**

○ Yes ◉ **No**
If yes, please provide a description of the contracted service(s):

* Please specify the IRB that has oversight of the firm's activity(ies):

Name of Site / Institution	IRB Approval Document	FWA Number

There are no items to display

5.0 **Collaborations**
Please list any non-VAPHS institutions or individuals (i.e. co-authors, mentors, etc.) that you will collaborate with and describe their specific role in the research:

5.1 If this is not Multi-Site Research, please upload the appropriate written agreement(s) here:

Name

There are no items to display

ID: Pro00003666 View: 1.5 Project Information

1.0 **Does the project involve any of the following (check all that apply):**

	Type
☐	Biological Hazards (including human biological specimens)
☐	Chemicals
☐	Ionizing radiation or use of radioactive materials
☐	Drug, Biological, or Nutritional (e.g. herbal or dietary) Supplement

2.0 Project Focus (check if applicable):

	Type
☐	Traumatic Brain Injury (TBI)
☐	Post Traumatic/Post Deployment Stress Disorder (PTSD/PDSD)
☐	Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF)

3.0

KEYWORDS

Please provide a minimum of 3, maximum of 6 keywords. Please use MeSH terms.

* sleep initiation and maintenance disorders
* pulmonary disease, chronic obstructive
* cognitive behavioral therapy

4.0 * Please describe the type of study:

This is a multi-center, evaluator-blinded, randomized clinical trial of Internet-based cognitive-behavioral therapy for insomnia versus online insomnia patient education in male and female veterans with COPD and insomnia. Outcome measures will include changes in sleep, quality of life, exercise capacity, fatigue, lung function, and daily activity at post-intervention and at 3-month follow-up.

5.0 * Will any of the research being conducted as a part of this study be used to fulfill academic requirements (e.g., master's thesis, dissertation, or other academic program requirements necessary to obtain a degree/certification, etc.)? ○ Yes ◉ **No**

ID: Pro00003666 View: 1.6 (CR) Study Locations

Study Locations

1.0 * Please add the local sites where this study will be conducted:

	Location
View	VAPHS University Drive Division

If Other, Please Specify:

ID: Pro00003666 View: 1.6.1 (CR) Multi-Site Study

1.6.1 Multi-Site Study

1.0 * Is this a multi-site study:

○ Yes ◉ **No**

ID: Pro00003666 View: 1.7 Section Chief and Service Line VP approvals

Please upload the approval of the Section Chief, if applicable and the Service Line VP.

1.0 * **Institutional Approval Document:**
Institutional Approval Luyster PJS(0.01)

ID: Pro00003666 View: 2 Study Objectives & Design

Study Summary

1.0 **Funding End Date:**
3/31/2025

2.0

* **Abstract. Please provide a brief description of the study**.

Objective: The proposed study will compare the efficacy of Internet-based cognitive-behavioral therapy for insomnia (CBT-I) versus online insomnia patient education (PE) on sleep and health-related functioning (quality of life, exercise capacity, fatigue, lung function, and daily activity levels).

Research Design: The study is a multi-site, prospective, evaluator-blinded, randomized clinical trial.

Methodology: A sample of 96 veterans with insomnia and COPD will be enrolled. Participants will be recruited through the VAPHS clinics and VA Detroit Healthcare System clinics. Pre-screen medical records review via HIPAA waiver will be conducted to determine preliminary eligibility for veterans with COPD. For those who are preliminarily eligible based on pre-screen medical records review and who have agreed to be contacted, research staff will call the veteran and provide a thorough explanation of the study and conduct an eligibility semi-structured interview. The eligibility interview will review basic study criteria to establish eligibility. If eligible based on phone screening, veterans will be invited to come for an in-person visit to sign the informed consent and the HIPAA authorization and complete the full baseline assessment in person. Primary outcome assessments (planned prior to data collection initiation) include Insomnia Severity Index and the St. George's Respiratory Questionnaire. Secondary outcome assessments include PROMIS Sleep Scales, sleep diary, actigraphy measures of sleep parameters and daily activity, six-minute walk test, PROMIS Fatigue Scale, spirometry, Physical Activity Scale for the Elderly, and COPD self-efficacy. Assessments will take place a baseline, post-intervention (9 weeks), and 3 months. A self-guided, 6-module, Internet version of CBT-I (iCBT-I), "Sleep Health Using the Internet", will be used. Online insomnia patient education will be accessed through a website and will consist of nontailored and fixed material about insomnia symptoms, and the effect, prevalence, and causes of insomnia along with basic lifestyle, environment, and behavioral strategies to improve sleep.

3.0 * **Describe the study objectives. Please include primary aim and hypothesis, if applicable any secondary aims and hypotheses.**

The proposed study will test the efficacy of an Internet-based cognitive-behavioral therapy for insomnia (CBT-I) intervention on sleep and health-related functioning in veterans with COPD and insomnia.

Specific Aim 1: Compare the efficacy of iCBT-I versus online insomnia patient education (PE) on sleep in COPD patients with insomnia. The primary sleep outcome will be insomnia severity assessed by the Insomnia Severity Index and secondary sleep outcomes will include the PROMIS Sleep Scales and sleep diary and actigraphy measures of sleep parameters. Hypothesis 1: Compared to PE, iCBT-I will demonstrate greater improvements in sleep outcomes at post-treatment and 3-month follow-up.

Specific Aim 2: Compare the efficacy of iCBT-I versus PE on health-related functioning. The primary outcome will be quality of life assessed by the St. George's Respiratory Questionnaire. Secondary outcomes include exercise capacity assessed by six-minute walk test, fatigue assessed by the PROMIS Fatigue Scale, lung function assessed by spirometry, daily activity assessed by actigraphy and self-report, and COPD self-efficacy assessed by the Self-Care in Chronic Obstructive Pulmonary Disease Inventory. Hypothesis 2: Compared to PE, iCBT-I will demonstrate greater improvements in measures of health-related functioning, which will be sustained (and possibly increased) at 3 months.

Specific Aim 3. To examine whether sleep mediates the effects of treatment on health-related functioning at 3 months. Hypothesis 3: Improvements in sleep (from baseline to post-treatment) will mediate the effects of treatment (iCBT-I versus PE) on sustained (and possibly increased) improvements in health-related functioning at 3 months.

4.0 * Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous studies that provides a basis to show that the proposed research can be carried out without undue risk to human subjects.

Chronic obstructive pulmonary disease (COPD) is a progressive lung disease that is highly prevalent among veterans (1). Insomnia is common is veterans with COPD and is associated with limitations in activities of daily living (ADL), lower levels of physical activity, poor quality of life, greater COPD symptoms, and reduced exercise performance (2-4). Implementing an insomnia-specific treatment in COPD patients is likely to lead to improvements in sleep that could facilitate improvements in quality of life and exercise capacity and enhance daily activity levels. Cognitive-behavioral therapy for insomnia (CBT-I) not only improves sleep-specific symptoms of insomnia but also improves quality of life, reduces ADL limitations, and improves condition-specific symptoms (5). We postulate that CBT-I will lead to improvement in sleep quality that will facilitate achievement of optimal and enduring functional outcomes in patients with COPD and insomnia.

Asthma shares some common features with COPD in that both are characterized by underlying airway inflammation that leads to breathlessness and coughing due to airflow limitation (6). A single-group pilot study to determine preliminary efficacy of Internet-delivered CBT-I in adults with moderate to severe, not well-controlled asthma (N = 23). found improvements in insomnia severity, sleep quality, asthma control, and disease-specific quality of life at post-intervention, with moderate to large treatment effects (7).

5.0 * Describe the overall significance of the research in terms of the problem to be studied and potential findings, as well as its relevance to the care of veterans, the VAPHS, and the VHA:

Testing the effects of CBT-I has broad clinical implications in light of the high prevalence of insomnia in veterans with COPD. Insomnia is associated with limitations in activities of daily living (ADL), lower physical activity levels, poor quality of life, greater COPD symptom severity, and reduced exercise performance (2-4). Fatigue associated with insomnia can impede engagement in daily activities (8). Therefore, targeted treatments that effectively improve insomnia could protect patients from declines in quality of life and exercise capacity and enhance active living, ultimately reducing the burden of disease on veterans, their families, and the VA system. Treating insomnia via a non-pharmacological, VA-endorsed treatment (CBT-I) with known effectiveness in the veteran

population is a viable strategy for helping veterans improve quality of life and exercise capacity and enhance daily activity levels (9). Utilizing Internet-based CBT-I reduces barriers to treatment associated with face-to-face CBT-I, such as the need to schedule in-person sessions, travel to a VA facility, and limited access to CBT-I providers, and acknowledges veteran's preference for electronic methods to deliver insomnia treatment, specifically the Internet. Improvements in sleep via insomnia treatment is likely to lead to sustained health-related functioning, thus improving the overall health of our veterans with COPD.

6.0 Please upload any additional documents:

Name	Version
There are no items to display	

ID: Pro00003666 View: 2.1 Required Reviews

Required Reviews

1.0

Type of Submission:

New study

If this is a 'New Paper Conversion' please include the MIRB Number:

Please upload a letter certifying that you have made no modifications or amendments in converting this research study from paper to electronic:

2.0 * **Requested Review Type:**

	Name
○	Exempt
◉	**Expedited**
○	Full IRB Review
○	Not Human Subject Research

3.0

	Please check which of the following Service Lines/Departments/Entities	**Upload Letter of Support**

	will be impacted or used in the conduct of this study	
☐	Clinical Support	
☑	Medical Specialty	VAPHS Service Line LOS Memo_v2.1_1MAR2017_final PJS 12.14.20.pdf(0.01)
☐	Investigational Drug Service	
☐	Imaging	
☐	Community Based Care	
☐	Patient Care Services	
☐	Behavioral Health	
☐	Primary Care	
☐	Surgical Specialty	
☐	Critical Care	
☐	Clinical Trials Center	
	☐ Regulatory Coordinator Support Core	
	☐ Clinical Coordinator Support Core	
	☐ Ancillary Support Core	
	☐ Data Support Core	
☐	Research Registry Registry Number:	
☐	Other	

If Other, please specify:

ID: Pro00003666 View: 2.1.1 Expedited Qualification

REQUEST FOR EXPEDITED REVIEW

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in

daily life or during the performance of routine physical or psychological examinations or tests.

AND

Identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, or reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

1.0 * **Please certify that ALL of the following are true:**

Case
Research presents no more than MINIMAL RISK to subjects (considering physical, psychological, social, legal and economic risk)
Identification of the subjects and/or their responses WOULD NOT reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, OR reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.
The research is not classified.
The research involves only procedures listed in one or more of the categories listed in Section 2.

2.0 **If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidelines.**
* **Select all that apply:**

	Description
☐	1. Clinical studies of drugs and medical devices only when condition **(a)** or **(b)** is met: **(a)** Research on drugs for which an investigational new drug application **(21 CFR Part 312)** is not required. **(b)** Research on medical devices for which an investigational device application **(21 CFR 812)** is not required OR the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☐	2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: **(a)** From healthy, non-pregnant adults who weigh at least 110 pounds. [not to exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or **(b)** From other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected: The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐	3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples: **(a)** hair and nail clippings in a nondisfiguring manner; **(b)** deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; **(c)** permanent teeth if routine patient care indicates a need for extraction; **(d)** excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

- [x] **4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are used, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical devices are not generally eligible for expedited review, including studies of cleared medical devices for new indications)**
- [ ] 5. This research involves materials (data, documents, records, or specimens) that have been collected for any purpose including previous research or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- [ ] 6. This research involves the collection of data from voice, video, digital, or image recordings made for research purposes.
- [x] **7. This research will be performed on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

ID: Pro00003666 View: 3 Research Design

Methods & Procedures

1.0

* **Does this research study involve any of the following:**

	Name
☐	Deception
☐	Interview/Focus Groups
☐	Use of Drug, biological, or nutritional (e.g., herbal or dietary) supplement (investigational or FDA approved)?
☐	Use of medical devices
☐	Prospective Analysis of Specimens
☐	Banking of Specimens-Data
☐	Retrospective use of specimens
☐	Audio/Video Recordings or Photographs
☐	Honest Broker or other similar service

☑ **None of the Above**

ID: Pro00003666 View: 4 Research study methods

Research Study Methods

Describe all study related procedures following enrollment of a subject in this study.

Please see Section 6 for where the study team defines when a subject will be considered enrolled in the study.

1.0

* **Research Procedures/Interventions:**

Study Interventions:

Internet CBT-I (iCBT-I). Sleep Healthy Using The Internet (SHUTi) is a 9-week self-guided, automated, interactive, and tailored web-based program modeled on the primary tenets of CBT-I: sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention. SHUTi intervention content is allocated over time through 6 “Cores.” Users obtain access to a new Core based on a time and event-based schedule (e.g., 7 days after completion of previous Core). SHUTi uses online sleep diaries to track progress, to tailor treatment (e.g., assign a sleep restriction window), and to assess adherence to the sleep restriction window. Each Core acts as an online analog for the weekly sessions of traditional CBT-I, and follows the same structure: (1) core objectives (what will be learned and why it is important), (2) review of previous week’s homework and sleep diary data, (3) new intervention material, (4) assignment of homework (treatment strategies for the coming week), and (5) summary of the Core’s main points. Intervention content is enhanced through interactive features including personalized goal-setting, graphical feedback based on participant-specific symptoms, animations/illustrations, quizzes to test user knowledge, patient vignettes, and video-based expert explanations. Each Core requires 45-60 minutes to complete, and users are free to revisit Cores that they have already completed. Users are also prompted to complete daily Sleep Diaries, which typically only take a few minutes to enter each day. Automated emails encourage program adherence. SHUTi is completed entirely online. There will be no face to face contact with patients. Participants will access the program through a personal portal to the SHUTi program which will be created for this research study. The program is not available via a mobile app. Data collected as part of the SHUTi program (e.g., sleep diary data) will not be transmitted to study staff. The study staff member who randomized participants will have access to participants' standard clinician report within the SHUTi program through the personal portal. The report includes information about participants' progress generated from sleep diary entries within the program.

Online insomnia patient education (PE). Participants will be provided access to a website that will provide insomnia patient education. The website was developed by the creators of SHUTi to serve as an active control. The PE is similar to the control interventions used in other RCTs of SHUTi (10,11). The patient education website provides fixed information about: insomnia symptoms; the impact, prevalence, and causes of insomnia; when to see a doctor; and basic lifestyle, environmental, and behavioral strategies to improve sleep. The content included in the PE was based on a review of established insomnia education websites (10). In some areas, content between the PE and SHUTi web programs overlap; however, SHUTi differs from the PE website in important ways. In contrast to SHUTi, the PE website (1) Does not personalize or individually tailor treatment recommendations based on user input; (2) Presents content in a simple, static form, without interactive assets; and (3) Delivers content all at once, meaning the user can access full site content immediately, rather than having to wait for content to be metered, or unlocked, over time. No data are collected on the patient education website.

Study Procedures:

Research assessments will be completed at VAPHS and in the home. All participants will complete baseline and follow-up assessments at post-treatment and 3 months after treatment. Once participants complete all baseline assessments, they will be randomly assigned to either 1) PE or 2) iCBT-I. Participants will complete a set of self-report measures via paper and pencil format, will complete 1 week of actigraphy, and will undergo spirometry and a six-minute walk test. It is estimated that the total time for the self-report assessments, exclusive of the sleep wake diary, spirometry, and six-minute walk test will take approximately 2 hours. If preferred, participants will be mailed the self-report assessments prior to the baseline and follow-up study visits and will be asked to bring the completed assessments to the study visit. Participants may be contacted by email (if preferred) for notification of eligibility based on in-home sleep apnea testing and randomization group assignment and for reminders of upcoming study visits and to mail back their actiwatch and sleep diary. The emails to participants are intended to be one way. However, it is possible that participants will send a response to the email. In all email correspondence, we will include a line that states that should the participant have a question, then they should contact research staff at a TBD phone number.

Questionnaires: The following questionnaires will be completed by all participants at baseline, post-treatment, and 3 months: Insomnia Severity Index (ISI) (16), Patient Reported Outcomes Measures Information System (PROMIS) Sleep Disturbance and Sleep-Related Impairments Scales-Short Forms (17), St. George's Respiratory Questionnaire (SGRQ) (18), PROMIS Fatigue Scale–Short Form (19), Physical Activity Scale for the Elderly (PACE) (20), and Self-Care for Chronic Obstructive Pulmonary Disease Inventory (SCCOPDI) (21). These questionnaires should take approximately 20-30 minutes to complete. For those in the iCBT-I group, the following questionnaires will be completed at the post-treatment visit: Internet Intervention Utility Questionnaire (UQ) and Internet Intervention Impact Questionnaire (IQ) (22). The Patient Health Questionnaire-9 (PHQ-9) (23) will be collected to determine study eligibility.

Diary and actigraphy assessment: Participants will complete the Consensus Sleep Diary for 1 week at baseline, throughout treatment, and 1 week at the post-treatment and 3-month follow-up. Sleep diaries are completed daily, but take less than 5 minutes per day to complete. Sleep diary measures will be supplemented by actigraphy. Participant sleep-wake patterns and daily activity will be measured with an Actiwatch. The Actiwatch will be worn for 7 days to track the participant's sleep and physical activity following baseline, post-treatment, and 3-month study visits.

Spirometry. Spirometry will be performed according to American Thoracic Society guidelines after appropriate withholding of medications (24). Maximum bronchodilation will be performed with spirometry to assess bronchodilator reversibility. Participants will receive two inhalations of albuterol from a metered dose inhaler and spirometry will be repeated 15 minutes later. Pre- and post-bronchodilator forced expiratory volume in 1 second (FEV1), FEV1 % predicted, forced vital capacity (FVC), and FEV1/FVC ratio, in addition to bronchodilator responsiveness (change in FEV1 after inhaled bronchodilator), will be evaluated. Albuterol will be utilized and obtained through the pharmacy. If participants are allergic to Albuterol, an alternative Xopenex inhaler will be available.

Six-minute walk test. The six-minute walk test is a validated, simple test that is responsive to changes in exercise endurance in COPD patients. It measures the distance that a patient can walk on a flat, hard surface in a period of six minutes. Participants will be asked to walk indoors in a flat 30 meter walking course supervised by a well-trained study coordinator. They will be allowed to stop and rest during the test, but will be instructed to resume walking as soon as possible.

In-home sleep apnea testing: Following baseline study visit, participants will undergo home sleep apnea testing using the WatchPat, a portable in-home sleep testing device. Patients who have been evaluated for OSA in the past year and met study criteria or whose sleep apnea has been treated will not be required to undergo home sleep apnea testing. Patients will be instructed to wear the WatchPat for one night. The coordinator will give the participant a self-addressed stamped envelope for returning the WatchPat. Apnea-hypopnea index (AHI) will be obtained from the WatchPat download. Patients

who have an AHI ≥ 55 will be deemed ineligible to participate in the study and will be referred to the VAPHS Sleep Medicine team to be further evaluated and offered treatment. Patients who have an AHI 5-54 will be eligible to participate in the study and will be referred to the VAPHS Sleep Medicine team to be further evaluated and offered treatment. Patients who have an AHI < 5 will also be eligible to participate in the study. For those undergoing home sleep apnea testing, randomization will be dependent on home sleep apnea testing results. Acceptance and adherence to positive airway pressure (PAP) therapy, which is tracked as part of standard care, will be collected.

Please upload a table of procedures if applicable.
The study procedures table must be completed for:
- All Greater than Minimal Risk (GTM) studies; and
- All Minimal Risk studies that use Standard of Care or Usual Care/Interventions.

Name	Modified Date
Study Procedures Table.docx	12/3/2020 10:33 AM

2.0

* **Will Usual Care Procedures/Interventions be used?"**

○ **Yes** ◉ **No**

If yes, please specify and include a description of what the usual care or expected level of care is at VAPHS (e.g., medications, testing, timing, etc.) for patients, similar to those individuals that meet the inclusion/exclusion criteria for this research study:

2.1 If Usual Care Procedures/Interventions will be used, who is the individual or entity responsible for relevant aspects of the usual care (i.e., which of the above usual care activities will the research study team be responsible for)?:

2.2 Does the usual care at VAPHS for the condition of interest in this research study differ from national guidelines/recommendations (i.e. standard of care)?

○ Yes ○ **No**

If yes, please describe the differences:

2.3 Are any procedures that are considered standard for this patient population performed more frequently than usual care?

○ Yes ○ **No**

If yes, please indicate which time points are considered usual care and which are considered research.

2.4 If there is more than one standard, does VAPHS limit which one is followed (e.g. warfarin use for atrial fibrillation vs. one of the newer anticoagulants).

○ Yes ○ **No**

If yes, please explain:

3.0

*** Does clinical expertise need to be enlisted?**

(•) **Yes** ( ) No

If yes, please provide the provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties, if the investigator is not a clinician [i.e. reviewing the data, adverse events, and new study findings; also making required decisions to protect the health of the subject (e.g., stopping the participant's involvement in the study or determining when to notify the subject or the subject's health care provider of information that may affect the health of the subject)]:

Dr. Tony Macedonia who is Co-Investigator and Staff Physician at VAPHS will review data collected as part of the study and adverse events along with make decisions about stopping participant's involvement in the study and determining when to notify participant or participant's health care provider of information that may affect participant's health.

4.0 Please upload any surveys, questionnaires, and data collection forms.

	Document	Description	Version Number
View	Demographics(0.01)		0.01
View	DSM-5 Insomnia Criteria Questions(0.01)		0.01
View	Epworth Sleepiness Scale(0.02)		0.02
View	Insomnia Severity Index(0.01)		0.01
View	Internet Intervention Impact Questionnaire.pdf(0.01)		0.01
View	Internet Intervention Utility Questionnaire.pdf(0.01)		0.01
View	Medical History(0.01)		0.01
View	NIDA QUICK SCREEN.pdf(0.01)		0.01
View	Patient Health Questionnaire-9(0.01)		0.01
View	Physical Activity Scale for the Elderly.pdf(0.01)		0.01
View	PROMIS Fatigue(0.01)		0.01
View	PROMIS Sleep Disturbance(0.01)		0.01
View	PROMIS Sleep-related Impairment(0.01)		0.01
View	Sleep Diary(0.01)		0.01
View	St. George's Respiratory Questionnaire.pdf(0.01)		0.01

ID: Pro00003666 View: 4.1 Research study methods: analysis Plan

1.0 * Please describe the analysis plan for the study *(it is acceptable to refer to the sponsor/multi-site protocol for section if applicable):*

Preliminary Analyses: Exploratory analyses will be performed involving data description and screening for anomalies (e.g., outliers, missing data, non-normality). To describe the sample, descriptive statistics, including frequencies, percentages, means, medians, and standard deviations, will be computed for the demographic variables (e.g., age, race/ethnicity, gender, and education) and clinical variables (e.g., insomnia severity, COPD severity, apnea-hypopnea index, PR completion). Preliminary analyses of variance (ANOVA) and chi-square tests will be conducted on

selected demographic and clinical variables to ensure comparability of the two groups at baseline. The results from these analyses will be used to (1) describe univariate and bivariate distributions, (2) identify group imbalances and associations between dependent variables and suspected covariates/confounders, (3) evaluate missing data, and (4) check for violation of statistical assumptions. If assumptions are violated, data transformations or more statistically robust procedures will be considered. Covariates/confounders (e.g., age at study entry, PR completion, use of sleep altering medications, adherence to COPD medications, use of supplemental oxygen, adherence to PAP therapy, smoking status) will be included in models secondarily, and their effects on primary predictors/factors will be evaluated. The randomness of missing data will be investigated using available information on participant characteristics to help discern missing data patterns, identify possible missing data mechanisms, and inform strategies to address missing data. If the missing data are ignorable (MAR or MCAR), the likelihood estimation procedures to be used will produce unbiased estimates, while allowing us to retain observations with missing values on the outcome variables. If needed, multiple imputation would be used to impute missing values on covariates. If the missing data are non-ignorable, we will use selection or pattern mixture modeling to investigate the sensitivity of results. Although directional hypotheses have been posited, two-sided hypothesis testing will be performed. To limit inflation of type 1 error, the level of significance will be set at a more conservative threshold of .025 for hypothesis testing. Confidence intervals for estimators will be computed at 97.5%.

Analysis Plan for Specific Aim 1: The hypothesis for Specific Aim 1 is that compared to PE, iCBT-I will demonstrate greater improvements in sleep outcomes at post-treatment and 3-month follow-up. The primary sleep outcome variable for Specific Aim 1 is insomnia severity as measured by the ISI total score. Secondary sleep outcomes include the PROMIS Sleep Scales, sleep diary, and actigraphy measures of sleep parameters. An intent-to-treat (ITT) approach will be used, where all participants will be included in the groups to which they were randomly assigned, regardless of whether they actually received it. Although this approach is recommended for RCT efficacy analyses, the sensitivity of the results assuming ITT will be assessed using information collected about participant adherence to the iCBT-I intervention (e.g., per protocol, amount of treatment received). Linear mixed-effects modeling with linear contrasts be used to examine the effect of randomized treatment assignment (iCBT-I vs. PE) on each sleep measure over time. When fitting models, time will be a repeated within-subjects factor, while treatment assignment will be a between-subjects factor, with an interaction between time and group. Random effects for subjects will also be included. Fixed and/or time-dependent covariates (including baseline values) may be included secondarily to adjust for group imbalances or variables related to the dependent variables. Standard

fit criteria (e.g., AIC and BIC) also will be used to identify the best-fitting covariance structure. F-tests will test the main and interaction effects included in the model. Individual regression parameters will be computed and reported with standard errors to yield confidence intervals. For each model, residual analysis will be conducted to identify sources of model misspecification, outliers, and influential observations. Sensitivity analyses will be performed to discern the impact of influential cases on modeling results. Linear contrasts will be specified and estimated in the repeated measures models to test whether iCBT-I will demonstrate greater improvements in sleep measures at post-treatment (9 weeks) and 3 months relative to baseline value compared to PE. Wald t-statistics will be used to test each linear contrast. Point and interval estimates will be obtained for each of the comparisons tested. Marginal modeling with generalized estimating equations also will be used to analyze each sleep measures because it tends to be more robust to misspecification of the covariance structure and violations in normality assumptions. Results from the application of each modeling approach will be compared via sensitivity analyses. To explore sex as a moderator of the treatment efficacy of iCBT-I relative to PE, the linear mixed models for each sleep measure will be expanded to include sex (coded as a [0,1]-indicator variable) and its interactions with the other model terms (treatment group, time and treatment group by time). The linear contrasts will also be re-specified and re-estimated to explore the interaction of sex and treatment group on changes in sleep measures from baseline to post-treatment and 3-months. To explore unique subgroups of iCBT-I treatment non-responders, descriptive analyses will provide the proportion of participants who achieve sleep treatment response (defined as clinically significant change on the ISI (ISI: > 6 points) at post-treatment). t-tests and chi-square tests will be conducted to examine differences in demographic (age, sex, marital status (married/living with partner vs. single/divorced/widowed), employment status (employed vs. unemployed/retired), smoking status (current vs. former/never smoked), insomnia-related (duration, severity, sleep medication usage (yes/no)), COPD-related (duration, severity, corticosteroid use (yes/no), COPD exacerbation (yes/no)), and intervention acceptability (usability, likeability, convenience, perceived effectiveness) variables between treatment responders and non-responders.

Analysis Plan for Specific Aim 2: The hypothesis for Specific Aim 2 is that compared to PE, iCBT-I will demonstrate greater improvements in measures of health-related functioning, which will be sustained (and possibly increased) at 3 months. The primary health-related functioning outcome will be quality of life based on the SGRQ total score. Secondary health-related functioning outcomes include the 6-minute walk test, spirometry, PROMIS Fatigue Scale, PACE, total log-transformed activity counts from actigraphy, and SCCOPDI. A similar analysis plan will be used as described for Specific Aim 1 in which linear mixed models will be fit for health-related functioning outcomes at

baseline, post-treatment (12 weeks), and 3 months after treatment. Group comparisons between treatment groups (iCBT-I vs. PE) will be performed at post-treatment and 3 months. Additionally, we will examine changes in health-related functioning from post-treatment to 3 months and baseline to 3 months.

Analysis Plan for Specific Aim 3: The hypothesis for Specific Aim 3 is that improvements in sleep (from baseline to post-treatment) will mediate the effects of treatment (iCBT-I versus PE) on sustained (and possibly increased) improvements in health-related functioning at 3 months. Simple mediational models (i.e., models containing a single predictor, single mediator, and single outcome) will be specified and estimated considering the changes from baseline to post-treatment (9 weeks) and from baseline to 3 months after treatment. The predictor variable will be treatment group assignment (iCBT-I versus PE), the mediator variable will be the change in a single sleep measure, and the outcome variable will be the change in a single health-related functioning measure. The primary sleep outcome will be insomnia severity based on the ISI total score and the primary health-related functioning outcome will be quality of life based on the SGRQ total score. Observed variable path analysis will be used to fit the proposed mediation models. Path coefficients with standard errors and R2 values for the proximal (sleep) and distal (health-related functioning) endogenous variables will be estimated. The observed variable path analysis via bias-corrected bootstrapping (with 5,000 bootstrapped samples) will be used to test for mediation effect and to yield point and interval estimates of indirect, direct, and total effects. In addition to better accommodating non-normality and having greater statistical power than traditional approaches to mediation analyses (e.g., Baron-Kenny approach, Sobel test), bias-corrected bootstrapping with Goodness-of-fit will be assessed using the recommended indices including root mean square error of approximation (RMSEA) and comparative fit index (CFI). Residual analyses will be performed for each path analysis model fitted to identify sources of model misspecification, outliers, and influential observations.

ID: Pro00003666 View: 5 Sub-Studies

1.0 * **Is there a sub-study or are there sub-studies associated with this study?**
There is no sub-study associated with this study.

ID: Pro00003666 View: 6 Study Population Summary

Study Population Summary

1.0 * **What is the maximum number of subjects you plan to enroll at VAPHS?**
48 subjects

2.0

*** Do you plan on enrolling patients into different categories:**

○ Yes ◉ **No**

If yes, please explain:

3.0 If this is a multi-site study, indicate the projected total subject accrual: 96

4.0

*** Please provide a justification for the sample size:**

We based our sample size and power calculation on the feasibility to recruitment given the time left on the grant. SHUTi has large effect sizes for insomnia severity (assessed by the ISI) at post-intervention (1.01-1.77) and 6 months follow-up (0.94) and generally medium to large effect sizes for health-related functioning outcomes (0.48-0.92) in published studies of older adults and samples with medical comorbidities (11-15). Using GPower, the minimum number of participants needed for attaining 80% power at $p < 0.05$ was calculated. The sample size of 80 at 3-month follow-up will enable us to detect between group differences in changes in our primary outcome in Aim 1 (insomnia severity) and Aim 2 (quality of life) as small as $d = 0.63$. To account for a predicted 20% attrition rate at 3 month follow-up (10), an additional 16 participants will be needed. Thus, a final baseline sample size of 96 (n = 48 per group) will be needed to power our primary and secondary aims. For the mediation model in Aim 3, given that the effect sizes of the mediating paths range from medium to large, a sample of 80 will provide sufficient power (> 0.80) to detect the mediation effect on health-related functioning.

ID: Pro00003666 View: 6.1 Study Population

Study Population

1.0 * Check all that apply to describe your study population:

	Study Population
☐	Non-Veterans
☑	**Special Populations**
☑	**Veterans**
☐	Vulnerable populations
☐	Other

2.0 * Indicate the inclusion criteria for enrollment:

- Age 40 years and older
- Primary diagnosis of COPD in the electronic medical record

- Meets criteria for Diagnostic and Statistical Manual –version 5 (DSM-5) Insomnia Disorder
- At least moderate insomnia severity based on Insomnia Severity Index score ≥ 7
- Stable psychiatric and medical conditions
- Must have telephone, email, and reliable Internet access via computer, smartphone, or tablet

3.0 * **Indicate exclusion criteria for enrollment:**
- Untreated current major depression
- Serious suicidal risk (Patient responds positively to Patient Health Questionnaire-9 (PHQ-9) question #9)
- Substance abuse disorder within past 3 months
- History of bipolar or psychosis
- Untreated restless legs syndrome, delayed sleep phase syndrome, irregular sleep schedules (i.e., with usual bedtimes outside of 9:00pm to 1:00am or arising time outside of 4:30am to 9:30am)
- Very severe untreated obstructive sleep apnea
- Severe excessive daytime sleepiness based on Epworth Sleepiness Scale score > 16
- Restrictive lung disease (FEV1/FVC ≥ 70 and FEV1 < 80% predicted) or asthma
- Plans to move during the following 6 months
- Non-English speaking or sensory deficits

4.0 **If there are any age, ethnic, language, or gender-based exclusion criteria, including the exclusion of any pregnant or lactating women, or those of child-bearing potential, please provide justification:**
Given the predominance of COPD in middle-aged and older persons, we will enroll patients aged ≥ 40 years.
Given that the Internet-based CBT-I program is only available in English, we will exclude patients who are non-English speaking. There will be no exclusion based on ethnicity or gender.

5.0 **Please specify why vulnerable subjects and/or special populations will not be enrolled:**

6.0 **With some exceptions as listed in VHA Handbook 1200.05, incompetent subjects cannot be enrolled in VAPHS approved research. Specify that you will not enroll incompetent subjects and the general rules to be used in making that determination:**
We will not enroll incompetent subjects.

ID: Pro00003666 View: 6.3 Study Population- Special Populations

Study Population

1.0 * **Check all that apply to describe your study population:**

	Name
☐	Employee and Student Subjects
☑	**Investigators Clinical Population**

2.0 * **Provide a justification for including these subjects:**Tony Macedonia, MD, Co-Investigator, is a Staff Physician at VAPHS. He primarily sees COPD outpatients.

ID: Pro00003666 View: 6.3.2 Investigators clinical population

Investigators clinical population

1.0 * **Please indicate how you will minimize the potential for them to feel coerced to participate. Discuss how the potential confusion in roles will be addressed:**

Patients will be informed of the potential for the patient's doctor to be an investigator. Patients will be informed that they are under no obligation to participate in this research study and that they are free to discuss their care with another doctor who is not associated with this research study at any time. This information is in the informed consent document.

ID: Pro00003666 View: 7 Risk/Benefit Assessment-Risks

Risk/Benefit Assessment-Risks

1.0 * Risk classification for this study (select one).

	Name
◉	**Minimal Risk**
○	Greater than Minimal Risk

2.0 * Basis for making the above recommendation:

Research activities present no more than minimal risk to human subjects, and data collection will occur through noninvasive procedures routinely employed in clinical practice (questionnaires, wearable device, 6-minute walk test, spirometry, electronic medical record review).

All patient identifiers will be kept in a secure location, either in a locked file cabinet or secure VA computer as explained in section 10 Data Security. We will collaborate with the VA privacy officer and VA IRB to comply with VA data security policies and procedures.

3.0 * Describe the safety precautions that will be taken to minimize risks/harms:

All procedures will be conducted in adherence with the IRB's policies for reporting serious and unexpected adverse events. Breach of confidentiality will be minimized by maintaining strict security on information provided by participants. Any information obtained from this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Research records may be released or disclosed if required by federal law. We will collect and review private health information from providers and electronic medical records, which may include diagnoses. Identifiable information will be collected such as name, date of birth, social security number, phone number, and address. Any electronic or hard/paper copies of the information collected will be stored in a secured location. Any copies that contain information that could be used to identify participants (such as your name, address, date of birth, etc.) will be stored separately from any information that does not contain identifiers. Records will be de-identified by assigning a case number and the information linking the case number to the participant's identity will be stored in a separate, locked location. All participant information will be kept in password-protected computers. Paper source documents of the coded research records will be kept in file cabinets within a locked file room. Access to these files is restricted to the Principal Investigator and the associated research staff working on the project. Study participants will not be specifically identified in any publication of research results. Records will be maintained in accordance with the VHA Records Control Schedule.

Risks associated with telephone interview and self-rated questionnaires will be minimized by utilizing staff with clinical evaluation experience. Participants will be allowed to skip questions or instruments they find upsetting.

Risks associated with six-minute walk test. The Project Coordinator performing the six-minute walk test will be trained to recognize symptoms necessitating the immediate stopping of the six-minute walk test such as chest pain, staggering, and leg cramps. The six-minute walk test may also be stopped at the request of the patient.

Risks associated with lung function testing. If participants experience shortness of breath, wheezing, or chest tightness that does not go away on its own, bronchodilator treatment be will administered.

Withholding COPD medications. If COPD symptoms worsen or participants are unable to hold their medications, they will be instructed to take the medication as needed and to call the study staff.

Risk associated with SHUTi will be minimized by carefully explaining and describing all intervention procedures. Participants will be instructed to exercise caution when driving a vehicle or operating machinery during the first few weeks of SHUTi, when sleep restriction effects are likely to be maximal. Participants' sleep diaries and self-reports will be monitored weekly by study staff during the intervention, and the study will be discontinued if participants experience significant distress or wish to discontinue. To minimize the risks associated with fully conducting a study online (i.e., no in-person assessment or intervention), participants will be instructed to contact study staff if they have any concerns or questions. They can contact study staff through either email or phone calls. Study staff are also well-trained to provide technical support. In addition, participants will receive contact prompted by study staff if they fail to complete assigned tasks. All interactions are carefully tracked (number of contacts, type of contact, and number of minutes spent on the contact). This information ensures clear communication and prompt responses with participants.

No clinical support will be provided to participants beyond what recommendations are made within SHUTi. If participants contact study staff, participants will be redirected to the program content or instructed to contact their physician. Study staff will work to address barriers to using the SHUTi program but will not be providing treatment advice. All clinical situations that arise will be discussed with the team and one of the investigators will respond if needed. With respect to a clinician's advantage of being able to flexibly respond to adherence problems and promote therapeutic reliance and accountability, SHUTi is designed with adherence concerns at the forefront. Automated emails are sent to the user after failing to complete different program components and after certain time periods of failing to log in. Feedback is also tailored to the individual user to promote his or her feelings of the program being credible.

4.0 * **Provide details regarding the nature of each risk using the area provided below:**

	Risk Name
View	Lung function testing (spirometry)
View	Six-minute walk test
View	Actiwatch
View	Questionnaires, sleep diary, phone screen
View	Withholding COPD medications
View	Internet-based cognitive-behavioral therapy for insomnia intervention (SHUTi)
View	Breach of confidentiality

5.0

* **Do you plan on using the research answering service:** ○ Yes ◉ **No**

If yes, please Upload the research answering service form:

6.0 **If your study involves a treatment or intervention, please upload the Patient ID Card:**

ID: Pro00003666 View: 7.1 Risk/Benefit Analysis-Potential Benefits and Alternatives

Risk/Benefit Analysis-Potential Benefits and Alternatives

Describe any potential for benefits to participants in this study:

1.0 * **Direct and Indirect Benefits to Subjects:**

There is no certain benefit to research participants from study participation. Although it is possible

that patients may experience some relief of symptoms from insomnia as the Internet-based CBT-I program is used clinically for treating insomnia.

Benefits to others include improved understanding of insomnia treatment for veterans with COPD. This could lead to more effective intervention in the future.

2.0 * **Describe alternatives (research or non-research) that are available to subjects if they choose not to participate in this study:**
Alternative courses of treatment include pharmacological treatments for insomnia and face-to-face CBT-I. Patients will be informed via the informed consent that pharmacological (drug) therapies for insomnia and face-to-face CBT-I are also available. Participants will be encouraged to discuss the use of these treatment options with their physician as appropriate.

ID: Pro00003666 View: 8 Methods of Recruitment and Retention

Recruitment Methods and Materials used for Retention

1.0 * **Select recruitment methods used on this study:**

	Name
☐	Mail Campaign
☐	Referral by independent source
X	Advertising such as fliers, letters, or ads (newspaper, TV, radio)
☐	Web Site
☐	Research registry
☑	**Selected from pre-existing records**
☐	Pre-existing relationship with participants
☑	**Other**

If Other Methods Specify:
We will promote recruit for the study by advertising the study with VA physicians and fellows in the Pulmonary department (who care for COPD patients) and VA physicians in the primary care department, sleep clinic, and home oxygen program. A one-page study description will be distributed to the physicians and fellows through email and hard copy. Participants will be recruited through the VAPHS pulmonary, primary care, and sleep clinics and the home oxygen program based at the University Drive campus. We will review charts of patients with scheduled appointments in the pulmonary, primary care, and sleep clinics and home oxygen program for inclusion and exclusion criteria (HIPAA authorization waiver approved). We will notify physicians of potentially eligible patients who are coming in for a scheduled appointment. The physician will ask the patient first if they are interested in the study and willing to have someone from the study team speak with them either in person or by telephone prior to any study member initiating contact with potential participants.

A study flyer will be distributed by healthcare providers and the study team to potentially eligible patients seen in VAPHS clinics.

2.0 * **Specify how subjects will be identified and how study eligibility will be determined:**
1. We will review charts of patients with scheduled appointments in the pulmonary, primary care, and sleep clinics and home oxygen program for inclusion and exclusion criteria (HIPAA authorization

waiver approved). 2. When a patient is determined to be preliminarily eligible, we will notify the physician who will be seeing the patient during their scheduled appointment. 3. The physician will ask the patient first if they are interested in the study and willing to have someone from the study team speak with them either in person or by telephone prior to any study member initiating contact with potential participants. Physicians will request that research staff contact potentially eligible patients if he/she agrees to such contact via email or through CPRS consult. 4. For interested patients, we will either provide a thorough explanation of the study in person at the time of the scheduled appointment or contact the patient via telephone. We will also conduct a semi-structured interview along with completion of questionnaires (Insomnia Severity Index (16); NIDA Quick Screen (25); Epworth Sleepiness Scale (26)) to review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subject will be invited to come to VAPHS University Drive campus for an in-person visit to sign the informed consent and the HIPAA authorization and complete the full baseline assessment.

In order to ensure all COPD patients who meet preliminary eligibility criteria are notified about the study as physician introduction and referral to the study is not guaranteed, we will also utilize an opt-out letter for recruitment. Research staff will use data from the Corporate Data Warehouse initially to identify Veterans who have had appointments in the past year or in the upcoming 3 months on a continuing basis every three months going forward, by clinic, who have specific ICD 10 codes that correspond with the eligibility criteria. Research staff will request the full SSN, ICD 10 code, provider, date and time of the upcoming appointment as well as appointments from the past year, and the Veteran's contact information (address and phone number) from the CDW. The IRB approved letter describing the study will sent to unique eligible Veterans and will be sent from Tony Macedonia, MD, who is a co-investigator and staff physician in the COPD outpatient clinic. Another IRB approved letter describing the study out will sent to unique eligible Veterans who are part of the home oxygen program and will be sent from Charles Atwood, MD, who is a co-investigator and medical director of the home oxygen program, and Angelica Howell, RRT, who is manager of the home oxygen program. Another IRB approved letter describing the study will be sent to unique eligible Veterans who are seen in the Sleep Medicine Clinic and will be sent from Charles Atwood, MD, who is co-investigator and Chief of Sleep Medicine. The letters will provide the Veterans with a return mail envelope and reply form and ask them to indicate whether they would like to be contacted further about the study or not. If a Veteran does not respond after three weeks, study staff will phone the Veteran and ask if they have any questions or would like to consider participating using an IRB approved phone script. For interested patients, we will provide a thorough explanation of the study via telephone. We will also conduct a semi-structured interview along with completion of questionnaires (Insomnia Severity Index (16); NIDA Quick Screen (25); Epworth Sleepiness Scale (26)) to review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subject will be invited to come to VAPHS University Drive campus for an in-person visit to sign the informed consent and the HIPAA authorization and complete the full baseline assessment.

3.0

*** Provide the location (or locations) of the sites where participants will be recruited:**

VAPHS University Drive campus

4.0 Please include information regarding any advertisements (print, TV, radio, etc) that will be used to recruit subjects including a general description of where this information will be posted:

5.0

Please UPLOAD the documents that will be used for recruitment and an introductory statement or letter to accompany consent for those studies obtaining written informed consent using methods such as fax, email or mail (if applicable). Please also upload any

screening/recruitment questions that will be verbally asked of potential research subjects. Also, if you will be providing any retention materials, please upload them here.

Name	Reviewer	Modified Date	Version Number
Introductory Script 12-16-20.docx	Luyster, Faith	12/17/2020 11:20 AM	0.02
Telephone Screening	Luyster, Faith	1/4/2021 10:55 AM	0.01

ID: Pro00003666 View: 9 Informed Consent

Informed Consent

1.0

*** Indicate the types of consent that will be involved in this study (check any or all that apply):**

Informed Consent Category
Written/signed consent by subject
Waivers are being requested.

2.0 *** Waivers: If you are applying for any waivers of consent (check any or all that apply):**

	Name
☐	Waiver of Informed Consent
☑	**Waiver of HIPAA Authorization**
☐	Waiver of Documentation of Informed Consent (telephone consent, verbal script)
☐	No Waiver at all

3.0 *** Will this study include non-English speaking participants?**

○ Yes ◉ **No**

ID: Pro00003666 View: 9.1 Waiver of HIPAA

You have indicated you are requesting a waiver of HIPAA.

1.0 *** Is the request only for Screening/Recruitment purposes?**

◉ **Yes** ○ No

If yes, please describe your screening/recruitment method:

We will review charts of patients with scheduled appointments in the pulmonary, primary care, and sleep clinics and home oxygen program for inclusion and exclusion criteria (HIPAA authorization waiver approved). 2. When a patient is determined to be preliminarily eligible, we will notify the physician who will be seeing the patient during their scheduled appointment. 3. The physician will ask the patient first if they are interested in the study and willing to have someone from the study team speak with them either in person or by telephone prior to any study member initiating contact

with potential participants. 4. For interested patients, we will either provide a thorough explanation of the study in person at the time of the scheduled appointment or contact the patient via telephone. We will also conduct a semi-structured interview along with completion of questionnaires (Insomnia Severity Index (16); NIDA Quick Screen (25); Epworth Sleepiness Scale (26)) to review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subject will be invited to come to VAPHS University Drive campus for an in-person visit to sign the informed consent and the HIPAA authorization and complete the full baseline assessment.

In order to ensure all COPD patients who meet preliminary eligibility criteria are notified about the study as physician introduction and referral to the study is not guaranteed, we will also utilize an opt-out letter for recruitment. Research staff will use data from the Corporate Data Warehouse initially to identify Veterans who have had appointments in the past year or in the upcoming 3 months on a continuing basis every three months going forward, by clinic, who have specific ICD 10 codes that correspond with the eligibility criteria. Research staff will request the full SSN, ICD 10 code, provider, date and time of the upcoming appointment as well as appointments from the past year, and the Veteran's contact information (address and phone number) from the CDW. The IRB approved letter describing the study out will sent to unique eligible Veterans and will be sent from Tony Macedonia, MD, who is a co-investigator and staff physician in the COPD outpatient clinic. Another IRB approved letter describing the study out will sent to unique eligible Veterans who are part of the home oxygen program and will be sent from Charles Atwood, MD, who is a co-investigator and medical director of the home oxygen program, and Angelica Howell, RRT, who is manager of the home oxygen program. Another IRB approved letter describing the study will be sent to unique eligible Veterans who are seen in the Sleep Medicine Clinic and will be sent from Charles Atwood, MD, who is co-investigator and Chief of Sleep Medicine. The letters will provide the Veterans with a return mail envelope and reply form and ask them to indicate whether they would like to be contacted further about the study or not. If a Veteran does not respond after three weeks, study staff will phone the Veteran and ask if they have any questions or would like to consider participating using an IRB approved phone script. For interested patients, we will provide a thorough explanation of the study via telephone. We will also conduct a semi-structured interview along with completion of questionnaires (Insomnia Severity Index (16); NIDA Quick Screen (25); Epworth Sleepiness Scale (26)) to review inclusion/exclusion criteria to confirm eligibility. Once eligibility and willingness to participate is confirmed, the subject will be invited to come to VAPHS University Drive campus for an in-person visit to sign the informed consent and the HIPAA authorization and complete the full baseline assessment.

If no, the request is for the full study (e.g. retrospective chart reviews and certain observational studies)

Please describe the types of records and/or databases to be accessed:

CPRS electronic medical record and Corporate Data Warehouse will be accessed for screening purposes.

THE IDENTIFIABLE INFORMATION BEING REQUESTED:
Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must select Names, Addresses and Social Security Numbers as that information will be disclosed for payment purposes.

2.0 * **Identifiable Information per HIPAA Definition**

	Name
☐	None
☐	Account numbers
☐	Biometric identifiers, including finger and voice prints
☐	Certificate/license numbers
☐	Device identifiers and serial numbers
☑	**Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)**
☐	Email Address
☐	Fax Numbers
☐	Full-face photographic images or any comparable images
☑	**Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)**
☐	Health plan beneficiary numbers
☐	Internet Protocol (IP) address numbers
☑	**Medical Record Numbers**
☑	**Name or any derivative of name such as initials**
☑	**Social Security Numbers**
☑	**Telephone Numbers**
☐	URLs (Web Universal Resource Locators)
☐	Vehicle identifiers and serial numbers, including license plate numbers
☐	Any other unique identifying number, characteristic, or code (Note: The study ID number, code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification)

3.0 * **Patient Protected Health Information:**

	Name
☑	**Demographic Information (e.g., Name, Address, Phone Number, Social Security Number**
☐	Billing and Payment Information
☑	**Hospital or Medical Records**
☑	**History and Physical Exam Notes**
☐	Mental Health Records
☐	Data Previously Collected for Research Purposes
☑	**Progress Notes**
☑	**Consultation Reports**
☑	**Laboratory Test Results**
☑	**Operative Reports**
☐	Other

Please indicate the 'Other' Patient Protected Health Information:

4.0 **Other Health Information:**

Name
There are no items to display

ID: Pro00003666 View: 9.1.1 Waiver of HIPAA - More Information

Waiver of HIPAA- More Information

1.0 * **Describe how the identifiable information is to be used and/or disclosed only by members of the research team and the following persons *(identify with specificity and justify the need to disclose the information to anyone outside the VHA.)* Note: If participants will be receiving payment and HIPAA Authorization is not being obtained, you must also describe this disclosure to representatives of the VA for administrative purposes here.**

Also describe how this activity meets the "minimum necessary standard" described in the HIPAA Privacy Rule:
The patients electronic medical record will be reviewed for study eligibility. A screening log will be kept on a password protected spreadsheet in a study specific shared research drive. This screening log will include the patient's last name, last four digits of his/her social security number, an indicator of eligibility, an indicator of enrollment, and any other information pertinent to the screening process. No paper records will be kept as part of the screening process.

The proposed study poses minimal risk to the privacy of the subjects because...

2.0 * **Describe how the identifiable information will be protected from improper use or disclosure by (detail how this will be accomplished including the limitations of physical or electronic access to the information and other protections):**
The identifiable information will be maintained on a study specific shared drive on a password-

protected spreadsheet and/or database. Only study members will have access to the spreadsheet password.

3.0 * **Describe how the identifiers will be destroyed at the earliest opportunity consistent with the research (discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them) (Note: At this time, identifiers used for research screening and all other screening records must be retained indefinitely and this must be documented by checking "Other" below):**
All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

* **When will screening data be de-identified or destroyed:**

Name
completion of study accrual
Other

If Other, please describe:
All research records will be maintained in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.

4.0 * **Describe how the identifiable information will not be reused or disclosed to any other person or entity outside the VHA other than the manner described in the protocol, except as a required by law, for authorized oversight of this research study, or as specifically approved for used in another study by an IRB:**
The identifiable information will only be available to the study staff and will not be reused or disclosed to any other person or entity outside the VHA except as required by law or for authorized oversight of this research study.

5.0 * **Describe why the proposed study cannot be practicably conducted without a waiver of authorization: (discuss reasons why it would not be possible to obtain authorization from individual subjects. Time constraints themselves are generally not considered adequate for this justification:**
It will not be possible to recruit a target sample of appropriate subjects without this screening procedure. Inclusion and exclusion criteria are quite specific for this project and it will be necessary to screen larger numbers of potential subjects than will be admitted to the study.

It is not practicable to determine eligibility without confirming the PHI (such as age, current medical diagnoses) with the subject on the phone. This confirmation is important as it identifies Veterans who have a high probability of meeting criteria for the study and avoids Veterans having to make needless trips to our research site.

6.0 * **Describe why the proposed study cannot be done without the specified identifiable information: Discuss reasons why it would not be possible to conduct the research without the identifiable information being collected.**
In order to access the patient's medical information for pre-screening, we need to access their electronic medical record that includes their name, date of birth, and social security number.

ID: Pro00003666 View: 9.4 Consent Forms & Process of Consent

Consent Forms & Process of Consent

1.0 Upload the completed forms into the correct lists below.

1.1 Informed Consent Form (clean copy):

	Document	Modified Date	Version Number
View	Informed Consent Form(0.03)	1/7/2021 12:00 AM	0.03

1.2 Provider Behavior Informed Consent Form (clean copy):

Document	Modified Date	Version Number
There are no items to display		

1.3 Screening Informed Consent Form (clean copy):

Document	Modified Date	Version Number
There are no items to display		

2.0 Consent Forms (modified copy):

	Document	Modified Date	Version Number
View	Informed Consent Form - Modified(0.02)	1/8/2021 9:43 AM	0.02

3.0 * Describe how, where, when, and by whom the consent process will be initiated:
Subjects will sign an informed consent prior to initiation of the study procedures. The consent will be presented to the subject in both oral and written form by a study member (either coordinator, PI, or co-I) and a baseline diagnostic evaluation will be conducted after informed consent is received. Informed consent will be obtained during an in-person discussion with the subject in a private room and it will be documented on a VAPHS consent form. The consent will be presented in English. All questions and concerns will be answered prior to the subject signing the consent form and time will be given to the subject to think about participation in the study. A copy of the signed consent will be provided to the subject.

4.0 * Will you be maintaining a Master List of Subjects?
Yes

5.0 * Describe when the subject's name will be added to the master list and how the list will be maintained in a secure fashion.
The subject's name will be added when they have signed informed consent. The list be stored on a shared drive limited only to research staff.

ID: Pro00003666 View: 10.0.0 Data Security and Privacy: Data Types Storing

10.0 Data Types Collecting and Storing

1.0

Click the add button (below) to open an entry form to indicate the types and/or sources of the data that will be collected/stored as part of the project.

***Instructions:* For each type/source of data that will be collected as part of the project, this includes screening data, click the add button to open an entry form that lists the types and/or sources of data. Select a source/type of the data that will be collected/stored. Then indicate what, if any, identifiers or sensitive information will be collected/stored from the source/type (None is an option). To add another source/type click "OK Add Another" button to open up a new entry form to repeat the process.**

Example 1: You are collecting data from VA Medical records including names, last 4 of

SSN, and addresses. Therefore, you would select "VA medical record data" as the source, and then select in the identifiers: "Name or any derivative of name, such as initials," "Social Security Numbers," and "Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)" as the identifiers being collected.

Example 2: You are screening VA Medical Records and recording the information you use to screen (i.e.: names, last 4 of SSN, and addresses, etc.) Note: This information must be treated as a Source document, please select "Screening" as the source and then select the identifiers "Name or any derivative of name, such as initials," "Social Security Numbers,", as applicable.

*

	Data Type/Source	Collection Details	Identifiers
View	Other *Data will be collected on the Actiwatch device that subjects wear.*	Devices will be provided by study team. Data is not transmitted. It is stored in the device and then the data from the device is downloaded using docking station attached to a research-associated computer. Data will be uploaded to the VAPHS Network (shared drive) with limited access that only approved research staff will have access. The file will be password protected and only limited approved staff will have access.	Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89)
View	Questionnaires/Surveys, paper	Data will be collected by a study team member and will be stored in a locked cabinet in the MIRECC and on the study-specific VA shared drive on password-protected spreadsheets or databases.	Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89) Medical Record Numbers Telephone Numbers Email Address

			Social Security Numbers Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code)
View	VA medical record data (i.e., diagnoses, procedures, visits) via **chart review**	The data will be collected by a study team member during either the screening process or after enrollment. The data will be collected via chart review and via interview with the study participant. All collected data will be stored in the study-specific shared drive in either a password protected spreadsheet or database. Only study team members will have access to this password protected data.	Elements of dates (except year, for example, date of birth, admission date, discharge date, date of death, date of procedures; and all ages over 89) Telephone Numbers Social Security Numbers Geographical subdivisions smaller than a State (street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code) Name or any derivative of name such as initials
View	Other *Internet-based cognitive-behavioral therapy for insomnia intervention – Sleep Healthy Using The Internet (SHUTi).*	A personal portal to the SHUTi program will be created for this research study. SHUTi will not be installed or used on VA computers, instead, it will be used by Veterans on the computer from which they access the Internet. Veterans will be asked to use their own personal email account to set up logins and receive	Email Address

	reminders for the SHUTi program. Data will be securely collected by the SHUTi program, stored securely outside the VA (University of Virginia's secured computer networks); the data will then be securely accessed online by VA research study staff. Participant's email address and any personally identifiable information submitted by the participant to the SHUTi website during the intervention will only be used if necessary for the operation and maintenance of the website, to comply with legal requirements, or protect an individual's personal safety in an emergency situation. The informed consent for the research study will include a discussion about any potential privacy and security risks associated the SHUTi program.

ID: Pro00003666 View: 10.0.1 Data Security and Privacy: Social Security Numbers

10.0.1 Data Security and Privacy: Social Security Numbers

1.0 You indicated that you will be using all or some part of the research subjects' SSNs as part of this study. Which of the following will you be using:

Real Social Security numbers	*	**Yes**	No
Scrambled Social Security numbers	*	Yes	**No**
Last 4 digits of Social Security Number	*	**Yes**	No
Other (some derivation of the SSN)	*	Yes	**No**

If other, please explain:

2.0 * Please describe how subjects' Social Security numbers will be used in this study:
We will be accessing the patient's medical records and will need to use social security numbers in their entirety or in part to access these records. We will use subjects' social security numbers in order to provide subject payment. EFT/Direct Express Debit MasterCard will be used for subject payment. SSNs will not be transferred to another entity to make payments.

3.0 * Please describe the security measures that will be taken to protect SSNs.
Any data collected on subjects will be stored on the study-specific shared drive on password protected spreadsheets and databases. Only study team members will have access to this information.

ID: Pro00003666 View: 10.1.0 Data Security and Privacy: Incoming Data

10.1.0 Incoming Data

1.0 * **Will data be transferred into VAPHS?**
Yes. Data is being obtained from a non-VA source and will be transferred to VAPHS

ID: Pro00003666 View: 10.1.1 Data Security and Privacy: Incoming Data - Identifiable Data

10.1.1 Incoming Data - Identifiable Data

1.0

* **Is any of the data being transferred *into* VAPHS identifiable?** ○ Yes ◉ **No**

If yes, please describe what the identifiable data is and where it is coming from:

ID: Pro00003666 View: 10.2.0 Data Security and Privacy: Outgoing Data

10.2.0 Outgoing Data

1.0 * **Will any of the data being collected/stored be transferred outside of VAPHS?**
No. The data is not being transferred outside of this facility.

ID: Pro00003666 View: 10.3.0 Data Security and Privacy: Local Data Storage Types

10.3.0 Local Data Storage Types

1.0 * **How will data be stored on this project? (Select all that apply)**
On Paper
Electronically

ID: Pro00003666 View: 10.3.1 Data Security and Privacy: Local Data Storage Types - Paper

10.3.1 Local Data Storage Types - Paper

1.0

* **All VA research data collected in paper must be stored in a locked room at VAPHS. List the room number(s) and the campus(es) where data will be stored in the text box below.**

All data collected in paper will be stored in a locked filing cabinet in the MIRECC cubical 1-15.

ID: Pro00003666 View: 10.3.2 Data Security and Privacy: Local Data Storage Types - Electronic

10.3.2 Local Data Storage Types - Electronic

1.0 * **Where is the electronic data being stored? Select all that apply.**
VAPHS Network (shared drive)

If "Other" please describe OR if you would like to provide additional information for clarification, please elaborate in the text box below.

If you selected VAPHS or VA Network (Shared Drive), please provide the name of the drive (i.e. "MySharedDriveName (\\vapthshsare) (X:)"):

(Z): Luyster_Pro3666 (\\oitpthhsmsvm200.v04.med.va.gov\Research)

ID: Pro00003666 View: 10.4.0 Data Security and Privacy: Reusing Data

10.4.0 Data Security and Privacy: Reusing Data

1.0

*** Will the data collected in this study be reused in other studies?** ○ Yes ◉ **No**

If yes, please describe where the data to be reused will be stored and how access to that data will be provided and monitored:

2.0 If this research is part of a grant, please upload the Data Management Access Plan (DMAP) or Resource Sharing Plan for this study.

Name	Modified Date
09_VA_DMAP.pdf	12/8/2020 2:32 PM

ID: Pro00003666 View: 10.6.0 Data Security and Privacy: HIPAA

10.6.0 Data Security and Privacy: HIPAA

The Healthcare Insurance Portability and Accountability Act (HIPAA) prohibits the use of a person's Protected Health Information without a valid authorization.

1.0 * Select the option which fits this study:

	Name
○	Not applicable: No PHI is being used or disclosed by VAPHS
○	Not applicable: Waiver has been requested
◉	**HIPAA Authorization (Combined Consent and HIPAA Authorization)**
○	HIPAA Authorization (Standalone)

Upload HIPAA authorization (Standalone) here:

Document	Modified Date	Version Number
There are no items to display		

2.0 At screening will clinical personnel be asked to share potential participants PHI:

○ Yes ◉ **No**

If yes, please upload the 10-5345:

ID: Pro00003666 View: 10.7.0 Data Security and Privacy: Additional Information

10.7.0 Data Security and Privacy: Additional Information

1.0

Does this research involve...

* **...specially obtained software?** **Yes** No

If yes, please describe the software and what it is being used for:

Dacima Clinical Suite - data entry. The software is TRM approved with constraints.
All constraints will be followed.

Actiware version 6.0. software will be used. The software is TRM approved with constraints.
All constraints will be followed.

zzzPAT version 5.1 software will be used. The software is TRM approved with constraints.
All constraints will be followed.

* **...one or more Web-based applications?** **Yes** No

If yes, please describe the application and what it is being used for:

Dacima Clinical Suite - data entry. https://www.dacimasoftware.com/products/dacima-clinical

* **...mobile devices?** **Yes** No

If yes, please describe:

The Actiwatch Spectrum Plus device will be used. No Identifiable data is stored on the Actiwatch. Data will be downloaded directly to the computer into the study-specific shared drive. Data will be stored on the devices for only as long as the participant has the device. The device will be mailed back to VAPHS. Once returned, the data will be downloaded and the device will be cleared. Once downloaded any data that was collected will be stored following the VA destruction and retention requirements.

The WatchPat device will be used. No identifiable data is stored on the WatchPat. Data will be downloaded directly to the computer into the study-specific shared drive. Data will be stored on the devices for only as long as the participant has the device. The device will be mailed back to VAPHS. Once returned, the data will be downloaded and the device will be cleared. Once downloaded any data that was collected will be stored following the VA destruction and retention requirements.

2.0

*** Will a Certificate of Confidentiality be obtained for this study?** ○ Yes ◉ **No**

If yes, please attach the Certificate of Confidentiality:

3.0

*** Will VA sensitive information be transported and utilized outside protected environments?** ○ Yes ◉ **No**

If you answered yes above, please upload a fully executed VAPHS Memo to Take VA Sensitive Information Outside a Protected Environment by following **these instructions** .

ID: Pro00003666 View: 10.8.0 Data Security and Privacy: Certifications

10.8.0 Certifications

1.0 *** I certify that all study staff are up-to-date and will remain up-to-date with Information Security Awareness Training, Rules of Behavior, and VHA Privacy Training.** ◉ **Yes** ○ No

2.0 *** I also certify that when an individual is no longer part of the study team, access will be removed to research study data.** ◉ **Yes** ○ No

3.0 *** I certify that all research records will be maintained in accordance with the Veterans Health Administration (VHA)Records Control Schedule. Paper records will be disposed of using methods deemed appropriate by the VAPHS Privacy Officer, and all electronic data will be sanitized using methods rendered appropriate by the VAPHS ISO.** ◉ **Yes** ○ No

4.0 *** I certify that any loss or compromise of any VA sensitive information (including research data), VA equipment or device, or any non-VA equipment or device that is used to transport, access, or store VA information will be reported in accordance with the reporting requirements outlined in VA Handbook 6500.** ◉ **Yes** ○ No

5.0 *** I certify that, in accordance with VA Handbook 6500, no personal laptops will be used for official VA business in conjunction with this study.** ◉ **Yes** ○ No

ID: Pro00003666 View: 11 Local Data Safety Monitoring Plan

Local Data Safety Monitoring Plan

For local studies, a data and safety monitoring plan (DSMP) must be established.

1.0 *** Please describe how the study procedures and data being collected will be continuously monitored so that changes in the risk/benefit ratio can be determined in a timely fashion during the course of the study:**
An Institutional Data and Safety Monitoring Board (IDSMB) will be created to review this study. The initial responsibility of the IDSMB will be to approve the initiation of this clinical trial. After this approval and at biannual intervals during the course of the trial, the IDSMB responsibilities are to:

1. Review the research protocol, informed consent documents and plans for data and safety monitoring;

2. Evaluate the progress of the trial, including assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect study outcome;

3. Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;

4. Review clinical center performance, make recommendations and assist in the resolution of problems reported by the PI;

5. Protect the safety of the study participants;

6. Report on the safety and progress of the trial;

7. Ensure the confidentiality of the trial data and the results of the monitoring;

8. Assist the PI by commenting on any problems with study conduct, enrollment, sample size, and/or data collection.

The IDSMB will include experts in pulmonary diseases, clinical trials methodology, and insomnia. Members will consist of persons affiliated with the VAPHS and/or the University of Pittsburgh, and independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to the absence of conflict of interest will be required.

2.0 * **Describe how frequently Investigators, study personnel, and the clinical coordinators involved in the study will meet and/or review study data.**
The investigators, study personnel, and clinical coordinators involved in the study will meet monthly to review study data as a group. The PI also will meet with the principal coordinator on a weekly basis.

3.0 * **Will this study use a Data Safety Monitoring Board or Data Monitoring committee?**

(•) **Yes** ( ) No

4.0 * **Will this study use a Medical Monitor?**

( ) Yes (•) **No**

ID: Pro00003666 View: 11.1 Data Safety Monitoring Board/ Data Monitoring Committee

Data Safety Monitoring Board/ Data Monitoring Committee

1.0 * **List the affiliations and qualifications of those monitors who are not associated with the study or describe the composition of the DSMB:**
The IDSMB will include experts in pulmonary diseases, clinical trials methodology, and insomnia. Members will consist of persons affiliated with the VAPHS and/or University of Pittsburgh, and independent of the investigators who have no financial, scientific, or other conflict of interest with the trial. Written documentation attesting to the absence of conflict of interest will be required.

2.0 * **Describe how frequently the independent monitor(s) or DSMB will meet and/or review study data:**
The IDSMB will meet on a biannual basis to review study data.

3.0 * **Describe the type of data (e.g., blinded or unblinded) to which the independent monitor(s) or DSMB will have access:**
The DSMB will have access to blinded and unblinded data.

4.0 **Document that minutes will be kept.**
Minutes of the IDSMB meetings will be kept and submitted at continuing review or more frequently if requested by the IRB.

5.0 * **Please upload the DSMB/DMC Charter:**
DSMB Charter_12-4-2020.docx(0.01)

ID: Pro00003666 View: 12 Costs and Payments

Costs and Payments

1.0 * **Does this study have a budget?:**

(●) **Yes** ( ) No

If yes, please upload the current budget:
VA_Budget.pdf(0.01)

2.0

* **Will patients receive payments for this study?**

(●) **Yes** ( ) No

If yes, please upload the financial letter of support (either from the Business Service line or the Veterans Health Foundation) or documentation waiving the requirement of a letter of support:
VA Financial LOS Memo_v3_Sept2018.Luyster.pdf 0.01

3.0 * **Are you paying patients using the WePay system?**
no

ID: Pro00003666 View: 12.1 Costs

Costs

1.0 * **Will subjects be required to pay for any services outside of the VHA that may be required as part of participating in this research study?**
No, subjects will not be charged for participation in the study.

ID: Pro00003666 View: 12.2 Participant Payments

Participant Payments

1.0 * **Please explain how the proposed payments are reasonable and commensurate with the expected contributions of the subject:**
The participants will be paid $225 for participation in the study. They will be asked to perform baseline, post-treatment, and 3-month six-minute walk testing, spirometry, and answer questionnaires. They will also be asked to wear a Actigraph to monitor their physical activity and sleep/wake patterns for 1 week at baseline, post-treatment, and 3-month follow-up. Participants in the intervention arm will participate in a online self-guided CBT-I intervention (9 weeks). This payment is reasonable and commensurate with the number of procedures required and travel time.

2.0 * **Please provide information on how the subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. In additional the payments do not constitute (or appear to constitute) coercion to participate in, or continue to participate in, the research study:**
The payments will compensate for the subject's time and travel back to the facility for baseline and follow up testing. They do not constitute undue pressure or influence on the prospective research subjects to volunteer for, or to continue to participate in, the research study. Subjects are free to quit the study at any time.

3.0 * **Specify the amount, form of payment and the specific disbursement schedule of payments:**
Subjects will be paid $60 after returning the actigraph following the baseline assessment, $75 after returning the actigraph following the post-treatment assessment, and $90 after returning the actigraph following the 3-month follow-up assessment. EFT/Direct Express Debit MasterCard will be used for subject payment.

4.0 * **Are the subjects being paid employees?**
no
If yes, please describe how it will be in accordance with the SOP:

ID: Pro00003666 View: 14 References

References:

1.0

* **Please provide a list of references** *(Multi-site protocols: You may reference the page numbers in the original protocol):*

References

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ID: Pro00003666 View: 15 Miscellaneous Documents

Miscellaneous Documents

If you have any documents that need to be included in this submission, but do not fit in any of the previous sections please upload them here.

	Document	Description	Version Number
View	Investigator COVID Risk Assessment and ACOS decision v7_june.pdf(0.01)		0.01

ID: Pro00003666 View: SF - Final Page

Final Page

You have completed your application!

Please hit "Finish" to save and exit the application. Doing so will NOT submit the application for review.

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must press the "SUBMIT STUDY" button in My Activities for this Study ID:Pro00003666.

You can track the ongoing status of your submission by logging into the study workspace.

Please feel free to contact the IRB with any questions or concerns.

ID: Pro00003666 View: Create/Edit

Study Funding Source

1.0 * **Funding Source Name:**
Merit Review (CC 103)
If you can't find the Funding Source above, choose "Other" and enter it here:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interatction, and follow-up/monitoring procedure:

* Research Activity:
Lung function testing (spirometry)

Common Risks:

Infrequent Risks:
Participants will get 2 puffs of albuterol for this test. This may cause racing heart, jittery or nervous feeling, increased blood pressure, nausea, or headache.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Six-minute walk test

Common Risks:

Infrequent Risks:
This test is considered to carry a low risk of harm, but may occasionally cause slight soreness in muscles and/or breathlessness due to the effort involved.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Actiwatch

Common Risks:

Infrequent Risks:
There is a small risk that participants' skin may be irritated by the actiwatch. This is very rare.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Questionnaires, sleep diary, phone screen

Common Risks:

Infrequent Risks:
Participants may feel uncomfortable while answering questions.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Withholding COPD medications

Common Risks:

Infrequent Risks:
Participants will be asked to not use certain COPD medications (i.e., short-acting beta-agonists and long-acting beta-agonists) prior to each visit for the purpose of lung function testing (spirometry). This is standard clinical procedure for spirometry. As a result, participants may experience an increase in their COPD symptoms.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Internet-based cognitive-behavioral therapy for insomnia intervention (SHUTi)

Common Risks:

Infrequent Risks:
Participants may experience short-term sleepiness, concentration and attention deficits, irritability, and other mood changes associated with the SHUTi intervention. The sleep restriction effects of the intervention could, in theory, lead to increased risk of accidents, including motor vehicle accidents, and to interpersonal conflict. However, no such serious adverse effects have been reported in the literature. No human or clinical support will be provided for the insomnia intervention beyond what is made available via SHUTi.

Other Risks:

ID: Pro00003666 View: Risk Detail Entry

Address for each screening procedure, research intervention/interaction, and follow-up/monitoring procedure:

* Research Activity:
Breach of confidentiality

Common Risks:

Infrequent Risks:
Information regarding participants' clinical evaluations or information associated with the SHUTi intervention could be stolen by individuals beyond the study personnel, despite careful steps to protect confidentiality.

Other Risks: