

AWARD NUMBER: W81XWH-19-1-0747

TITLE: Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) for Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: Dr. Megan L. Callahan, PsyD

CONTRACTING ORGANIZATION: Oregon Health & Science University

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PREPARED FOR: U.S. Army Medical Research and Development Command  
Fort Detrick, Maryland 21702-5012

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| REPORT DOCUMENTATION PAGE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |              |                          |                            | Form Approved<br>OMB No. 0704-0188              |                                           |
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| 1. REPORT DATE<br>OCTOBER 2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |              | 2. REPORT TYPE<br>Annual |                            | 3. DATES COVERED<br>15 Sept 2019 - 14 Sept 2020 |                                           |
| 4. TITLE AND SUBTITLE<br><br>Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) for Traumatic Brain Injury                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              |                          |                            | 5a. CONTRACT NUMBER                             |                                           |
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| 6. AUTHOR(S)<br>Megan Callahan, PsyD<br><br>E-Mail: callameg@ohsu.edu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              |                          |                            | 5d. PROJECT NUMBER                              |                                           |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |              |                          |                            | 5f. WORK UNIT NUMBER                            |                                           |
| 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)<br>Oregon Health & Science University<br>3181 SW Sam Jackson Park Rd,<br>Portland, Oregon 97239-3098                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |              |                          |                            | 8. PERFORMING ORGANIZATION REPORT NUMBER        |                                           |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)<br><br>U.S. Army Medical Research and Development Command<br>Fort Detrick, Maryland 21702-5012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |              |                          |                            | 10. SPONSOR/MONITOR'S ACRONYM(S)                |                                           |
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| 13. SUPPLEMENTARY NOTES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |              |                          |                            |                                                 |                                           |
| 14. ABSTRACT: The primary objective of the Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) intervention with Veterans who have a history of traumatic brain injury (TBI) is to reduce their negative cognitive and psychiatric health outcomes and promote personal resilience. The long-term objective of this study is to develop an accessible and acceptable intervention that can be broadly disseminated to address the complex rehabilitation needs within this population of Veterans. Participants will be Veterans and Service members with a history of TBI enrolled for health services at any VA medical center or satellite program. A total of 192 participants will be enrolled. Participants will be randomly assigned to either the treatment (Tele-CABA) or a usual-care control group (UC). Participants randomly assigned to the Tele-CABA group will receive the manualized intervention delivered by telephone over the course of 10 weekly, 90-minute sessions. Participants in the UC group will continue to receive their regular medical, psychiatric, and psychotherapeutic care. All participants will undergo evaluation at baseline, post-treatment, and 6-months following the completion of treatment. At baseline, participants will complete a diagnostic TBI interview, self-report questionnaires measuring cognitive and psychiatric symptom severity including the Neurobehavioral Symptom Inventory (NSI) and a brief cognitive screening battery. Self-report questionnaires and cognitive testing will be repeated at post-treatment and follow-up. We will evaluate the following primary outcomes: cognitive symptoms, psychiatric distress symptoms, utility of compensatory strategies, self-efficacy, adaptive functioning, quality of life, and treatment satisfaction. |              |                          |                            |                                                 |                                           |
| 15. SUBJECT TERMS<br>traumatic brain injury (TBI); Veterans; Service Members; telehealth; cognitive, rehabilitation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |              |                          |                            |                                                 |                                           |
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| a. REPORT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | b. ABSTRACT  | c. THIS PAGE             |                            |                                                 | USAMRMC                                   |
| Unclassified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Unclassified | Unclassified             | Unclassified               | 18                                              | 19b. TELEPHONE NUMBER (include area code) |

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## 1. INTRODUCTION

Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) for TBI, investigates a 10-week, manualized, cognitive rehabilitation treatment that will be delivered by telephone for Veterans and Service Members with a history of TBI. Tele-CABA involves identifying personally meaningful goals and activities while simultaneously learning cognitive strategies to aid in working towards those goals. The **long-term objective** of this study is to develop an accessible intervention to address the complex needs of patients with TBI. The **overall objective** of Tele-CABA is to reduce cognitive and psychiatric health distress and promote personal resilience so that Veterans and Service Members may feel more productive and satisfied in life.

**2. KEYWORDS:** traumatic brain injury (TBI); Veterans; Service Members; telehealth; cognitive, rehabilitation

## 3. ACCOMPLISHMENTS

### What were the major goals of the project?

We hypothesize that participants in the Tele-CABA group, compared to usual care (UC), will demonstrate greater reduction of cognitive and psychiatric symptoms and more significant improvement in adaptive functioning. We are addressing two Specific Aims:

Specific Aim 1: To determine if Tele-CABA is effective for reducing cognitive and neuropsychiatric symptoms in Veterans and Service Members with a history of TBI.

Specific Aim 2: To determine if Tele-CABA is effective at improving adaptive functioning and quality of life for Veterans and Service Members with a history of TBI.

We had four Milestones for Major Task 1 in Y1. All four are now fully completed (C). We had two Milestones for Major Task 2 in Y1. Both are fully completed (C).

|                                                                                                                                    | Year 1 |    |    |    | Year 2 |    |    |    | Year 3 |    |    |    |
|------------------------------------------------------------------------------------------------------------------------------------|--------|----|----|----|--------|----|----|----|--------|----|----|----|
|                                                                                                                                    | Q1     | Q2 | Q3 | Q4 | Q1     | Q2 | Q3 | Q4 | Q1     | Q2 | Q3 | Q4 |
| <b>Major Task 1: Study Initialization. IRB approval, Implement data collection and management systems, recruit and train staff</b> |        |    |    |    |        |    |    |    |        |    |    |    |
| Subtask 1: IRB submission and approval                                                                                             | C      |    |    |    |        |    |    |    |        |    |    |    |
| Refine eligibility criteria, exclusion criteria, screening protocol                                                                | C      |    |    |    |        |    |    |    |        |    |    |    |
| Finalize consent form & human subjects protocol                                                                                    | C      |    |    |    |        |    |    |    |        |    |    |    |
| Finalize assessment materials and study forms                                                                                      | C      |    |    |    |        |    |    |    |        |    |    |    |
| Verify software for data entry, tracking, and database management                                                                  | C      |    |    |    |        |    |    |    |        |    |    |    |
| Submit joint VA-OHSU IRB materials                                                                                                 | C      |    |    |    |        |    |    |    |        |    |    |    |
| Submit Military 2nd level IRB review (ORP/HRPO)                                                                                    | C      |    |    |    |        |    |    |    |        |    |    |    |
| Submit amendments, adverse events and protocol deviations as needed to the joint IRB                                               | C      |    |    |    |        |    |    |    |        |    |    |    |
| Submit required HRPO materials as needed (i.e. annual Continuing Review)                                                           | C      |    |    |    |        |    |    |    |        |    |    |    |
| Subtask 2: Implement data collection and management systems                                                                        | C      |    |    |    |        |    |    |    |        |    |    |    |
| Setup FITBIR and coordinate                                                                                                        | IP     | C  |    |    |        |    |    |    |        |    |    |    |

|                                                                                                    |         |        |   |   |    |    |    |    |    |    |    |  |
|----------------------------------------------------------------------------------------------------|---------|--------|---|---|----|----|----|----|----|----|----|--|
| yearly transfer of study data                                                                      |         |        |   |   |    |    |    |    |    |    |    |  |
| Conduct in house testing of data systems                                                           | C       |        |   |   |    |    |    |    |    |    |    |  |
| Subtask 3: Hire and train staff                                                                    | C       |        |   |   |    |    |    |    |    |    |    |  |
| <i>Milestone: Joint VA-OHSU IRB approval</i>                                                       | 10.2019 |        |   |   |    |    |    |    |    |    |    |  |
| <i>Milestone: HRPO approval</i>                                                                    | IP      | 3.2020 |   |   |    |    |    |    |    |    |    |  |
| <i>Milestone: FITBIR setup and operational</i>                                                     | IP      | 1.2020 |   |   |    |    |    |    |    |    |    |  |
| <i>Milestone: Research staff hired and trained</i>                                                 | 10.2019 |        |   |   |    |    |    |    |    |    |    |  |
| <b>Major Task 2: Enrollment, randomization, intervention, and data collection for Aims 1 and 2</b> |         |        |   |   |    |    |    |    |    |    |    |  |
| Subtask 1: Enrollment and randomization                                                            |         |        |   |   |    |    |    |    |    |    |    |  |
| Announce study recruitment and disseminate study flyer                                             |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| Enroll study participants (n=192; 3 years)                                                         |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| Randomize study participants to Tele-CABA or usual care (UC) (n=96 per group)                      |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| Subtask 2: Provide Tele-CABA intervention                                                          |         |        |   |   |    |    |    |    |    |    |    |  |
| Deliver Tele-CABA intervention by telephone to n=96 participants                                   |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| Monitor adverse events and report if needed                                                        |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| Subtask 3: Data collection and entry                                                               |         |        |   |   |    |    |    |    |    |    |    |  |
| Collect study data from all participants at baseline, 12 weeks, and 6 months                       |         | C      | C | C | IP | IP | IP | IP | IP | IP | IP |  |
| Enter study data into database                                                                     |         | C      | C | C | IP | IP | IP | IP | IP | IP | IP |  |
| <i>Milestone: First participant screened, consented, and enrolled</i>                              |         | 3.2020 |   |   |    |    |    |    |    |    |    |  |
| <i>Milestone: n=192 participants recruited and enrolled</i>                                        |         | C      | C | C | IP | IP | IP | IP | IP | IP |    |  |
| <i>Milestone: Last participant recruited</i>                                                       |         |        |   |   |    |    |    |    | IP |    |    |  |

### What was accomplished under these goals?

We successfully began study recruitment in Y1. We have enrolled 20 participants and are actively screening additional study candidates and scheduling consent appointments. We are collecting baseline data and entering the data into the database. To date, eight of the twenty participants enrolled have completed mid treatment. None have completed the study, thus far, though we expect 5-10 to have completed by the end of 2020.

We have reached out to collaborators nationwide and set up referral sources at VAs around the country. We have had considerable difficulty setting up recruitment at DoD facilities, in part due to the COVID-19 pandemic as well as the challenges that come with seeking site approval by Command. We continue to cultivate these relationships and hope to improve our recruitment of Service Members in Y2.

### Human Subjects Enrollment Tables 1 and 2:

| Report Period | Enrolled (#Tele-CABA/UC) | Baseline data collection completed (#Tele-CABA/UC) | 12 weeks data collection completed (#Tele-CABA/UC) | 6 months data collection completed (#Tele-CABA/UC) |
|---------------|--------------------------|----------------------------------------------------|----------------------------------------------------|----------------------------------------------------|
| Year 1 Annual | 20                       | 20                                                 | 8                                                  | 0                                                  |
|               |                          |                                                    |                                                    |                                                    |
|               |                          |                                                    |                                                    |                                                    |
|               |                          |                                                    |                                                    |                                                    |

|                             |                         |                            | Enter information regarding number of subjects |                   |                    |                   |                    |
|-----------------------------|-------------------------|----------------------------|------------------------------------------------|-------------------|--------------------|-------------------|--------------------|
| <u>HRPO Protocol Number</u> | <u>Protocol PI Name</u> | <u>Organization (Site)</u> | <u># Target</u>                                | <u># Enrolled</u> | <u># Completed</u> | <u># Screened</u> | <u># Recruited</u> |
| E00975.1a & E00975.1b       | Callahan                | VAPORHCS                   | 192                                            | 20                | 0                  | 36                | Open recruitment   |
|                             |                         |                            |                                                |                   |                    |                   |                    |
|                             |                         |                            |                                                |                   |                    |                   |                    |

**PHS Inclusion and Demographic Enrollment Table:**

| Racial Categories                         | Ethnic Categories      |      |                       |                    |      |                       |                                |      |                       |       |
|-------------------------------------------|------------------------|------|-----------------------|--------------------|------|-----------------------|--------------------------------|------|-----------------------|-------|
|                                           | Not Hispanic or Latino |      |                       | Hispanic or Latino |      |                       | Unknown/Not Reported Ethnicity |      |                       | Total |
|                                           | Female                 | Male | Unknown/ Not Reported | Female             | Male | Unknown/ Not Reported | Female                         | Male | Unknown/ Not Reported |       |
| American Indian/ Alaska Native            |                        | 1    |                       |                    | 2    |                       |                                | 1    |                       | 4     |
| Asian                                     |                        |      |                       |                    |      |                       |                                |      |                       | 0     |
| Native Hawaiian or Other Pacific Islander |                        |      |                       |                    |      |                       |                                |      |                       | 0     |
| Black or African American                 |                        |      |                       |                    |      |                       |                                |      |                       | 0     |
| White                                     | 4                      | 11   |                       |                    |      |                       |                                |      |                       | 15    |
| More than One Race                        |                        | 1    |                       |                    |      |                       |                                |      |                       | 1     |
| Unknown or Not Reported                   |                        |      |                       |                    |      |                       |                                |      |                       | 0     |
| <b>Total</b>                              | 4                      | 13   | 0                     | 0                  | 2    | 0                     | 0                              | 1    | 0                     | 20    |

## A. Human Use Regulatory Protocols

**TOTAL PROTOCOLS:** One human subject research protocol will be required to complete the Statement of Work.

### **PROTOCOL(S) (2 of 2 total):**

Protocol [HRPO Assigned Number]: E00975.1a and E00975.1b.

Title: Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) for Traumatic Brain Injury (TBI)

Target required for clinical significance: N/A

Target approved for clinical significance: N/A

**SUBMITTED TO AND APPROVED BY:** Joint OHSU/VAPORHCS IRB

### **STATUS:**

- (i) Number of subjects recruited/original planned target: 36/192  
Number of subjects screened/original planned target: 36/192  
Number of patients enrolled/original planned target: 20/192  
Number of patients completed/original planned target: 0/192
- (ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
  - a. Amendment 1; 11.22.19; OHSU Modification Number: MOD00023711:  
Minor modifications were made to recruitment materials, study questionnaires, and the patient manual
  - b. Amendment 2; 3.27.2020; OHSU Modification Number: MOD00025370:  
Minor modifications were made to recruitment materials and patient contact letters; the study protocol was updated to more clearly define the questions from the NSI asked during screen, rather than the entire measure. The VA screening waiver was updated to include collection of the last four of a participant's SSN prior to consent in order to conduct VINCI/CDW medical record review for recruitment.
  - c. Amendment 3; 5.6.2020; OHSU Modification Number: MOD00027313:  
Minor modifications were made to the protocol to allow patients and providers to text message images of homework assignments. Additional updates were made to patient info letter to update the list of forms mailed to participants, the telephone script to be more descriptive of the study intervention, and the study flyer.
  - d. Amendment 4; OHSU Modification Number: MOD00030015:  
Minor updates were made to the Tele-CABA lost to contact letter, telephone script, ICF, Protocol, Surveys and Questionnaires and Questionnaires Cover Letter. Additionally, we have included a lost to contact letter for potential participants who have not yet been consented. The Tele-CABA study abstract has also been updated to include the study's progress.
- (iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
  - a. Serious, Unanticipated Problem; 6.30.2020; OHSU RNI #00004721:  
A participant packet being returned to the study was tracked to a VA Post Office Box off campus and unable to be accessed by study staff. The packet contained the study ICF, HIPAA authorization form,



and baseline questionnaires. The packet is unable to be retrieved, per the VA letter carrier and local post office. The study uses tracking numbers and pre-addressed envelopes to minimize the risk of this event occurring. The VA will provide credit monitoring service for the participant. As of August 12, 2020, the package was found and intact. The IRB did not modify its ruling of the security incident.

**What opportunities for training and professional development has the project provided?** Nothing to report.

**How were the results disseminated to communities of interest?**  
Nothing to report.

**What do you plan to do during the next reporting period to accomplish the goals?** During the next reporting period, we plan to continue to enroll and recruit prospective participants. Due to the COVID-19 pandemic, recruitment has progressed slowly. As a result, we expanded our National recruitment efforts to a broader catchment area. We additionally conducted a medical record search to identify potential participants.

#### **4. IMPACT:**

What was the impact on the development of the principal discipline of the project? **Nothing to report**

What was the impact on other disciplines? **Nothing to report**

What was the impact on technology transfer? **Nothing to report**

What was the impact on society beyond science and technology? **Nothing to report**

#### **5. CHANGES/PROBLEMS:**

##### **i. Actual Problems or delays and actions to resolve them**

Due to the on-going COVID-19 response, the VA has transitioned all patient visits to telephone or telehealth. Although our study is equipped to operate entirely remotely, we have experienced a significant disruption to recruitment. We initiated a data search to identify potentially eligible study participants and will be sending recruitment opt-in/out letters soon. We hope that this search will identify potential study candidates to boost recruitment.

##### **ii. Anticipated Problems/Issues**

See above.

**6. PRODUCTS:** Nothing to report.

#### **7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

**Name:** Megan Callahan

**Project Role:** PI

**Nearest person month worked:** 6 calendar months

**Contribution to Project:** Hiring, training, and supervising all study personnel on proposed study. Providing oversight for all study procedures including the submission of IRB materials, recruitment, enrollment and retention, data collection, and monitoring adherence to study protocol and procedures. Responsible for data analysis and dissemination, including sharing data with the Federal Interagency Traumatic Injury Research (FITBIR) informatics system. Dr. Callahan also serves as a backup therapist on the project.

**Name:** James Henry

**Project Role:** Co-I

**Nearest person month worked:** 2.4 calendar months

**Contribution to Project:** Responsible for assisting with study startup, reviewing progress of the project at frequent intervals to ensure that productivity matches or exceeds established goals, participating in routine meetings with study staff, preparation and submission of scientific peer-reviewed presentations and publications, and the development of future research proposals.

**Funding Support:** (if different than this award) His effort is cost shared to the VA

**Name:** Melissa Papesh

**Project Role:** Co-I

**Nearest person month worked:** 1.2 calendar months

**Contribution to Project:** Works closely with the study team to guide participant recruitment and retention efforts; contribute to data collection, linkage, and analysis, including VA clinical records (administrative) data; and contribute to the sharing of relevant (i.e. TBI-related) data to FITBIR to support initiatives focused on the brain and TBI. Dr. Papesh will help prepare and submit scientific peer-reviewed presentations and publications.

**Funding Support:** (if different than this award) Her effort is cost shared to the VA

**Name:** Kathleen Carlson

**Project Role:** Co-I

**Nearest person month worked:** 1.2 calendar months

**Contribution to Project:** Works closely with the study team to guide participant recruitment and retention efforts; contribute to data collection, linkage, and analysis, including VA clinical records (administrative) data; and other stakeholders. Facilitates the contribution of relevant (i.e. TBI-related) data to FITBIR to support initiatives focused on the brain and TBI.

**Name:** Daniel Storzbach

**Project Role:** Co-I

**Nearest person month worked:** 1 calendar month

**Contribution to Project:** Works closely with the study team to guide participant recruitment and retention efforts, participate in routine meetings with study staff, prepare and submit scientific peer-reviewed presentations and publications, and develop of future research proposals.

**Name:** Halina Kowalski

**Project Role:** Co-I/Therapist

**Nearest person month worked:** 2.4 calendar months

**Contribution to Project:** She supports this study as a therapist.

**Name:** Mai Roost

**Project Role:** Co-I/Therapist

**Nearest person month worked:** 3.6 calendar months

**Contribution to Project:** She is currently a Co-Investigator and the lead therapist for the randomized controlled trial of CABA for Veterans with mTBI and PTSD. Dr. Roost has also provided training and fidelity review support to the CABA study. Thus, her expertise as a study therapist in CCT and CABA is of great value to the study.

**Name:** Jennifer Hallman

**Project Role:** Co-I/Therapist

**Nearest person month worked:** 12 calendar months

**Contribution to Project:** She supports this study as a therapist.

**Name:** Emily Thielman

**Project Role:** Research Coordinator

**Nearest person month worked:** 2.4 calendar months

**Contribution to Project:** Responsible for many day-to-day activities, including: (1) fulfilling R&D and IRB requirements, (2) consenting new participants, (3) reviewing and entering data, and (4) database management and upkeep. Ms. Thielman is also responsible for designing, programming, and maintaining the study databases, as well as the organization and validation of data throughout the study. She may provide preliminary statistical analyses as requested by the PI and/or study team, and will assist the study biostatistician with interim and final analyses.

**Name:** Deanna Gold

**Project Role:** Research Assistant

**Nearest person month worked:** 8.1 calendar months

**Contribution to Project:** Plays a central role on the study, including: (1) fulfilling R&D and IRB requirements; (2) arranging study advertisements and leading recruitment efforts; (3) screening potential subjects by telephone to determine eligibility; (4) scheduling appointments; (5) greeting subjects, administering informed consent, and obtaining demographic information; (6) reviewing questionnaires and entering data; (7) data cleaning in study databases; (8) arranging for subject payments, (9) obtaining and organizing cognitive testing supplies and equipment; and (10) completing telephone cognitive assessments.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

- There are no changes in senior/key personnel.

***Changes in active support for Dr. Callahan. Besides adding this award to her active support, the following changes occurred since the JIT.***

***New - none***

***Ended***

PT160162 (Heinricher, PI) 10/17-09/21 4.8 calendar months  
DoD CDMRP Award  
Jonathan Ryder, 1077 Patchel Street, Ft. Detrick, MD  
*Photosensitivity and Pain in Complex Traumatic Brain Injury*  
Goal: To quantify photosensitivity in Veterans with complex traumatic brain injury, determine whether photosensitivity is related to pain, and understand brain circuits engaged by light in these individuals.  
Role: Study Clinician; Collaborator

***Changes in active support for Dr. Henry. Besides adding this award to his active VA Appointment support, the following changes occurred since the JIT.***

***VA Appointment, New:***

CENCIIR Carlson, Henry (PIs) 10/19-09/24n 1.2 calendar months  
DoD/CDMRP & DVA/CSR&D  
Mary McDougal, Dept. Physical Medicine & Rehabilitation, PO Box 980677, Richmond, VA  
*Long-Term Impact of Military-Relevant Brain Injury Consortium (LIMBIC)*  
Goal: This project will expand an ongoing longitudinal epidemiology study to focus specifically on the auditory sequelae of mild traumatic brain injury among recent combat Veterans. This study will help estimate the direct effects of mild TBI on auditory dysfunction while accounting for potentially confounding factors such as noise and ototoxic exposures, post-traumatic stress disorder, and number of and time-since mild TBI events.

**VA Appointment, Ended:**

CENC IIR Carlson (PI)

10/16-09/19

3.0 calendar months

DVA

Mary McDougal, Dept. Physical Medicine &amp; Rehabilitation, PO Box 980677, Richmond, VA

*Longitudinal Effects of Mild TBI and Other Military Exposures on Auditory Functioning in Recently-Discharged Veterans and Active Duty Service Members*

**Project Goals:** The proposed project would expand an ongoing longitudinal epidemiology study to focus specifically on the auditory sequelae of mild traumatic brain injury among recent combat Veterans. This study will help estimate the direct effects of mild TBI on auditory dysfunction while accounting for potentially confounding factors such as noise and ototoxic exposures, post-traumatic stress disorder, and number of and time-since mild TBI events.

Role: Co-PI

**OHSU Appointment, New - none****OHSU Appointment, Ended - none**

**Changes in active support for Dr. Papesh. Besides adding this award to her active VA appointment support, the following changes occurred since the JIT.**

**VA Appointment, New:**

RH180010

Molis (PI)

08/19-07/22n

1.0 calendar months CDMRP

HRRP

*Toward Development of a Mobile Assessment and Differential Diagnosis of Auditory Dysfunction: Hidden Hearing Loss and Central Auditory Processing Disorders*

Susan M. Dellinger, Department of the Army, 820 Chandler St., Fort Detrick, MD

**Project Goals:** To develop an auditory screening tool for identification of suprathreshold auditory deficits that will also provide an initial differential diagnosis of the type of auditory dysfunction.

Role: Co-Investigator

CX002149

Theodoroff (PI)

07/20-06/24n

1.2 calendar months

VA CSR&amp;D, Merit

*Evaluating Possible Auditory and Psychological Biomarkers of Sound Intolerance*

**Project Goals:** Hyperacusis and noise sensitivity are types of decreased sound tolerance (DST) disorders, and frequently reported in patients with tinnitus and head injury respectively. When any degree of DST is seen in patients, it is paramount to address the problems tolerating sounds because it negatively impacts every aspect of daily functioning; severe DST manifests as everyday sounds being perceived as too loud, overwhelming, and annoying. Due to the paucity of research on DST, limited knowledge exists pertaining to fundamental aspects of its pathophysiology and how best to treat it.

**VA Appointment, Ended – none****OHSU Appointment – no changes**

**Changes in active support for Dr. Carlson. Besides adding this award to her active OHSU appointment support, the following changes occurred since the JIT.**

**VA appointment, New:**

RRP C1020-216 Teo (PI)

06/20-12/20n

1.8 calendar months

DVA HSR&amp;D

Robert O'Brien, PhD, HSR&amp;D Scientific Program Manager, 810 Vermont Ave. NW, Washington DC

*Adapting Caring Contacts to Counteract Adverse Effects of Social Distancing Among High-Risk Veterans During the COVID-19 Pandemic*

Project Goals: In this planning project, we will determine how to adapt Caring Contacts to reach Veterans especially at risk for adverse events during COVID-19 social distancing measures.

Role: Co-Investigator

I01 CX-002097-001 Walker; Cifu (PI) 10/19-09/24n 2.4 calendar months  
DVA CSR&D

Dana Herndon; US Army Medical Research Acquisition Activity; 504 Scott Street Ft. Detrick, MD 21702  
*Long-Term Impact of Military-Relevant Brain Injury Consortium (LIMBIC): Longitudinal Study*

Project Goals: The overall goal of LIMBIC is to identify and longitudinally follow Veterans with TBI to examine prevalence of, and risk factors for, decline over time consistent with neurodegeneration.

Role: Site PI

I01 RX003443-01 Pugh (PI) 10/19-09/24n 1.2 calendar months  
DVA RR&D

Dana Herndon; US Army Medical Research Acquisition Activity; 504 Scott Street Ft. Detrick, MD 21702VA-DoD  
*Long-term Impact of Military-Relevant Brain Injury Consortium (LIMBIC): Phenotypes of Persistent Comorbidity in Post-9/11 Era Veterans with mTBI*

Project Goals: This study leverages administrative data from the Departments of Defense and Veterans Affairs to examine the trajectories of health and functioning across similar symptoms groups in Post-9/11 Veterans with and without mild TBI.

Role: Co-Investigator

VRHRC 0160 RH Carlson (PI) 10/19-09/20n 1.2 calendar months  
DVA Office of Rural Health

Melissent Zumwalt, MPA; Veterans Rural Health Resource Center – Portland; Melissent.Zumwalt@va.gov; 503.220.8262 x57699

*Firearm Injuries among Rural Veterans in the US*

Project Goals: This project uses: 1) VA healthcare data to examine patterns and outcomes of rural versus non-rural Veterans' firearm injuries; and 2) DIPEX methodology to understand the culture of firearms among rural Veterans.

Role: Co-Investigator

VRHRC-PDX-FY20-3 Denneson (PI) 10/19-09/20n 0.6 calendar months  
DVA Office of Rural Health

Melissent Zumwalt, MPA; Veterans Rural Health Resource Center – Portland; Melissent.Zumwalt@va.gov; 503.220.8262 x57699

*Spatiotemporal Clustering of Veteran Suicides in Rural Oregon*

Project Goals: This project aims to examine the spatiotemporal community factors associated with suicide clusters among Veterans in Oregon and identify methods to expand this work nationally.

Role: Co-Investigator

I01 HX002162-01A1 Pogoda (PI) 05/18-04/22n 0.6 calendar months  
DVA HSR&D

*Improving Access to Supported Employment for Veterans with Polytrauma/Traumatic Brain Injury*

Project Goals: The purpose of this study is to increase access to Supported Employment (SE) among OEF/OIF/OND Veterans with polytrauma/traumatic brain injury by identifying actionable barriers and facilitators to SE referral, developing and implementing a customizable intervention package, and conducting preliminary assessment of its effectiveness at local VA sites that are below SE capacity.

Role: Co-Investigator

**VA Appointment, Ended - none**

**OHSU Appointment, New – none, besides adding this award.**

**OHSU Appointment, Ended:**

PH/TBI IIR Hammer (PI)

07/16-06/20

0.6 calendar months

DoD CDMRP

*Evaluation of a Work-Family and Sleep Leadership Intervention in the Oregon National Guard: A Behavioral Health Leadership Approach*Project Goals: This randomized controlled trial will develop and test an intervention involving behavioral health leadership combined with an individual service member health promotion program. Effects of the intervention on risk behaviors, psychological health, and workplace outcomes will be examined within the context of the Oregon National Guard.

Role: Co-Investigator

***Changes in active support for Dr. Storzbach. Besides adding this award to his active OHSU support, the following changes occurred since the JIT.*****VA Appointment, New:**

I01CX001592 (Twamley, Huckans Co-PI)

01/18-12/22n

0.6 calendar months

CSR&amp;D Merit Award

Sarah Clark, CSR&amp;D Office, 810 Vermont Ave. NW, Washington DC

*Cognitive Rehabilitation for Older Veterans with Mild Cognitive Impairment*Goal: This study is a randomized controlled trial of Motivationally-Enhanced Compensatory Cognitive Training for older veterans with Mild Cognitive Impairment. Role: Co-I.**VA Appointment, Ended:**

CSP #573 (Saunders PI)

11/13-08/19e

2.4 calendar months

VA CSP Study

Grant Huang, CSP Central Office, 810 Vermont Ave. NW, Washington DC

*Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD?*Goal: To assess the efficacy of pairing service and emotional support dogs with Veterans of all eras in the treatment of PTSD.

Role: Site PI

***OHSU Appointment: besides adding this award, there are no changes.******Changes in active support for Halina Kowalski. Besides adding this award to her active support, the following changes occurred since the JIT.*****New**

No Grant # Kowalski (Manager)

09/01/19-09/30/21 (NCE)

6 cal months

VA Adaptive Sports Grant

Alison Pruziner, Program clinical manager, alison.pruziner@va.gov

Horses Healing Heroes: Equine-Assisted Psychotherapy for Disabled Veterans and Servicemembers.

Goal: This is a program grant aimed at providing 384 unique Veterans and Servicemembers with an 8-week treatment course of EAGALA Model equine-assisted psychotherapy to address disability from trauma and related mental health issues.

Role: Principle Manager

**Ended**

CSP #573 (Saunders PI) 11/13-08/19 10.2 calendar months  
VA CSP Study  
Grant Huang, CSP Central Office, 810 Vermont Ave. NW, Washington DC  
*Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD?*  
Goal: To assess the efficacy of pairing service and emotional support dogs with Veterans of all eras in the treatment of PTSD.

***Changes in active support for Mai Roost. Besides adding this award to her active support, the following changes occurred since the JIT.***

***New - none***

**Ended**

CSP #573 (Saunders PI) 11/13-08/19 3.5 calendar months  
VA CSP Study  
*Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD?*  
Grant Huang, CSP Central Office, 810 Vermont Ave. NW, Washington DC  
*Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD?*  
Goal: To assess the efficacy of pairing service and emotional support dogs with Veterans of all eras in the treatment of PTSD.  
Role: Co-LSI

D1189-I (Storzbach, Wagner Co-PI) 04/15-09/20 1.0 calendar months  
VA Rehabilitation Research and Development  
Ricardo Gonzalez Rehab R&D Service, 810 Vermont Ave NW, Washington DC  
*Cognitively Augmented Behavioral Activation for Veterans with Comorbid TBI/PTSD*  
Goal: To assess the efficacy of a cognitively augmented behavioral activation individual treatment intervention with returning veterans from the recent conflicts in Iraq and Afghanistan.  
Role: Co-I

***Changes in active support for Hallman. Besides adding this award to her active support, the following changes occurred since the JIT.***

***New - None***

**Ended**

CSP #573 (Saunders PI) 11/13-08/19 7.2 calendar months  
VA CSP Study  
Grant Huang, CSP Central Office, 810 Vermont Ave. NW, Washington DC  
*Can Service Dogs Improve Activity and Quality of Life in Veterans with PTSD?*  
Goal: To assess the efficacy of pairing service and emotional support dogs with Veterans of all eras in the treatment of PTSD.  
Role: Research Assistant; Local Site Coordinator

D1189-I (Storzbach, Wagner Co-PI) 04/15-09/20 4.8 calendar months  
VA Rehabilitation Research and Development  
Ricardo Gonzalez Rehab R&D Service, 810 Vermont Ave NW, Washington DC  
*Cognitively Augmented Behavioral Activation for Veterans with Comorbid TBI/PTSD*  
Goal: To assess the efficacy of a cognitively augmented behavioral activation individual treatment intervention

with returning veterans from the recent conflicts in Iraq and Afghanistan.  
Role: Co-I.

***What other organizations were involved as partners?***

Nothing to report.

**8. SPECIAL REPORTING REQUIREMENTS:** see following Quad Chart



# Telephone Delivery of Cognitively Augmented Behavioral Activation (CABA) for Veterans with Traumatic Brain Injury (TBI)

Log Number: PT180068

W81XWH-18-CTRR-CTA

PI: Callahan

Org: VA Portland HCS/NCRAR

Award Amount: \$1,434,077.00



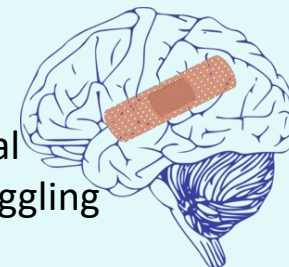
## Study/Product Aim(s)

- Specific Aim 1: Determine if Tele-CABA is effective for reducing cognitive and neuropsychiatric symptoms in Veterans with TBI.
- Specific Aim 2: Determine if Tele-CABA is effective at improving adaptive functioning and quality of life for Veterans with TBI.

## Approach

We propose a clinical trial of Telephone-delivered Cognitively Augmented Behavioral Activation (Tele-CABA) compared to usual care (UC) for Veterans with TBI at national VA Health Care Systems. The remote access implementation of this established treatment will examine the effectiveness for cognitive symptom reduction and improved adaptive functioning for Veterans and Service members who are unable or unwilling to travel to an urban hospital. The proposed trial will directly address interdisciplinary and comprehensive prevention and life-skills training strategies to strengthen brain health. Tele-CABA promotes resilience as a core part of the treatment, and makes this intervention maximally accessible to Veterans.

**Goal: To reduce negative cognitive and psychiatric outcomes and promote personal Resilience among Veterans struggling to recover from TBI.**



Preliminary effectiveness trials indicate that CABA reduces cognitive problems and psychiatric distress in Veterans with TBI. Additional research examining the effectiveness of an evidence-based tinnitus management program by telephone is strong, supporting the use of telephone therapy for TBI patients. The proposed trial tests efficacy of increased access through telephone delivery of a patient-centered cognitive rehabilitation.

## Timeline and Cost

| Activities                            | CY | 19               | 20               | 21               |
|---------------------------------------|----|------------------|------------------|------------------|
| Grant submission and IRB              |    | On track         |                  |                  |
| Participant recruitment               |    | On track         |                  |                  |
| Tele-CABA and assessment              |    | On track         |                  |                  |
| Data entry, analysis, publication     |    |                  | On track         |                  |
| <b>Estimated Budget (\$1,500,000)</b> |    | <b>\$475,000</b> | <b>\$482,000</b> | <b>\$491,000</b> |

## Goals/Milestones (Example)

**CY19 Goal** – Telephone implementation and preliminary recruitment

- ☐ Establish telephone protocols for Tele-CABA administration
- ☐ Begin recruitment of 40 Veterans with TBI history
- ☐ Pilot test Tele-CABA intervention with initial group of 10 participants

**CY20 Goals** – Tele-CABA full implementation

- ☐ Complete all participant recruitment
- ☐ Complete Tele-CABA intervention with 192 total participants
- ☐ Begin data entry and preliminary data analysis

**CY21 Goal** – Tele-CABA completion and evaluation

- ☐ Complete Tele-CABA and assessment for 192 participants
- ☐ Complete data entry and analysis
- ☐ Begin publication of findings

## Budget Expenditure to Date

Projected Expenditure: 0

Actual Expenditure: 0

Updated: 10/1/2020

**9. APPENDICES: none**