AWARD NUMBER: CDMRPL-17-0-PT160118

TITLE: The Use of Mobile Visual and Auditory Technologies to Implement Augmented Reality Tasks for Vestibular Physical Therapy

PRINCIPAL INVESTIGATOR: Pinata Sessoms, Ph.D.

CONTRACTING ORGANIZATION: Naval Health Research Center

REPORT DATE: MARCH 2021

TYPE OF REPORT: Annual Report

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

 Report No. 19-37 was supported by the U.S. Army Medical Research and Materiel Command under work unit number N1801.
The study protocol was approved by the Naval Health Research Center Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects. Research data were derived from an approved Naval Health Research Center, Institutional Review Board protocol number NHRC.2019.0002.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
MARCH 2021	Annual Report	15 FEB 2020 - 14 FEB 2021

4. TITLE AND SUBTITLE

The use of mobile visual and auditory technologies to implement augmented reality tasks for vestibular physical therapy

5a. CONTRACT NUMBER
CDMRPL-17-0-PT160118

5b. GRANT NUMBER
PT160118

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Pinata H. Sessoms, Ph.D.

E-Mail: Pinata.h.sessoms.civ@mail.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Health Research Center

140 Sylvester Road
San Diego, CA 92106-3521

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, MD 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The Military Health System (MHS) has made investments in developing multimodal virtual reality (VR) systems that can address the unique challenges faced by patients suffering from vestibular and sensory issues related to traumatic brain injury (TBI). VR systems have emerged as tools in rehabilitation that can be used independently or as an adjunct to traditional TBI therapies. The Computer Assisted Rehabilitation Environment (CAREN) is a fixed, large-scale, sophisticated VR-based system that allows patients to interact with virtual environments using body movement. In this research study, virtual applications will be custom designed to work with both the CAREN and a mobile system (i.e., augmented reality {AR}/VR head mounted display with 3D audio) to assess visual, auditory, and vestibular impairments in those with TBI as well as provide the necessary tools to meet the individual patient's therapeutic needs for rehabilitation. The overall aim is to improve neurosensory symptoms in TBI patients through the use of more accessible and affordable mobile AR/VR technologies that can be utilized in clinics and potentially in the home.

15. SUBJECT TERMS

Vestibular Physical Therapy, Traumatic Brain Injury, Concussion, Virtual Reality, Augmented Reality.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	Unclassified	23	**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified			

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

Table of Contents

1. INTRODUCTION:

Over the past decade the Military Health System (MHS) has made investments in developing sophisticated multimodal virtual reality (VR) systems that can address the unique challenges faced by service members suffering from vestibular and sensory issues related to traumatic brain injury (TBI). VR-based systems have emerged as a tool in rehabilitation that can be used independently or as an adjunct to traditional TBI therapies. The Computer Assisted Rehabilitation Environment (CAREN) is a fixed, large-scale, sophisticated VR-based system that includes a six degree-of-freedom motion platform, an instrumented treadmill, immersive visuals projected onto a 180-degree screen, and a motion capture system which allows for interaction with each virtual environment through body movement. In this research study, both the CAREN and a portable system, comprised of mobile visual and auditory technologies, will be developed and refined to meet the requirements of skilled clinical providers, and then further customized to meet the individual visual, auditory and vestibular therapeutic needs of each service member. The overall aim is to improve neurosensory symptoms in service members with TBI through the use of more accessible and affordable mobile visual and auditory technologies that can be utilized as a modality to standard care in clinical settings and at home.

2. KEYWORDS:

Mild traumatic brain injury; virtual reality; augmented reality; Computer Assisted Rehabilitation Environment; rehabilitation; mobile technologies; operational assessment; operational readiness; concussion; vestibular physical therapy.

3. ACCOMPLISHMENTS:

What were the major goals of the project?

There are two major goals of this project:

Aim 1: To test the hypothesis that mobile visual and auditory technologies (e.g., head mounted displays) provide similar feedback to the user when compared with visual and auditory inputs from a large-scale immersive VR system (e.g., CAREN).

Aim 2: To conduct a small randomized clinical trial (N=36) that will evaluate the efficacy of using mobile visual and auditory technologies for service members with TBI participating in vestibular therapy.

What was accomplished under these goals?

In order to accomplish our goals, the project was broken down into eight (8) tasks (Aim 1 – Tasks 1 through 4; Aim 2 – Tasks 5 through 8). The status of each task is as follows:

Major Task 1: IRB, CRADA/MOA Approval (15 months; 100% completion).

Subtask 1: Prepare Regulatory Documents for Research Agreements
All Aim 1 agreements have been obtained and reported in previous reports.

Subtask 2: Finalize consent form & human subjects' protocol including Military 2nd level IRB review (ORP/HRPO)
The initial IRB protocol for this project – the first of two study related protocols – was approved by the NHRC IRB on Dec 17, 2018 (NHRC.2019.0002 – "Comparison of visual and auditory technologies in large scale and mobile virtual reality systems"). Informed consent forms and study participant recruitment flyers were also IRB approved. NHRC IRB approved the Continuing Review of the study on Dec 17, 2019 and determined no further Continuing Review is necessary until the completion of the study. The IRB offices of Naval Medical Center San Diego (NMCSD) and WRNMMC/NICoE approved to defer oversight of this study to NHRC IRB. The U.S. Army Medical Research and Materiel Command's Office of Research Protections and Human Research Protections Office (USAMRMC ORP HRPO) approved the initial study protocol on Jan 06, 2020, and the IRB-approved Continuing Review was provided to their office on Jan 06, 2020.

Most recently, separate Aim 1 study protocol modifications were submitted for IRB review to incorporate the following changes: 1) addition of COVID-19 safety guidelines; 2) additional study questionnaires; 3) updated study personnel; and 4) updated study participant recruitment methods. IRB approvals for these protocol modifications were granted on 01JUN2020, 28OCT2020, and 20JAN2021.

Major Task 2: Coordinate Study Staff and Equipment (14 months; 90% completion).

Subtask 1: Staff training and coordination of sites.
All staff positions have been filled and all study team members have completed required trainings. Meetings and trainings have occurred with staff at all sites to communicate about progress and discuss pending taskers. The most recent in-person meeting between WRNMMC/NICoE and NHRC was held in January 2020. Due to COVID-19-related travel restrictions, all meetings since February 2020 have been held via teleconference or video conference at least every 3 weeks with representatives from project sites to discuss troubleshooting and progress status toward project milestones. The best method to collaborate and troubleshoot virtually were tested (e.g. Microsoft Teams, Slack) and hardware needed to move to this transition were acquired. Additional teleconferences occurred between WRNMMC/NICoE, MIT LL and AFRL to discuss the development of virtual audio capabilities. The most recent teleconferences occurred between NHRC and WRNMMC/NICoE to discuss final development and debugging of the software applications for Aim 1, as well as discussions regarding the final content of the Phase 2 protocol (Aim 2) and associated documentation.

Subtask 2: Development of hardware and virtual applications.
Development and final testing of virtual applications is behind schedule by approximately 15 months. The delay is due to COVID-19-related onsite work restrictions at NHRC and WNRMMC/NICoE, as well as the decision to change the augmented reality head mounted display (AR HMD) to be used based on clinician input and final reprogramming of the applications to function similarly between the AR HMD and CAREN system. The team is currently performing final testing and de-bugging to ensure the applications run as expected and the data outputs are similar between the data collection sites for both the AR HMD and CAREN platforms.

Several accomplishments have been made since the last reporting period:

- Software development of a Number Wall application (originally developed by Creare) to properly function on both the new AR HMD and CAREN platforms has been completed and final testing and de-bugging is in progress. The Number Wall task requires the study participant to locate a target (represented by a tile with a specific color and number combination) using an audio cue (represented by a specific spoken phrase that must be distinguished among other simultaneously spoken phrases). The participant is instructed to listen for the correct phrase, find the corresponding target by scanning the "number wall" and select the correct tile (Figure 1). This incorporates an audio cognitive task, head turning tasks, and physical movement to challenge the patient.

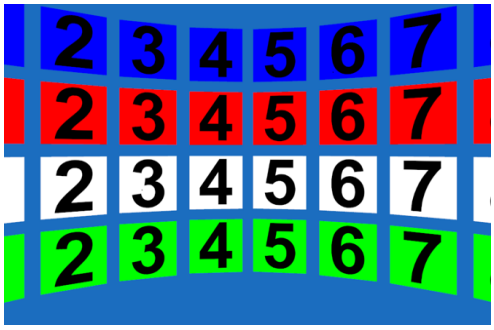

Figure 1(a)

Figure 1(b)

Figure 1(a) *shows the targets (i.e. colored/numbered tiles) on the "number wall" application;* ***Figure 1(b)*** *shows the participant selecting the correct target using a cursor (i.e. yellow highlighted box) that is synchronized with their head movement.*

- Software development of NHRC's Soccer Ball application to properly function on both the AR HMD and CAREN HMD platforms has been completed and final testing and de-bugging is in progress. The standard Soccer Ball task requires the study participant to swat moving targets (i.e. soccer balls) using their hands, which are synced using motion capture markers (Figure 2). The Stroop version of the Soccer Ball task displays a word with a specific font color, but the font color does not match the word text (e.g. the word "red" but in yellow font color). The study participant is instructed to look at the word, determine the font color of the word, and then find and select the soccer ball that matches the font color. Once the correct soccer ball is located, the participant uses their hand to "swat" the soccer ball to select it.

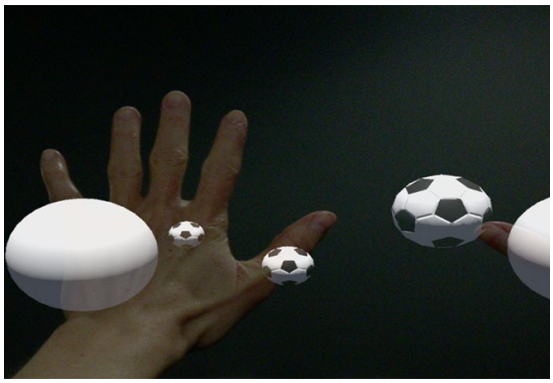

Figure 2(a)

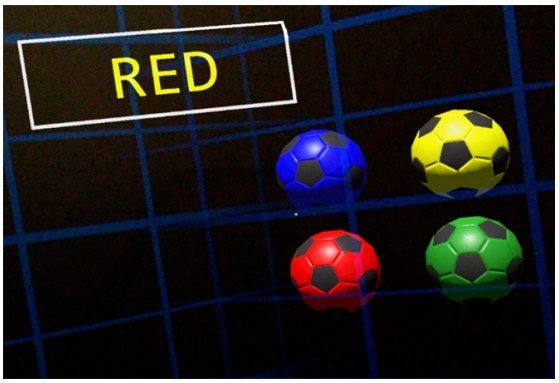

Figure 2(b)

Figure 2(a) *shows the standard Soccer Ball application with hand tracking represented by white spheres;* ***Figure 2(b)*** *shows the Stroop version of the Soccer Ball application with the visual cue (i.e. text) and different colored targets (i.e. soccer balls).*

- For all applications in Aim 1, motion capture, heart rate monitoring and eye tracking (AR HMD only) have been integrated to allow for real-time data collection throughout Task 1 and Task 2.

- Software refinements were applied to the Shark Hunt and Balance Cube applications (Task 2) to improve visuals and overall functionality.

- A treadmill masking sound was developed by WRNMMC/NICoE and integrated into Number Wall and AAVS, which incorporate virtual audio, in order to achieve similar audio environments between the CAREN and the AR HMD.

- Creare, a technology partner for the project, provided firmware and software updates to perform the Creare Hearing Assessment (CHA) that will be used as a screening tool to determine hearing profiles of participants and to obtain baseline

auditory measures that may be incorporated in the interpretation of the audio-based tasks.

- Data files are now being generated for all applications. These files have been reviewed to ensure that all relevant outcomes are being collected and that data is consistent and robust.

- Local network configurations and device installation procedures were verified for the AR HMDs. Additionally, all AR HMD applications were tested on different WiFi networks to ensure that the tasks functioned properly at both WRNMMC/NICoE and NHRC. These procedures are being written up to ensure the AR HMDs can be set up properly in different clinical settings in the future.

- Personal Protective Equipment has been purchased at NHRC and WRNMMC/NICoE in order to follow additional safety precautions to mitigate the risk of COVID-19 during the informed consent process, eligibility screening, and data collection procedures. No additional equipment purchases are expected prior to initiation of study participant enrollment for Phase 1.

- Several full-day pilot testing on all Task 1 and Task 2 applications have been performed at NHRC, including testing by Dr. Jose Dominguez and Dr. Kim Gottshall, the project's senior clinical consultants and subject matter experts in vestibular physical therapy. Drs. Dominguez and Gottshall commented on the high degree of similarity with respect to visual and audio inputs and overall experience of applications between the AR HMD and CAREN virtual environments. Additionally, WRNMMC/NICoE has conducted similar pilot testing to obtain feedback and collect preliminary data. Tables 1 and 2 illustrate pilot data from testing applications on the AR HMD for both Task 1 and 2.

Virtual Environment	Time (s)	Accuracy
AAVS (Audio/Visual)	10.92 (7.01)*	98% (4%)
Audio Localization	1.68 (1.48)*	-
Visual Discrimination	0.49 (0.05)*	99% (1%)

***Table 1**. Task 1 application pilot testing (n=3) performed on the AR HMD that shows time to complete each task as well as test subject response time (*).*

Virtual Environment		Time (s)	Accuracy
Balance Cubes	*Zoom In*	51.28 (7.75)	-
	Zoom Out	39.19 (7.07)	-
Shark Hunt		62.96 (35.32)	-
Soccer Balls	*Standard*	31.88 (0.35)	83% (6%)
	Static Stroop	60.80 (8.35)	87% (13%)
	Dynamic Stroop	50.29 (6.24)	72% (15%)
Number Wall	*Co-located*	3.49 (0.43)*	48% (3%)
	Separated	3.60 (0.15)*	50% (0%)

Table 2. *Task 2 application pilot testing results performed on the AR HMD that shows time to complete each task as well as test subject response time (*).*

- NHRC has developed electronic versions of all questionnaires and data collection forms for the Phase 1 protocol, allowing for uniform and efficient data acquisition between WRNMMC/NICoE and NHRC.

Major Task 3: Establish secure data storage location and create study in FITBIR (12 months; 100% completion).

Subtask 1: Establish secure storage location for data.
Data will be stored on approved servers at project sites (NHRC and WRNMMC/NICoE).

Subtask 2: Submit data into repository as collected.
Federal Interagency Traumatic Brain Injury Research (FITBIR) accounts were established for all NHRC personnel and weekly trainings were attended via FITBIR video conference seminars on use of FITBIR.

Major Task 4: Collect and analyze data for validation with enrolled research subjects (27 months; 0% completion).

Data collection has not yet begun. Application development is complete and final software de-bugging is in progress with expected completion in April 2021.

The following tasks for Aim 2 (randomized clinical trial for TBI patients undergoing vestibular therapy) have been accomplished:

Major Task 5: Development of a battery of virtual applications to be used by the CAREN and portable system (mobile visual and auditory technologies) for treatment of vestibular symptoms in service members with complex TBI.

All of the applications from Aim 1, Task 2 will be expanded for Aim 2. Enhanced features to better support therapy will be added (i.e., different background textures, visual cognitive tasks, etc.). These changes will allow the therapist to systematically increase or decrease the level of challenge based on the presentation/symptoms of study participants that will be treated on the CAREN or with the AR HMD and compared against Traditional vestibular physical therapy (Figure 3 – images courtesy of WRNMMC/NICoE).

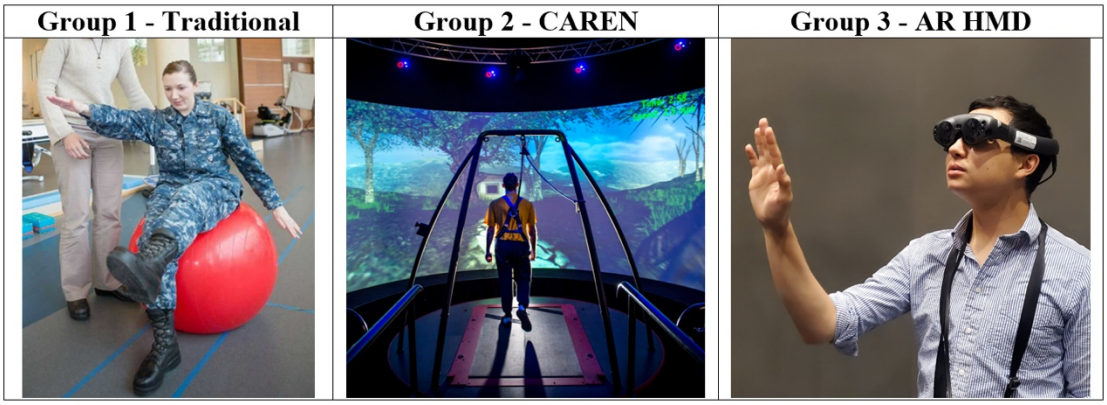

Figure 3. *In Aim 2 of the study, study participants will be randomized into three different treatment groups: Traditional therapy only, CAREN-based therapy, and AR HMD-based therapy.*

We also plan to expand the battery of vestibular tasks to include more applications (e.g. Maze, Ski) which will be recreated in Unity and were chosen based on their utilization with vestibular patients referred to the CAREN over the last decade. Time permitting, we also plan to create a virtual grocery task with assets (i.e. graphics and models) provided by Dr. Charles Levy, Associate Director of the Center of Innovation on Disability & Rehab Research, and his colleagues, Drs. Lok and Zalake, from the University of Florida. They previously developed a virtual grocery store model to treat veterans with PTSD, and we plan to redevelop that model by creating a new task that is appropriate for vestibular physical therapy.

Additionally, NHRC and NICoE has filled in appropriate agreements, and will be evaluating a novel vestibular home exercise program called VestAid that was developed by Intelligent Automation, Inc with sponsorship from the U.S. Army Medical Research and Materiel Command (SBIR). VestAid was created to help

Service Members with mTBI perform vestibular rehabilitation exercises at home. If the therapists believe it would be beneficial to care, this device could potentially be incorporated into the Phase 2 protocol which covers Aim 2.

Major Task 6: Prepare research protocol for the treatment portion of the study and obtain IRB approval.

For Aim 2 of this study, NHRC's IRB requested that we obtain a Study Risk Determination from the U.S Food and Drug Administration (FDA). On 03 MAR 2020, the FDA provided a written determination that Aim 2 of the study was a nonsignificant risk (NSR), and a copy of the determination was provided to both NHRC and WRNMMC/NICoE IRB offices.

WRNMMC/NICoE will serve as the IRB of record for the Aim 2 study protocol. The study protocol was submitted for IRB review on 03 DEC 2020 and the IRB reviewed the protocol on 04 FEB 2021. They determined that the study was greater than minimal risk, despite the FDA determination, and requested changes be made to the protocol and associated forms before granting final approval. The NICoE team has replied to two rounds of stipulations in EIRB to address all inquiries, and as of 11 MAR 2021 are waiting for the IRB's response. Once WRNMMC/NICoE IRB approval is granted, NHRC and NMCSD will submit their site-specific study protocols for local IRB review, before returning the WRNMMC/NICoE IRB (IRB of record) for final approvals and submission to HRPO.

Major Task 7: Data collection on both CAREN and portable systems.

This task has not yet been initiated.

Major Task 8: Data analysis and interpretation.

This task has not yet been initiated.

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

Study team members including clinicians have attended several professional conferences and educational trainings to share study information, ideas and technologies. These include the following to date:

i. February 2019: Technical Exchange on Augmented Reality in Maintenance and Material Management (TEAR 3M) in San Diego CA.
ii. May 2019: Vestibular Oriented Research Meeting in Dayton, OH.
iii. June 2019: Collaborative Auditory and Vestibular Research Network (CAVRN) in Lexington, MA.

iv. August 2019: Military Health Systems Research Symposium (MHSRS) in Orlando, FL.
v. December 2019: Interservice/Industry Training, Simulation and Education Conference (I/ITSEC), Orlando, FL.
vi. January 2020: Military Vestibular Assessment and Rehabilitation (MVAR) advanced training course in Bethesda, MD.
vii. March 2020: National Capitol Area TBI Symposium, Bethesda, MD
viii. April 2020: Vestibular Health Summit (virtual)
ix. September 2020: Concussion Health Summit (virtual)
x. September 2020: NICoE Annual Research Fair (virtual)
xi. February 2021: American Physical Therapy Association Combined Sections Meeting (virtual)

How were the results disseminated to communities of interest?

Project overview presentations were given at the 2018 and 2019 Collaborative Auditory and Vestibular Research Network (CAVRN) meetings as well as the Interservice/Industry Training, Simulation and Education Conference 2019 (I/ITSEC) meeting. Symposia were submitted to the 24th Annual CyberPsychology, CyberTherapy & Social Networking Conference (CYPSY) in 2020; however, this meeting was canceled due to COVID-19.

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

Final testing of all Aim 1 applications on the CAREN and AR HMD will be completed in preparation to begin study participant recruitment. The team will also perform final testing of all electronic data collection forms at WRNMMC/NICoE and NHRC to ensure the forms are working properly at both sites; this effort is approximately 90% complete. Additionally, a technical report is being drafted by WRNMMC/NICoE, NHRC and MIT LL that details the integration of the Unity platform for use with the CAREN system. The study teams aim to submit the report to the Defense and Technical Information Center (DTIC) following PAO approvals. This report will benefit other CAREN sites that want to improve their application development using Unity for clinical and research applications. Study participant recruitment and enrollment for Aim 1 is expected to begin in the 2nd quarter of 2021. We expect to receive IRB approval across sites for the Aim 2 study protocol as well as receive HRPO approval in order to commence this portion of the study. Finalization of applications for Aim 2 useful for clinical care will also be finalized.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

We are in discussions with other related researchers in the field, who are utilizing VR and AR for vestibular therapy.

What was the impact on other disciplines?
Development of a method to integrate the Unity platform within the CAREN system allows the CAREN to be utilized in many more ways, from human and cognitive performance testing to various rehabilitation protocols that were more difficult or not possible to be done within the CAREN's traditional D-flow software. This has expanded potential for use of the CAREN, as well as HMD systems, in a variety of disciplines from neuropsychological testing to biomechanical and fatigue analysis.

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:

Changes in approach and reasons for change.

In September 2019, the study team agreed to change the type of AR HMD being used in this study from the Microsoft HoloLens to the Magic Leap. There were a variety of reasons for this change, most notably that the Magic Leap has integrated hand-tracking and eye-tracking, a larger field of view, and improved comfort when wearing for an extended period of time, as noted by the clinicians. No other changes in approach for Aim 1 or Aim 2 have been made.

Actual or anticipated problems or delays and actions or plans to resolve them.

WRNMMC/NICoE and NHRC software developers completed the reprogramming of all virtual applications to function properly on the both the AR HMD and CAREN, which was the primary source of delay and was further compounded by COVID-19-related onsite work restrictions during most of the 2020 calendar year. Onsite work restrictions due to COVID-19 are still in place at NHRC and WRNMMC/NICoE.

WRNMMC/NICoE does not have approval for use of FITBIR for central data entry which is currently under discussion.

Changes that had a significant impact on expenditures.
Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.
Nothing to report.

Significant changes in use or care of human subjects.
Nothing to report.

Significant changes in use or care of vertebrate animals.
N/A.

Significant changes in use of biohazards and/or select agents.
N/A.

6. PRODUCTS:

This project will result in the development of Unity virtual applications for use in AR HMDs and the CAREN to perform vestibular therapy tests by multiple collaborators. The applications that are still being developed and tested include: 1) Visual Baseline; 2) AAVS; 3) Balance Cubes; 4) Soccer Balls w/ Stroop; 5) Shark Hunt; and 6) Number Wall. In addition, a new method to run applications created using Unity will expand the utilization of the CAREN and other AR platforms.

Publications, conference papers, and presentations.

1. Jacob Van Dehy and Dawn Bodell. What Work is Being Done to Improve Vestibular Physical Therapy for Service Members? Collaborative Auditory and Vestibular Research Network (CAVRN), 06 June 2019.

2. Sarah Kruger, Kathleen Delpy, Kerry Rosen, and Kyle Fitzgibbons. Comparison of visual and auditory technologies in large scale and mobile virtual reality systems. NICoE Research Roundtable, 11 December 2019.

3. Pinata Sessoms. Use of Virtual Reality Systems for Care of the Injured Warfighter. Interservice/Industry Training, Simulation and Education Conference (I/ITSEC), 05 December 2019.

4. Sarah Kruger, Kathleen Delpy, Kerry Rosen, and Kyle Fitzgibbons. Comparison of visual and auditory technologies in large scale and mobile virtual reality systems. NICoE Research Roundtable, 3 March 2020.

5. Sarah E. Kruger. Conducting Translational Research through Collaborative Innovation. NICoE Annual Research Fair. Bethesda, MD, 24 September 2020.

6. Kerry B. Rosen, Kathleen B. Delpy, Marcy M. Pape, Paula N. Kodosky, Sarah E. Kruger. Examining the Relationship between Conventional Outcomes and Immersive Balance Task Performance in Service Members with Mild Traumatic Brain Injury. *Military Medicine.* 2021 [Online ahead of print: https://doi.org/10.1093/milmed/usaa578]

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

This project will develop a new technical capability by utilizing virtual environments developed in Unity 3D (game engine software) on the CAREN system and with AR HMDs to perform therapeutic tasks that help physical therapists assess and treat vestibular symptoms in patients with TBI. This technology can potentially be used in other military patient populations for other clinical issues or return to duty assessments.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Pinata H. Sessoms, PhD*
Project Role:	*Principal Investigator (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-6960-0659*
Nearest person month worked:	*3*
Contribution to Project:	*Dr. Sessoms has held in-person meetings and regular teleconferences with the Co-Investigators and collective study team across all sites. She has submitted materials for support agreements and contracts needed to execute funds and work to collaborating sites. She has directed the development of the technical infrastructure, overseen all regulatory submissions and approvals, and managed all study funding and equipment purchases.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBI RP)*

Name:	Dawn Bodell, DPT
Project Role:	*Co-Investigator (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*TBD*
Nearest person month worked:	*4*
Contribution to Project:	*Dr. Bodell is the Research Physical Therapist on the project at NHRC. She has been working collaboratively to develop eligibility criteria and methodology related to the vestibular rehabilitation portion of the project, as well as provide feedback to the technology, applications, and protocol for the project. She also attends the regularly scheduled group meetings for the project, and works with potential mTBI patients for the study within NMCSD's vestibular physical therapy clinic.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Paula Poh, PhD*
Project Role:	*Data Core Manager (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-0915-6119*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Poh is the Data Core Manager on the project at NHRC. She has been working collaboratively with the team at NICoE to develop and prepare the research protocol documents required for IRB submission at both sites. She also organized and attended the team meeting at MHSRS. She has completed FITBIR online and video conference trainings and communicated directly with FITBIR and project staff to establish the project's FITBIR account.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Amanda Markham, MPH*
Project Role:	*Project Manager/Coordinator (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-5761-4068*
Nearest person month worked:	*1*

Contribution to Project:	*Amanda Markham has served as the Project Manager on this project. She has attended meetings with project staff. She assisted with the development and submission of support agreements and contracts related to this project. She has also supported the purchase of project equipment and contributed to the development of the project IRB protocol.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Jacob Van Dehy, MSE*
Project Role:	*Biomedical Engineer (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-2471-0528*
Nearest person month worked:	*5*
Contribution to Project:	*Jacob Van Dehy is the biomedical engineer/CAREN Operator at NHRC. He has been creating and validating software applications for use in the VR and CAREN systems. He has attended all study meetings, coordinates the hardware and software components needed for the project with the other collaborating sites, and oversees all software development aspects of the study at NHRC.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Vrajeshri Ordek, PhD*
Project Role:	*Biomedical Engineer (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-4398-484X*
Nearest person month worked:	*5*
Contribution to Project:	*Vrajeshri Ordek is the biomedical engineer at NHRC. She has been creating and validating software applications for use in the VR and CAREN systems. She has attended all study meetings and coordinates the hardware and software components needed for the project.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Rasmus Grunnet-Jepsen, BS*
Project Role:	*Computer Scientist (NHRC)*

Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*5*
Contribution to Project:	*Rasmus Grunnet-Jepsen is a computer scientist at NHRC. He has been creating and validating software applications for use in the VR and CAREN systems. He has attended all study meetings and coordinates the hardware and software components needed for the project, and serves as a developer for the centralized database for administration of electronic informed consent and electronic data capture.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Jeff Pawelek, BS*
Project Role:	*Project Manager (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-1419-6131*
Nearest person month worked:	*9*
Contribution to Project:	*Jeff Pawelek serves as Project Manager on this project at NHRC. He organizes all in-person meetings and teleconferences, prepares sponsor reports, prepares regulatory submissions, meets individually with the PI and various members of the study team to track study progress, and provides the necessary infrastructure to help the study team meet project milestones.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Kim Gottshall, PhD, PT*
Project Role:	*Clinician/consultant (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-3031-873*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Gottshall is a clinician with expertise in vestibular physical therapy. She has attended all in person study meetings as well as discussions at MHSRS related to this project. She has reviewed and commented on both Aim 1 and Aim 2 study protocols. She has also evaluated all of the Aim 1 applications on both the CAREN and AR HMD for both Task 1 and Task 2 and provided detailed feedback. She*

	will continue to support the project by speaking with other clinicians and providing her subject matter expertise.
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Jose Dominguez, PhD, PT*
Project Role:	*Clinician/consultant (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-1504-8712*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Dominguez is a clinician with expertise in vestibular physical therapy. He has tested all of the Aim 1 applications on both the CAREN and AR HMD for both Task 1 and Task 2 and provided detailed feedback. He has reviewed and commented on both Aim 1 and Aim 2 study protocols, and he will continue to support the project by speaking with other clinicians and providing her subject matter expertise.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Kerry Rosen, PhD*
Project Role:	*Research Assistant (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-3353-6528*
Nearest person month worked:	*9*
Contribution to Project:	*Kerry Rosen has participated in regular project meetings and has assisted with the WRNMMC IRB submission of the Phase 1 and 2 protocols. She provided support in the development of electronic methods of collecting data and helped with the preparation for recruitment and data collection for Phase 1. She was involved in the collection of pilot data, the refinement of task and setup SOPs, the review of data output, and the analysis of preliminary data.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Kyle Fitzgibbons, BS*
Project Role:	*Application Developer (WRNMMC/NICoE)*

Researcher Identifier (e.g. ORCID ID):	*TBD*
Nearest person month worked:	*9*
Contribution to Project:	*Kyle Fitzgibbons continues to participate in regular meetings about the project. He has been programming in Unity, re-creating virtual environments currently used in the CAREN as well as developing new software applications for use with both virtual reality and augmented reality-based head mounted displays as well as developing support documentation for these applications. He has also been actively collaborating with the NHRC developers and attending tech telecons regularly.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Sarah Kruger, MS*
Project Role:	*Co-Investigator (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-4366-8505*
Nearest person month worked:	*3*
Contribution to Project:	*Ms. Kruger continues to participate in regular meetings with the Co-Investigators. She worked collaboratively to develop and revise the Phase 1 protocol and facilitated the approval of support agreements and contracts necessary for the Phase 2 protocol. She worked to submit the Phase 2 protocol to the WRNMMC IRB and continues to supervise the development of the technical infrastructure at NICoE, directing software development efforts, and assisting with hardware integration. She also helped collect pilot data and develop recruitment strategies for Phase 1.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Kathleen Delpy, DPT*
Project Role:	*Research Physical Therapist (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	*TBD*
Nearest person month worked:	*9*
Contribution to Project:	*Dr. Delpy participated in regular meetings about the project. She worked collaboratively with the other PTs on the project*

	to refine the eligibility criteria language, as well as screening and data collection procedures for the Phase 1 and 2 protocols. She worked with Mr. Fitzgibbons on the development of new virtual environments as well as their refinement by readily volunteering to try new versions of the tasks weekly. She also helped to collect pilot data and compiled feedback to refine the task SOPs.
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	*Douglas Brungart, PhD*
Project Role:	*Co-Investigator (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	*0000-0002-0163-2734*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Brungart attended project meetings and has provided direction on project methodology for the mobile visual and audio components of the project. He also assists in managing the contract for the WRNMMC portion of the project.*
Funding Support:	*JPC-8 CRMRP PH/TBI RP*

Name:	Grant Meisenholder, DPT
Project Role:	*Co-Investigator (NMCSD)*
Researcher Identifier (e.g. ORCID ID):	*TBD*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Meisenholder directs the vestibular physical therapy clinic at Naval Medical Center San Diego (NMCSD). He provides clinically related updates to Dr. Bodell that may be related to this project.*
Funding Support:	*Naval Medical Center San Diego*

Name:	Griffin Romigh, PhD
Project Role:	*Co-Investigator (AFRL)*
Researcher Identifier (e.g. ORCID ID):	0000-0002-6341-6762
Nearest person month worked:	*1*

Contribution to Project:	*Dr. Romigh has attended project meetings and has provided direction on project methodology for the mobile audio testing and validation component of the project.*
JPC-8 CRMRP PH/TBI RP	*JPC-8 CRMRP PH/TBI RP*

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

No staffing changes have been made since the last reporting period.

b) What other organizations were involved as partners?

i. **Organization Name:** Creare, LLC

ii. **Location of Organization:** Hanover, NH

iii. **Partner's contribution to the project:** Enhanced audio capabilities for applications.

iv. **Financial support:** N/A

v. **In-kind support**: Company has provided several speech-based cognitive task applications within Unity to use in the rehabilitation portion of the study.

vi. **Facilities:** N/A

vii. **Collaboration**: N/A.

viii. **Personnel exchanges**: N/A

ix. **Other:** N/A

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards: N/A.

Quad Chart: See attached.

9. APPENDICES (none)