Cognitive Rehabilitation for Homeless OEF/OIF/OND Veterans

NCT02657954

February 20, 2022

General Information

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

Cognitive Rehabilitation for Homeless OEF/OIF/OND Veterans

***Please enter the Study Number you would like to use to reference the study:**

CogSMART Homeless
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add departments

and Specify Research Location:

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

Assign key study personnel(KSP) access to the study

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

Twamley, Elizabeth W., PhD

3.1 If applicable, please select the Research Staff personnel

A) Additional Investigators

Jak, Amy J., PhD
Co-Investigator

B) Research Support Staff

Austin, Tara, PhD
Post-Doc
Clark, Jillian M., PhD
Research Associate
Hernandez, Jeffrey
Technician
Keller, Amber Victoria
Research Associate
Maye, Jacqueline E., PhD
Post-Doc

Parikh, Mili, PhD
Participating Clinician
Seewald, Paula Michelle, MA
Research Associate
Van Schie, Felicia
Research Associate
Wyckoff, Janae Ruth
Research Associate

***Please add a Study Contact**

Seewald, Paula Michelle, MA
Twamley, Elizabeth W., PhD

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

VASDHS IRB
Human Subjects Protocol
v20190121

Section 1 - Preliminaries

Principal Investigator:

Elizabeth W. Twamley, PhD

Protocol Title:

Cognitive Rehabilitation for Homeless OEF/OIF/OND Veterans

IRB Protocol Number:

H150168

Protocol Nickname:

CogSMART Homeless

Form Template Version:

v20150115

Date Prepared:

02/02/2023

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:

Was this study initially approved prior to January 21, 2019?

○ Yes ○ No

Were you instructed to convert to the 2018 Common Rule Requirements?

○ Yes ○ No

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).

98

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

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. *Note: if this study involves remote participation of subjects, please indicate "no" and describe their remote participation in section 9 of the application. This question is intended to understand whether participants must physically go to a non-VA location to participate in this VA research study.*

○ Yes ◉ No

Section 3.2 Specimen Use and Data Repository

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

○ 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

3.4d) **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)

5 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 impairments are present in up to 80% of homeless individuals, and may contribute to homelessness in OEF/OIF/OND Veterans. We propose to investigate these issues in homeless, treatment-seeking returning Veterans, who arguably face multiple potential barriers to recovery and reintegration, and with whom we have the greatest opportunity to prevent long-term homelessness. We plan to conduct a 15-week randomized controlled trial of an evidence-based, 10-week Compensatory Cognitive Training (CCT) intervention vs. an education control condition

pandemic. We expect CCT-associated improvements in cognition and functional skills and generalization to reduced levels of disability, along with improved community reintegration outcomes. By attending to and treating cognitive impairments, we can potentially prevent future homelessness and its negative health consequences, resulting in both healthcare cost savings and improved quality of life for Veterans.

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. Investigate the efficacy of cognitive rehabilitation in homeless returning veterans with mental health conditions and cognitive impairment by conducting a randomized controlled trial of Compensatory Cognitive Training (CCT) vs. education control for 10 weeks, with a 5-week follow-up, followed by 1 year of monthly post-discharge follow-up phone calls to assess community reintegration outcomes.
H1a: Positive CCT-associated effects on cognition, functional capacity (co-primary outcomes), and disability will emerge over the 15-week study.
H1b: Positive CCT-associated effects on community reintegration outcomes (housing stability, participation in employment/education, healthcare appointment attendance) will be detected at the end of the 1-year follow-up.

Aim 2. Investigate mechanisms of CCT effects.
H2: Improved cognition and cognitive strategy use will mediate improvements in functional capacity, disability, and community reintegration.

Exploratory Aim 3. Investigate moderators of CCT effects.
Presence and severity of PTSD, depression, history of substance abuse, and TBI, as well as duration of homelessness and baseline cognitive functioning, will be explored as potential moderators of CCT effects.

Section 7 - Background and Significance

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

Ending homelessness among Veterans is a national priority. Although there is great heterogeneity in homeless Veterans, the pathway to homelessness frequently involves a failure in planning, problem-solving, or both. Planning and problem-solving are executive functions dependent upon intact brain functioning, and these and other neurocognitive abilities may be impaired in up to 80% of homeless individuals, affecting their organization, judgment, decision-making, and ability to benefit from psychosocial interventions. Difficulty with planning, organization, and learning /memory can interfere with the tasks necessary to sustain income to support housing, as well as to navigate, access, and sustain engagement in rehabilitative efforts to reintegration. Thus, cognitive impairment may be an underappreciated yet pervasive barrier to efforts toward ending homelessness. Causes of cognitive impairment in homeless individuals include traumatic brain injury (TBI), psychiatric illness, substance abuse, and other medical conditions. Cognitive impairment appears to interact with these conditions to result in poor housing outcomes, poor treatment adherence, and risk of continued homelessness. Neuropsychological assessment to identify cognitive strengths and weaknesses is not common in homeless services, but identification of cognitive impairments would also identify Veterans for whom cognitive training or cognitively-adapted psychosocial interventions would be beneficial. Cognitive rehabilitation in the setting of homeless services is also not common, with no known studies to date.

We have a golden opportunity to address these research gaps by studying Veterans at the Aspire Center, a 40-bed VA Residential Rehabilitation Treatment Program (domiciliary) serving homeless returning Veterans with mental health conditions (psychiatric illness, substance abuse, and traumatic brain injuries). By attending to and treating the cognitive impairments that many of these Veterans will have, we can alter the course of the Veterans' trajectories and prevent future homelessness and its negative health consequences, resulting in both healthcare cost savings and improved quality of life for Veterans. This application responds to RFA RX-15-005, RR&D Merit Review Award for Deployment Health Research, which requests applications seeking to "improve or restore function through innovative therapies, interventions…improve the ability to obtain and

these issues in homeless, treatment-seeking returning Veterans, who arguably face *multiple* potential barriers to recovery and reintegration, and with whom we have the greatest opportunity to prevent the personal and societal impacts of long-term homelessness.

Our study integrates cognitive rehabilitation in residential care for homeless Veterans. In a 15-week randomized controlled trial, we will compare an evidence-based, 10-week Compensatory Cognitive Training (CCT) intervention *to* an education control condition for homeless Veterans with cognitive impairment. CCT aims to improve real-world cognitive performance by teaching strategies to improve prospective memory (remembering to do things), attention, learning /memory, and executive functioning. Strategies to reduce stress and improve sleep are also included. CCT has been shown to improve cognition, functional capacity, neurobehavioral symptom severity, and quality of life in individuals with cognitive impairment associated with psychiatric illness and in Veterans with TBI. During the trial, assessments will be administered at baseline, 5 weeks, 10 weeks, and 15 weeks, and monthly follow-up phone calls will assess housing and employment/education status for one year following program discharge. We expect CCT-associated improvements in cognition and functional skills (co-primary outcomes) and generalization to reduced levels of disability, along with improved community reintegration outcomes (better housing stability, participation in work or school, and healthcare appointment attendance). If effective, the CCT intervention could be exported to the 80+ residential VA programs serving homeless Veterans.

eScreening Tablet:
IRB approved for use in protocol: H120045
Technology Solution to Improve OEF/OIF Intake and Assessment Program
PI: Niloofar Afari

Research shows that using technology to increase consumer mental health care services is an effective way to improve patient care and satisfaction. Chinman et al., 2004 found that computer assisted self-assessment was reliable for use with those with severe mental illness and that it was easier and more private. Chinman et al, 2007 found that it was enjoyable, easy to use, and improved communication with their provider. Providers found the assessment summary easy to understand and use and requested that it be more comprehensive.

In response to the Broad Agency Announcement (BAA), solicitation number VA118-10-RP-0418, sponsored by the Veterans Affairs Innovation Initiative (VAi2) in which private sector companies, entrepreneurs and academic leaders contribute ideas for innovations that increase Veteran access to VA services, reduce or control costs of delivering those services, enhance the performance of VA operations and improve the quality of service that Veterans and their families receive, the PI paired with a private technology company, Triple i, a Transformation Twenty One Total Technology (T4) prime contractor, to develop and evaluate an electronic version of the current paper screening tool used by the VA VISN 22 OEF/OIF/OND Care Management Programs.

To address the limitations of the current VASDHS clinical screening process, CESAMH investigators, VASDHS leadership, and VISN-22 leadership paired with Triple i. Triple i has been contracted to design an electronic solution that dramatically addresses and improves the capabilities of VASDHS to support its returning Veterans. **The solution provides VASDHS's paper screening packet through a mobile platform that can be utilized on any PC, including Tablets in the hospital. Combined with automated scoring, immediate feedback and education to Veterans, automated CPRS note generation, and automated setup and coordination of clinical services, the solution should very efficiently dramatically improve the number of Veterans who receive services and their level of engagement and satisfaction, without an increase in staff and resource requirements.** It is anticipated that veterans of the OEF/OIF/OND age cohort (generally in their 20s, 30s, and 40s) will have sufficient computer literacy to complete the eScreening process on a computer or tablet. In the unlikely event that the veterans in the study find the computer or tablet difficult to use, they may ask questions and receive guidance from the research assistant.

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.

The subject population in this study will be 98 male and female O/O/O veterans with mental health conditions and cognitive impairment served by the Aspire Center. It is anticipated that we will need to enroll and test 200 participants to end up with 98 who have cognitive impairment. We anticipate the top four mental health conditions to be PTSD, depression, history of substance use disorder, and history of TBI. Our inclusion criteria were selected in order to increase generalizability to other treatment-seeking homeless O/O/O Veterans with cognitive impairment. Participants will be men and women of any race/ethnicity, aged 18-55 years (which will represent the vast majority of O/O/O Veterans, but not introduce age-related dementing disorders as a confound). Complete inclusion/exclusion criteria are as follows:

Inclusion Criteria:
1) Male or female, any race/ethnicity, and age 18-55
2) Meets criteria for Aspire Center program entry
    a) O/O/O Veteran
    b) presence of at least one DSM-V mental health condition
    c) does not meet criteria for substance use disorder for 28 days prior to admission
    d) homeless or unstably housed (per HEARTH Act definition; HUD, 2011b)
    e) not a sex offender or violent offender
    f) capable of performing activities of daily living and transfers
    g) not judged by a clinician to be at current risk to self or others
3) Has cognitive impairment in at least one cognitive domain (i.e., T-score < 40)
4) Able to speak and read English
5) Capable of and willing to provide signed informed consent

Exclusion Criteria:
None

Although it is recognized that the effects of chronic alcohol abuse can last longer than 28 days, the number of individuals in the study with recent alcohol abuse should be equally allocated across the two treatment groups by virtue of the power of randomization. In the unlikely event in a study this size that the treatment groups differ in this regard, alcohol history may be used as a covariate in the analyses.

All participants will provide voluntary informed consent (we will not enroll participants who require surrogate consent). All potential participants who meet the inclusion and exclusion criteria above will be invited to participate; we anticipate that about 50% of the Aspire Center residents will meet these criteria and choose to participate, based on our prior research experience with homeless individuals (Vella et al., 2014). Those who enroll but turn out not to have cognitive impairment will end their research participation and will not participate in the randomized controlled trial; these participants will be replaced until the target enrollment of 98 participants is reached. Potential participants will meet with a project staff member, who will describe the study and answer any questions. In all cases, fully informed consent will be obtained. Dr. Twamley will be directly available to answer any questions raised by a potential participant. A copy of the consent form, which includes a description of the study, will be provided to all subjects. The study population is at risk for diminished capacity to consent to research by virtue of their expected cognitive impairment, so participants will be assessed for capacity to consent for this study with a post-consent quiz, which will include questions about the purpose of the study, types of assessments, number of groups, voluntariness, 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. We have used this procedure in prior studies to ensure decisional capacity. Four out of the five questions are open-ended in order to reduce the chance that the consenter could inadvertently reveal the right answer.

Inclusion of Women, Ethnic Minorities, and Children

Our study will recruit male and female Veterans of all racial/ethnic backgrounds in approximately similar population strata as that of the San Diego County homeless O/O/O Veteran population. San Diego has one of the most ethnically diverse and highest proportions of female Veteran populations in the nation, and 6 of the 40 beds at the Aspire Center are reserved for women. According to the National Center for Veterans Analysis and Statistics (as of 2011), those figures for San Diego County are: 90.6% male and 9.4% female; American Indian/Alaska Native = 1%; Asian = 5%; African-American = 9%; White = 68% and Hispanic-Latino (all races): 14%. Of the 95 Aspire Center Veterans served thus far, 16% have been women, 15% have been African Americans, and 4% have been Native Americans, Alaska Natives, or Native Hawaiians. Thus, women, African Americans, and Native peoples have actually been overrepresented in the Aspire Center population compared to their proportions in the San Diego Veteran community. We will regularly review our sample's racial/ethnic and sex distribution and any systematic deviations from these figures will result in increased efforts to recruit underrepresented subgroups. Our study will not include children aged 0 to 17 given that the sampling population is restricted to Veterans of the U.S. military. We will include children aged 18 to 21.

Recruitment

Our team has an excellent track record of recruiting sheltered homeless participants (90% in the Vella et al., 2014 study), and recruitment of participants and informed consent procedures will follow established methods in previous studies. Veterans with cognitive impairments are frequently highly motivated to participate in cognitive rehabilitation. When we queried the first 10 Aspire Center residents, 9/10 reported that they had "problems with attention, learning, memory, planning, or being organized" and 9/10 reported that they would "be interested in learning skills that could help [them] improve these areas." Veteran comments included:

- "My memory is terrible when I get stressed, which is all the time."
- "I have too many ways of remembering stuff and I get confused with so many notes, calendars, lists, stickies."
- "My memory is what caused me to lose my job."

The sole recruitment source for this study will be the VA Aspire Center, a 40-bed Residential Rehabilitation Treatment Program serving homeless O/O/O Veterans with mental health conditions such as PTSD, depression, and TBI. A rate of accrual of 10 participants enrolled per quarter during the recruitment period (last three quarters of Year 1; Year 2; first quarter of Year 3) would be required to support our targeted accrual. The average length of stay is 3-6 months, meaning that between 80 and 160 participants per year would be eligible for the study. We aim to enroll 30 participants in the last three quarters of Year 1, 40 in Year 2, and 10 in the first quarter of Year 3, making our enrollment goals feasible. Our research team has held several planning meetings with the Aspire Center team and has identified a plan for successful recruitment that maximizes the possibility that participants will be enrolled while being minimally disruptive to Aspire Center operations. To facilitate recruitment, our PI and study staff will be highly visible at the Aspire Center and will coordinate with program intake staff (please see Letter of Support from Deborah Dominick, LCSW, Chief of the Aspire Center). Individuals who meet the inclusion criteria outlined above will then be approached for potential participation in the study and, if interested, will complete the consenting process and the baseline assessment.

Retention

During the trial, assessments will be administered at baseline, 5 weeks, 10 weeks, and 15 weeks, and brief monthly follow-up phone calls will assess housing and employment/education status for one year following program discharge. Participants will be compensated for their time spent in assessments ($25 per assessment X 4 assessments = $100 maximum total compensation) as a way to enhance retention. Based on prior studies of Veterans with PTSD and/or TBI, we expect about 20% attrition, for a final sample size of 78 (39 per group). Attrition may be even lower, given that all participants will be residing on-site. Monthly follow-up assessment of housing /employment status will be brief and not burdensome to participants.

Procedure

Following study enrollment, participants will complete a baseline assessment and will then be randomly assigned to receive either CCT or the education control condition, "Holistic Cognitive Education," for 10 weeks, as described in Table 1. All treatment will be provided by the Cognitive Specialist, a doctoral level neuropsychologist with experience in cognitive rehabilitation. Note that one page (page 4) of the CCT manual (Appendix 1) contains education regarding TBI, and we do not expect all participants to have a history of TBI. If a participant does not have a history of TBI, page 4 will be skipped.

The Cognitive Specialist and the participant will choose whether to receive sessions in-person at the clinic or via home-based video telemedicine (HBVT) modality. 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 HBVT 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. Further, the study team has successfully implemented and used this software in two ongoing clinical trials evaluating HBVT service delivery of mental health services to Veterans. The most recent Home-Based Telemental Health Standard Operating Procedures Manual [61] will be used in order to best implement HBVT. Data on the type and amount of assistance required for successful home-based delivery will be tracked.

Randomization will be carried out by the Research Health Scientist, based on randomization tables created by the statistical consultant, Dr. Shah Golshan. The psychometrist and research associate will be blind to randomization status. All participants will continue to receive their usual

Outcome assessment will occur at 5 weeks (treatment midpoint), 10 weeks (post-treatment), and 15 weeks (follow-up). Housing status and participation in work/school will be assessed by telephone monthly for 12 months following program discharge. Healthcare appointment attendance rates during the 12-month follow up period will be ascertained from CPRS records. We will maximize our data collection efforts by gathering participant cell phone numbers (most O/O/O Veterans, even those who are homeless, have cell phones). Furthermore, at baseline and discharge, we will obtain contact information for the Veteran and for at least two family members and close associates who can be contacted in case the Veteran cannot be contacted for monthly follow-up assessments of housing status. In the event that the Veteran still cannot be reached by telephone, we will use CPRS to track housing status (e.g., via V codes and progress notes), with appropriate HIPAA consent.

Table 1. Experimental and Control Conditions

Compensatory Cognitive Training (Appendix 1)	**Education Control (Appendix 2)**
CCT is a 10-week adaptation of Cognitive Symptom Management and Rehabilitation Therapy (CogSMART; Twamley et al., 2014b; Twamley et al., in press) that was developed in collaboration with colleagues at the Portland VA and tested in a recently-concluded 4-site randomized controlled trial (Merit Review D7217-R to Daniel Storzbach, PhD). Efficacy data is presented in the Preliminary Data section. CCT is a 10-week intervention to improve real-world cognitive performance by teaching compensatory strategies to improve prospective memory (remembering to do things), attention, learning/memory, and executive functioning. Stress reduction and sleep improvement strategies are also provided. CCT is used routinely in Dr. Jak's TBI Cognitive Rehabilitation Clinic at the VA San Diego Healthcare System, and the manual (see Appendix 1) has been distributed to hundreds of VA, DoD, and community clinicians across the country via website.	To control for therapist time and attention, the education control condition, "Holistic Cognitive Education," will provide information and discussion regarding common causes of and treatments for cognitive impairment, with one session each devoted to: 1) Alcohol and Substances, 2) Medical Conditions (e.g., diabetes, cardiovascular conditions), 3) Concussion/TBI, 4) PTSD, 5) Depression, 6) Sleep Disturbance, 7) Stress, 8) Pain, 9) Nutrition and Exercise, and 10) Cognitive Stimulation. The education control condition will use internet-based materials carefully selected from respected websites (e.g., NIH, Mayo Clinic, WebMD, CNN; see Appendix 2), and sessions will consist of the Cognitive Specialist and participant reviewing and discussing the relevant information together. Any remaining time in each session will be used to search for additional relevant information or educational videos regarding the topics above.

Treatment Fidelity

Treatment fidelity will be closely monitored by Dr. Twamley and the Research Health Scientist. Intervention sessions in both conditions will be audio-recorded, and a randomly selected 20% of sessions will be rated by Dr. Twamley or the Research Health Scientist using the CCT fidelity monitoring tool (Appendix 3). Scores < 90% for CCT or >10% for the education control condition will trigger a review and plan for improving fidelity.

Measures Overview

We have selected measures based on 4 criteria: 1) importance for assessing constructs in our theoretical model, 2) brevity (to reduce subject burden), 3) reliability, and 4) demonstrated validity.

Subject Characterization Measures

Measures of demographics, residential and vocational history, and history of alcohol and substance abuse will be administered by Aspire Center staff as part of the routine clinical intake process at program entry (Table 2). Subject characterization measures we will add (Table 3) include the Warrior Administered Retrospective Casualty Assessment Tool (WARCAT; Terrio et al., 2009), a short, structured interview of TBI history that allows for diagnosis of mild, moderate, or severe TBI based on the American Congress of Rehabilitation Medicine criteria, and the Wide Range Achievement Test-4 (Wilkinson et al., 2006) Reading subtest, which provides an estimate of premorbid IQ by measuring ability to read non-phonetically spelled English words.

Table 2. Measures Administered during Aspire Center Intake (no additional subject burden)

Measure	**Construct Assessed**
Demographic Form	Age, sex, education, race/ethnicity, marital status, service connection, medications prescribed
Residential Timeline Follow-Back (Tsemberis et al., 2007)	Residential history (number of days homeless, unstably housed, in an institution, or housed in the past 6 months)

(Zvikis et al., 2012)	time in the past 6 months)
Alcohol Use Disorders Identification Test (Saunders et al., 1993)	Alcohol use history
Drug Abuse Screening Test (Skinner, 1982)	Substance use history

Study Measures

Additional study measures are listed in Table 3 and further described below. Time required for these measures will be about 2 hours, 15 minutes, and breaks will be provided as needed by participants. We will administer a comprehensive, standardized battery at all four time points, including the following:

Performance validity will be measured with the Test of Memory Malingering (TOMM; Tombaugh, 1997), a commonly-used validity measure. Sub-optimal effort (i.e., scores below standard cut-offs) is associated with significantly poorer neuropsychological test battery performance, thus making impaired scores uninterpretable. If a Veteran performs below standard cut-offs, indicating non-effortful performance, he/she will be excluded from the remainder of the study, because the cognitive test results will not be interpretable. We expect that the rate of non-effortful performance in this sample will be < 10%, based on estimates of effort-test performance in our archival database of over 400 O/O/O Veterans with TBI who have been referred for neuropsychological assessment. About 12% of that sample had invalid test results, but we expect our rate to be lower, given that not all Aspire Center residents will have sustained a TBI and the assessments will be administered in a research context rather than for clinical purposes.

Processing speed, attention/vigilance, working memory, verbal and visual learning, reasoning and problem-solving, and social cognition will be measured with the MATRICS Consensus Cognitive Battery (MCCB; Nuechterlein et al., 2008; see Table 4), a 60-minute battery of tests funded by an NIH initiative and developed through systematic selection and psychometric evaluation of the tests. Each test's relationship to functional outcomes, high test-retest reliability, and low practice effects were considered paramount, as the MCCB was designed to be used to detect clinically meaningful cognitive change (Nuechterlein et al., 2008). The four-week test-retest intraclass correlation coefficient for the MCCB composite score is .90. Of the ten MCCB tests, three (those measuring verbal learning, visual learning, and problem-solving) have alternate forms that will be used for assessment sessions after the baseline assessment; the other tests have very low practice effects.

To augment the MCCB, we will add three additional tests of executive functioning, which we believe plays a significant role in homelessness. These tests include Delis-Kaplan Executive Function System (D-KEFS; Delis et al., 2001) subtests measuring cognitive flexibility (Verbal Fluency) and inhibition (Color-Word Interference), which are sensitive to frontal lobe brain damage (Baldo et al., 2001; McDonald et al., 2005). We will also administer the Trail Making Test, Part B (Reitan, 1958), a gold-standard test of cognitive flexibility that can be compared to Part A, administered as part of the MCCB. This test is sensitive to neuropsychological impairment in homeless adults (Gonzalez et al., 2001). We will also administer the Bethesda Eye and Attention Measure (BEAM; Ettenhofer et al., 2016), a computer-administered measure of eye tracking during an attention task. Research suggests that BEAM saccadic metrics are able to reliably capture unique aspects of attention and executive performance (Ettenhofer, Hershaw & Barry, 2016), and may be sensitive chronic impairments associated with mild TBI (Ettenhofer & Barry, 2016).

As an assessment of everyday functional capacity, we will administer the UCSD Performance-Based Skills Assessment-Brief (UPSA-B; Mausbach et al., 2007), which assesses functional skills in communication and financial management. Scores on the UPSA-B, especially a cutoff score of 60 out of 100 points, have been shown to distinguish between those living independently vs. living in supported settings among people with psychiatric illness (Mausbach et al., 2007; Mausbach et al., 2010). Furthermore, the UPSA has been used in homeless individuals before, and homelessness was found to be associated with a 9-point lower score (out of 100 points) on the UPSA (Stergiopoulos et al., 2011), establishing it as a feasible measure with construct validity.

Cognitive strategy use will be measured with the Cognitive Problems and Strategies Assessment (CPSA; Twamley et al., 2012), a measure directly assessing the use of compensatory strategies taught in CCT.

Psychiatric symptom severity will be measured with the PTSD Checklist-Military Version (Weathers et al., 1991), the Patient Health Questionnaire-9 (Kroenke et al., 2001), the Neurobehavioral Symptom Inventory (Cicerone & Kalmar, 1995), and the Insomnia Severity

insomnia symptom severity, respectively. All are brief gold-standard measures that are used routinely at Aspire Center intake.

The related constructs of disability, community integration, and quality of life will be assessed by the World Health Organization Disability Assessment Scale 2.0 (WHODAS 2.0; WHO, 2012), the WHOQOL-BREF (WHO, 1998) and the Community Reintegration of Service Members-Computer Adaptive Test (CRIS-CAT; Resnik et al., 2012), three brief, well-validated measures. The CRIS-CAT is a self-administered computer adaptive test specifically designed for military and Veteran populations; the authors have obtained permission for the CRIS-CAT to be available on VA computers.

We will also measure heart rate variability via a brief (5 minute) heart rate monitor test. Heart rate variability may be a predictor of outcome in this population.

Table 3. Study Measures

Measure	**Construct Assessed**	**Time (min)**
Warrior Administered Retrospective Casualty Assessment Tool	History of TBI	5 (baseline only)
Wide Range Achievement Test-4 Reading	Reading ability (premorbid IQ estimate)	5 (baseline only)
Test of Memory Malingering	Test-taking effort	10
MATRICS Consensus Cognitive Battery (see Table 4)	Neuropsychological functioning (see domains in Table 4)	60
Additional tests: D-KEFS Verbal Fluency, Color-Word Interference, BEAM, heart rate variability	Executive functioning tests measuring cognitive flexibility, inhibition, attention; heart rate variability	25
Trail Making Test, Part B	Additional executive functioning test	5
UCSD Performance-Based Skills Assessment-Brief	Functional capacity	10
Cognitive Problems and Strategies Assessment*	Self-reported cognitive problems and strategy use	5
PTSD Checklist-5*	PTSD symptom severity	3
Patient Health Questionnaire-9*	Depressive symptom severity	2
Neurobehavioral Symptom Inventory*	Neurobehavioral symptom severity	3
Insomnia Severity Index*	Insomnia symptom severity	2
WHODAS 2.0*	Disability and community integration	7
WHOQOL-BREF*	Quality of life	2
Community Reintegration of Servicemembers-Computer Adaptive Test	Community reintegration	10

Note that assessments marked with * above will be administered via eScreening.
The electronic screening packet (i.e., the tablet and software) was developed by ”Triple i”, a Transformation Twenty One Total Technology (T4) prime contractor, and approved for use by the VASDHS ISO (Mr. Jesse Christmas) and CIO (Mr. Darryel Simmons) and Network 22 CIO (Randy Quinton) on November 21, 2012 (see attached Risk Based Decision Memo; note: although the RBDM diagrams VistA connectivity, this protocol does not utilize this feature).
Data from the screening packets will be de-identified with a code and entered into a secure database on the VA server for analysis.

Table 4. MCCB Tests and Descriptions

Domain	**Test**	**Description**
Speed of processing	BACS Symbol-Coding Animal Naming Trail Making Test: Part A	Timed in which respondent uses a key to write digits corresponding to symbols Oral test in which respondent names as many animals as she/he can in 1 minute Timed test requiring drawing a line to connect consecutively numbered circles

Vigilance	Identical Pairs	Which respondent presses a response button to consecutive matching numbers
Working memory	WMS-III Spatial Span Letter-Number Span	Respondent taps cubes in same (or reverse) sequence as test administrator Oral test in which respondent mentally reorders strings of number and letters
Verbal learning	Hopkins Verbal Learning Test-Revised (HVLT-R)	Oral list-learning task requiring acquisition of a list of 12 words from 3 categories over 3 trials
Visual learning	Brief Visuospatial Memory Test-Revised (BVMT-R)	A test that involves learning and reproducing six geometric figures from memory
Reasoning/ prob. solv.	Neuropsychological Assessment Battery (NAB) Mazes	Seven timed paper-and-pencil mazes of increasing difficulty that measure foresight and planning
Social cognition	Mayer-Salovey-Caruso Emotional Intelligence Test: Managing Emotions	Paper-and-pencil multiple-choice test that assesses how people manage their emotions

Design Considerations

Our research design purposely includes all Aspire Center residents with cognitive impairment. We recognize that the etiologies of such impairment may differ between individuals, but we are taking a trans-diagnostic approach in this practical clinical trial so the results will be as generalizable as possible to the population of homeless, treatment-seeking O/O/O Veterans with mental health conditions and cognitive impairment. In keeping with our pragmatic goals, we chose not to restrict the sample with regard to types of mental health conditions, types of cognitive impairment, types of medications, and so on. These factors may affect the cognitive profiles of the participants, as well as their response to CCT, however, our first goal in this pilot trial in a new population is to see if CCT works; thus, our primary goal is to examine efficacy broadly. If the randomized groups differ with regard to mental health conditions, types or level of cognitive impairment, types of medications, and so on, we will take those differences into account in our analyses, and we will additionally examine moderators of treatment outcome. With regard to the control group, we considered a wait-list control group, but rejected that option because it does not control for therapist time and attention, may introduce cohort effects, and would be impractical in a residential setting where participants in the wait-list group could be discharged before they were able to participate in CCT. We also considered a treatment as usual control group, but rejected that option because it does not control for therapist time and attention. Therefore, we designed the Holistic Cognitive Education control group that will control for these potential confounds.

Quality Assurance

The PI will train and supervise the research staff collecting data via observation of the assessment sessions of the first 10 subjects enrolled and further observation of one session every three months. Protocol adherence will be enhanced by means of an electronic calendar to track participant enrollment, assessment, and discharge dates, as well as to project dates for the monthly post-discharge calls. Treatment fidelity will be carefully monitored with procedures described above.

Data Management and Information Security

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 subject numbers with subject names. Paper records will be coded by subject number only, and will not include participant names, with the exception of consent forms, which will be stored separately and will include names, but no subject numbers. All paper records will be kept in locked cabinets in a locked room. A 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. Consultation regarding data management and information security issues will be provided by Dr. Shah Golshan, with whom Dr. Twamley has worked for over 10 years.

Analytic Plan and Power Analyses

Data analyses will proceed in stages, with Dr. Shah Golshan serving as a statistical consultant during the award period. At first, descriptive statistics and exploratory graphing will be used to assess the normality of the data in terms of the presence of skewness and/or outliers. The continuous outcome data will be transformed if necessary by using an appropriate transformation such as the log transformation for skewed long tailed data. We will check to ensure that the randomization worked and there are no significant differences between the experimental and control group on demographics, clinical characteristics, and/or baseline cognition/functional

as Random Regression Modeling and Hierarchical Linear Modeling) which takes advantage of all existing data points for minimal loss of data, will be used to analyze the data related to our main hypothesis (H1a). Therefore, we will not impute missing data because our analytic method uses all existing data points, including all subjects with missing data or those who were terminated early in the study, without relying on data imputation procedures (Diggle et al., 1994; Laird & Ware, 1982; Hedeker et al., 1991). The mixed effects approach provides more information and, therefore, more power compared to cross-sectional analyses that focus on the analysis of one summary index or more traditional analytic approaches such as a change score, end-point, or repeated measures analysis of variance (ANOVA). We will also use pattern-mixture models to assess if there is bias due to drop out or missing data. As described by Hedeker and Gibbons (1997), these mixed models allow us to assess whether important estimates are dependent on missing data patterns, and provide overall estimates of effects by averaging over the various missing-data patterns. In addition, we will consider the extension of the Pattern-Mixture models as described by Guo et al. (2004), which includes the incorporation of random effects in the pattern mixture model, allowing subject-to-subject heterogeneity. Missing data will be examined to assess randomness. The pattern of missing data will be examined according to the procedure recommended by Little and Rubin (1987), which includes comparing group differences in the primary outcomes of subjects with versus without missing data. SPSS and SAS statistical software will be used to analyze the data. Type I error will be controlled by a Bonferroni adjustment to the alpha per outcome domain for Hypotheses 1a and 1b. Specific plans for testing each hypothesis are below.

H1a: Positive CCT-associated effects on cognition, functional capacity (co-primary outcomes), and disability will emerge over the 15-week study.
Dependent variables: Cognition (global deficit score [GDS] composite; Heaton, et al., 1995), UPSA-B (co-primary outcomes), WHODAS 2.0.
Independent variables: Treatment group (CCT vs education control) and Time (0, 5, 10, 15 weeks).
Statistical analyses: We will analyze data on all randomized subjects with a baseline assessment and at least one post-baseline evaluation, using mixed effects models, described above. The mixed effects model method provides an estimate of the individual variability around the population trend, the variability of the individual intercepts (baseline values) and slopes (changes across time), and the correlation between them. A fully saturated treatment by time model will be utilized for inference. Covariance structure will be chosen based on Akaike's Information Criterion (AIC). Random group level treatment effects will also be evaluated for importance based on the model AIC. This method allows for any group level effects to be incorporated into the model. Denominator degrees of freedom will be calculated using the Kenward-Roger small sample correction.
Power Analysis: We used procedures described by Hedeker et al. (1999) for Random Regression Models for the proposed study to estimate needed sample size (the RMASS program provided by Hedeker). We estimated that with a final sample size of 78 (target n=98, with a drop-out rate of 20%), the study will have .80 power to yield a statistically significant result for a .72 effect size, accounting for Type I error correction, .5 correlation between time points, and one random effect in the model. We have previously found CCT-associated effect sizes of .72 for prospective memory functioning in Veterans with mild to moderate TBI (74% of whom had PTSD), as well as for the UPSA-B in individuals with severe mental illness. Although we have not previously used the WHODAS 2.0 to assess disability, we have also found CCT-associated effect sizes of .81-1.0 for quality of life in these populations. The trial was therefore powered to detect effect sizes in the .72 range.

H1b: Positive CCT-associated effects on community reintegration outcomes (housing stability, participation in employment/education, healthcare appointment attendance) will be detected at the end of the 1-year follow-up.
Dependent variables: Proportion of months housed, proportion of months engaged in productive activity (work or school), and proportion of VA healthcare appointments attended during the 1-year follow up period (all three outcomes based on monthly data collected during the 1-year follow-up period). Any missing data on housing and work/school status will be accounted for by using a proportion based on the available data points. Healthcare appointment attendance will be gathered from CPRS data and will not be subject to missing data.
Independent variable: Treatment group (CCT vs education control).
Statistical analyses: ANOVA models comparing the treatment and control group on the three dependent variables above. We have selected ANOVA over alternative models (t-test; Wilcoxon Rank Sum; Poisson regression) due to the type of dependent variables (continuous) and the option to include any covariates that might be imbalanced between the treatment groups.
Power analysis: With 78 subjects (39 subjects per group), we will have .80 power to detect an effect size of .64, a medium-to-large effect size.

capacity, disability, and community reintegration.
Dependent variables: UPSA-B at 15 weeks, WHODAS 2.0 at 15 weeks, proportion of months housed, proportion of months engaged in productive activity (work or school), and proportion of VA healthcare appointments attended during the 1-year follow up period.
Independent variables: Treatment group (CCT vs education control).
Mediators: Cognitive improvement in GDS composite from 0-10 weeks (slope of change across weeks), improvement in CPSA cognitive strategy use from 0-10 weeks (slope of change across weeks).
Statistical analyses: For this hypothesis, we will use the regression analytic strategy described by Krull and MacKinnon (1999, 2001). In this approach, four conditions must be met: a) a significant relationship between the independent variable (treatment group) and the dependent variables listed above, b) a significant relationship between the independent variable (treatment group) and the proposed mediators listed above, c) a significant relationship between the mediator and the dependent variables listed above, and d) the relationship between the independent variable (treatment group) and dependent variables listed above must be significantly lower after controlling for the proposed mediator. To test for significant mediation, we will conduct a Sobel test (Sobel, 1982). We will also use the formula provided by MacKinnon and Dwyer (1993) to determine the percentage of the intervention condition to primary outcome path that was accounted for by change in the mediator.
Power analysis: For the second hypothesis, we used the procedures defined by Fritz and MacKinnon (2007) for estimating sample sizes needed to achieve 80% power to detect the mediated effect. Similar to previous hypotheses, we have assumed a medium effect for the relationships between intervention condition and dependent variables and between mediators and our primary outcome. Using the Sobel test procedure described in our statistical analysis section above, we estimate that the proposed sample size would be sufficient to achieve 80% power to detect a mediated effect.

Exploratory Aim 3. Examine moderators of CCT effects.
Dependent variables: GDS composite, UPSA-B, WHODAS 2.0, proportion of months housed, proportion of months engaged in productive activity (work or school), and proportion of VA healthcare appointments attended during the 1-year follow up period.
Independent variable: Treatment group (CCT vs education control).
Moderators: Presence and severity of PTSD, depression, history of substance abuse, and TBI, duration of homelessness, baseline cognitive functioning (GDS composite)
Statistical analyses: These potential moderators will be entered into the mixed effects models from H1a (GDS, UPSA-B, WHODAS 2.0) and the ANOVA models from H1b (proportion of months housed, proportion of months engaged in productive activity [work or school], and proportion of VA healthcare appointments attended during the 1-year follow up period) to assess interactions between the moderators and the independent variable (treatment group).

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.***

1. Performance validity will be measured with the Test of Memory Malingering (TOMM; Tombaugh, 1997), a commonly-used validity measure. Sub-optimal effort (i.e., scores below standard cut-offs) is associated with significantly poorer neuropsychological test battery performance, thus making impaired scores uninterpretable. If a Veteran performs below standard cut-offs, indicating non-effortful performance, he/she will be excluded from the remainder of the study, because the cognitive test results will not be interpretable. We expect that the rate of non-effortful performance in this sample will be <10%, based on estimates of effort-test performance in our archival database of over 400 O/O/O Veterans with TBI who have been referred for neuropsychological assessment. About 12% of that sample had invalid test results, but we expect our rate to be lower, given that not all Aspire Center residents will have sustained a TBI and the assessments will be administered in a research context rather than for clinical purposes.

2. Processing speed, attention/vigilance, working memory, verbal and visual learning, reasoning and problem-solving, and social cognition will be measured with the MATRICS Consensus Cognitive Battery (MCCB; Nuechterlein et al., 2008; see Table 4), a 60-minute battery of tests funded by an NIH initiative and developed through systematic selection and psychometric evaluation of the tests. Each test's relationship to functional outcomes, high test-retest

test-retest intraclass correlation coefficient for the MCCB composite score is .90. Of the ten MCCB tests, three (those measuring verbal learning, visual learning, and problem-solving) have alternate forms that will be used for assessment sessions after the baseline assessment; the other tests have very low practice effects.

3. To augment the MCCB, we will add additional tests of executive functioning, which we believe plays a significant role in homelessness. These tests include Delis-Kaplan Executive Function System (D-KEFS; Delis et al., 2001) subtests measuring cognitive flexibility (Verbal Fluency) and inhibition (Color-Word Interference), which are sensitive to frontal lobe brain damage (Baldo et al., 2001; McDonald et al., 2005). We will also administer the Trail Making Test, Part B (Reitan, 1958), a gold-standard test of cognitive flexibility that can be compared to Part A, administered as part of the MCCB. This test is sensitive to neuropsychological impairment in homeless adults (Gonzalez et al., 2001). We will also administer the Bethesda Eye and Attention Measure (BEAM; Ettenhofer et al., 2016), a computer-administered measure of eye tracking during an attention task. Research suggests that BEAM saccadic metrics are able to reliably capture unique aspects of attention and executive performance (Ettenhofer, Hershaw & Barry, 2016), and may be sensitive chronic impairments associated with mild TBI (Ettenhofer & Barry, 2016).

4. As an assessment of everyday functional capacity, we will administer the UCSD Performance-Based Skills Assessment-Brief (UPSA-B; Mausbach et al., 2007), which assesses functional skills in communication and financial management. Scores on the UPSA-B, especially a cutoff score of 60 out of 100 points, have been shown to distinguish between those living independently vs. living in supported settings among people with psychiatric illness (Mausbach et al., 2007; Mausbach et al., 2010). Furthermore, the UPSA has been used in homeless individuals before, and homelessness was found to be associated with a 9-point lower score (out of 100 points) on the UPSA (Stergiopoulos et al., 2011), establishing it as a feasible measure with construct validity.

5. Cognitive strategy use will be measured with the Cognitive Problems and Strategies Assessment (CPSA; Twamley et al., 2012), a measure directly assessing the use of compensatory strategies taught in CCT.

6. Psychiatric symptom severity will be measured with the PTSD Checklist-Military Version (Weathers et al., 1991), the Patient Health Questionnaire-9 (Kroenke et al., 2001), the Neurobehavioral Symptom Inventory (Cicerone & Kalmar, 1995), and the Insomnia Severity Index (Bastien et al., 2001), as measures of PTSD, depression, neurobehavioral symptoms, and insomnia symptom severity, respectively. All are brief gold-standard measures that are used routinely at Aspire Center intake.

7. The related constructs of disability, community integration, and quality of life will be assessed by the World Health Organization Disability Assessment Scale 2.0 (WHODAS 2.0; WHO, 2012), the World Health Organization Quality of Life-BREF (WHOQOL Group, 1998), and the Community Reintegration of Service Members-Computer Adaptive Test (CRIS-CAT; Resnik et al., 2012), three brief, well-validated measures. The CRIS-CAT is a computer adaptive test specifically designed for military and Veteran populations; the authors have obtained permission for the CRIS-CAT to be available on VA computers.

Section 9.9 Data Safety Monitoring Board or Plan

9.9) Provide a Data Safety Monitoring Plan (DSMP) or the details of a Data Safety Monitoring Board; if a written plan is available, attach a copy of the plan to the submission form.

Protections Against Risk

Assessment: During interviews and neuropsychological/functional testing, trained raters will closely monitor for signs of stress, fatigue, and distress. Rest breaks will be provided as needed during all assessments to reduce fatigue and boredom. Also, subjects may refuse to answer any specific questions or to complete any given tests. They will also be advised that they can withdraw from the study at any point. If a participant discloses that he or she is experiencing suicidal ideation during diagnostic interviewing or on standard clinical measures, the rater will immediately contact the PI and the Aspire Center clinician on call to ensure that steps are taken to ensure the participant's safety.

Confidentiality: In order to protect confidentiality, all participant data will be de-identified by assigning each participant a unique ID in computer files, and all physical files from the study will

files will be stored on a secure VA server. Only study investigators and personnel will have access to these data. All documentation will identify participants only by their Unique ID number and not other personally identifying information.

Treatment: Although the CCT and education control conditions are expected to be low-risk, they will be delivered by trained mental health professionals under Dr. Twamley's direct supervision. All participants will be monitored for mood changes and any indications of ideation of harm to self or others will be immediately addressed by Dr. Twamley and the Aspire Center staff, including the Medical Director, Dr. Scott Matthews.

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).***

Audio recordings will be used to ensure adherence to the treatment manuals (i.e., treatment fidelity). All audiorecordings will be stored on digital recorders stored in locked file cabinets in locked offices.

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 subject population in this study will be 98 male and female OEF/OIF/OND Veterans with mental health conditions served by the Aspire Center. Complete Inclusion/Exclusion Criteria are as follows:
b) presence of at least one DSM-V mental health condition
c) does not meet criteria for substance use disorder for 28 days prior
Inclusion Criteria:
1) Male or female, any race/ethnicity, and age 18-55
2) Meets criteria for Aspire Center program entry
a) O/O/O Veteran
to admission
d) homeless or unstably housed (per HEARTH Act definition; HUD, 2011b)
e) not a sex offender or violent offender
f) capable of performing activities of daily living and transfers
g) not judged by a clinician to be at current risk to self or others
3) Has cognitive impairment in at least one cognitive domain (i.e., T-score <40)
4) Able to speak and read English
5) Capable of and willing to provide signed informed consent

Exclusion Criteria:
None

We anticipate that about half of consented participants will NOT have cognitive impairment (criterion 3, above). Those participants will end their participation after completing the baseline assessment

Section 10.2 Pregnant Women

10.2a) Are pregnant women the focus of the research?

○ Yes ○ No

10.2b) Provide the justification for including pregnant women and address any special risks, protections, and safeguards.

Although we are not targeting pregnant women specifically, there is no reason to exclude a pregnant woman who would like to participate in the study and meets the inclusion criteria.

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.***

The trial is to study an intervention to improve cognition in Veterans with cognitive impairment.

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.

The sole recruitment source for this study will be the VA Aspire Center, a 40-bed Residential Rehabilitation Treatment Program serving homeless O/O/O Veterans with mental health conditions such as PTSD, depression, and TBI. To facilitate recruitment, our PI and study staff will be highly visible at the Aspire Center and will coordinate with program intake staff (with the support of Deborah Dominick, LCSW, Chief of the Aspire Center). Individuals who meet the inclusion criteria will then be approached for potential participation in the study and, if interested, will complete the consenting process and the baseline assessment. We will also post a flyer at the Aspire Center to let Veterans know about the study.

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). However, you may request to advertise on the e-boards (located at the elevators and throughout the facility) or on the VASDHS Research Opportunities web-page.***

We will have a flyer posted at the VA Aspire Center.

Section 12 - Informed Consent

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

prospective subject or the prospective subject's LAR?

○ Yes ◉ No

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 and/or HIPAA waiver when required)?

◉ 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.

Potential participants may take a copy of the consent to review and consider before signing. Dr. Twamley or study staff will be available to answer any questions potential participants may have.

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.***

Post-consent quiz (attached).

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

N/A, participants will only be enrolled if they demonstrate decisional capacity.

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:

N/A

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

N/A

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:

N/A

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 13 - Alternatives to Participation

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

Section 14 - Potential Risks

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

A. Fatigue, boredom, or stress while completing the assessments. These are not rare, but are not serious.
B. As with any research study, the possibility of breach of confidentiality exists. These are rare. Dr. Twamley has been conducting research with human subjects for 20 years and has never had a breach of confidentiality in her lab. Veterans will provide identifying data. In addition, we will obtain information from Veterans' medical record. Data obtained from Veterans are rigorously protected by identifying subjects' data by code number. The key to this code will be stored in a locked cabinet in the Aspire Center Occupational Therapy Office. Only the project investigators, UCSD IRB, and VA R&D will have access to them. Hard copy paper screens will be kept inside locked file cabinets inside locked office space inside the VA-designated office space for the study. The tablets will be kept in a locked cabinet in the Aspire Center Occupational Therapy Office when not in use. Password protected login on the tablet is done by study staff only, minimizing the risk of participants having access to others' information. In addition, the "Triple I" contract specifies that the information collected on the tablet will be immediately uploaded to a server behind the VA firewall and will not be stored on the tablet, further reducing the risk of privacy breach.

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.

Assessment: During interviews and neuropsychological/functional testing, trained raters will closely monitor for signs of stress, fatigue, and distress. Rest breaks will be provided as needed during all assessments to reduce fatigue and boredom. Also, subjects may refuse to answer any specific questions or to complete any given tests. They will also be advised that they can withdraw from the study at any point. If a participant discloses that he or she is experiencing suicidal ideation during diagnostic interviewing or on standard clinical measures, the rater will immediately contact the PI and the Aspire Center clinician on call to ensure that steps are taken to ensure the participant's safety.

Confidentiality: In order to protect confidentiality, all participant data will be de-identified by assigning each participant a unique ID in computer files, and all physical files from the study will be kept in a locked cabinet in a locked office in the Aspire Center. All electronic data and files will be stored on a secure VA server. Only study investigators and personnel will have access to these data. All documentation will identify participants only by their Unique ID number and not other personally identifying information. Research Material: Data obtained from Veterans and service providers are rigorously protected by identifying subjects' data by code number. Each Veteran will be assigned a unique identifier which will be used as a study ID number on all electronic and hard copy data. Hard copy paper screens will be kept inside locked file cabinets inside locked office space inside the VA-designated office space for the study. The tablets will be kept in a locked cabinet in the Aspire Center Occupational Therapy Office when not in use. Password protected login on the tablet is done by study staff only, minimizing the risk of participants having access to others' information. In addition, the "Triple I" contract specifies that the information collected on the tablet will be downloaded to a server behind the VA firewall and will not be stored on the tablet, further reducing the risk of privacy breach.

Additional information on data security plan is detailed in the VASDHS Privacy and Data Security Plan.

Treatment: Although the CCT and education control conditions are not expected to confer risk beyond usual clinical care, they will be delivered by trained mental health professionals under Dr.

and the Aspire Center staff, including the Medical Director, Dr. Scott Matthews.

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)

Subjects may learn cognitive strategies that improve their daily functioning. The researchers will learn more about how to improve functioning via cognitive training.

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.

Given the low risks of this psychosocial intervention and the potential for benefit and new knowledge, the risk/benefit ratio appears favorable.

Section 20 - Compensation for Participation

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

Participants will be compensated for their time spent in assessments ($25 per assessment X 4 assessments = $100 maximum total compensation) as a way to enhance retention. This amount was felt to be sufficient compensation for time, but not so high as to be coercive.

Section 21 - Responsibilities and Qualifications

Here are the identified study staff members

Elizabeth W. Twamley, PhD

Amy J. Jak, PhD, Matthew R. Morgan, Mili Parikh, PhD, Amber Victoria Keller, Felicia Van Schie, Janae Ruth Wyckoff, Jillian M. Clark, PhD, Paula Michelle Seewald, MA, Jeffrey Hernandez, Jacqueline E. Maye, PhD, Tara Austin, PhD

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.

Elizabeth Twamley - PI, Research Health Science Specialist
Amy Jak - co-I, neuropsychologist
Paula Michelle Seewald -- clinical research associate
Matthew Morgan - clinical research associate (psychometrist)
Mili Parikh -- study psychologist
Jillian Clark -- postdoctoral fellow
Jacqueline Maye -- postdoctoral fellow
Janae Wyckoff -- clinicl research associate
Amber Keller -- clinical research associate / doctoral student
Felicia Van Schie -- research associate
Tara Austin -- postdoctoral fellow

All study staff will be authorized to obtain consent.

Jeffrey Hernandez will provide technical support for the eScreening devices. Software support may require that he have access to identified data, including PHI.

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.)

Depp, C.A., Vella, L., Orff, H.J., & Twamley, E.W. (2015). A quantitative review of cognitive functioning in homeless adults. Journal of Nervous and Mental Disease, 203, 126-131.

Stergiopoulos, V., Burra, T., Rourke, S., & Hwang, S. (2011). Housing status as an independent predictor of functional capacity in patients with schizophrenia. Journal of Nervous and Mental Disease, 199, 854-860.

Twamley, E.W., Jak, A.J., Delis, D.C., Bondi, M.W., & Lohr, J.B. (2014b). Cognitive Symptom Management and Rehabilitation Therapy (CogSMART) for Veterans with traumatic brain injury: A pilot randomized controlled trial. Journal of Rehabilitation Research and Development, 51, 59-69.

Twamley, E.W., Thomas, K.R., Gregory, A.M., Jak, A.J., Bondi, M.W., Delis, D.C., & Lohr, J.B. (in press). CogSMART compensatory cognitive training for traumatic brain injury: Effects over one year. Journal of Head Trauma Rehabilitation.

Twamley, E.W., Vella, L., Burton, C.Z., Heaton, R.K., & Jeste, D.V. (2012). Compensatory Cognitive Training for psychosis: Effects in a randomized controlled trial. Journal of Clinical Psychiatry, 73, 1212-1219.

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.

Participation in this study may involve a loss of privacy, but information will be handled as confidentially as possible. Participation in study assessments and any study related treatment will be documented in your electronic medical record. Research records will be labeled with a code number. The list that matches the participant name with
the code number will be kept in a locked file in the research team's office. Any research records that identify the participant will be kept only as paper records in a secure VASDHS location, or as files
behind the secure VASDHS computer firewall. Any presentations or publications from this information will not identify the participant. Audio recordings of treatment sessions will be stored on a VA
secure server and will be accessed by Dr. Twamley or her staff for the purposes of rating the psychologist's adherence to the treatment manuals.
We will keep confidential all research and medical records that identify the participant to the extent allowed
by law. However, there are some circumstances in which we may have to show participant information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, and federal compliance officers may look at or copy portions of records that identify the participant.

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.***

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

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:

- [x] Protected Health Information (PHI)
- [x] Names
- [ ] Device identifiers and serial numbers
- [x] 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
- [ ] 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
- [ ] Social security numbers or scrambled SSNs (describe below)
- [ ] Other unique identifying number, characteristic, or code (describe below)

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.)?

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

○ Yes ◉ No

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

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. 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.

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 who undergo HBVT delivery of care may use one of their own devices or computers available at the Aspire Center VA clinic. 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. This software package allows 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

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

○ Yes ◉ No

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

◉ Yes ○ No

27.2d1) 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 generated using these tools.

https://vaww.escreening.va.gov/sdc/ Escreening is available on the VA network behind the secured firewall. Each participant uses a VA computer to access and fill out questionnaires.

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

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

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.

Hard copy data is stored in a locked filing cabinet located in a locked office, within the Aspire Center, a secured building located at 2121 San Diego Ave, San Diego, CA 92110. Second floor, room 203

(●) 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.

Information is stored behind the VA firewall in the Twamley shared R drive. Participant contact information, coding sheet, and data entered into the Access database are all stored on this secured drive.

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".

Information is stored behind the VA firewall in the Twamley shared R drive. Participant contact information, coding sheet, and data entered into the Access database are all stored on this secured drive.

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.

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

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

Section 29 - Existing Project Association

29) The associated R&D Project should already exist in the database. Identify the R&D Project(s) that correspond to this protocol.

Project Status	Proposal Number	Project Title	Principal Investigator
No Projects are Linked to this Study			

The Protocol Application is now complete for a Protocol attached to an existing Project.

Next you will go on to the Initial Review Submission Form. This form is used to collect the Application and any other needed attachments for submission to the IRB for review.

Press *Save and Continue*