Sleep-SMART for Veterans with MCI and Insomnia: A Pilot Study

NCT05016960

July 21, 2021

Human Protocol (Version 1.1)

General Information

***Please enter the full title of your protocol:**

Sleep-SMART for Veterans with MCI and Insomnia: A Pilot Study

***Please provide a short name (nickname) to reference this protocol:**

Sleep-SMART
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Add Site(s)

VA Site (******** DO NOT ADD OR CHANGE, just save and continue **********):**

Primary Dept?	Department Name
◉	**VASDHS** - VASDHS

Identify protocol staff members

***Please add a Principal Investigator for the study:**

Erin L. Almklov, PhD

3.1 Add all other VA research staff personnel (if name is not in the list, please contact Research Staffing to confirm appointment status)

A) Additional Investigators

Orff, Henry J., PhD
Co-Investigator
Pittman, James O. E., PhD
Co-Investigator
Rabin, Adrienn Borsika, PhD
Co-Investigator
Twamley, Elizabeth W., PhD
Co-Investigator

B) Research Support Staff

Salamat, Jennifer S.
Study Coordinator

***Please select the Research Contact(s)**

Almklov, Erin L., PhD

Salamat, Jennifer S.

The Research Contact(s) will receive all important system notifications along with the Principal Investigator. (Research Contacts are typically Study Coordinators or the Principal Investigator themselves).

VASDHS IRB
Human Subjects Protocol

v20190121

Section 1 - Preliminaries

Principal Investigator:

Erin L. Almklov, PhD

Protocol Title:

Sleep-SMART for Veterans with MCI and Insomnia: A Pilot Study

IRB Protocol Number:

H210118

Protocol Nickname:

Sleep-SMART

Form Template Version:

v20150115

Date Prepared:

07/21/2021

Please be advised that this protocol application form has changed as a result of the 2018 Common Rule. There are new questions and sections, and you may be required to provide additional information to previous sections.

1a) Is this study considered human research?

- (•) Yes
- ( ) No
- ( ) I don't know

1b) Please select:

- (•) This is an application for a NEW human subject research protocol
- ( ) This is a revision of an existing protocol

Section 2 - Research Subjects

2a) What is the total planned number of VA-consented subjects?

Include the total number of subjects who will prospectively agree to participate in the study (e.g., documented consent, oral consent, or other).

31

2b) What is the total number of VA subjects who WILL NOT be consented?

Include the total number of subjects that will be included without consent (e.g., chart review). *Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still should enter the number of charts as your "planned subjects."*

0

Section 2.1 Consented Subject Groups

2.1) For each of the subject categories listed below, indicate whether or not these subject groups will participate in the study:

2.1a) Children under the age of 18
Note: If neonates or children will be involved in this study, certification by the Medical Center Director will be required. Only minimal risk research may be performed with children. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

○ Yes ◉ No

2.1b) Pregnant women

○ Yes ◉ No

2.1c) Individuals with cognitive/decisional impairment

◉ Yes ○ No

2.1d) Non-English-speaking individuals

○ Yes ◉ No

2.1e) Prisoners of War (explicitly targeting this group)

○ Yes ◉ No

2.1f) Non-Veterans (Note: Justification for inclusion of non-Veterans will be required)

○ Yes ◉ No

2.1g) Incarcerated individuals (Note: VA CRADO approval will be required)

○ Yes ◉ No

2.1h) VA employees - including VA paid, IPA, or WOC (Note: Union review and authorization may be required)

○ Yes ◉ No

2.1i) Students of the institution (e.g., resident trainees) or of the investigator

○ Yes ◉ No

2.1j) Patients with cancer (or high cancer risk) [explicitly targeting this group]

○ Yes ◉ No

Section 3 - Study Features (these items default to "No" for convenience)

3) This section consists of several Yes/No questions addressing protocol characteristics. Click on *Save and Continue*.

Section 3.1 Protocol Basics

Select all that apply

3.1a) The research **intends to change** the participant.

◉ Yes ○ No

3.1b) **Interactions** with living participants to collect data or specimens with no intent to change them.

○ Yes ◉ No

3.1c) This is a study that **never** has any **subject contact and does not collect subject identifiers**

○ Yes ◉ No

3.1d) This is a **chart review** study involving retrospective or prospective medical records.

○ Yes ◉ No

3.1e) This is a **multi-site** study occurring in-part or in-full at other locations.

○ Yes ◉ No

3.1f) There is an **international** component to this research. *International research includes sending or receiving human derived data or specimens (identifiable, limited data set, coded, or deidentified) to or from an international source. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator.*

○ Yes ◉ No

3.1g) This study includes **off-station activity** (not including VA-leased space or CBOC clinics) conducted under VASDHS IRB approval. *Note: this does not include research conducted by a collaborator at their home institution under their institutional approval.*

○ Yes ◉ No

3.1h) VA subjects will **participate** in part or in full **at other locations** (not including VA-leased space or clinics) under VASDHS IRB approval.

○ Yes ◉ No

Section 3.2 Specimen Use and Data Repository

Indicate whether or not each of the following applies to this protocol

3.2a) Involves specimens that are left over from pathological or diagnostic testing (**non-research specimens**)

○ Yes ◉ No

3.2b) Involves **specimens collected for research** purposes **only**

○ Yes ◉ No

3.2c) This study includes **specimen banking** (specimens are retained for use outside of the purposes of this protocol)

○ Yes ◉ No

3.2d) The study involves **DNA** genotyping or other **genetic analysis**

○ Yes ◉ No

3.2e) Biological **specimens/material** will be sent outside of the VA.

○ Yes ◉ No

3.2f) A **data repository** is maintained (data are retained after completion of the protocol for other uses, IMPORTANT: see **?** before checking "yes")

○ Yes ◉ No

3.2g) **Data will be shared outside** of the VA (identifiable, coded, limited data set, or deidentified)

◉ Yes ○ No

Section 3.3 Treatment and Clinical Trials

Indicate whether or not each of the following applies to this protocol

3.3a) Includes a **treatment** component (a research treatment)

◉ Yes ○ No

3.3b) Study is a **clinical trial.** *Note: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.*

○ Yes ◉ No

3.3c) Has a data safety monitoring board (**DSMB)** or data safety monitoring committee.

○ Yes ◉ No

3.3d) Has a **data safety monitoring plan** (but not a DSMB) (this is not the data security plan, it is a safety plan).

○ Yes ◉ No

Section 3.4 Drugs and Devices

Indicate whether or not each of the following applies to this protocol

3.4a) **Drugs** that require **FDA** action such as an Investigational New Drug (IND) approval or exemption or 510(k) approval.

○ Yes ◉ No

3.4b) Other drugs, supplement, etc. that **do not require FDA** action for inclusion in the study.

○ Yes ◉ No

3.4c) Medical **devices requiring FDA** IDE approval or waiver

○ Yes ◉ No

3.4d) **Other** medical **devices**

○ Yes ◉ No

Section 3.5 Risk and Hazards

Indicate whether or not each of the following applies to this protocol

3.5a) Study places subjects at **greater than minimal risk** (do not include risks that are due to standard care)

○ Yes ◉ No

3.5b) Human subjects are exposed to **radioisotopes** (do not include standard care).

○ Yes ◉ No

3.5c) Subjects have other **radiation exposure** (e.g., x-rays) (do not include standard clinical use).

○ Yes ◉ No

3.5d) Target population has psychiatric diagnosis or behavioral complaint.

◉ Yes ○ No

Section 3.6 Clinical Facilities and Standard Care

Indicate whether or not each of the following applies to this protocol

3.6a) Study **uses VA clinical services** (e.g., adds required tests run in the VA lab for study purposes; research procedures concurrent with clinical care)

○ Yes ◉ No

3.6b) Includes procedures or drugs that will be considered **part of standard care.**

○ Yes ◉ No

3.6c) Involves **lab tests done for research** purposes.

○ Yes ◉ No

Section 3.7 Subject Expenses and Compensation

Indicate whether or not each of the following applies to this protocol

3.7a) There may be expense or added **costs to the subject** or the subject's insurance.

○ Yes ◉ No

3.7b) This is a **qualifying cancer treatment trial** and subjects may be billed for study drugs or procedures.

○ Yes ◉ No

3.7c) This is a cancer treatment trial but **subjects will not be billed** for study drugs or procedures.

○ Yes ◉ No

3.7d) Subjects will be **compensated** (either in cash or other means such as a gift certificate).

◉ Yes ○ No

Section 3.8 Subject Activities

Indicate whether or not each of the following applies to this protocol

3.8a) Involves **surveys or questionnaires** completed by subjects

◉ Yes ○ No

3.8b) Includes the use of **recruitment materials** such as flyers, advertisements, or letters

◉ Yes ○ No

3.8c) Involves facial **photographs** or audio or video **recordings** of **patients**

◉ Yes ○ No

Section 3.9 Sponsors and Collaboration

Indicate whether or not each of the following applies to this protocol

3.9a) This research is a funded research project **(commercial (industry) sponsor, NIH, VA, other).**

(•) Yes ( ) No

3.9b) Other **commercial (industry) non-financial support** is provided (e.g., drugs or supplies).

( ) Yes (•) No

3.9d) The protocol has **Department of Defense** involvement (e.g., subjects or funding).

( ) Yes (•) No

3.9c) The PI or other study staff member has a financial interest or other **real or potential conflict** related to this study.

( ) Yes (•) No

3.9e) This study involves **collaborative** research activities (research conducted at other institutions under the authorities or approvals of the other institution/s). *Note: this may include other VA and/or non-VA institutions, but does not include off-site VA research.*

( ) Yes (•) No

Section 4 - Estimated Duration

4) What is the estimated duration of the entire study? (From IRB approval to IRB closure)

2 years

Section 5 - Lay Language Summary

5) Provide a summary or synopsis of the proposed study using non-technical language (not more than 1 paragraph)

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the first-line treatment for chronic insomnia. However, cognitive impairments may limit progress in CBT-I for older Veterans with Mild Cognitive Impairment (MCI). This study will develop and pilot test Sleep-SMART (Sleep Symptom Management and Rehabilitation Therapy), an adapted CBT-I treatment that incorporates Cognitive Symptom Management and Rehabilitation Therapy (CogSMART) principles with a goal of improving sleep treatment and rehabilitation outcomes for Veterans with co-occurring MCI and insomnia. The innovation of this study centers on enhancing CBT-I by providing supportive cognitive strategies designed to improve treatment adherence, learning, and acceptability. We anticipate that by improving sleep we can concurrently improve daily functioning, increase quality of life, prevent or reduce late-life disability, and mitigate long-term cognitive decline in this Veteran population.

Section 6 - Specific Aims

6) Provide a statement of specific aims and hypotheses that serve as the basis for this protocol. Emphasize those aspects that justify the use of human subjects.

Aim 1: Develop the Sleep-SMART intervention and treatment manual using a participatory research approach during a 6-month development phase.
Aim 2: Assess the feasibility and acceptability of Sleep-SMART in 26 Veterans aged 60 or older with MCI and insomnia.
H1: Feasibility. 26 Veterans will be enrolled. At least 20 Veterans will complete the treatment. Feasibility will also be assessed by collecting data on recruitment; refusal rate; reasons for treatment discontinuation; treatment fidelity; and tracking contextual barriers and facilitators for implementation.
H2: Acceptability. Veterans will find Sleep-SMART acceptable as measured by the Client Satisfaction Questionnaire (CSQ); Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM); qualitative interview data; percent of sessions attended; and treatment adherence (percent homework completion, basic skills assessment of treatment material, and discrepancy scores between prescribed sleep time and objectively recorded sleep).
Aim 3: We will explore the effects of Sleep-SMART on rehabilitation outcomes (WHODAS 2.0, ILSS), quality of life (QOLI), sleep (PSQI, ISI, sleep efficiency), and cognitive functioning (subjective: Neuro-QOL and ECog; objective: neuropsychological assessment).

Section 7 - Background and Significance

7) Provide a succinct discussion of relevant background information to justify performing the proposed study.

The population of older Veterans is growing rapidly, with approximately 13 million Veterans age 55 or older, representing over two-thirds of all Veterans. Given the exponential increase in aging Veterans, cognitive decline and dementia are a significant public health issue. Mild Cognitive Impairment (MCI) is a transitional state between normal aging and dementia characterized by deficits in memory or other cognitive domains with intact everyday functioning. The prevalence of MCI is 15-20% in people over 60. However, aging veterans are at an elevated risk for developing MCI and dementia. Sleep disturbance is one of the core non-cognitive symptoms of MCI, with over half of MCI patients experiencing insomnia symptoms. Chronic insomnia is associated with greater risk of cognitive decline, and recent research has shown that sleep disturbances are associated with the pathogenesis of dementia.

In addition to increased risk of cognitive decline, a growing number of studies demonstrate associations between insomnia symptoms and disability among older adults. Insomnia has been linked to limitations in activities of daily living, greater difficulty with household tasks, and restricted participation in community events. Insomnia is associated with a decline in physical functioning and greater fall risk, which can lead to injuries and increased disability. Veterans are particularly vulnerable to insomnia, with rates double and even triple those of civilian populations. Thus, older Veterans with MCI and comorbid insomnia represent a high-risk population for future development of more severe cognitive and functional decline.

Cognitive Behavioral Therapy for Insomnia (CBT-I) is the first-line treatment for chronic insomnia and is effective in older adults and Veterans. Compared to pharmacologic treatment, CBT-I is as effective in the short-term and more effective in the long term for treatment of insomnia. However, cognitive impairments may limit the rate of progress in CBT-I for older Veterans with MCI. For example, memory impairment is associated with worse treatment adherence and poorer clinical outcomes. Incorporating supportive cognitive strategies from Cognitive Symptom Management and Rehabilitation Therapy (CogSMART) into a CBT-I protocol has the potential to improve treatment learning, adherence, and outcomes for this Veteran population. CogSMART is an evidence-based manualized intervention that provides compensatory strategies to improve attention, learning, memory, and executive functioning. It has been shown to improve cognition, functional capacity, neurobehavioral symptom severity, and quality of life in Veterans with psychiatric illness, TBI, and MCI.

The proposed study aims to develop and pilot test Sleep-SMART (Sleep Symptom Management and Rehabilitation Therapy) - a modified CBT-I treatment that incorporates select CogSMART strategies to enhance CBT-I learning and adherence for Veterans with co-occurring insomnia and MCI. CBT-I has been adapted for various populations, including older adult civilians with MCI. However, Veterans face unique barriers and challenges. Therefore, Sleep-SMART will be developed for and with Veterans. Specifically, we will develop the Sleep-SMART intervention and manual using a systematic user-centered process that will allow for maintaining fidelity to core CBT-I components while improving the fit for Veterans with MCI by incorporating purposely selected CogSMART strategies - the goal of which is to assist Veterans with cognitive impairments in maintaining adherence to the CBT-I regimen, thereby leading to faster and more complete sleep treatment benefits. Sleep-SMART will consist of six 50-minute individual sessions and will be delivered via telehealth (video-conferencing), creating the potential for wide dissemination and broader reach to Veterans who may face barriers to accessing care or safety concerns related in-person treatment. By attending to and addressing the cognitive barriers to successful sleep treatment, we can alter the course of the Veterans' trajectories and help prevent the negative consequences of chronic insomnia in this vulnerable Veteran population.

Section 9 - Design and Methods

9) Describe the research design and the procedures to be used to accomplish the specific aims of the project. Provide a precise description of the planned data collection (include what systems or databases will be used/accessed to gather data), analysis and interpretation. For chart review studies, include the timeframe of collection. Address sample size, inclusion of women and minorities. Define in clear terms exactly what will be done to the human subjects.

Phase I – Sleep-SMART Treatment Development (6 months)

Overview: We propose to develop the Sleep-SMART intervention and manual over the first 6 months of the project. The standard CBT-I approach is based on the VA Evidence-Based CBT-I Treatment Roll-out manual, and involves six 50-minute sessions, addressing several important concepts including the underlying causes of insomnia, sleep restriction and stimulus control techniques, sleep hygiene, stress

management, and relapse prevention. CogSMART is a manualized intervention providing training in strategies to improve prospective memory, attention, learning/memory, and executive functioning. CogSMART is based on theories of cognitive compensation and habit learning. Sleep-SMART is intended to be a treatment for insomnia that will follow the standard 6 session 50-minute CBT-I format and will deliver CBT-I treatment along with training in select CogSMART strategies to enhance intervention learning and adherence.

Development Approach: The study team, whose members have expertise working with the target population and in developing manualized treatments currently used at the VASDHS, will develop the Sleep-SMART treatment and manual using a multistep, participatory, and systematic approach (IM Adapt) with input from diverse stakeholders.

Development Process: 5 Veterans from the target population will be recruited to participate in a confidential focus group in which they will answer semi-structured questions about their interest in a cognitively enhanced insomnia treatment; their perspectives on the adequacy of current treatment-as-usual; personal reservations about behavioral treatment for sleep; current challenges with sleep, cognition, and daily living; perceptions about CBT-I and CogSMART strategies; opinions on telehealth and technology for the delivery of health services; etc. The focus group will be audio-recorded and transcribed for qualitative analysis. The investigators will make revisions to the existing VA Evidence-Based CBT-I Treatment Roll-out manual based on professional expertise and stakeholder feedback while ensuring protection of key CBT-I ingredients. Subsequently, 2-4 VHA providers (who work with the populations of interest) will individually review the manual and will be asked to make notes of their perceptions, including ease of use, content, structure, length, exercises, and components that may not resonate with the Veteran population or would not be feasible. This information will be used to guide additional revisions and adaptations. All focus group and expert feedback will be reviewed and discussed by the full study team using decision making rules outlined in Goldstein et al. (2012) before finalizing adaptations and pilot testing the intervention. We will use the expanded Framework for Reporting Adaptations and Modifications (FRAME) model as a guide for tracking and organizing adaptations. Deliverables from the development phase will include the Sleep-SMART treatment manual.

***P*hase II – Pilot Testing the Sleep-SMART Intervention**

For Phase II, we will enroll 26 participants ages 60 and older.

Pre-Treatment Assessment (2 hours in person): Following informed consent, insomnia diagnosis will be confirmed based on a structured clinical sleep disorder interview and ISI score >7. Participants will also be administered a battery of self-report questionnaires selected to assess quality of life, daily functioning, disability, sleep, and subjective cognitive functioning, as well as a brief (45 min) standardized neuropsychological battery to pilot procedures for a larger trial. To reduce fatigue, participants will be offered and encouraged to take breaks as often as needed when appropriate. Participants will then complete a sleep diary for 14-days to prospectively record sleep and will be given an actigraph (a wearable activity/sleep monitor) to wear continuously for the 14-day baseline evaluation.

Sleep-SMART Treatment Phase (6 sessions virtual): A licensed clinical psychologist with experience delivering CBT-I will deliver the 50-minute 6-session Sleep-SMART intervention via secure home-based video teleconferencing (e.g., Veteran Video Connect or Webex). Throughout the treatment phase, Veterans will be asked to keep a sleep diary as part of treatment. Missed and rescheduled appointments will be allowed, however we will limit total treatment completion time to 8 weeks from the first treatment session.

Post-treatment Assessment (2 hours in person): After completing the treatment, all Veterans will fill out a sleep diary and wear an actigraph for the 14-day post-treatment evaluation. Veterans will also be scheduled for a post-treatment assessment that will include completion of a) self-report questionnaires, b) neuropsychological testing, and c) a brief semi-structured interview.

Measures

Self-report measures of quality of life, daily functioning, disability, sleep, and cognition : WHO Disability Assessment Schedule 2.0 (WHODAS 2.0); Independent Living Skills Survey (ILSS); Quality of Life Inventory (QOLI); Neuro-QOL scales: Applied Cognition Executive Functions Scale and Applied Cognition General Concerns Scale ; Everyday Cognition Scale (ECog); Sleep Diaries; Actigraphy; Insomnia Severity Index (ISI); Pittsburgh Sleep Quality Index (PSQI); Hopkins Verbal learning Test Revised (HVLT-R); Brief Visuospatial Memory Test-Rev (BVMT-R); Wechsler Adult Intelligence ScaleIV (WAIS-IV) Digit Span ; DKEFS Trails (Number and Letter Sequencing & Number-Letter Switching); D-KEFS Verbal Fluency.

Feasibility: Feasibility in this investigation will be measured by: 1) **Recruitment:** absolute number, proportion, and representativeness of individuals willing to participate, documenting the utility of recruitment strategies, recording reasons for not participating, and noting challenges in meeting inclusion /exclusion criteria; 2) **Accrua**l: estimated as the number of patients accrued divided by the number of months of accrual; 3) **Refusal Rate:** estimated as the number of patients who refuse to participate divided by the number eligible; 4) **Retention:** defined as the percentage of Veterans who complete the 6-session treatment; 5) Participants who drop out will be contacted via telephone to document **Reasons for**

Treatment Discontinuation; 6) **Treatment Fidelity:** Therapist Checklist; 7) Feasibility of Intervention Measure (FIM) completed by study therapists at post-intervention; and 8) **Periodic Reflections** in which the research team will engage in guided monthly discussions, using the template provided by Finley et al. 2018, to ensure consistent documentation of key activities and other phenomena, e.g., barriers and facilitators.

Acceptability: Acceptability in this investigation will be measured by collecting the following data from Veteran participants: 1) client Satisfaction Questionnaire (post-treatment); 2) **Percent of sessions attended;** 3) **Treatment adherence** : percent homework completion, basic skills assessment of treatment material, and discrepancy scores between prescribed sleep time and objectively recorded sleep; 4) **Telehealth Usability Questionnaire** (TUQ); and 5) **Semi-Structured Interview** in which a trained clinical research staff member will conduct a 20-minute audio-recorded, post-intervention semi-structured qualitative interview which will involve administration of the Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) followed by the collection of qualitative data for each of these scales as well as additional information regarding barriers, facilitators, etc., to inform refinements to the intervention and to inform future delivery and scale up of Sleep-SMART via telehealth.

Data Analytic Plan

Qualitative data: Interview and focus group data will be independently coded by two project team members using a rapid qualitative analytic approach described by Hamilton and colleagues. A third team member will assess coding quality and resolve conflicts. Using a mixed-methods convergent design approach, the qualitative data will be used to explain and support/refute the quantitative data and to inform treatment refinement as well as future implementation efforts.

Quantitative data : Descriptive statistics will be obtained for all quantitative variables, including distributions, means, medians, variances, standard deviations, skewness, kurtosis, ranges, and quartiles. SPSS Version 27 will be used for all quantitative analyses.

Section 9.8 Questionnaires & Surveys

9.8) Provide the name and a reference for questionnaires/surveys that are standard or identify them here and attach a copy of the questionnaire/survey. ***Questionnaires or surveys that are not clinical standard references must be uploaded. Reference the help link for additional information related to surveys administered to VA personnel and approved platforms for web-based surveys.***

WHO Disability Assessment Schedule 2.0 (WHODAS 2.0): Üstün TB. Measuring Health and Disability: Manual for WHO Disability Assessment Schedule WHODAS 2.0. World Heal Organ. 2010.

Independent Living Skills Survey (ILSS): Wallace CJ, Liberman RP, Tauber R, Wallace J. The Independent Living Skills Survey: A comprehensive measure of the community functioning of severely and persistently mentally ill individuals. Schizophr Bull. 2000. doi:10.1093/oxfordjournals.schbul.a033483

Quality of Life Inventory (QOLI): Frisch MB, Cornell J, Villanueva M, Retzlaff PJ. Clinical Validation of the Quality of Life Inventory: A Measure of Life Satisfaction for Use in Treatment Planning and Outcome Assessment. Psychol Assess. 1992. doi:10.1037/1040-3590.4.1.92

Neuro-QOL scales- Applied Cognition Executive Functions Scale and Applied Cognition General Concerns Scale: Cella D, Nowinski C, Peterman A, et al. The neurology quality-of-life measurement initiative. Arch Phys Med Rehabil. 2011. doi:10.1016/j.apmr.2011.01.025

Everyday Cognition Scale (ECog): Farias ST, Mungas D, Reed BR, et al. The Measurement of Everyday Cognition (ECog): Scale Development and Psychometric Properties. Neuropsychology. 2008. doi:10.1037/0894-4105.22.4.531

Insomnia Severity Index (ISI): Bastien CH, Vallières A, Morin CM. Validation of the insomnia severity index as an outcome measure for insomnia research. Sleep Med. 2001. doi:10.1016/S1389-9457(00)00065-4

Pittsburgh Sleep Quality Index (PSQI): Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Res. 1989. doi:10.1016/0165-1781(89)90047-4

Feasibility of Intervention Measure (FIM);Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM): Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017. doi:10.1186/s13012-017-

0635-3

Client Satisfaction Questionnaire (CSQ): Attkisson CC, Zwick R. The client satisfaction questionnaire. Eval Program Plann. 1982.

Telehealth Usability Questionnaire (TUQ): Parmanto B, Lewis, Jr. AN, Graham KM, Bertolet MH. Development of the Telehealth Usability Questionnaire (TUQ). Int J Telerehabilitation. 2016. doi:10.5195/ijt.2016.6196

Columbia-Suicide Severity Rating Scale (CSSRS): Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., Currier, G. W., Melvin, G. A., Greenhill, L., Shen, S., & Mann, J. J. (2011). The Columbia-Suicide Severity Rating Scale: Initial validity and internal consistency findings from three multisite studies with adolescents and adults. The American Journal of Psychiatry, 168(12), 1266–1277. https://doi.org/10.1176/appi.ajp.2011.10111704

Section 9.11 Pictures and Audio/Video Recordings of Patients

9.11) Describe the purpose of photographs (facial), or audio, or video recordings of patients. Describe whether the recordings will contain, or potentially contain, identifiers. ***Note: use of photographs or recordings must be covered in the informed consent process and documented consent documents (e.g., consent form, information sheets, telephone screen scripts).***

The focus group and qualitative interviews will generate digital voice files, which are considered identifiers. To minimize risk, during recorded interviews participants will only be identified using their project ID number, and there will be no mention of their name or other identifiers. All digitally recorded interviews will be transcribed by research staff for verbatim transcription. The transcription will not include any identifying information accidentally disclosed in interviews. In addition, Webex treatment sessions will be video recorded for training and fidelity purposes.

Section 10 - Human Subjects

10) Describe the characteristics of the proposed subject population. Include age, gender, ethnicity, and health status as appropriate. ***Note: Data about people are still considered "human subjects" by the IRB, so even if you do not intend to contact the patients whose charts you will review, you still describe the characteristics related to the subjects whose charts you will review.***

- **Provide inclusion and exclusion criteria as appropriate. Provide a statement how non pregnancy is confirmed if pregnancy is an exclusion criteria.**
- **For multisite studies, provide the total number of subjects from all sites and include description of the local site's role as a coordinating center if applicable.**
- **Indicate the number of VA participants to be studied.**
- **Indicate the estimated number of consented subjects that will fail the screening process, if any.**

The proposed study will consist of two phases: development of the Sleep-SMART intervention and treatment manual (Phase I) and pilot testing to assess feasibility and acceptability of the intervention (Phase II).

In Phase I, we will recruit 5 Veterans ages 60 and older with co-occurring MCI and insomnia to participate in a onetime 45-minute focus group.

For Phase II, we will enroll 26 participants ages 60 and older with co-occurring MCI and insomnia.

We will make every effort to recruit women for this study. To ensure adequate ethnic/racial diversity in our sample we will also attempt to recruit a sample composed of at least 25% of individuals from ethnic/racial minority groups, including Hispanic/Latino and African American, consistent with the 2013 US Census. We will not include children in the study.

Inclusion criteria for this study include:
1.Veteran ages 60 or older who are competent to provide informed consent.
2.Chart diagnosis of MCI based on previously published criteria, as assessed by the VASDHS Neuropsychological Assessment Unit.
3.A DSM-5 diagnosis of insomnia corroborated by an Insomnia Severity Index score >7 at intake.
4.Must be able to understand, speak, and read English with acceptable visual and auditory acuity.

Exclusion criteria for this study include:
1.Sleep disorders other than insomnia as determined by medical chart review and clinical interview.
2.History of a neurological disorder, dementia, and moderate or severe TBI.
3.Auditory, visual, or other impairments that would prevent ability to use the computer device or participate in assessments.
4.Schizophrenia, psychotic disorder, bipolar disorder, and/or current substance use disorder.
5.Evidence of suicidality more than "low risk" as assessed by the Columbia Suicide Severity Rating Scale (CSSRS)at intake (pre-treatment assessment)

Section 10.5 Individuals with Cognitive/Decisional Impairment

10.5) Provide the rationale and additional study procedures that will be required for including individuals with known cognitive impairment or institutionalized individuals. ***Address Decisional Capacity Assessment and Surrogate Consent Sections 12.6 and 12.7.***

Informed consent will be obtained at the time of the first study visit (i.e., focus group or pre-treatment evaluation). When the subject arrives for the appointment, a verbal explanation of the protocol will be given by the Principal Investigator or a member of the research team. A post-consent quiz will also be administered to ensure adequate understanding of the key elements of the study. If the subject performs adequately on the post-consent questionnaire, they will be asked to sign the consent form. If the subject is unable to demonstrate capacity to sign the consent form, they will be thanked for being a possible subject in the study and excused from the rest of testing. Given that we will be recruiting patients with mild cognitive impairment, as opposed to demented individuals, it is not anticipated that any patients will be unable to consent.

Section 11 - Recruitment

11) Describe, step-by-step, the plans for recruitment of subjects (or selection of subjects as in record review). This description must include how, when, and where potential subjects are approached as well as procedures for identifying potential participants (through medical records, physician referral, third-party sources, etc.). Include how selection is equitable. Indicate if vulnerability to coercion may be present and if so plans to ensure voluntary participation.

Eligible Veterans be recruited from relevant VASDHS clinics, though primarily from colleagues in the Neuropsychological Assessment Unit, which receives an average of 55 to 60 new consults per month. MCI is among the most common diagnosis and roughly 75-100% of Veterans screened through the neuropsychology unit report symptoms consistent with insomnia.

Recruitment will be accomplished through:

1. A flyer (Recruitment Brochure) describing study participation posted in VASDHS clinics.

2. Dr. Bondi will also directly refer patients from the Neuropsychological Assessment Unit (using the Research Candidate form).

3. Potential participants may be recruited from co-investigators' research studies previously completed (e. g., Dr. Twamley's research studies). If a research participant who is potentially eligible for our study indicated in the previously completed research study that they would like to be contacted for future research opportunities, he or she will be informed of our research opportunities via phone call by a research assistant. If the patient indicates that they are not interested, the research assistant will thank them for their time and will not contact them again regarding the study.

4. Potential participants may also be recruited by a search of ICD codes for MCI and insomnia in CPRS. Any patients not previously referred to our study from VASDHS clinics and sources aforementioned, who may be eligible for
the study, will be notified via the uploaded Recruitment Letter (Recruitment Contact Form) that a research assistant on this protocol will be contacting them approximately 2 weeks from the day the letter is sent. A research assistant will then call the patient to explain the study and gauge interest in participating. If the patient indicates that they are not interested, the research assistant will thank them for their time and will not contact them again regarding the study.

All potential participants will meet via telephone or in-person with a member of the research team who will explain the study's purpose and answer any initial questions. If the individual expresses interest in the study, they will be administered an pre-consent screen, which will inquire about the inclusion/exclusion criteria to determine eligibility.

Participants will be recruited from both genders and each ethnic group in proportions representative of those in VASDHS.

Section 11.1 Recruitment Materials

11.1) Identify all recruitment materials (flyers, advertisements, letters, etc.) that will be used; include the web address for any web-based advertisements. The text of all communications with prospective participants must be reviewed and approved by the IRB before it can be used. You will be reminded to attach copies of recruitment materials to the initial submission packet.
Note: Posting of flyers with pull tabs is not permitted within VASDHS (including the VMRF building).

Recruitment will take place at the VA San Diego. Recruitment methods include:

1. Obtaining referrals through VA San Diego's Neuropsychology Clinic via the Research Candidate Form.

2. Recruitment brochures will be posted in relevant VASDHS clinics.

3. Recruitment Contact Form will be sent to potential participants based on a search of ICD codes for MCI and insomnia in CPRS.

Participants will also be recruited from other studies completed if they had indicated they would like to be contacted for future research opportunities.

Section 12 - Informed Consent

12) Indicate whether or not each category of consent is involved in this study:

12a) Will the study team obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without (or prior to) obtaining informed consent of the prospective subject or the prospective subject's LAR?

(●) Yes ( ) No

Check one or both of the below boxes if they apply to this study:

Information will be obtained through oral or written communication with the prospective subject or the subject's Legally Authorized Representative (LAR) and this is not a FDA regulated study.

(●) Yes ( ) No

Identifiable information or biospecimens will be obtained by accessing records or stored identifiable biospecimens and this is not an FDA regulated study.

(●) Yes ( ) No

If either or both of the above boxes is checked "yes", an informed consent waiver does not have to be requested for this activity if the protocol is initially approved after 01/01/2019 or if it has been converted to the 2018 Common Rule requirements. However, a request for a HIPAA waiver will still need to be requested and informed consent obtained for any research interventions after eligibility is established. Otherwise, waivers of consent and authorization must be requested for this activity. Waivers of consent and authorization are required for screening purposes for FDA regulated research.

12b) **Signed** informed consent

(●) Yes ( ) No

12c) Waiver of documented consent (e.g., **oral** consent) for all or part of the study.

( ) Yes (●) No

12d) Request for a **waiver** of consent for all or some study activities.

○ Yes ◉ No

12e) Alteration of **other required elements** of consent.

○ Yes ◉ No

12f) **Child** assent to participate (Director approval will be required)

○ Yes ◉ No

12g) Will any language **other than English** be used by those obtaining consent and understood by the prospective participant or the legally authorized representative?

○ Yes ◉ No

12h) **Decisional Capacity Assessment** to determine if participants have the capacity to consent for themselves.

◉ Yes ○ No

12i) **Surrogate** consent (legally authorized representative)

○ Yes ◉ No

Section 12.1 Informed Consent Process

12.1a) Will consent be obtained before any study procedures are performed (including screening procedures except screening procedures with Consent/HIPAA waiver approval)?

◉ Yes ○ No

12.1b) Will the information being communicated to the participant or legally authorized representative during the consent process include exculpatory language through which the participant or legally authorized representative is made to waive or appear to waive any of the participant's legal rights or release or appear to release the Researcher, Sponsor, the VA or its agents from liability for negligence.

○ Yes ◉ No

12.1c) A master list of all VA subjects consented (written or not) under this protocol will be maintained.

◉ Agree ○ Disagree

12.1d) Identify the circumstances under which consent will be obtained including where the process will take place; any waiting period between describing the research and obtaining consent including sufficient time for the prospective participant to consider participation, and any steps taken to minimize the possibility of coercion or undue influence.

Informed consent will be obtained at the time of the baseline (pre-intervention) assessment visit or prior to participating in the focus group. All potential interested participants will have previously spoken or met with a member of the research team who explained the study's purpose, answered any questions, and conducted a prescreening interview to determine eligibility.

During consenting, the research study personnel will read the informed consent to the participants while they follow along with their own copy. Participants will receive a thorough explanation of the nature of the intervention, their study involvement duration, compensation for their participation, possible risks and benefits, and potential alternative treatments. Study personnel will answer participant questions as they arise. Additionally, participants will be administered a decisional capacity assessment to ensure that they understand all parts of the study.

All participants will be provided with a copy of the consent document and a copy of the Experimental Subject' s Bill of Rights. Informed consent will be documented with the VA IRB-approved written consent form that each participant will sign in-person prior to participation. Signed and witnessed consent forms

will be kept on file in a specially secured cabinet. To avoid coercion, potential participants will be informed verbally, and in the consent form, that they may withdraw at any time, skip any questions they choose not to answer, and that the information they provide will not affect their care at VASDHS.

Section 12.6 Decisional Capacity Assessment

12.6a) Describe the method(s) for determination of decisional capacity: (see ? for guidance) ***Please note that documentation of the assessement is required.***

Capacity to consent for this study will be evaluated with a consent quiz, which will include questions about the purpose of the study, length of the study, potential risks and benefits, and the ability to withdraw at any time without penalty. Potential participants will be given three chances to answer each question correctly, with the correct information provided in the event the individual answers incorrectly. The Veteran will be given ample time to ask questions about the study and will also be given time to make a decision and discuss with other appropriate parties his or her participation in the study prior to giving informed consent. If the investigator determines that the participant does not meet the criteria to provide informed consent, he/she will not be enrolled in the study.

12.6b) If subjects with limited decisional capacity will be enrolled, describe methods for obtaining subject assent or why they are not indicated:

Participants with limited decisional capacity will not be enrolled.

12.6c) If subjects with limited decisional capacity will be enrolled, describe procedures for respecting subject dissent and any additional safeguards or why these features are not needed:

Participants with limited decisional capacity will not be enrolled.

12.6d) If subjects with limited decisional capacity will be enrolled, describe the risk and, if greater than minimal, the relation to potential benefits:

Participants with limited decisional capacity will not be enrolled.

12.6e) If subjects with limited decisional capacity will be enrolled, describe the justification for the inclusion of any incompetent persons or persons with impaired decision-making capacity:

Participants with limited decisional capacity will not be enrolled.

Section 12.9 HIPAA Authorization

For each category below, indicate whether or not this study involves the indicated process:

12.9a) **Signed** HIPAA Authorization. ***New Template is available in the ? Help section****

(•) Yes ( ) No

12.9b) HIPAA waiver to cover the entire study

( ) Yes (•) No

12.9c) HIPAA waiver for recruitment, screening, and/or for a portion of the study.

(•) Yes ( ) No

12.9d) HIPAA Authorization or waiver is **not required** for some or all of the study subjects (e.g. no health data).

( ) Yes (•) No

Section 12.10 HIPAA Waivers and Alterations

12.10a) Describe the purpose/nature of the HIPAA waiver or alteration and list specifically, what identifiers and health information are being requested under the waiver/alteration and identify whether the waiver is for access, use, and/or collection of this information.

1) The waiver will be used to conduct a brief phone screen used to determine eligibility for the study so that potential participants do not waste time and unnecessary hardship traveling to the VASDHS. The study could not be practically conducted without the waiver and without access to and use of PHI.

The subjects will be screened via phone call to determine eligibility to participate. Contact information will also be collected to provide potential participants information on the study and follow-up with eligibility. The data that will be collected under the waiver will include:
-Name
-Mailing address
-Phone number(s)
-Neurological and psychiatric diagnoses
-Age
-Last 4 of SSN

Immediate inclusion/exclusion questions include questions about sleep, insomnia, other sleep disorders, cognitive functioning, major medical conditions, and other general health-related questions (See attached Phone Screen).

2) The waiver will also be used to recruit potential study participants through the Neuropsychology Assessment Unit and other relevant clinics at VASDHS. Veterans who may be interested will be asked to sign a Research Candidate Form while at clinic, and a research assistant will contact them if they indicate on the form that they agree to be contacted. Additionally, the provider may inform the research team of a potential study participant. At that point, a research assistant will either go speak to the patient in person about the study if the patient expresses interest in meeting with study staff, or will send the patient a letter stating that we will be calling them about a research opportunity.

The Research Candidate form asks for the patient's name, provider name, appointment day/time, and telephone number (if they indicate they would like to be contacted). Calling the subject will require patient's name and telephone number to later be contacted.

3) The waiver will also be used to reach potential study participants through CPRS (using the ICD codes for MCI and insomnia) as well as to confirm diagnoses of MCI and insomnia for eligibility determinations. Recruiting by ICD code search requires knowing the patient's medical diagnoses (MCI and insomnia). Verifying eligibility requires Veteran's last name and last 4 of SSN.

4) Finally, the waiver will also be used to reach potential study participants through previously completed research studies, if they had agreed to be contacted for future research opportunities. Any patients who may be eligible will be called to inform them of our new research opportunities. This will This will require the patient's name, mailing address, and telephone number to be contacted in the future.

12.10b) The proposed access, use, and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals.

(•) Agree ( ) Disagree

12.10c) The plan to protect the identifiers from improper use and disclosure is adequate.

(•) Agree ( ) Disagree

Describe the plan

Participant identity will be coded immediately upon entry into the study, and neither the participants' names nor any identifying information will be present in the data set. Study records entered into a computer system will be assigned code numbers and will not be individually identifiable. Hardcopy data will be stored in a locked cabinet that is maintained in the PI's locked office (building 1 room 2253) within the VA. All electronic data will be stored within the VA secure network in the PI's VASDHS R: drive folder (R:\PIfolders\Almklov) and will be accessed only by approved study personnel using VA secured workstations.

All SI related to this study will be destroyed in accordance with RCS-10 and under the direction of the VA Records Control Manager. In the event of a real or suspected breach of security, the VA Police, the VA Information Security Officer, and the VA Privacy Officer will be notified.

12.10d) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

◉ Agree ○ Disagree

12.10d2) Describe the plan:

SI, such as subject's medical diagnosis, will be used for the purpose of enrollment and subject's personal information, such as age, gender, and education, will be used to characterize the subject pool utilized in this study. Addresses and telephone numbers will also be collected as a means to contact the subjects for follow-up when indicated. All data used in this study will be de-identified and linked to SI by a subject number. Hard copy SI will also be stored for backup purposes in the PI's office, within Building #1 room 2253.

Data will be destroyed according to RCS-10 under Records Control Manager guidance.

12.10e) By signing this protocol for submission, the PI is providing written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule. 38 U.S.C. 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), by signing this protocol for submission the PI is providing written assurance that the purpose of the data is to conduct scientific research and that no personnel involved may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. (Ref: 38 U.S.C. 7332(b)(2)(B))

◉ Agree ○ Disagree

12.10f) The research could not practicably be conducted without the waiver or alteration.

◉ Agree ○ Disagree

12.10f2) Describe how the waiver/alteration enables the research to be conducted

Without the phone screen for contact information and brief exclusionary criteria there would be no feasible way for us to send participants directions and appointment confirmation. There would also be potential for many participants to travel to VASDHS to participate in the study, sign a consent form only to find out they are ineligible for the study and be excused. This would waste the time of the participant as well the VASDHS.

The ability to contact VA patients directly will allow us to recruit more veterans to be enrolled in the study.

Finally, the ability to access medical diagnoses consistent with study inclusion criteria in CPRS will reduce burden on potential study participants as research staff will be able to verify diagnostic eligibility.

12.10g) The research could not practicably be conducted without access to and use of the PHI.

◉ Agree ○ Disagree

12.10g2) Describe why it would be impracticable to conduct this research without the PHI described 12.10a. (v3/8/18)

The data collected by phone screen is necessary to assess study eligibility.

The research candidate form allows research staff on this protocol to call the Veteran and recruit them for the study, if interested and eligible. This form provides the means to contact the potential participant.

The Veteran's name and contact information will be required for calling individuals who were not presented the opportunity to sign the form (this includes subjects previously enrolled in other studies). The patient's phone number will be required to contact the patient.

Accessing medical diagnoses in CPRS allows the research team to focus recruiting attention on those who

are likely eligible. Additionally, Veteran last name and last 4 of SSN are required to verify diagnostic information in CPRS. Having access to this information will reduce participant burden.

Section 13 - Alternatives to Participation

13) Describe the alternatives to participation in this research study (see ? for guidance)

The alternative to participating is to not participate.

Section 14 - Potential Risks

14) Describe any potential or known risks or discomforts and assess their likelihood and seriousness (see ? for guidance)

Risks to confidentiality (research risk): participation may result in loss of confidentiality due to unforeseen circumstances (fire or flood that may compromise locked data) or in the context of regulatory audits and mandated reporting. Every effort will be made to protect the confidentiality of participant records. However, a risk for potential loss of a participant's confidentiality exists. This is highly unlikely given the precautions taken in the data management plan, but the possibility is not zero.

Risks associated with data collection (research risk and therapeutic risk) include feeling frustrated, bored and/or fatigue during the assessments; and feeling discomfort during focus group or interviews due to talking about emotional topics or symptoms.

Risks associated with sleep treatment (research and therapeutic risk) include feeling discomfort during the therapy process due to talking about emotional topics or symptoms; and initial exacerbation of nighttime sleep difficulties and/or an increase in daytime sleepiness due to sleep restriction component of CBT-I.

Risks associated with video-based treatments (research and therapeutic risk) include the use of video-conferencing to deliver the Sleep-SMART intervention which could potentially result in technical challenges as well as loss of privacy.

Section 15 - Risk Management

15) Describe the procedures for protecting against or minimizing any potential risks/discomforts, and the adequacy of resources for conducting the study and resources participants may need as a consequence of the research. When applicable, include detail of the following safety measures: (a) The type of safety information to be collected, including AEs; (b) Frequency of safety data collection; (c) Frequency or periodicity of review of cumulative safety data; (d) Statistical tests for analyzing the safety data to determine if harm is occurring; and (e) Conditions that trigger an immediate suspension of the research. See ? for further requirements.

Protection from Risks Associated with Confidentiality: The following steps are taken to minimize the risk to confidentiality. Electronic data will be stored on a secure research drive on our VA network, accessible only to VA research personnel associated with the proposed study. Electronic records will include a password-protected key linking participant numbers with subject names. Paper records will be coded by participant number only and will not include names. All paper records will be kept in locked cabinets in a locked room. A special custom-tailored database system will be developed for this project to ensure the highest possible data reliability. Data entry programs will include double data entry, item prompts, skip patterns, range checks, and logical validity routines. Copies of audio files from staff qualitative interviews will be stored on the VA secure server. The focus group and qualitative interviews will generate digital voice files, which are considered identifiers. To minimize risk, during recorded interviews participants will only be identified using their project ID number, and there will be no mention of their name or other identifiers. All digitally recorded interviews will be transcribed by research staff for verbatim transcription. The transcription will not include any identifying information accidentally disclosed in interviews. Participants will be instructed not to state any names or other identifying information in their interviews. Any identifying information found in voice files from the qualitative interviews would be accidental and rare; no identifying information will be found in transcripts. The transcription files will be stored on a VA server behind the VA firewall. Members of the investigative team will be well educated regarding the protection of patients' rights to confidentiality. Identities of participants will not be revealed in the publication or presentation of any results from this project. Procedures specified in the consent forms are consistent with HIPAA regulations. All investigators and research staff will complete the VA human subject'

s certification requirements, as well as certification in HIPAA regulations.

Protection from Risks Associated with Data Collection: To minimize the risk of patient discomfort, Veterans will be informed that they have the right to refuse to answer questions or to terminate their participation in the study at any time without prejudice. In cases where Veterans are frustrated, bored, and/or fatigued during assessments they will be given the opportunity to take breaks prior to resuming work on these tasks. Clinical staff will be available if immediate in-person evaluation is required for medical or mental health issues.

Protection from Risks Associated with Sleep Treatment: Patients will be given adequate time during therapy sessions to address significant concerns that may arise in session and between sessions. The CBT-I treatment utilizes sleep restriction in early sessions, which may lead initially to poorer nighttime sleep and/or greater levels of daytime sleepiness. Therefore, during treatment Veterans will be carefully and repeatedly advised of this potential side-effect. At the session prior to initiation of sleep restriction treatment, adequate safety measures will be planned and discussed with each Veteran. Adverse events, including those unlikely to be the result of participation in the research will be monitored at every study contact, including therapy as well as assessment sessions.

Protection from Risks Associated with Video-Based Treatments: The home-based video-conferencing delivery of care will be accomplished using one of participant's own devices or a loaner device (e.g., tablet) provided by the study team. Participants who do not have access to high-speed internet will be provided with a device that has been preconfigured for cellular data. Participants will be instructed to complete treatment sessions from a private, quiet setting of their choosing. Research team staff will be available for home-based equipment set-up and training if necessary. To assure patient confidentiality and HIPAA compliance, we will use VA-approved software, such as the VA Video Connect platform currently in use within the VA. Final selection of software will be performed at the time of study launch to avoid issues related to changes in policy, access, or availability. These software packages allow standard computers with standard connections to teleconference (video and audio) in real time, using federal government tested and approved encryption. Importantly, these software encryption packages meet Federal Government Standards for encryption at a level that does not require a virtual private network (VPN; however, the software is VPN compatible) and this encryption is already Federal Information Processing Standard (FIPS) 140-2 certified and can be installed on Federal government and VA computers. The most recent Home-Based Telemental Health Standard Operating Procedures Manual (VHA Office of Connected Care, 2017) will be used in order to best implement the intervention. Data on the type and amount of assistance required for successful home-based delivery will also be tracked.

Section 17 - Potential Benefits

17) Discuss benefits that may be gained by the subject as well as potential benefits to society in general (see ? for guidance)

Veterans will receive free evaluations of their sleep and neuropsychiatric functioning. If any previously unknown medical conditions or sleep disorders are discovered as a result of these exams, we will discuss the results with the participant and make an appropriate referral for treatment. We will also provide the Veteran or his/her doctor, with appropriate written release, any of the medical information gathered as part of this study. Veterans will also receive free individual therapy for their sleep problems, and they will be paid for participation in the assessments. Other than these items, participants will not personally benefit from their participation. Benefits to society at large include testing and evaluating evidence-based treatments for co-occurring MCI and Insomnia.

Section 18 - Risk/Benefit Analysis

18) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

The primary risks of participating in this study are things like fatigue, emotional discomfort, and potential brief exacerbation of nighttime sleep difficulties and /or daytime sleepiness. As noted above, there are specific plans in place to lessen the likelihood of any of these potential risks.

To the best of our knowledge, the risk/benefit ratio appears to be reasonable in relation to the anticipated benefits to be gained by the participants and others. The study involves minimal risk and most participants are eager to contribute to furthering sleep treatment research.

Section 20 - Compensation for Participation

20) Provide all details and justifications of the compensation plan. See ? for detailed requirements.

Year 1 focus group participants (N= 5) will receive a $20 gift card for a total of $100. Phase II participants (N=26) will be compensated for their baseline and post-treatment assessment points ($100 total per participant; $50 per assessment). The total over 2 years will be $2,700.

Section 21 - Responsibilities and Qualifications

Here are the identified study staff members

Erin L. Almklov, PhD

Adrienn Borsika Rabin, PhD, Elizabeth W. Twamley, PhD, Henry J. Orff, PhD, James O. E. Pittman, PhD, Jennifer S. Salamat

21) For each staff member listed above, describe their role and qualifications. Also indicate which of the study staff are authorized to obtain consent, when applicable to the study.

Erin Almklov, Ph.D., study PI, is a licensed clinical psychologist at VA san Diego Healthcare System (VASDHS) and is a member of the Education and Dissemination unit in the VASDHS Center for Stress and Mental Health (CESAMH). She is a formally trained neuropsychologist. Clinically, she has worked extensively with older adults with Mild Cognitive Impairment and dementia. She is experienced in treating Veterans including providing Cognitive Behavior Therapy for Insomnia (CBT-I). Her research focus has been on issues related to sleep, aging, and the use of health technology to improve care; and she is well published in these areas. On the proposed project, Dr. Almklov will work with the Co-Is and other key stakeholders to develop the Sleep-SMART intervention and manual. She will oversee the coordination of the activities of co-investigators and other personnel in implementing the study protocol and testing hypotheses. She will supervise project staff daily; monitor adherence to study protocol and procedures; oversee regulatory activities; supervise data collection and entry; collaborate on planning and conducting data analyses; prepare articles for publication; and develop future proposals arising from this project.

Elizabeth Twamley, Ph.D., Co-Investigator, is the Director of the Clinical Research Unit of the Center of Excellence for Stress and Mental Health (CESAMH) at the VASDHS; Professor of Psychiatry at the University of California San Diego (UCSD); and RR&D Research Career Scientist. She is a neuropsychologist with expertise in MCI, dementia, TBI, PTSD, neuropsychological assessment, measurement of functional outcomes, cognitive rehabilitation interventions, and randomized controlled trial methodology and data analysis. She is the developer of Cognitive Symptom Management and Rehabilitation Therapy (CogSMART) and Compensatory Cognitive Training (CCT) interventions and has served as PI in multiple randomized controlled trials involving these interventions, funded by VA, NIMH, the Department of Defense, and NARSAD. She will participate in the development of the Sleep-SMART treatment and manual. She will also be responsible for providing therapist training and oversight related to the delivery of CogSMART cognitive strategies, attend regular research team meetings, collaborate on data analyses and interpretation, help prepare articles for publication, and assist in the development of future proposals arising from this project.

Henry Orff, Ph.D. Co-Investigator, is an expert in Behavioral Sleep Medicine whose research focuses on the impact of sleep disturbance (particularly insomnia) on mental/physical health and quality-of-life functioning. His work also addresses a variety of issues that include neuropsychological performance, neurophysiological outcomes, and evaluation of treatment approaches for insomnia in specific clinical populations (e.g., Veterans with history of mild traumatic brain injury). On the current project, he will participate in the development of the Sleep-SMART intervention and provide training and oversight related to the delivery of the CBT-I treatment components. He will also attend regular research team meetings, and play an active role in recruitment, data analyses/interpretation, manuscript writing, and grant development.

James Pittman, Ph.D., Co-Investigator, is Section Chief of La Jolla Outpatient Mental Health Programs; Lead Mental Health Social Work; Associate Director of Education and Dissemination in the Center for Stress and Mental Health (CESAMH); Director of the CESAMH eScreening Core; and co-developer of the VA eScreening program. He has expertise in the use of technology to aid in health-related screening, triaging, and monitoring of clinical outcomes. Furthermore, he is experienced in user centered design, participatory research, mixed methods, and implementation science methodology. On the proposed

project, Dr. Pittman will participate in the development of the Sleep-SMART intervention, supervise the use of technology of collect data and provide care, and assist with the collection and analysis of qualitative data. He will also participate in data interpretation, research team meetings, and the development of scientific publications and future proposals arising from this project.

Borsika Rabin, Ph.D., is an Assistant Professor in the Department of Family Medicine at UCSD; Co-Director of the UC San Diego Dissemination and Implementation Science Center; Co-Lead of the Implementation Science Triple Aim QUERI at the Eastern Colorado VA Healthcare System; and Implementation Scientist for CESAMH at the VASDHS. She will provide guidance and consultation during the Sleep-SMART development phase, including use of the IM-adapt framework. She will also help guide modifications to the intervention based on stakeholder feedback. In addition, Dr. Rabin will be available to provide consultation pertaining to developing, analyzing, and interpreting qualitative interview data, feasibility and acceptability measures, and other implementation-related outcomes.

Ms. Jennifer Salamat, will function as the research coordinator. She will assist with day-to-day research coordination including participant recruitment, screening, consenting, scheduling, and retention activities. She will administer assessments and self-report measures; transcribe interview data; and will be responsible for data scoring and entry. She will also assist with administrative and regulatory tasks.

Section 22 - Bibliography

22) List relevant articles that the IRB can use to provide necessary background for the protocol. Do not include an extensive NIH-grant-style bibliography. (Up to 5 recommended, but use more if needed to support the protocol or citations above.)

Roberts R, Knopman DS. Classification and epidemiology of MCI. Clin Geriatr Med. 2013. doi:10.1016/j.cger.2013.07.003

da Silva RAPC. Sleep disturbances and mild cognitive impairment: A review. Sleep Sci. 2015. doi:10.1016/j.slsci.2015.02.001

Matthews EE, Arnedt JT, McCarthy MS, Cuddihy LJ, Aloia MS. Adherence to cognitive behavioral therapy for insomnia: A systematic review. Sleep Med Rev. 2013. doi:10.1016/j.smrv.2013.01.001

Twamley EW, Jak AJ, Delis DC, Bondi MW, Lohr JB. Cognitive symptom management and rehabilitation therapy (CogSMART) for veterans with traumatic brain injury: Pilot randomized controlled trial. J Rehabil Res Dev. 2014. doi:10.1682/JRRD.2013.01.0020

Twamley EW, Vella L, Burton CZ, Heaton RK, Jeste D V. Compensatory cognitive training for psychosis: Effects in a randomized controlled trial. J Clin Psychiatry. 2012. doi:10.4088/JCP.12m07686

Twamley EW, Thomas KR, Gregory AM, et al. CogSMART compensatory cognitive training for traumatic brain injury: Effects over 1 year. J Head Trauma Rehabil. 2015. doi:10.1097/HTR.0000000000000076

Section 23 - Sponsors and Collaborators

23) Clarify any industry financial or other support (e.g., NIH funds the study or Company X provides the assay kits). Identify non-VA Research collaborators and their role in this protocol, including whether or not they have access to subjects or identified data.

Sponsor: VA Rehabilitation Research & Development Small Projects in Rehabilitation Research (SPiRE) Grant 1 I21 RX003721-01A1.

Michael Thomas, Ph.D. (non-VA Research Consultant/Statistician) is an Assistant Professor in the Department of Psychology at Colorado State University and Assistant Adjunct Professor in the Department of Psychiatry at the University of California, San Diego. As the statistical consultant on this project, he will work closely with the principle investigator and the study team to provide statistical support for the study. He will only have access to aggregate de-identified quantitative data to provide statistical support. Data will be transferred via encrypted VA email.

In the submission form, upload a copy of the grant, subaward, CRADA, etc. as appliable to the study.

Section 27 - Privacy, Confidentiality, and Information Security

27a) Provide a brief description of how participant privacy and confidentiality will be protected in this study. Describe the circumstance under which it may be possible for a research team member to identify subjects and any related protections or assurances to prohibit or avoid identification. Describe how the number of people with access to identifiers for research purposes is limited in order to protect a participant's privacy.

All electronic data will be stored within the VA secure network in the PI's VASDHS R: drive folder (R: \PIfolders\Almklov) and will be accessed only by approved study personnel using VA secured workstations. All paper records will be kept in locked cabinets in a locked room. In the event of a real or suspected breach of security, the VA Police, the VA Information Security Officer, and the VA Privacy Officer will be notified.

27.b) Entry of a CPRS Research Informed Consent Note is required when subjects will be admitted as inpatients or treated as an outpatients for research *and* the study involves research medical care or may affect medical care.

- ***If a Research consent Note is required, then a Research Progress Note should also be entered for each procedure or intervention.***
- ***Scanning the Consent and HIPAA Authorization into CPRS is not required. Linking the Consent to the Research Informed Consent Note may be permitted and can be useful for trials involving the Research Pharmacy or when research will be performed in conjunction with clinical procedures.***
- ***For Non-Veterans, if Research Informed Consent Notes are entered, then the NOPP Acknowledgment must be scanned into the record. Otherwise a copy of the signed NOPP must be retained with the Investigator's research records and a copy sent to the Privacy Officer; see the ? Help for more information.***

27.b1) Is entry of CPRS notes required based on the above criteria?

- ○ CPRS notes are needed for ALL subjects
- ◉ CPRS notes are needed for SOME subjects
- ○ CPRS notes are NOT needed for any subjects

Identify for which group or groups CPRS records will be entered and to which groups this requirement does not apply.

CPRS will be entered for subjects who pass eligibility screening, are enrolled, and attend at least one treatment session. CPRS records will not be entered for those who fail eligibility screening after signing informed consent or who drop out prior to treatment.

27c) Select the VA Sensitive Information (VASI) use category

- ○ This study does not collect or use any VASI
- ○ This study uses but does not save, collect, copy, or record VASI
- ◉ This study does collect or record VASI

Section 27.1 VA Sensitive Information (VASI)

27.1a) For each type of VASI, indicate all that apply:

Indicate which of the following will be collected/recorded:

- ☑ Protected Health Information (PHI)
- ☑ Names
- ☐ Device identifiers and serial numbers
- ☑ E-mail addresses

- [ ] Medical record numbers
- [ ] URLs (Universal Resource Locator)
- [ ] All elements of dates (except year) or any age over 89
- [ ] Health plan beneficiary numbers
- [ ] IP Addresses (Internet Protocol)
- [x] Telephone numbers
- [x] Account numbers
- [ ] Biometric Identifiers including finger and voice print
- [ ] Fax numbers
- [ ] Certificate or license numbers
- [ ] Full face photographic images and comparable images
- [ ] All geographic subdivisions smaller than a state
- [ ] Vehicle ID and serial numbers including license plate numbers
- [x] Social security numbers or scrambled SSNs (describe below)
- [ ] Other unique identifying number, characteristic, or code (describe below)

27.1a1) Describe why SSN are needed for this study

SSN are needed for subject payment and last 4 are needed to verify medical diagnoses for eligibility determinations.

27.1b) Consent Forms and/or HIPAA Authorization

(•) Yes ( ) No

27.1c) Images with personal identifiers are used for this study (x-rays, MRI images with patient names, record numbers, dates, etc.)?

( ) Yes (•) No

27.1d) Photos with faces or audio video recordings are used for this study.

(•) Yes ( ) No

27.1d1) Identify the device or devices that will be used to take/make the photographs or recordings.

Audio recording device - the Pocket Memo Voice Recorder DPM8000 or Olympus 7000 Voice Recorder.

For those who complete the remote treatment intervention, we will use the video recording option available in VA WebX.

27.1d2) Identify where images will be stored (e.g., in the medical record, with study hardcopy records, with study electronic VASI records

The digital audio recordings will be uploaded to a folder in the PI's VASDHS R: drive folder (R:\PI folders\Almklov) immediately following the session for secure storage and the information will be deleted from the recorder. The recordings will not be individually identifiable. The key relating group numbers to the individuals will be stored separately and accessible only by approved study personnel. The audio recordings will be transcribed by a trained member of the research team. Any named individual or location discussed will be struck from the text record to avoid a potential breach in confidentiality.

Video recordings from the VA WebX system are automatically saved to the WebX's host account, which

will then be downloaded/saved to the secure R-drive (in R:\Almklov) and will only be accessible to the approved study staff through PIV log in.

27.1e) Biological specimens with identifiers are used for this study.

○ Yes ◉ No

Section 27.2 Data Collection, Tools, and Resources

27.2a) Will any specially obtained software be used?

◉ Yes ○ No

27.2a1) Describe the software, and identify license requirements and the ownership of the software or license. Identify on what computer/network the software will be used (e.g., VA, VA Research/VMRF, local hard drive) and any data that will be stored in temporary files on the computer's hard drive

Software provided with the Actiwatch Spectrum by Philips Respironics will be used to analyze actiwatch data. We will also use VA approved software to (e.g., ATLAS.ti) analyze qualitative data. Finally, we will use SPSS 26.0 or newer to analyze quantitative data. All programs and data will be stored on the VA network.

27.2b) Will any mobile devices (laptop, tablet, portable hard-drive, etc.) be used in support of this study?

◉ Yes ○ No

27.2b1) Provide details of the device/s. Indicate whether the device is FIPS 140-2 encryption validated and confirm that the device is listed in the VA EIL. Provide details regarding the nature of the data that will be stored or transmitted on the device and confirm whether a copy of all data will be stored on the VA network.

Participants without access to a smartphone, tablet, or computer with webcam will be given a loaner tablet for the 6-session treatment phase, which are available through Co-I Pittman's lab, purchased through VA mobile. The tablets are FIPS 140-2 encryption validated and listed in the VA EIL. The tablets will be used for the video-based Sleep-SMART sessions. No data will be stored on the tablets, but a video recording of each session will be stored on the VA network.

Those who participate in the Sleep-SMART treatment will be given an Actiwatch Spectrum (Philips Respironics, Bend, OR) to wear for 2 week prior to treatment and for two weeks after completing the treatment. The Actiwatch is a wrist-watch styled device designed to objectively measure levels of activity, sleep, and illumination exposure. The actiwatches are FIPS 140-2 encryption validated and listed in the VA EIL. Data (i.e., sleep, activity, and light exposure information) collected from the actiwatches will be transferred from the watches and stored on the VA network.

27.2c) Does the study require use of an electronic data capture system?

◉ Yes ○ No

27.2c1) Provide the web address, details regarding their security features, the nature of the data involved, and the research purpose. Also include a description of how VA retains a copy of the data entered into the system.

The secure VA eScreening program may be used to collect some self-report questionnaire data.

VA approved software (e.g., ATLAS.ti) may used to analyze qualitative data.

SPSS 26.0 will be used to analyze quantitative data.

We will use the Actiwatch Spectrum (Philips Respironics, Bend, OR): a wrist-watch styled device designed to objectively measure levels of activity, sleep, and illumination exposure. Use of the Actiwatch will allow us to objectively measure sleep and wake activity during the baseline and post-treatment assessment weeks.

The data entered into these systems will be exported by research staff and stored within the VA secure network in the PI's folder in the R drive.

27.2d) Will any other web-based applications be used (e.g., for recruitment, completing online questionnaires, or processing data)?

○ Yes ◉ No

27.2e) Will coded data that excludes personal identifiers be used? Coded data excludes *all* HIPAA identifiers (per VHA Handbook 1605.1 Appendix B), including dates

◉ Yes ○ No

27.2e1) Identify where the code key is stored and in what format (electronic, paper).

The code key will be in an electronic and hardcopy format but separate from the coded data

Section 27.3 Data Sharing and Transportation

27.3a) Does this study involve collecting, sharing or transporting any type of data outside of the local VA?

◉ Yes ○ No

27.3b) This study collects VASI outside of VA (i.e., at a non-VA location).

○ Yes ◉ No

27.3c) VASI is transported outside of VA for any purpose other than sharing.

○ Yes ◉ No

27.3d) PHI may be disclosed to monitoring/auditing agencies by HIPAA Authorization. ***Note: The Research Office must be notified when monitors come to audit***

◉ Yes ○ No

27.3e) Data may be shared with collaborators or others in the conduct of this protocol.

(•) Yes ( ) No

27.3e1) Describe the data to be shared or disclosed, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data. For PHI and VASI, indicate the authority/ies permitting the sharing or disclosure of data (HIPAA Authorization, Limited Data Set, Data Use Agreement, VA Form 10-5345-Request for and Authorization to Release Health Information., etc.).

Michael Thomas, Ph.D. (non-VA Research Consultant/Statistician) is an Assistant Professor in the Department of Psychology at Colorado State University and Assistant Adjunct Professor in the Department of Psychiatry at the University of California, San Diego. As the senior statistician on this project, he will work closely with the principle investigator and the study team to provide statistical support for the study. He will only have access to aggregate de-identified quantitative data to provide statistical support.

This data will contain no identifiers and will be sent via secure VA encrypted email; and while being analyzed, will be stored on a password-protected computer
by the collaborator.

Section 27.4 Research Record Storage and Retention

For each type of record, indicate whether it is collected for this study

27.4a) Hardcopy records/data (includes paper, pictures, film, etc.)

(•) Yes ( ) No

27.4a1) Identify precisely where hardcopy data will be stored to include physical site, building, and room number, etc. For each location identify whether VASI or non-sensitive information is stored at that location. For VASI, identify how the data is secured.

Neuropsychological tests, administered in a pencil-and-paper format, will be administered and recorded answers, VASI, and non-sensitive information will be stored in the PI's lab space (building 1 room 2253) in locked cabinets.

27.4a2) Are all of the above locations at VA?

(•) Yes ( ) No

27.4b) Electronic study records (includes computer files, removable disk files, digital files, etc.).

(•) Yes ( ) No

27.4b1) Identify precisely where ***non-sensitive*** electronic records/data will be stored to include the full map drive, network location/server name, etc., and a brief description of what data/information is stored at each location.

Location of Electronic non-sensitive records/data: \\R01SDCHSM02.R01.MED.VA.GOV\Research\Almklov

The data stored on the R-Drive can only be accessed through a VA computer and study staff who are on the protocol will have specific access to the PI's research folder. Non-sensitive electronic data include the following: questionnaires, assessment data, and audio recordings.

Questionnaire and assessment data will have a participate code and will not contain any identifying information.

Audio recordings of interviews and focus groups will be transferred to the VA computer R drive for transcription and qualitative analysis, and all audio files will be destroyed at the end of the study. Participants will be instructed to refrain from stating their name and any other identifying information.

27.4b2) Identify precisely where ***VASI*** electronic records/data will be stored to include the full map drive, network location /server name, etc., and a brief description of what data/information is stored at each location.

If no VASI is collected or recorded for this study, simply indicate that the "Study does not collect or record VASI".

Location of Electronic VASI: \\R01SDCHSM02.R01.MED.VA.GOV\Research\Almklov

VASI will be stored on the secure VA computer R:\ drive (local network storage behind VA firewall) which requires PIV access. The folders will be backed-up by VASDHS IT service. Only study staff who are on the protocol will have access to the PI's research folder.

VASI including name, contact information, code key, appointment dates, and last four of SSN will be stored. Video recordings of the treatment sessions will also be stored for training and fidelity purposes.

27.4b3) Are any of the locations described in 27.4b outside of the VA Secure Network? *Note: this includes storage on a computer local hard drive.*

○ Yes ◉ No

27.4c) Record Retention - VHA requires compliance with Records Control Schedule (RCS-10) for retention of electronic and hard copy records. Following study closure, these temporary records must be retained for six years and then destroyed. Longer retention may be permitted if requred by other Federal regulations or requirements. Will RCS-10 requirements be followed (i.e., 6-year retention)?

◉ I will adhere to VHA Records Control Schedule-10 requirements
○ I request an exception to RCS-10 requirements

Section 27.5 Additional Privacy or Information Security Details

Provide any other privacy or information security details here.

None

Section 27.6 Attestations

In the event of real or suspected breach of security, the Information Security Officer, Privacy Officer, VA Police (if appropriate), and the individual's supervisor will be notified within one hour of learning of the event.

◉ Agree ○ Disagree

Study staff will be up to date on any required VHA Privacy Policy and Information Security training or they will not be allowed access to VA Sensitive Information.

◉ Agree ○ Disagree

Access to research sensitive information, if any, will be removed when study personnel are no longer part of the research team.

◉ Agree ○ Disagree

At least one copy of all study records (whether sensitive or non-sensitive) will be retained under VA control and only destroyed in compliance with the approved Records Control Schedule

◉ Agree ○ Disagree

The VA retains ownership of the research data. Should the investigator leave the VA, custody of the research records will be assigned to another investigator and the Research Service notified in writing, or custody of the research records will be transferred to the Research Service.

◉ Agree ○ Disagree

Section 28 - Protocol Association to New or Existing Project

28) Is this a new R&D Project? Before you go on to complete the *Initial Review Submission Form* (which is used for attachments), please address the association of this Protocol to an R&D Committee Project. This Protocol may represent a new R&D Project, or it may be an additional Protocol under an existing R&D Project (such as when a single grant supports multiple Protocols). Will this Protocol be submitted to the R&D Committee as a new Project?

◉ Yes ○ No

The Protocol Application is now complete for a Protocol that will also be a new R&D Committee Project.

Next you will go on to the Initial Review Submission Form which is used to package up the Protocol Application and any needed attachments and submit them to the IRB.

Click on *Save and Continue*