

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

CONTRACTING ORGANIZATION: Oregon Health & Science University, Portland, OR

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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. Analyses are currently in progress and no updates to the results are available.					
15. SUBJECT TERMS traumatic brain injury (TBI); Veterans; Service Members; telehealth; cognitive, rehabilitation					
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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.

All Milestones for this study are complete.

	Year 1				Year 2				Year 3				Year 4			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q1	Q2	Q3	Q 4
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	C															

protocol																	
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	C																

testing of data systems																
Subtask 3: Hire and train staff	C															
<i>Milestone: Joint VA-OHSU IRB approval</i>	C															
<i>Milestone: HRPO approval</i>	IP	C														
<i>Milestone: FITBIR setup and operational</i>	IP	C														
<i>Milestone: Research staff hired and trained</i>	C															
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	C	C		
Enroll study participants (n=192; 3 years)		C	C	C	C	C	C	C	C	C	C	C	C	C	(2/15/23)	
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	C	C		
Subtask 2: Provide Tele-CABA intervention																
Deliver Tele-CABA intervention by telephone		C	C	C	C	C	C	C	C	C	C	C	C	C		C

to n=96 participants																
Monitor adverse events and report if needed		C	C	C	C	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	C	C	C	C
Enter study data into database		C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
<i>Milestone: First participant screened, consented, and enrolled</i>		C														
<i>Milestone: n=192 participants recruited and enrolled</i>		C	C	C	C	C	C	C	C	C	C	C	C	C	(2/15/23)	
<i>Milestone: Last participant recruited</i>														C	(2/3/23)	

What was accomplished under these goals?

In Y4, we enrolled 14 new participants to the study to meet a total sample of 99 subjects. All participants have completed study visits per the protocol. All data has been entered into the study database and is currently undergoing data checks for additional verification prior to analysis.

In Y4, we requested an additional extension to complete the analyses and data submission to FITBIR and ClinicalTrials.gov. This will also enable us to retain key statistical support for the study to accomplish these end goals and prepare for publication.

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
Year 4 Annual	99	99	74	70

			Enter information regarding number of subjects				
HRPO Protocol Number	Protocol PI Name	Organization (Site)	# Target	# Enrolled	# Completed	# Screened	# Recruited
E00975.1a & E00975.1b	Callahan	VAPORHCS	192	99	99	281	Closed 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: 1220
 Number of subjects screened/original planned target: 281/192
 Number of patients enrolled/original planned target: 99/192
 Number of patients completed/original planned target: 99/192
- (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.
 - i. Amendment 9; 6.20.2023; OHSU Modification Number: MOD00049030:
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 complete our dissemination of the final results to FITBIR, data verification, statistical analysis, and reporting to ClinicalTrials.gov. We will prepare a manuscript for publication.

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 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?

Name: Megan Callahan

Project Role: PI

Nearest person month worked: 1.8 calendar months

Contribution to Project: She will hire, train, and supervise all study personnel on proposed study. She will provide 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 will be responsible for data analysis and dissemination, including sharing data with the Federal Interagency Traumatic Injury Research (FITBIR) informatics system. Dr. Callahan will also serve as a backup therapist on the project.

Name: Emily Thielman

Project Role: Research Coordinator

Nearest person month worked: 1 calendar month

Contribution to Project: She has been 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 will also be responsible for designing, programming, and maintaining the study databases, as well as the organization and validation of data throughout the study. She will 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: Brittney Markey

Project Role: Co-Investigator/Therapist

Nearest person month worked: 11.4 calendar months

Contribution to Project: She has supported this study as a therapist.

Name: Kylie Courtwright

Project Role: Research Assistant

Nearest person month worked: 3.4 calendar months

Contribution to Project: She has played 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: Halina Kowalski

Project Role: Co-I/Therapist

Nearest person month worked: 1.3 calendar months

Contribution to Project: She supported this study as a therapist.

Name: Mai Roost

Project Role: Co-I/Therapist

Nearest person month worked: 1.1 calendar months

Contribution to Project: She was 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 was invaluable on this study.

Name: Deanna Gold

Project Role: Research Assistant

Nearest person month worked: 8.2 calendar months

Contribution to Project: She played 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?

These key personnel are no longer working on this project: Dr. Henry, Dr. Papesh, Dr. Carlson, Dr. Storzbach, Ms. Gold, Ms. Kowalski, and Dr. Roost.

Changes in active support for Dr. Callahan.

New - none

Ended

D1189I (Wagner and Callahan, Co-PI) 04/15-09/23 NCE 1.2 calendar months
VA Rehabilitation Research and Development
Cognitively Augmented Behavioral Activation for Veterans with Comorbid TBI/PTSD
Goal: To assesses the efficacy of a cognitively augmented behavioral activation individual treatment intervention with returning veterans from the recent conflicts in Iraq and Afghanistan.

What other organizations were involved as partners?

Nothing to report.

8. Special Reporting Requirements:

Quad Charts: See appended.

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	19	20	21	22	23
Grant submission and IRB	C				
Participant recruitment (comp 2/15/23)		C	C	C	
Intervention and Assessment (Subtask 3; IP)		C	C	C	C
Data entry, analysis, publication		C	C	C	C
Estimated Budget (\$1,500,000)	\$475k	\$482k	\$491k	NCE	

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