

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

REPORT DATE: OCTOBER 2022

TYPE OF REPORT: Annual Report

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGEForm Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE OCTOBER 2022		2. REPORT TYPE Annual		3. DATES COVERED 15 Sept 2021- 14 Sept 2022	
4. TITLE AND SUBTITLE Telephone Delivery of Cognitively Augmented Behavioral Activation (Tele-CABA) for Traumatic Brain Injury				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-19-1-0747	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Megan Callahan, PsyD E-Mail: callameg@ohsu.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Oregon Health & Science University 3181 SW Sam Jackson Park Rd, Portland, Oregon 97239-3098				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
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 traumatic brain injury (TBI); Veterans; Service Members; telehealth; cognitive, rehabilitation					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 15	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4 - 9
4. Impact	9
5. Changes/Problems	9
6. Products	9
7. Participants & Other Collaborating Organizations	9 - 13
8. Special Reporting Requirements (Quad Chart)	14
9. Appendices (Inclusion Enrollment Report)	15

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
Major Task 1: Study Initialization. IRB approval, Implement data collection and management systems, recruit and train staff												
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 yearly transfer of study data	IP	C										
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											
Major Task 2: Enrollment, randomization, intervention, and data collection for Aims 1 and 2												
Subtask 1: Enrollment and randomization												
Announce study recruitment and disseminate study flyer		C	C	C	C	C	C	C	C	C	C	C
Enroll study participants (n=192; 3 years)		C	C	C	C	C	C	C	C	C	C	C
Randomize study participants to Tele-CABA or usual care (UC) (n=96 per group)		C	C	C	C	C	C	C	C	C	C	C
Subtask 2: Provide Tele-CABA intervention				C	C	C	C	C	C	C	C	C
Deliver Tele-CABA intervention by telephone to n=96 participants		C	C	C	C	C	C	C	C	C	C	C
Monitor adverse events and report if needed		C	C	C	C	C	C	C	C	C	C	C
Subtask 3: Data collection and entry												

Collect study data from all participants at baseline, 12 weeks, and 6 months		C	C	C	C	C	C	C	C	C	C	C
Enter study data into database		C	C	C	C	C	C	C	C	C	C	C
<i>Milestone: First participant screened, consented, and enrolled</i>		3.2020			C	C	C	C	C	C	C	C
<i>Milestone: n=192 participants recruited and enrolled</i>		C	C	C	C	C	C	C	C	C	C	IP
<i>Milestone: Last participant recruited</i>												IP

What was accomplished under these goals?

In Y3, we enrolled approximately 27 new participants to the study. We continue to actively screen additional study candidates and schedule new consent appointments. We are collecting baseline data and entering the data into the database. To date, 54 participants have completed all study requirements.

Our full-time therapist left the project in Y3Q2. This significantly slowed our rate of recruitment as we only had so much available space to treat randomized participants. We also anticipated the possibility of losing our remaining two part-time therapists due to systemic problems. However, we were able to negotiate to keep them on the project and we hired another full-time therapist by the end of Y3Q3. Additionally, three unpaid part-time therapists were added in Y3Q3 to assist with study operations and intervention. With a full team, we increased our recruitment outreach in Q4 and have 16 additional participants pending enrollment to date.

In Y3, we submitted a request to extend this project another year to further support our recruitment initiatives and move closer toward our target recruitment numbers. Due to the unforeseen loss of our primary therapist, our numbers took a dip in Y3. However, we have made a strong recovery in Q4, giving promise to better recruitment into Y4 (approval pending).

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
Year 2 Annual	58	58	37	24
Year 3 Annual	85	85	60	54

	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	85	54	255	Open recruitment

A. Human Use Regulatory Protocols

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

PROTOCOL(S) (1 of 1 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: 1015/192
 Number of subjects screened/original planned target: 255/192
 Number of patients enrolled/original planned target: 85/192
 Number of patients completed/original planned target: 54/192

- (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.

e. Amendment 5; OHSU Modification Number: MOD00031316:

Minor updates were made to the Tele-CABA recruitment letter, opt-out recruitment letter, telephone script, ICF, and Protocol.

f. Amendment 6; OHSU Modification Number: MOD00032302:

Updates were made to the study ICF, Protocol, telephone script, ICF packet letters, Surveys and Questionnaires and Questionnaires Cover Letter, etc. to convert the ICF process to DocuSign. Using DocuSign to sign consent forms electronically and securely will facilitate faster enrollment of new participants.

g. Amendment 7; 5.11.2022; OHSU Modification Number: MOD00040412:

This modification included adding study personnel and a recruitment email script.

h. Amendment 8; 9.7.2022; OHSU Modification Number: MOD00044556:

This modification included removing study personnel.

(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 will continue to enroll and recruit prospective participants. Due to the COVID-19 pandemic, recruitment has progressed slowly and maintained. We will continue to expand our National recruitment efforts. We will continue to conduct 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 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 have been sending recruitment opt-in/out letters which will continue to do in the next reporting period. We have witnessed the benefits of this approach and will continue our efforts.

As previously addressed, we have reached out to collaborators nationwide and set up referral sources at VAs around the country. We 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. Our Service Officer helped to facilitate new connections with the DoD and we cultivated a few of these relationships into Y3 with the hope of improving our recruitment of Service Members. Unfortunately, these relationships have not manifested additional recruitment. The primary barriers continue to be the challenges of obtaining site approval from Command, and a lack of funding for DoD sites as separate multi-site locations. We will instead refocus our efforts on recruitment sources that are working well for us, including sending recruitment opt-in/out letters.

ii. Anticipated Problems/Issues

See above.

6. Products

Nothing to report.

7. Participants & Other Collaborating Organizations:

What individuals have worked on the project during the period of 10/15/21 to 10/14/22?

Name: Megan Callahan

Project Role: PI

Nearest person month worked: 6 calendar months

Contribution to Project: She hires, trains, and supervises all study personnel on proposed study. She provides 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. She is 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: Dr. Henry was 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 was cost shared to the VA

Name: Melissa Papesh

Project Role: Co-I

Nearest person month worked: 1.2 calendar months

Contribution to Project: She worked 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 helped prepare and submit scientific peer-reviewed presentations and publications.

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

Name: Kathleen Carlson

Project Role: Co-I

Nearest person month worked: 1.2 calendar months

Contribution to Project: She worked 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. Dr. Carlson also facilitated 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: 1.2 calendar months

Contribution to Project: He worked closely with the study team to guide participant recruitment and retention efforts, participates in routine meetings with study staff, prepares and submits scientific peer-reviewed presentations and publications, and development 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. Her expertise as a study therapist in CCT and CABA is invaluable on this study.

Name: Jennifer Hallman
Project Role: Co-I/Therapist
Nearest person month worked: 4 calendar months
Contribution to Project: She supported this study as a therapist.

Name: Emily Thielman
Project Role: Research Coordinator
Nearest person month worked: 2.3 calendar months
Contribution to Project: She is 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: 8.2 calendar months
Contribution to Project: She 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.

Name: Brittney Markey
Project Role: Co-Investigator/Therapist
Nearest person month worked: 1.9 calendar months
Contribution to Project: She supports this study as a therapist.

Name: Kylie Courtwright

Project Role: Research Assistant

Nearest person month worked: 1.1 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) reviewing questionnaires and entering data; (6) providing study intervention to UC participants after follow up.

Name: Liat Hoffman

Project Role: Postdoctoral Fellow

Nearest person month worked: 1 calendar months

Contribution to Project: She will support this study as a therapist.

Funding Support: (if different than this award) This person is a VA trainee and was not paid off the grant.

Name: Cassandra Smith

Project Role: Research Assistant

Nearest person month worked: 1 calendar months

Contribution to Project: She will support this study as a therapist.

Funding Support: (if different than this award) This person is a VA trainee and was not paid off the grant.

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

Changes in active support for Dr. Callahan.

ENDED:

PT160162 (Heinricher, PI) 10/17-09/21 4.8
calendar months

DoD CDMRP Award (annual)

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.

Dr. Henry's effort on this award will not continue during the NCE period (9/15/22 to 9/14/23).

Changes in active support for Dr. Papesh.

Dr. Papesh's effort on this award will not continue during the NCE period (9/15/22 to 9/14/23).

Changes in active support for Dr. Carlson.

Dr. Carlson's effort on this award will not continue during the NCE period (9/15/22 to 9/14/23).

Changes in active support for Dr. Storzbach.

Dr. Storzbach's effort on this award will not continue during the NCE period (9/15/22 to 9/14/23).

Changes in active support for Halina Kowalski.

No changes

Changes in active support for Mai Roost.

No changes

Changes in active support for Brittany Markey – newly added Co-I.

Brittany Markey was recently added as a Co-I to this project – her effort is 100% on this project and she has no other active or pending support.

What other organizations were involved as partners?

Nothing to report.

8. Special Reporting Requirements:

Quad Charts: See appended.

9. APPENDICES: Inclusion Enrollment Report

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

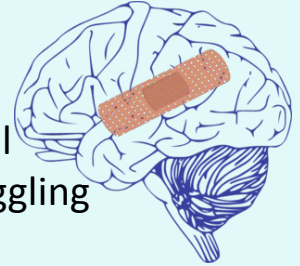
Study/Product Aim(s)

- 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	
Estimated Budget (\$1,500,000)		\$475,000	\$482,000	\$491,000

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

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001
Expiration Date: 3/31/2020

*Study Title (must be unique):

* Delayed Onset Study? Yes No

If study is not delayed onset, the following selections are required:

Enrollment Type	Planned	Cumulative (Actual)
Using an Existing Dataset or Resource	Yes	No
Enrollment Location	Domestic	Foreign
Clinical Trial	Yes	No

NIH-Defined Phase III Clinical Trial Yes No

Comments:

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										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More than One Race										
Unknown or Not Reported										
Total										