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CONTRACTING ORGANIZATION: University of New Mexico Health Sciences Center

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14. ABSTRACT
The purpose of this research is to use high-definition transcranial direct current stimulation (HD-tDCS) to treat neurosensory postconcussive symptoms (PCS) associated with mild traumatic brain injury (mTBI) in US Veterans and Warfighters. A randomized sham-controlled clinical trial will be performed. We will recruit 120 participants ages 18-59 for the study: 80 participants with mTBI to undergo the intervention, and 40 non-TBI healthy subjects to act as an imaging-only control group. The intervention is 10 days of anodal HD-tDCS to the left dorsolateral prefrontal cortex, paired with vision therapy and cognitive training. Magnetic source imaging (MSI), neuropsychological assessment, and neurosensory evaluation, are obtained before and after the intervention, to assess changes in brain function, postconcussive symptom burden, and quality of life. During this reporting period, preliminary data has been generated demontrating improvements in neurosensory function, cognitive control, and brain activation patterns with the intervention.

15. SUBJECT TERMS
Traumatic brain injury; postconcussive symptoms; neurosensory; transcranial direct current stimulation

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1. Introduction

The purpose of this research is to use high-definition transcranial direct current stimulation (HD-tDCS) to treat neurosensory postconcussive symptoms (PCS) associated with mild traumatic brain injury (mTBI) in US Veterans and Warfighters. A randomized sham-controlled clinical trial will be performed. We will recruit 120 participants ages 18-59 for the study: 80 participants with mTBI to undergo the intervention, and 40 non-TBI healthy subjects to act as an imaging-only control group. The intervention is 10 days of anodal HD-tDCS to the left dorsolateral prefrontal cortex, paired with virtual reality-based and computer-based sensory training. Magnetic source imaging (MSI), neuropsychological assessment, and neurosensory evaluation, are obtained before and after the intervention, to assess changes in brain function, postconcussive symptom burden, and quality of life. The specific aims are to (1) assess the efficacy of excitatory HD-tDCS combined with sensory training tasks to improve subjective neurosensory postconcussive symptoms, objective cognitive control, and quality of life in veterans and warfighters with mTBI relative to training tasks alone and (2) characterize aberrant neuromagnetic activation in cognitive control networks in complex mTBI and identify network responses to targeted brain stimulation.

2. Keywords

High-Definition Transcranial Direct Current Stimulation (HD-tDCS), traumatic brain injury (TBI), sensory deficits, veterans, Magnetic Source Imaging (MSI), post-concussive, neurosensory, prefrontal cortex, cognitive control, quality of life, brain stimulation.

3. Accomplishments:

3.1 Accomplishments:

What were the major goals of the project?

	Timeline (Months)	% Complete	Completion Date
Major Task 1: Prepare protocol for brain stimulation and training			
Subtask 1: Prepare Regulatory Documents and Research Protocol			
If Applicable, coordinate with Sites for CRADA submission, clinical trial agreements (CTAs) submission, nondisclosure agreements *Data transfer agreements are complete with all contributing consultant sites.*	1-3	100%	02/2018
Finalize eligibility, exclusions, screening, consent, protocol *Eligibility and exclusion criteria, consent and protocol complete.*	1-3	100%	04/2018
Coordinate with Sites for UNM and VA IRB submission/review *Initial IRB approval from UNM obtained 11/23/2016. Initial IRB approval from VA obtained 11/16/2017. All other modification approvals are listed below:*	1-3	100%	**Initial UNM Approval** 11/23/2016

UNM -Updates to protocol, consent, recruitment processes, approved 10/04/2017 -Continuing Review, approved 11/06/2017 -Submitted modifications requested by the DoD Scientific Office, approved 02/21/2018 -Updates to assessments, approved 04/18/2018 -Adding and removing study team members, approved 06/06/2018 -Modifying assessments, updates to consent and protocol, approved 07/06/2018 -Receipt of Certificate of Confidentiality reported, acknowledged 08/06/2018 -Modified consent to reflect receipt of CoC, approved 08/31/2018 -Continuing Review, approved 09/12/2018 -Added assessment, adding study team member, updated consent, approved 10/26/2018 -Adding study team member, approved 11/07/2018 -Protocol updates & adding study team member, approved 06/07/2019 -Continuing review, approved 07/03/2019 -Protocol & consent updates, approved 01/09/2020 -Protocol, consent, and case report form updates, approved 03/09/2020 -Reportable New Information/ COVID-19 memo, acknowledged 03/26/2020 -Adding new study team member, 04/05/2020 **- Continuing Review approval 06/03/20** **-**Study Safety updates to protocol, consent, adding forms approved 07/20/20 **-**Adding and removing study team members, approved 08/17/20 **VA** -Adding study team member, 01/09/2018 -Submitted modifications requested by the DoD Scientific Office, approved 02/26/2018 -Consent and protocol updates, approved 05/11/2018 -Consent and protocol updates, approved 07/20/18 -Adding study team member, approved 08/13/2018 -Adding study team member, approved 09/24/2018 -Continuing Review, approved 10/09/2018 -Updated protocol to reflect use of 10 electrodes, updated recruitment flyer to be clear that we are also recruiting Healthy Controls, approved 01/17/2019 -Adding study team member, approved 02/21/2019 -Continuing Review, approved 10/10/2019 -Removing study team member, 01/09/2020 - Protocol, consent, and case report form updates, approved 02/27/2020			**Initial VA Approval** 11/16/2017

- COVID-19 memo, acknowledged, 03/19/2020 -Removing study team member, approved 08/17/20 -Continuing Review approved 09/16/20			
Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO) *Received DoD approval to begin study on 05/18/2018. Annual report completed and accepted 12/18/18.*	1-6	100%	**Initial DoD Approval** 05/18/2018
Submit amendments, adverse events and protocol deviations as needed. *Reportable new information events submitted to UNM and VA, listed below. Note that "Reportable New Information" and "Event Determination" are synonymous language for reporting adverse events by UNM and VA respectively. All amendments and events submitted to UNM and VA IRB's have been submitted to DoD.* **Below includes adverse events and protocol deviations. All amendments listed in (a) Human Use Regulatory Protocols** - On 07/31/2019, M87111517 reported headache and vomited during neurosensory assessment. Submitted as RNI on 11/19/19 with intent to modify consent to indicate this as a risk with this assessment. Modification of consent in review with UNM IRB. - On 09/05/2019, M87103937 reported headache during neurosensory assessment, submitted as RNI on 11/19/19 with intent to modify consent to indicate this as a risk with this assessment. Modification of consent in review with UNM IRB. VA -On 11/22/2019, participant M87195559, reported having PTSD dreams the previous night, which he attributed to the stimulation. IRB determined: Event (isolated occurrence of PTSD-related dreams, not associated with subsequent treatment) was not serious, not anticipated, and not related to the research. No further action is required. No further reporting is required.	As needed	100%	Ongoing
Coordinate with Sites for annual IRB report for continuing review (CR): UNM -Continuing Review, approved 07/03/2019 -Continuing Review, approved 06/03/20 VA -Continuing Review approved 10/10/19 -Consent audit passed 12/06/19 -Full study audit passed 06/29/20 -Continuing review approved 09/16/20	Annually	100%	Ongoing
Major Task 2: Coordinate Study Staff and Resources for Clinical Trial			

***Subtask 1**: Hiring and Training of Study Staff*			
Coordinate with Sites for job descriptions, advertising, interviewing ***New study team member, Marcus Sterling, has been added to the study. He has begun training in study protocol and completed required trainings at UNM. Research technician, Emma Brandt, will be leaving study in May to pursue graduate studies in another state.***	1-8	100%	02/2018
Coordinate for space allocation for new staff *Space allocation finalized for UNM and VA, task complete. Dedicated Psychiatric Neuromodulation Lab space has been procured at Domenici Hall (UNM and Building 53 (VA) and all study procedures are now performed there.*	1-8	100%	01/2018
***Subtask 2**:*			
Coordinate with Sites for hiring, training Research Coordinator/Assistant, supervision, checks for 100% concordance *Coordinator and technicians, including new staff Nickolas Mertens, have completed training in neuropsychological testing, brain stimulation, sensory evaluation, and neuroimaging. Now conducting periodic procedural fidelity checks. Marcus Sterling is currently training in all study testing and procedures.*	8-20	100%	07/2019
Procure and test imaging protocols, brain stimulation equipment and eye tracking devices, and create pipelines for data procurement and storage *Eye tracking devices tested and pilot data obtained and analyzed through data pipeline. MEG and MRI scan sequences and related tasks tested and pilot data obtained and analyzed through data pipeline. Electrical field modeling pipeline and electrode placement algorithm 100% complete. Brain stimulation equipment, tested, operating as expected.*	8-20	100%	07/2018
Major Task 3: Participant Recruitment, Brain Stimulation, Sensory Rehabilitation, Neuromagnetic Scanning, Participant Evaluation			
Subtask 1:			
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements *Development of flow charts, Standard Operating Procedures for all protocol components, COINS data capture system, and data analysis tools complete.*	4-8	100%	04/2018
Finalize assessment measurements *Finalized assessments were submitted to the UNM and VA IRB for review and have been approved.*	1-4	100%	03/2018
Begin subject recruitment	8-36	19%	Ongoing

Recruitment activities that have taken place include: 1) flyer distribution to VA Polytrauma and Ambulatory Care Clinics; 2) information table staffed at VA Research Week and each month; 3) Polytrauma patients identified from registry and contacted, and recruitment letters mailed; 4) community veteran recruitment; 5) correspondence with UNM and VA clinicians for subject referrals.			
Participants complete testing and intervention over 3 weeks, N = 120 *# Potential subjects identified: 226* *# Screened by phone: 120 (38 HC, 82 TBI)* *# Enrolled: 40 (18 HC, 22 TBI)* *# Completed Visit 1: 40 (18 HC, 22 TBI)* *# Completed stimulation: 17 (17 TBI*)* *# Completed Visit 2: 17 (17 TBI*)* *1 participant dropped after Visit 1 (8 stimulations completed) in May 2019 and another dropped after first stimulation in August 2019. • **UPDATE: The 3 participants that were delayed for study treatment due to COVID-19 declined further participation due to schedule conflicts. One of these participants did complete 5 of the 10 treatment sessions but discontinued after the 5th session. The other 2 participants declined participation prior to any treatment sessions.**	8-36	33%	Ongoing
Complete follow-up assessments 1, 3, 6 months after completion of the brain stimulation treatment. *# Completed 1-month call: 17 (17 TBI)* *# Completed 3-month call: 17 (17 TBI)* *# Completed 6-month call: 17 (17 TBI)*	13-36	21%	Ongoing
Major Task 4: Data Analysis			
***Subtask 1**:*			
Report all analyses according to specifications, share output and finding with all investigators *Full analysis will be done once study data is obtained.*	36-48	0%	Ongoing
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD) *Abstract of preliminary fMRI study data presented to Academy of Consultation-Liaison Psychiatry Annual Meeting (November 12-16, 2019). (see attached slides)* ***Abstract of preliminary iSCAN study data accepted to Northeast Bioengineering Conference 2020*** ***Abstracts on neurosensory performance and fMRI/cognitive control data presented at MHRSR online August 26-27, 2020***	36-48	25%	Ongoing
Upload data to FITBIR for data sharing	36-48	10%	Ongoing

FITBIR compatibility of data storage currently ongoing. Upload will be done as study data is obtained. ***Common Data Element and Unique Data Element assessment performed with FITBIR. Ongoing construction of upload pipeline with collaborators.***			

*3.1.1 **Major Activities***

Our study team and PI for the project "HD-tDCS for Sensory Deficits in Complex Traumatic Brain Injury" have been productive with regards to Major Goals as outlined in the Statement of Work, although the COVID-19 pandemic has led to an unexpected but necessary pause in protocol enrollment.

The major activities accomplished of the study team and PI for the previous annual reporting period include the following:

(a) Regulatory: Continuing reviews by UNM IRB and VA IRB both completed successfully and submitted to DoD OHRP. Continuing review by DoD OHRP completed and approved.

(b) Administrative: Subawards have been finalized for Year 4. Investigator meetings now focus on pertinent study issues to successfully resume recruitment and protocol administration, ie. COVID-19 precautions, recruitment strategies during COVID-19 pandemic, and preliminary data analysis.

(c) Personnel: Nickolas Mertens Marcus Sterling has been added to the study, replacing Emma Brandt and Violet Fratzke. They have completed necessary trainings and certifications to perform the study tasks, including CITI, HIPAA, and FCOI certifications, MRI and MEG performance and safety training, brain stimulation performance and safety training, oculomotor and neurosensory assessment, neuropsychological testing. All study staff have been trained and certified with regard to local, state, and CDC guidelines regarding COVID-19 precautions, including cleaning and disinfection of equipment before, during, and after study visits, use of personal protective equipment (PPE), social distancing measures, and screening procedures.

(d) Scientific: Currently 47 participants (19 Healthy Controls and 28 TBI) have been enrolled and 19 of the TBI participants completed the treatment as indicated. Unfortunately, 5 subjects who were enrolled shortly before or during the COVID-19 pandemic decided not to continue in the study. Abstracts were presented at the online 2020 MHSRS. Study team is now analyzing baseline data to produce interim scientific report.

Recruitment continues to be a challenge given the COVID-19 pandemic. The recruitment of TBI patients is currently going well, given a substantial list of prospective subjects accumulated during the pandemic, both civilian and military. The recruitment of military healthy controls is now perceived as a greater challenge, given the inability to recruit from the grounds of the Albuquerque VA Hospital.

Strategies that the study team is pursuing include placing of advertisements and flyers with Veteran support services and organizations, and seeking out online and social media organizations for Albuquerque Veterans on which to advertise.

Study recruitment, enrollment, and procedures are now resuming with necessary and appropriate COVID-19 precautions in place to protect participants and staff.

A new Siemens Prisma 3T MRI scanner was installed during the months of April-June at the Domenici Hall/Mind Research Network. Pilot data indicated acceptable results to enable moving forward with data collection. Scanner type will be utilized as a covariate for future analyses.

3.2 **Specific Objectives**

The specific objectives of the study are:

Aim 1 (Symptom Reduction): To assess the efficacy of HD-tDCS combined with rehabilitation tasks to improve subjective postconcussive sensory symptoms, objective measures of cognitive control, and long-term quality of life in Veterans and Warfighters with complex TBI relative to rehabilitation training alone.

Aim 2 (Target Engagement): To characterize aberrant neuromagnetic activation in sensory and cognitive control networks in complex mTBI,and identify network responses to targeted brain stimulation.

3.3 **Significant Results or Key Outcomes**

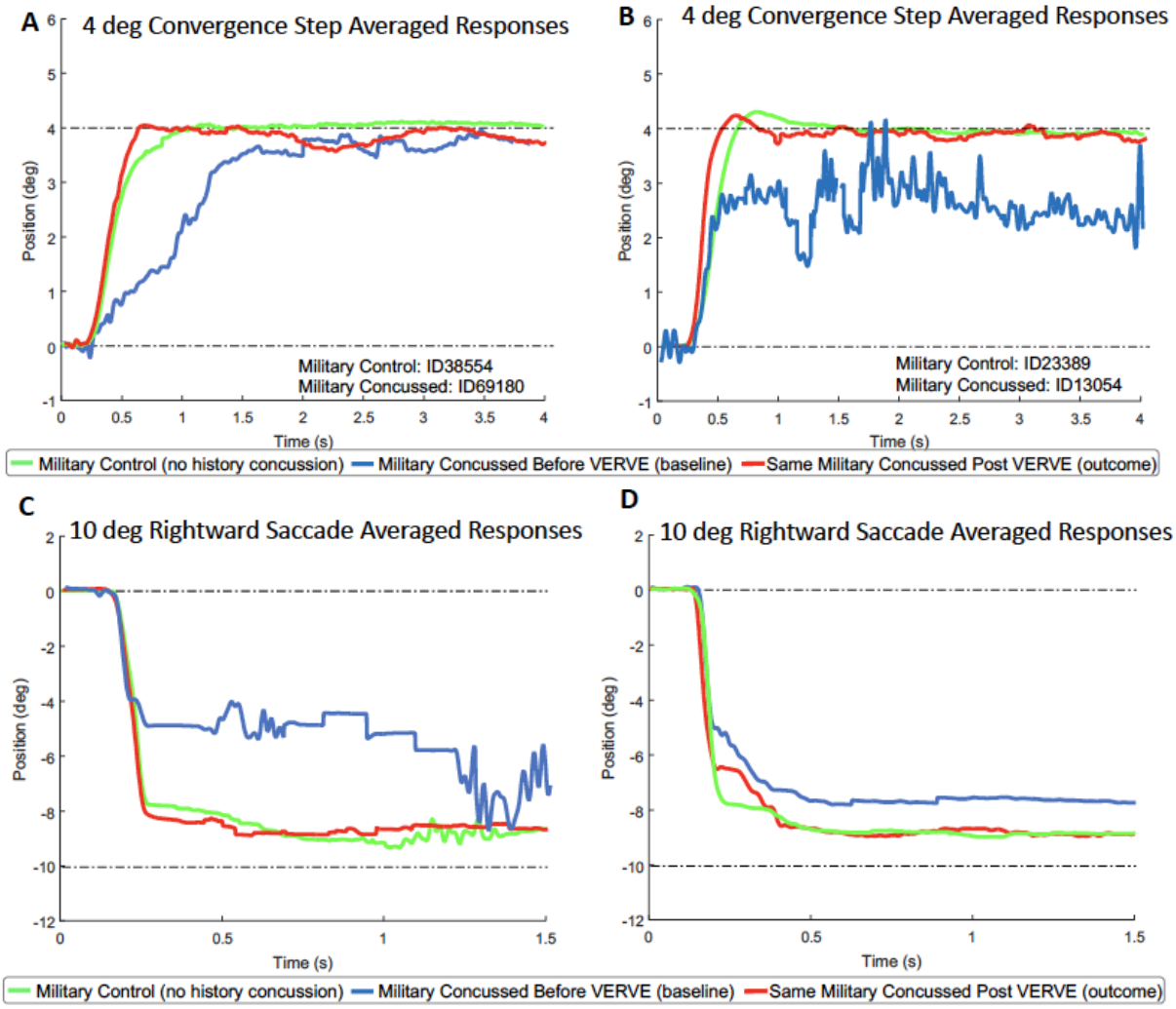
There have been several noteworthy preliminary findings generated by the study data collected thus far.

Most importantly, we have demonstrated objective neurosensory benefits stemming from our intervention thus far, utilizing the customized embedded eye-tracking platform ISCAN. We present several graphics showing this data.

Figure 1: Demonstration of impairment of convergence and saccade eye movements in two mTBI Veterans compared to healthy controls. With the combined visual training and brain stimulation, the eye movements of mTBI Veterans approximate those of controls.

Figure 2: Demonstration of impaired convergence step responses in an mTBI Veteran compared to healthy control, both at the beginning and the end of the task, indicating that pathologic response are present from the beginning, and not simply a result of fatiguing. After the intervention, responses have approximated that of healthy controls.

Figure 3: Group level data of 4 degree vergence steps peak velocity and final amplitude between healthy controls, mTBI Veterans before intervention, and mTBI Veterans after intervention. Peak velocity is significant impaired in mTBI Veterans and baseline, and recovers partially after training.



<u>Figure 1</u>. <u>TOP</u> (A) & (B): Examples of averaged 4 degree convergence step from a far to near jump target along a person's midline during the VRS3 oculomotor movements protocol, described in Project 1: OASIS. The military control subjects can attain new target in about 0.6 sec (green line) whereas concussed military subjects at baseline (blue line) take about 1.5 sec (A) or cannot attain target (B). After six 30-minute sessions of VERVE, convergence responses (red) are similar to control eye movements. <u>BOTTOM</u> (C) & (D): Example of averaged 10 degree saccade from midline to the right visual field during VRS3. The military control subjects (green lines) can attain new target (dash dotted line) whereas the concussed military subjects at baseline (blue lines) have difficulty fixating on the target. After VERVE, saccades of both concussed military subjects are similar to control eye movements (red lines).

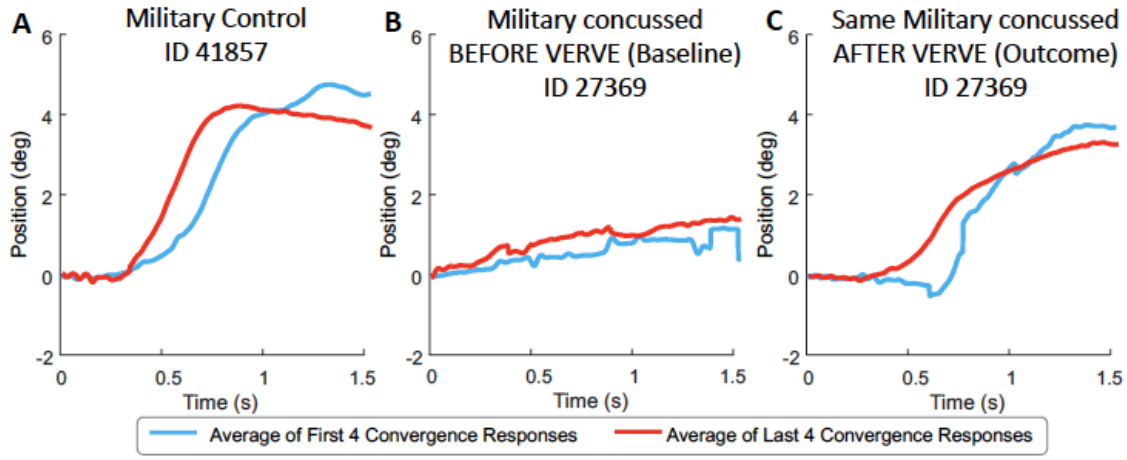


Figure 2. Example of averaged 4 degree convergence step from a far to near jump target along a person's midline during the Vergence Endurance Test (VET), performed during eye-tracking assessment at pre- and post-training visits. Military control subject convergence responses at the beginning (blue) and at the end of the VET reach the 4 deg target. (B). Military concussed subject at baseline is substantially slower throughout the experiment. C. The same concussed subject after VERVE showed improvement in convergence eye movement both at beginning and end of VET.

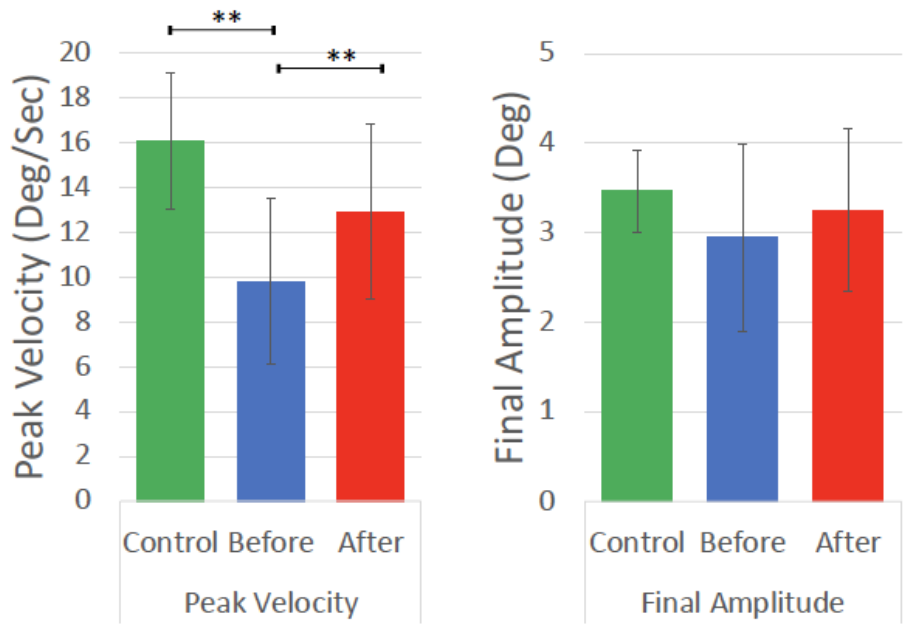


Figure 3. Data from NAVIGATE-TBI showing peak velocities and final amplitudes during 4 degree vergence steps assessed in Veteran controls (green), Veterans with chronic mTBI with neurosensory symptoms at baseline (blue), and same Veterans after multimodal intervention incorporating VERVE (red). Deficits in peak velocity in mTBI Veterans were significantly improved. Double asterisk (**) indicates p < .01.

*3.3.1 **Other Achievements***

Nothing to report

*3.3.2 **Stated Goals Not Met***

To date, the only study goals not met at the time of this annual report are the stated recruitment goals: 71 subjects were anticipated to have been enrolled by end of Year 2, whereas the study has recruited 36 subjects to date. This is attributable to several factors:

a) delays in full HRPO approval to begin the study, due to required necessary modifications to UNM and VA IRB protocols;
b) lack of an updated letter of support from the commanding officer of an identified Active Duty population, resulting in an inability to recruit this population
c) slower than expected intake of potential patients into the NMVAHCS Polytrauma Support Clinic.

Please see next section for description of efforts to meet this goal.

*3.4 **What opportunities for training and professional development has the project provided?***

Nothing to report.

*3.5 **How were the results disseminated to communities of interest?***

a) PI Quinn gave a presentation at the New Mexico Arts in Military Roundtable, held at historic Fort Bayard in Silver City, NM on October 8th, 2019. Topic of the presentation was the synergy between research in traumatic brain injury and post-traumatic stress disorder, and work to develop different and effective forms of art therapy for these conditions.

b) PI Quinn also gave a 2019 Veterans' Day television interview for the New Mexico Public Broadcasting Service television program, "Colores!" describing the work performed by him and the study team to investigate high-definition transcranial direct current stimulation for neurosensory symptoms in complex mTBI.

*3.6 **Planning***

What do you plan to do during the next reporting period to accomplish the goals and objectives?

To better meet planned recruitment goals, in consultation with our study team, institutional officials, and data safety and monitoring board, we will focus almost exclusively on these productive steps:

Step 1: Move stimulation sessions from VA to UNM.
We have moved the brain stimulation sessions to the UNM Center for Psychiatry Research (where testing and imaging are performed). This move allows civilians with prolonged post-concussive sensory symptoms after TBI to be enrolled in addition to Veterans. Civilians could not be enrolled at the VA due to lack of funds to pay for study-related injury. We have already begun enrolling civilian controls and TBI patients.

Step 2: Enroll civilians through the UNM IRB protocol.

Under the new configuration of the protocol: a) Veterans with mTBI and prolonged postconcussive symptoms will be recruited from the VA, and civilians will be recruited from UNM; b) Veterans and civilians will both be pre-tested at UNM; c) Veterans and civilians will both undergo stimulation sessions at UNM; d) Veterans and civilians will both be post-tested at UNM; e) Veterans will have followup visits at the VA, while civilians will have followup visits at UNM.

Step 3: Develop new productive recruitment efforts.
Our study over the past three years identified several strategies that lead to increased recruitment and retention of subjects, and will continue to maximize these strategies going forward. These include setting up study advertisement tables in the NMVAHCS lobby; and referrals from Dr. Harris-Carriman, our Polytrauma Clinic Co-Investigator.

However, because of the COVID-19 pandemic, the recruit of subjects cannot take place using the above methods. Therefore we are pioneering new recruit pathways, including social media posts, print ads in the local newspaper, and online ads on Veteran-centric websites.

4. Impact

4.1 ***What was the impact on the development of the principal discipline of the project?***

The study team has begun producing analyzed data which validates one of the key components of the intervention for neurosensory symptoms; virtual reality vision therapy. As shown by the graphics presented in this report, we are now seeing objective visual function deficits in our mTBI Veterans, which improves almost back to the level of healthy controls after only six sessions of the vision training, coupled with working memory training and brain stimulation.

This is a crucial finding, as vision therapy is normally performed in a clinic, with a large room filled with expensive and cumbersome equipment, and requires a trained optometric specialist to conduct. Unfortunately, this means that deployed personnel, or Veterans and Warfighters who are located far from such specialist services, cannot receive this treatment without significant expense or trouble. TO compound the problem, if vision therapy is attempted outside the clinic, it has been shown to be no more effective than placebo.

This platform that our team has developed, named VERVE, is prepared to solve this accessibility and effectiveness problem. If our preliminary data continue along their current course, they will validate a form of vision therapy via virtual reality that can be performed anywhere that a laptop and head-mounted display can be taken.

4.2 ***What was the impact on other disciplines?***

Nothing to report at this time.

4.3. ***What was the impact on technology transfer?***

Nothing to report at this time.

4.4 ***What was the impact on society beyond science and technology?***

The completion of this study, engaging the main academic medical centers in the Albuquerque metropolitan area, has the potential to raise the awareness of military TBI in the Southwest region, and to encourage further study of, advocacy for, and funding of interventions that will help improve the lives of Veterans and Warfighters living with TBI.

It also has the potential to shift the prevailing train of thought regarding postconcussive symptoms and their etiology. Currently, these are viewed as largely driven by psychological states, such as anxiety, stress, and depression. Our study shows early signs of determining a true difference in the neurosensory functioning of the brain after military mTBI, which could shift paradigms of treatment toward physiologically oriented therapies.

5. Changes/Problems

*5.1 **Changes in approach and reasons for change***

None at this time. As described in last year's report, we have begun recruiting civilian controls and TBI patients in order to offset recruitment deficits stemming from inability to recruit active duty personnel. We have now enrolled several civilians, and will continue to match them closely with military subjects.

*5.2 **Actual or anticipated problems or delays and actions or plans to resolve them***

a) COVID-19 pandemic restrictions: we had a six month delay in study progress. We are now back to full study activity. Enrollment pace is back to pre-pandemic rate, which is encouraging. However, we are contending with the fact of the 6-month delay and looking into measures that will allow us to complete the scientific aims within the original time-frame of the statement of work. COVID-19 study precautions will follow UNMHSC, HRPO, state public health office, and federal regulations to minimize the risk of infection. These may change given local infection rates over the next 3-6 months, and the study team is closely monitoring all local and regional public health information and directives.

b) COVID-19 precautions: All protective measures for COVID-19 have been instituted, including use of protective equipment, social distancing, and cleaning procedures.

c) Recruitment Lag: Approval to enroll civilians has been obtained and it is anticipated this will increase enrollment of participants. In addition to productive measures for recruitment of TBI subjects (polytrauma referrals, UNM clinic referrals), we are now instituting more aggressive measures to recruit healthy controls given the restrictions on in-person recruitment at the Albuquerque VA. These measures include online and print advertisements and flyers, as well as social media posts oriented toward Veterans.

*5.3 **Changes that had a significant impact on expenditures***

None at this time.

5.4 Significant changes in use or care of human subjects, vertebrate animals, biohazards, or select agents

In order to maintain safe conduct of study protocol during COVID-19 pandemic, we instituted significant changes to our protocol; All necessary PPE, cleaning supplies, and protocols are procured and in place, and staff have been fully trained in these measures. Participants are now enrolled in the protocol and are checked before each visit for concerning symptoms and evidence of fever.

Human Use Regulatory Protocols
TOTAL PROTOCOLS: 2

PROTOCOL (1 of 2 total):

Protocol [UNM HRPO Assigned Number]: 16-376

Title: High-Definition Transcranial Direct Current Stimulation for Sensory Deficits in Complex Traumatic Brain Injury

Target required for clinical significance: 120

Target approved for clinical significance: 120

Submitted to and approved by: University of New Mexico Health Sciences Center Human Research Review Committee, Human Research Protections Office

-Initial approval 11/23/2016

Status: Recruitment commenced June 2018

(i) Recruitment

-Number of subjects recruited/original planned target: 226/1000
-Number of subjects screened/original planned target: 120/400
-Number of patients enrolled/original planned target: 40/120
-Number of patients completed/original planned target: 35/120 (18 HC, 17 TBI)

(ii) Report amendments submitted to the UNM IRB and USAMRMC HRPO for review:

-Updates to protocol, consent, recruitment processes, approved 10/04/2017
-Continuing Review, approved 11/06/2017
-Submitted modifications requested by the DoD Scientific Office, approved 02/21/2018
-Updates to assessments, approved 04/18/2018
-Adding and removing study team members, approved 06/06/2018

-Modifying assessments, updates to consent and protocol, approved 07/06/2018
-Receipt of Certificate of Confidentiality reported, acknowledged 08/06/2018
-Modified consent to reflect receipt of CoC, approved 08/31/2018
-Continuing Review, approved 09/12/2018
-Added assessment, adding study team member, updated consent per adverse event submitted for MRI, approved 10/26/2018
-Adding study team member, approved 11/07/2018
-Updates to protocol and adding study team member, approved 06/07/19
-Continuing review, approved 07/03/19
-Modification: addition of sharing data with the FITBIR system, approved 01/09/20
-Modification to move stimulation sessions to UNM site that includes recruiting non-Veterans who will be seen only at the UNM site. Also included in this modification is the addition of language to the consent and protocol about possible risks associated with RNI's occurring on 07/31/19 and 09/05/19 and submitted to the IRB on 11/19/19 (see next section). Approved 03/09/20.
-Memo sent to UNM IRB stating that enrollment has been halted due to COVID-19, acknowledged 03/26/20
-Continuing Review, Approved 06/03/20
-Modification to study safety related to COVID-19: updated protocol, consent, and addition of symptom checklist, approved 07/20/20
-Adding study team member and removing study team member, approved 08/17/20

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
-On 09/27/18, participant became distressed during MRI while a technician was adjusting equipment. Although the consent covers some of the potential discomforts (i.e., claustrophobia, loud banging noises), it does not specifically note this type of event. "Harm" is indicated above as it appears that the participant experienced emotional distress that was unexpected. This event is clearly related to study procedures and was resolved by discontinuing the scan and discussing the event with the participant. Participant completed initial MRI without incident. PI met with MRI technicians and staff after this event to discuss the importance of communication during the MRI scan for this study. It is possible that future participants will have PTSD since this study recruits primarily from a veteran population. MRI technicians will only enter the MRI scan room if they communicate with a participant first. Reviewed by UNM IRB and consent modified on 10/26/19.

-On 09/04/18 participant reported a headache during the eye movement task. Testing was paused, virtual reality (eye testing) goggles removed, and the participant was allowed to rest. As session was nearly complete, decision made not to complete session. Once testing was discontinued all symptoms (headache) resolved. Reviewed by UNM IRB and consent modified on 10/26/19.

-On 07/31/2019, M87111517 reported headache and vomited during neurosensory assessment. Submitted as RNI on 11/19/19 with intent to modify consent to indicate this as a risk with this assessment. Consent changes approved 03/09/2020.

-On 09/05/2019, M87103937 reported headache during neurosensory assessment, submitted as RNI on 11/19/19 with intent to modify consent to indicate this as a risk with this assessment. Consent changes approved 03/09/2020.

PROTOCOL (2 of 2 total):

Protocol [VA HRPO Assigned Number]: 17-H245

Title: High-Definition Transcranial Direct Current Stimulation for Sensory Deficits in Complex Traumatic Brain Injury

Target required for clinical significance: 120

Target approved for clinical significance: 120

Submitted to and approved by: Institutional Review Board, New Mexico VA Health Care System (NMVAHCS)

-Initial Approval 11/16/2017

STATUS:

(i) Recruitment

-Number of subjects recruited/original planned target: 226/1000
-Number of subjects screened/original planned target: 120/400
-Number of patients enrolled/original planned target: 40/120
-Number of patients completed/original planned target: 35/120 (18 HC, 17 TBI)

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

-Adding study team member, 01/09/2018
-Submitted modifications requested by the DoD Scientific Office, approved 02/26/2018
-Consent and protocol updates, approved 05/11/2018
-Consent and protocol updates, approved 07/20/18
-Adding study team member, approved 08/13/2018
-Adding study team member, approved 09/24/2018
-Continuing Review, approved 10/09/2018
-Updated protocol to reflect use of 10 electrodes, updated recruitment flyer to be clear that we are also recruiting Healthy Controls, approved 01/17/19
-Adding study team member, approved 02/21/19
-Adding study team member, approved 03/04/19
-Updated consent, protocol, & flyer, approved 05/09/19
-Consent audit, passed 5/30/19
-Modification to recruit non-veterans was not approved (on 09/20/19). Per VA IRB, VA policies requires that all participant's including non-Veterans be afforded coverage for Research-related injury and the NMVAHCS has not identifiable resources to commit for payment of research-related injury for non-Veterans.
-Continuing Review, approved 10/10/19
-Consent audit passed, 10/06/19
-Modification to remove study team member, Violet Fratzke, approved 01/09/20
-Modification to move stimulation sessions to UNM site and follow-ups to the VA, approved 02/27/20

-Memo sent to VA IRB stating that enrollment has been halted due to COVID-19, acknowledged 03/19/20
-Full study audit passed 06/29/20
-Removing study team member approved 08/17/20
-Continuing review approved 09/16/20

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

On 09/05/18, a participant reported mild skin sensations experienced during setup of electrodes for the HD-tDCS session. Impedences monitored before all sessions and a new tDCS machine will arrive next week to replace current machine. Reviewed by IRB on 10/09/18 and deemed to not increase potential harm to participants, no changes recommended.

On 11/22/19, a participant reported having PTSD dreams the previous night, which he attributed to the stimulation. IRB determined that the event (was an isolated occurrence of PTSD-related dreams, not associated with subsequent treatment) was not serious, not anticipated, and not related to the research. No further action is required. No further reporting is required.

6. Products

*6.1 **Publications, conference papers, and presentations***

d) Journal publications:

Nothing to report

e) Books or other non-periodical, one-time publications:
Nothing to report

f) Other publications, conference papers, and presentations:

Roy D, **Quinn DK**, Fann J, Erickson J. “From Commotion to Emotion: Cutting-Edge Research in Mild Traumatic Brain Injury.” Symposium presented at the Academy of Consultation-Liaison Psychiatry Annual Meeting, San Diego, CA, November 14-17, 2019.

Brandt E, Fratzke V, Mertens N, Worth L, Upston J, Jones T, Yaramothu C, Alvarez T, Harris-Carriman S, Hoffer M, Stephen J, Richardson J, Mayer AR, **Quinn DK. “**Cognitive and Neurosensory Symptoms of Chronic Mild Traumatic Brain Injury Show Improvement Following Working Memory and Sensory Training Tasks.” Abstract accepted to the 2020 Military Health System Research Symposium (MHSRS), Kissimmee, FL, August 24-27, 2020.

Quinn DK, Upston J, Jones T, Fratzke V, Brandt E, Mertens N, Worth L, Yaramothu C, Alvarez T, Harris-Carriman S, Hoffer M, Stephen J, Richardson J, Mayer AR. “Cognitive Control Network Efficiency Improves with Neurosensory Training and Targeted Brain

Stimulation: Preliminary Findings from the NAVIGATE-TBI Study." Abstract accepted to the 2020 Military Health System Research Symposium (MHSRS), Kissimmee, FL, August 24-27, 2020.

6.2 Journal Publications

Nothing to report

6.3 Books or other non-periodical, one-time publications

Nothing to report

6.4 Other publications conference papers and presentations

Nothing to report

6.5 Websites or other Internet sites

Nothing to report

6.6 Technologies or techniques

The study team developed a customized, portable, gamified method for assessing for convergence insufficiency and delivering vision therapy. This will be described and disseminated to the public in the form of at least two journal manuscripts, planned for submission in early 2021.

6.7 Inventions, patent applications, and/or licenses

Nothing yet to report

6.8 Other products

Nothing yet to report

7 Participants & Other Collaborating Organizations

7.1 What individuals have worked on the project?

Name	**Davin Quinn, MD**
Project Role	Principal Investigator
Research Identifier	**0000-0002-1613-8018**

Nearest person month worked	**30**
Contribution to Project	Dr. Quinn is a Neuropsychiatrist at the University of New Mexico. He coordinates with Drs. Harris-Carriman at the NMVAHCS on planning the recruitment, retention, and conducting of Veterans and Warfighters through the study. He runs meetings and conference calls, and assist the other investigators in oversight and training of research assistants and the research coordinator. Dr. Quinn with Dr. Harris-Carriman oversees the creation and management of the regulatory binder, written updates, progress reports, data safety and monitoring reports, and random audits of the research data performed by the USAMRMC Human Research Protection Office, and maintain compliance with the UNM and NMVAHCS IRBs (the IRBs of record for the study). Dr. Quinn is also involved in the preparation of progress reports, manuscript preparation, presentation of the study's findings, and works closely with appropriate study personnel to make sure that all of the study assessments and procedures are completed as planned.

Name	**Stacey Harris-Carriman MD**
Project Role	Co-Investigator
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Harris-Carriman is a Physiatrist at the NMVAHCS. On this project she assists with the coordination of the proposed project at the NMVAHCS site helping to develop a recruitment plan for patients at the Polytrauma Veterans and Warfighters. She will oversee the delivery of brain stimulation paired with sensory training and is currently supporting the training of staff. She provides expertise in the evaluation and screening of sensory system impairments and common comorbidities within the OEF/OIF/OND Veteran population. Dr. Harris-Carriman with Dr. Quinn will oversee the creation and management of the regulatory binder, written updates, progress reports, data safety and monitoring reports, and random audits of the research data performed by the USAMRMC Human Research Protection Office, and maintain compliance with the UNM and NMVAHCS IRBs (the IRBs of record for the study).

Name	**Lindsay Worth**
Project Role	Research Coordinator

Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Lindsay Worth is a Clinical Research Manager at the University of New Mexico. For this study, she is responsible for running the protocol at MRN, UNM, CBRR, and NMVAHCS. Works closely with Drs. Quinn, Harris-Carriman, Mayer, Stephen, Alvarez, and Hoffer to complete trainings in conducting neurobehavioral and sensory system assessments including test scoring and the majority of the data entry. She will schedule assessments and the imaging data acquisition sessions with the research MRI and MEG staff. Currently helping to develop a plan (standard operating procedures) for identifying and recruiting the participants, performing pre-scan screening procedures, conduct neurobehavioral assessments, test scoring, and data entry. She coordinates IRB submissions as needed. She has created and maintains the regulatory binders, binders for signed consent forms and coded hard copies of completed test forms and electronic data. She coordinates and participates in meetings and conference calls.

Name	**Nickolas Mertens**
Project Role	Research Scientist
Research Identifier	
Nearest person month worked	**15**
Contribution to Project	Nickolas Mertens is a Research Technician at the University of New Mexico. For this study, he is working closely with Drs. Quinn and Harris-Carriman to train in and conduct sensory training and brain stimulation with HD-tDCS. He is supervised by Drs. Quinn and Harris-Carriman during the administration of these therapies. He is helping to develop a plan for scheduling sessions and for identifying and recruiting the participants, performing data entry and scoring. He supports the Research Coordinator in developing and maintaining the regulatory binders and binders for signed consent forms and coded hard copies of completed test forms and electronic data. He participates in meetings and conference calls.

Name	**Marcus Sterling**
Project Role	Research Assistant
Research Identifier	

Nearest person month worked	**1**
Contribution to Project	Marcus Sterling is a Research Technician at the University of New Mexico. For this study, she is working closely with Drs. Quinn and Harris-Carriman to train in and conduct sensory training and brain stimulation with HD-tDCS. She is supervised by Drs. Quinn and Harris-Carriman during the administration of these therapies. She is helping to develop a plan for scheduling sessions and for identifying and recruiting the participants, performing data entry and scoring. She supports the Research Coordinator in developing and maintaining the regulatory binders and binders for signed consent forms and coded hard copies of completed test forms and electronic data. She participates in meetings and conference calls.

Name	**Michael Hoffer, MD**
Project Role	Co-Investigator
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Hoffer is an Otolaryngologist, Otologist/Neurotologist at the University of Miami. His expertise is in the assessment, diagnosis, and treatment of vestibular and auditory disturbances following concussion, and is actively involved in developing various countermeasures against post concussive symptoms. He has been assisting in the final development of the study and has been involved in all aspects of the sensory system evaluation and training component, including data quality assurance planning, and the development of the plan for analysis of data. Dr. Hoffer coordinates with Drs.Quinn, Harris-Carriman, Alvarez, Mayer, and Stephen on the discussing the plan for interpretation of sensory outcome in relation to the neuroimaging data. He has been involved in training study staff in the evaluation of subjects with sensory symptoms after traumatic brain injury, participating in conference calls and meetings, assessing study progress, and will draft, coauthor, and edit manuscripts.

Name	**Tara Alvarez, PhD.**
Project Role	Paid Consultant
Research Identifier	**30**
Nearest person month worked	

Contribution to Project	Dr. Alvarez is a Biomedical Engineer at New Jersey Institute of Technology (NJIT). Dr. Alvarez has studied the neuronal activity underlying convergence insufficiency after concussion and has been providing expertise on eye-tracking technology platforms and data analytic methods to be used in the sensory system evaluation of participants as well as the sensory training paradigm paired with brain stimulation. She has assisted in the final development of the study, participated in meetings and conference calls, and provided training to study personnel to operate the eye-tracking equipment, acquire and analyze data, and provide quality assurance around these methods. Dr. Alvarez will coordinate with Drs. Quinn, Harris-Carriman, Hoffer, Mayer, and Stephen on the interpretation of sensory outcome in relation to the neuroimaging data.

Name	**Chang Yaramothu, PhD**
Project Role	Research Technician (NJIT)
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Yaramothu assisted Dr. Alvarez in setting up and training staff to operate the eye-tracking equipment, acquire and analyze data, and provide quality assurance around these methods.

Name	**Andrew Mayer, PhD**
Project Role	Co-Investigator
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Mayer is a Neuropsychologist at the Mind Research Institute in Albuquerque, New Mexico. He is a prolific scientist in the field of neuroimaging of mTBI and has provided expertise on the acquisition and analysis of MRI obtained before and after stimulation and training, as well as the neuropsychological assessments. He has assisted in the final development of the study and is involved in all aspects of the neuropsychological evaluation component, including data quality assurance, and analysis of data. He works with Drs. Quinn, Stephen, Hoffer, and Alvarez to develop a plan for interpreting results of MRI in relation to MEG, multisensory performance, and behavioral data, and with Drs. Quinn around developing methods for use of finite element current modeling to predict response. He has participated in conference calls and meetings, assessing study progress, and will draft, co-author, and edit manuscripts.

Name	**Jessica Richardson, PhD**
Project Role	Co-Investigator
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Richardson is a Speech and Language Pathologist at the University of New Mexico. She is extensively published in the areas of neurorehabilitation for aphasia after stroke, individualized high-definition transcranial direct current stimulation (HD-tDCS) optimization for stroke-induced aphasia, and blinding, safety, and fidelity in brain stimulation studies. She has assisted in development and design of the HD-tDCS aspect of the protocol, working with Drs. Quinn to train research staff in methods of conducting randomized controlled trials of brain stimulation, ensuring reproducibility of stimulation parameters and advising on individualization of electrode placement. She has participated in conference calls and meetings, assessing study progress, and will draft, co-author, and edit manuscripts.

Name	**Julia Stephen, PhD**
Project Role	Co-Investigator
Research Identifier	
Nearest person month worked	**30**
Contribution to Project	Dr. Stephen is a Physicist at the Mind Research Institute in Albuquerque, New Mexico. She has studied auditory, visual, and eye-tracking responses with MEG in multiple clinical populations, and has provided expertise on the acquisition and analysis of MEG obtained before and after stimulation and training. She has been working with Drs. Quinn, Mayer, Hoffer, and Alvarez to develop a plan for interpreting results of MEG in relation to MRI, sensory performance, and behavioral data. She has assisted in the final development of the study and is planning a training for study personnel to perform MEG scanning, acquire and analyze data, and provide quality assurance around these methods. She has participated in conference calls and meetings, assessing study progress, and will draft, co-author, and edit manuscripts.
Name	**Marom Bikson, PhD**
Project Role	Unpaid Consultant

Research Identifier	
Nearest person month worked	**0**
Contribution to Project	Dr. Bikson is a Biomedical Engineer who works with the City College of New York and New York Center for Biomedical Engineering. His lab developed HD-tDCS as well as finite element modeling of electric current in brain tissue, and he will provide as-needed input on the design, safety, and parameters of the brain stimulation component of the study, as well as data analytic methods for producing individualized models of current flow to be used as predictors of efficacy. He has been providing consultation about HD-tDCS for this study.

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

Davin Quinn, MD: His support from DoD and industry increased between 10/31/19 and 10/31/20.

- **Coordinating Principal Investigator** on "High-Definition Transcranial Direct Current Stimulation for Sensory Deficits in Complex Traumatic Brain Injury." W81XWH-17-1-0432, "Department of Defense, Congressionally Directed Medical Research Programs: Complex Traumatic Brain Injury Rehabilitation Research Award." PI: Quinn. FTE: 0.3/3.6 calendar months. Total costs: 11/1/2017-10/31/2021. Purpose: to characterize and ameliorate cognitive control deficits underlying multisensory postconcussive symptoms using magnetoencephalography and high-definition transcranial direct current stimulation in Veterans and Servicemembers with mild traumatic brain injury.

Andrew Mayer, PhD: His support from DoD/NIH increased between 10/31/19 and 10/31/20.

- **Control Network Neuromodulation to Enhance Cognitive Training in Complex Traumatic Brain Injury (The CONNECT-TBI Trial)** (Role: PI) Time Commitment: 10% FTE / 1.2 calendar**.** Supporting Agency: DOD**.** Performance Period: 09/30/2020 – 09/30/20**.** Level of Funding: (MRN subaward only)**.** Goals: The goals of this project are to conduct a clinical trial of Attention Process Training-3 (APT-3) paired with high-definition transcranial direct current stimulation (HD-tDCS) or repetitive transcranial magnetic stimulation (rTMS) to improve executive function.

- Title: **University of New Mexico (UNM) Center for Brain Recovery and Repair Phase II.** Time Commitment: 5% / 0.6 calendar months (Role: Co-I). Supporting Agency: NIH-MRN subaward from University of New Mexico Health Sciences Center. Performance Period: 7/1/20 – 6/30/25. Level of Funding: (MRN subaward only). Goals: Dr. Mayer will serve as a mentor for a junior investigator. Specific Aims: Dr. Mayer has served

as a mentor for junior faculty during Phase I of the Center for Brain Recovery and Repair COBRE. He will continue in that role during Phase II. Overlap: None

Tara Alvarez, PhD: Her support from NIH increased between 10/31/19 and 10/31/20.

Title:	Afferent and Efference Visual Systems during Abnormal Vision Development PI (Tawna Roberts)
Effort:	0.6-month hours
Supporting Agency:	National Institutes of Health
Grants Officer:	Houman Araj
Performance Period:	04/2020 to 03/2025
Funding Amount:	to Stanford subcontract of
Project Goals:	Discovery the underlying neural mechanism of office-based vergence and accommodative therapy
Specific Aims:	Discover why some infants develop strabismus and other develop hyperopia
Overlap:	Eye movement similar but much more simplistic because these recordings are from infants

Julia Stephen, PhD: Her support from NIH increased between 10/31/19 and 10/31/20.

- NIH-NIAAA 2P50AA022534-06 (PI: Savage) 07/20/2019 – 06/30/2024

Fetal Ethanol-Induced Behavioral Deficits: Mechanisms, Diagnoses and Intervention (Sub-Project 5392: Understanding Neurophysiological Deficits in Response Inhibition in Children with FASD)

The goal of this research is to evaluate the sensitivity of a novel combination of neuroimaging methods and psychological tests in the diagnosis of fetal alcohol spectrum disorders. **Role:** Project 5 PI

Michael Hoffer, MD: His support from industry increased between 10/31/19 and 10/31/20.

Title	**The use of Cannabinoids and Psilocybin in the Treatment of mild Traumatic Brain Injury and PTSD**
Effort	40%
Supporting Agency	Tessili Biosceince, Inc.
Grants Officer Name	Tesilli Bioscience, BOD
Performance Period	01/03/2020 – 04/30/2021
Funding Amount	

Project Goals	To study the use of a combination of Cannabinoids and Psilocybin for the treatment of the neurosensory effects of mTBI and PTSD
Specific Aims	Aim 1. Determine the impact of cannabinoids and psilocybin in a pre-clinical model of of mild traumatic brain injury. Aim 2. Determine the impact of cannabinoids and psilocybin in a pre-clinical model of of PTSD .

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

Organization Name: New Mexico Veterans Affairs Health Care System

Location of Organization: Albuquerque, NM

Partner's contribution to the project:

a) In-kind support: NMVAHCS has provided research administrative support for the study, including helping study staff obtain Without Compensation Status at NMVAHCS, obtaining access for study staff to medical records, and providing IRB oversight.
b) Facilities: NMVAHCS has provided research space to conduct brain stimulation sessions, including computers for accessing medical records.
c) Collaboration: NMVAHCS has permitted Dr. Harris-Carriman, physiatrist of the Polytrauma Support Clinic, protected time to collaborate with Dr. Quinn in the conduct of this study. They have also permitted access to the Polytrauma population of Veterans with TBI.

Organization Name: Mind Research Network

Location of Organization: Albuquerque, NM

Partner's contribution to the project:

a) Financial support:
b) In-kind support: MRN has provided free matching scans (20 MRI/MEG scans) to assist with study aims. They have made available their technological support staff for data storage (COINS), imaging analysis, training, and FITBIR curation.
c) Facilities: MRN is the site of the MEG and MRI that are currently used in the study protocol.
d) Collaboration: Drs. Mayer and Stephen are content experts and collaborators who provide as-needed expertise for MRI and MEG issues.

Organization Name: New Jersey Institute of Technology

Location of Organization: Newark, NJ

Partner's contribution to the project:

a) Collaboration: Drs. Alvarez and Yaramothu are collaborators who provide content expertise on eye tracking, data analysis and quality assurance, and technical expertise in the setup and training of the oculomotor assessment portions of the study.

Organization Name: University of Miami

Location of Organization: Miami, FL

Partner's contribution to the project:

a) Collaboration: Dr. Michael Hoffer is a collaborator who provides content expertise on neurosensory and TBI assessment, and has assisted with designing and refining the study protocol, as well as analyzing data.

8 Special Reporting Requirements:

Quad Charts: Updated quad chart included.

9 Appendices (attached)

No appendices at this time.