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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, 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.

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.

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											
Milestone: Joint VA-OHSU IRB approval	10.2019											
Milestone: HRPO approval	IP	3.2020										
Milestone: FITBIR setup and operational	IP	1.2020										
Milestone: Research staff hired and trained	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	IP	IP		
Enroll study participants (n=192; 3 years)		C	C	C	C	C	C	C	IP	IP		
Randomize study participants to Tele-CABA or usual care (UC) (n=96 per group)		C	C	C	C	C	C	C	IP	IP		
Subtask 2: Provide Tele-CABA intervention					C	C	C	C				
Deliver Tele-CABA intervention by telephone to n=96 participants		C	C	C	C	C	C	C	IP	IP		
Monitor adverse events and report if needed		C	C	C	C	C	C	C	IP	IP		
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	IP	IP	IP	
Enter study data into database		C	C	C	C	C	C	C	IP	IP	IP	
Milestone: First participant screened, consented, and enrolled		3.2020			C	C	C	C				
Milestone: n=192 participants recruited and enrolled		C	C	C	C	C	C	C	IP	IP		
Milestone: Last participant recruited									IP			

What was accomplished under these goals?

In Y2, we enrolled approximately 50 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, 24 participants have completed all study requirements.

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. Our Service Officer helped to facilitate new connections with the DoD and we continue to cultivate these relationships and hope to improve our recruitment of Service Members in Y3.

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

			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	58	24	153	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: 73/192
Number of subjects screened/original planned target: 153/192
Number of patients enrolled/original planned target: 58/192
Number of patients completed/original planned target: 24/192

(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.

(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.

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: 3.75 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.
Funding Support: (if different than this award) Since Feb. 2021 her effort has been cost shared to the VA at 20%.

Name: James Henry
Project Role: Co-I
Nearest person month worked: 2.4 calendar months
Contribution to Project: Dr. Henry will be 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: She will work 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: She will work 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 will also facilitate 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 will work 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 will support this study as a therapist.

Name: Mai Roost
Project Role: Co-I/Therapist
Nearest person month worked: 3.2 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 will be invaluable on this proposed study.

Name: Jennifer Hallman
Project Role: Co-I/Therapist
Nearest person month worked: 12 calendar months
Contribution to Project: She will support this study as a therapist.

Name: Emily Thielman
Project Role: Research Coordinator
Nearest person month worked: 2.4 calendar months
Contribution to Project: She will be 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 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: The Research Associate will play 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: Garnett McMillan
Project Role: Biostatistician
Nearest person month worked: 0.6 calendar months
Contribution to Project: Dr. McMillan will be responsible for establishing data management protocols, reporting, and longitudinal data analysis for the preparation of data for publications and presentations.

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:

No changes

Changes in active support for Dr. Henry:

No changes

Changes in active support for Dr. Papesh:

No changes

Changes in active support for Dr. Carlson:

VA appointment, New:
IIR I01 HX003088 Carlson (PI) 01/21-12/24 3.0 calendar months
DVA/HSR&D (total)
Guillaume Cheron, Health Services R&D Service, 810 Vermont Ave NW, Washington, DC

Community Care Utilization among Post 9-11 Veterans with Traumatic Brain Injury
Project Goals: The goal of this work is to examine use and effects of expanding VA Community Care programs (Veterans Choice Program and the MISSION Act) on health and functioning among post-9/11 Veteran VA users with a history of TBI.
Specific Aims: The aims of this project are to: 1) Examine the use of VA-paid Community Care among post-9/11 Veterans with a history of TBI; 2) Compare health and functioning among post-9/11 Veterans with a history of TBI who do, versus do not, receive care in the community; and 3) Quantify and examine clinical practice guideline-discordant care received by post-9/11 Veterans with a history of TBI who do, versus do not, receive care in the community.
Role: Principal Investigator
There is no scientific overlap and no duplication of funding or effort between the proposed project and current grants. (If the proposed project and others are funded, and an over-commitment of effort develops within a particular fiscal year, Dr. Carlson's effort will be reassessed and adjusted across projects as needed.)

RX003701 Henry (PI) 04/21-03/25 0.3 calendar months
DVA/RR&D (total)
Lina Kubli, PhD, Rehabilitation R&D Service, 810 Vermont Ave NW, Washington, DC. 20420.
Long-term Effects of Noise and Other Exposures on Auditory Functioning in Post-9/11 Veterans: NOISE Study 3.0
Project Goals: The purpose of this continuation study is to continue to collect data on the long-term effects of military and non-military exposures on auditory function, gathering up to 11 years of longitudinal data on the currently enrolled cohort of study participants. Continued funding would provide the unique opportunity to obtain evidence on whether military noise exposures can result in delayed-onset hearing loss and/or tinnitus in Veterans.
Specific Aims: The aims of this phase of our ongoing longitudinal study are to: 1) Determine if early patterns of hearing loss and tinnitus among recently separated Veterans persist, and whether new cases of hearing loss and tinnitus develop, in the decade following separation from military service; 2) Identify military and post-military exposures that are associated with the onset and progression of hearing loss and tinnitus in the decade following military service separation; and 3) Examine the roles of cochlear synaptopathy and central auditory dysfunction in complaints of hearing difficulty and early-onset tinnitus in the decade following military service separation.
Role: Co-Investigator
There is no scientific overlap and no duplication of funding or effort between the proposed project and current grants. (If the proposed project and others are funded, and an over-commitment of effort develops within a particular fiscal year, Dr. Carlson's effort will be reassessed and adjusted across projects as needed.)

VA Appointment, Ended:

RRP C1020-216 Teo (PI) 06/20-12/20 1.8 calendar months
DVA HSR&D (total)
Robert O'Brien, PhD, HSR&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.
Specific Aims: The aims of this planning project are to: 1) Convene a panel of subject matter experts and Veterans who will develop an adapted intervention ("Crisis Caring Contacts"); 2) Identify a cohort of high-risk Veterans from which to recruit participants for an RCT of Crisis Caring Contacts; and 3) Create data collection instruments, human subjects and safety protocols, and all other procedures and documents required for conduct of a pragmatic RCT of Crisis Caring Contacts.
Role: Co-Investigator

I01 RX003443-01 Pugh (PI) 10/19-09/24 1.2 calendar months
DVA RR&D (total)
Dana Herndon; US Army Medical Research Acquisition Activity; 504 Scott Street Ft. Detrick, MD 21702
VA-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.
Specific Aims: The aims of this project are to: 1) Extend the existing CENC Warfighter Cohort with respect to scope, duration of observation, and types of data included; 2) Advance CENC phenotype analyses by adding TMDS and MHS data to model the feature importance of mTBI, multiple mTBIs, and acute and chronic treatment approaches on emergence of key comorbidities (i.e., neurodegenerative disease, SUD, neurosensory dysfunction, psychological comorbidities, chronic pain/headache, and self-harm behaviors) among four study groups of SMs and Vs: Deployed+VA, Deployed-No VA, Non-deployed+VA, Non-deployed-No VA; 3) Use deep learning models to identify mTBI phenotypes, develop risk scores for poor military outcomes, and developing specific key comorbidities, and identify optimal processes of care for acute/chronic mTBI; and 4) Using phenotypes from Study E3, determine the economics of mTBI in DoD and VA by treatment characteristics, comorbidities and mechanisms of injury identifiable and by subpopulations of interest (e.g., women).
Role: Co-Investigator

SPiRE N3197-P Carlson (PI) 07/19-06/21 1.2 calendar months
DVA RR&D (total)
Stuart Hoffman, 810 Vermont Ave. NW, Washington DC
Effects of Opioid and Other Psychotropic Drug Exposures on Long-term Outcomes of TBI: Developing Measurement Best Practices
Project Goals: The goal of this work is to develop best practices for epidemiologic and clinical research, and serve as the foundation for a new research program, that evaluates the impact of opioids and other psychotropic medications on the long-term neurological outcomes of Veterans with TBI history.
Specific Aims: The aims of this project are to: 1) Identify valid approaches for identifying Veterans with TBI in VA administrative data; and 2) Develop methods to measure Veterans' complete opioid and other psychotropic medication exposures in clinical research examining the effects of these medications on long-term outcomes of Veterans with TBI.

Role: Principal Investigator

HSR&D IIR Pogoda (PI) 10/19-03/21 0.6 calendar months
DVA HSR&D (total)
Robert O'Brien, PhD, HSR&D Scientific Program Manager, 810 Vermont Ave. NW, Washington DC
Does Protecting Service-Connected Disability Income Motivate Return to Work in Veterans with TBI and PTSD?
Project Goals: This funding supports the planning phase of an HSR&D Innovation project to examine the effects of a type of minimal basic income on employment outcomes among post-9/11 Veterans with traumatic brain injury and post-traumatic stress disorder.
Specific Aims: The aims of this planning phase are to: 1) Develop intra-agency and interagency memoranda of understanding and partnerships for disability benefits protection; 2) Develop agreement in IRS to track Veteran samples; 3) Review VA administrative data to identify dense regions of Veterans with service-connected disability for Phase 2 sampling; 4) Foster collaboration with VA program offices to identify 12 VA medical centers that can provide treatment to address unmet physical, psychological, and psychosocial needs, and vocational rehabilitation; and 5) Engage in discussion with the VAMCs identified in #4 to obtain leadership buy-in.
Role: Co-Investigator

OHSU Appointment, New:

R01MH125027 Yu (PI) 10/20-09/25 1.2 calendar months
National Institutes of Health/NIMH (total)
Robert O'Brien, PhD, Scientific Program Manager, 810 Vermont Ave. NW, Washington DC
Improving Suicide Prediction Using NLP-Extracted Social Determinants of Health
Project Goals: The goals of this application are to systematically identify social determinants of health and their associations with suicidal behaviors, including death by suicide, by analyzing longitudinal EHRs using natural language processing and machine learning approaches.
Specific Aims: The aims of this project are to: 1) Establish NLP-enriched case definitions of social determinants of health (SDOH) and examine their incidence and prevalence by first annotating a total of 3,000 patients (or approximately 20,000 EHR notes, as the SDOH Cohort) and then developing and evaluating sophisticated NLP algorithms for automation; 2) Examine whether and how SDOH elements are associated with each other, whether and how SDOH elements are associated with suicidal behaviors, and whether effects vary by patient demographic and clinical characteristics. We will also create an SDOH index to predicts the one-year mortality for a patient who may have a range of SDOH elements; and 3) Incorporate SDOH to improve prediction of suicide.
Role: Co-Investigator

IIR O'Neil (PI) 09/20-03/22 1.8 calendar months
Department of Defense/CDMRP (total direct)
Joshua McKean, Grants Officer, US Army Medical Research Acquisition Activity, 820 Chandler St., Fort Detrick, MD. 21702-5014.
FITBIR: Accelerating Synthesis of TBI Research Using Novel Methods (FAST RUN Methods)

Project Goals: The goals of this project are to utilize novel methods to accelerate the synthesis of FITBIR data to uncover new findings and improve the outcomes of civilians, Service Members, and Veterans with TBI. We will use advanced software and analysis techniques to facilitate future use of FITBIR among other stakeholders using R and Shiny Apps software.
Specific Aims: The aims of this project are to: 1) Develop a model system for harmonizing data for key variables across FITBIR study datasets resulting in an integrated database containing pre-event, event, and post-event (outcomes) data on TBI; 2) Use merged datasets to estimate rates of psychological health and functional outcomes and identify outcome risk factors; and 3) Develop and share methodologic products that can be used to facilitate more rapid synthesis of FITBIR data in the future.
Role: Co-Investigator

IIR W81XWH2010564 Chisholm (PI) 10/20-09/23 1.2 calendar months (total)
Centers for Disease Control and Prevention/NCIPC
Laura Chisholm, PhD; Oregon Health Authority Public Health Department, Injury and Violence Prevention Program, Portland, OR; laura.f.chisholm@dhsoha.state.or.us
Firearm Injury Surveillance through Emergency Rooms (FASTER)
Project Goals: The work proposed under this grant opportunity will enhance local surveillance of nonfatal firearm injuries by increasing the timeliness of aggregate reporting on these outcomes and disseminating findings to key stakeholders working to prevent firearm injuries, to inform and enhance statewide injury prevention efforts.
Specific Aims: The aims of this project are to: 1) Improve surveillance methods for nonfatal firearm injury; 2) Increase dissemination of timely, geographically-specific information on nonfatal firearm injuries to local and state prevention stakeholders; and 3) Increase access to best practices by firearm injury prevention partners.
Role: Site Principal Investigator

RFTO#22 O'Neil (PI) 04/21-04/25 0.9 calendar months
AHRQ
Kim Wittenberg, Task Order Officer, Agency for Healthcare Research and Quality, 5600 Fishers Ln., Rockville, MD.
Pharmacologic and Nonpharmacologic Treatments of Posttraumatic Stress Disorder
Project Goals: The goal of this project is to provide updates and expansions to a large, systematic review database of published randomized controlled trials on pharmacologic and non-pharmacologic treatments for post-traumatic stress disorder.
Specific Aims: In overarching aims of this project are to: 1) Expand the data elements included in the prior work (on 389 RCTs); and 2) Include standardized effect sizes for improved cross-study comparisons, as well as expanded assessments of study risk of bias.
Role: Co-Investigator

OHSU Appointment, Ended:

None

Changes in active support for Dr. Storzbach:

VA Appointment, Ended (he has retired from the VA):
5I01RX001189-06 (Storzbach, Wagner Co-PI) 04/15-03/21 2.4 calendar months
VA Rehabilitation Research and Development (current)
Ricardo Gonzalez Rehab R&D Service, 810 Vermont Ave NW, Washington DC
Cognitively Augmented Behavioral Activation for Veterans with Comorbid TBI/PTSD
Goal: This study assesses the efficacy of a cognitively augmented behavioral activation individual treatment intervention with returning veterans from the recent conflicts in Iraq and Afghanistan.
Specific Aims: 1) To determine if CABA reduces PTSD symptoms. 2) To determine if CABA reduces cognitive-related functional impairment. 3) To determine if CABA is associated with additional positive clinical effects in patient-centered outcomes, including improved mood, adaptive cognitive function, and quality of life.
4) To evaluate the overall acceptability of this treatment.
Role: Co-PI

I01CX001592 (Twamley, Huckans Co-PI) 01/18-12/22n 0.6 calendar months
CSR&D Merit Award (current)
Sarah Clark, CSR&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.

OHSU Appointment: No Changes

Changes in active support for Halina Kowalski:

No changes

Changes in active support for Mai Roost:

No changes

Changes in active support for Hallman:

No changes

What other organizations were involved as partners?

Nothing to report.

8. Special Reporting Requirements:

Quad Charts: See appended.

9. Appendix

a. 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

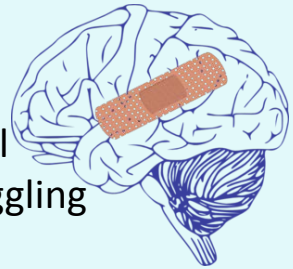
Study/Product Aim(s)

- 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**

Updated: 9/7/2021

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

* 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		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
Total	4	13	0	0	0	0	0	1	0	18

To ensure proper performance, please save frequently.