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

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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 a tool in rehabilitation that can be used independently and to complement traditional TBI therapies. The Computer Assisted Rehabilitation Environment (CAREN) is a fixed, large-scale, sophisticated VR-based system that allows the patient to interact with a virtual environment through their body movement. In this research study, both the CAREN and mobile VR systems (i.e., head mounted displays and 3D audio) will be custom designed to assess TBI patient's visual, auditory, and vestibular impairment as well as provide the necessary rehabilitative tools that meet the individual patient's therapeutic needs. The overall aim is to improve neurosensory symptoms in TBI patients – who are nonresponsive to prescribed traditional rehabilitation treatments – through the use of more accessible and affordable mobile VR technologies that can be utilized in clinics and at home.

15. SUBJECT TERMS

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

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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 VR-based 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 – who are nonresponsive to prescribed traditional rehabilitation treatments – through the use of more accessible and affordable mobile visual and auditory technologies that can be utilized in clinical settings and at home.

2. KEYWORDS:

Traumatic brain injury; vestibular system; virtual reality; augmented reality; Computer Assisted Rehabilitation Environment; rehabilitation; mobile technologies; operational assessment; operational readiness; concussion; vestibular 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=45) 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 tasks (Aim 1 – Tasks 1 through 4; Aim 2 – Tasks 5 through 8). The status of each task is as follows:

Task 1: IRB, CRADA/MOA approval (15 months; 100% completion). All agreements between study sites were put in place. DoD interagency agreements (7600

Forms) were executed between Naval Health Research Center (NHRC) and Hanscom Air Force Base/MIT Lincoln Laboratory (MITLL), Air Force Research Laboratory (AFRL), Spawar Systems Center Pacific (SSC-PAC), and Walter Reed National Military Medical Center and National Intrepid Center of Excellence (WRNMMC/NICoE). Additional contracts were established with consultants. The only pending agreement is an agreement to share virtual reality applications between NHRC and WRNMMC/NICoE which is currently being finalized by Naval Medical Research Command and will then be routed for signatures. The initial IRB protocol – first of two protocols – for this project was approved by the NHRC IRB on Jan 10, 2019 (NHRC.2019.0002 – "Comparison of visual and auditory technologies in large scale and mobile virtual reality systems"). That approved protocol is currently being uploaded into the eIRB system and is being submitted to Naval Medical Center San Diego (NMCSD) and WRNMMC/NICoE's IRB for review at the end of this quarter to request concurrence. It is expected to be submitted for 2nd level Human Research Protection Office (HRPO) review next quarter.

Task 2: Coordinate study staff and equipment (14 months; 90% completion). Most staff positions have been filled this past year. However, due to some position changes, NHRC hired a new project manager, Jeffrey Pawelek, and WRNMMC/NICoE hired a new research assistant, Kerry Rosen. WRNMMC also recently reposted their vestibular physical therapist position to seek a replacement for Donielle Brasure.

Meetings and trainings have occurred with staff at all sites. One in-person meeting involving all parties, occurred at Naval Medical Research Unit (NAMRU)-Dayton/AFRL in April 2018 and NHRC plans to continue having annual meetings until the project is complete. Following that meeting, phone conferences were held at least every 3 weeks with representatives from each project site participating to report progress toward milestones. Additional in-person meetings and phone conferences occurred, as needed, between WRNMMC/NICoE, MITLL and AFRL regarding the development of virtual audio capabilities; as well as between SSC-PAC and NHRC for the visual capabilities of the system.

Meetings were also held between NHRC and WRNMMC/NICoE to discuss hardware options as well as software development. Virtual applications in development were shared between sites to facilitate discussions of how they should be programmed so that the clinician/operator can change settings during therapy (e.g., to increase or decrease the challenge) and to control which objective outcomes are obtained and saved. WRNMMC/NICoE designed several Unity (gaming engine) applications for the HTC Vive, a virtual reality-based head mounted display (HMD), that mimic virtual environments currently utilized on the CAREN. These applications were designed to include a user interface which has multiple tabs and can visually display different application parameters that can be controlled by the clinician/operator, allowing for changes to be made in real time (see Figure 1). Unfortunately, displaying a user interface is not yet possible with *augmented reality* (AR) devices, as the visuals can only be shown to the user wearing the display. SSC-PAC is working to resolve this issue for this project.

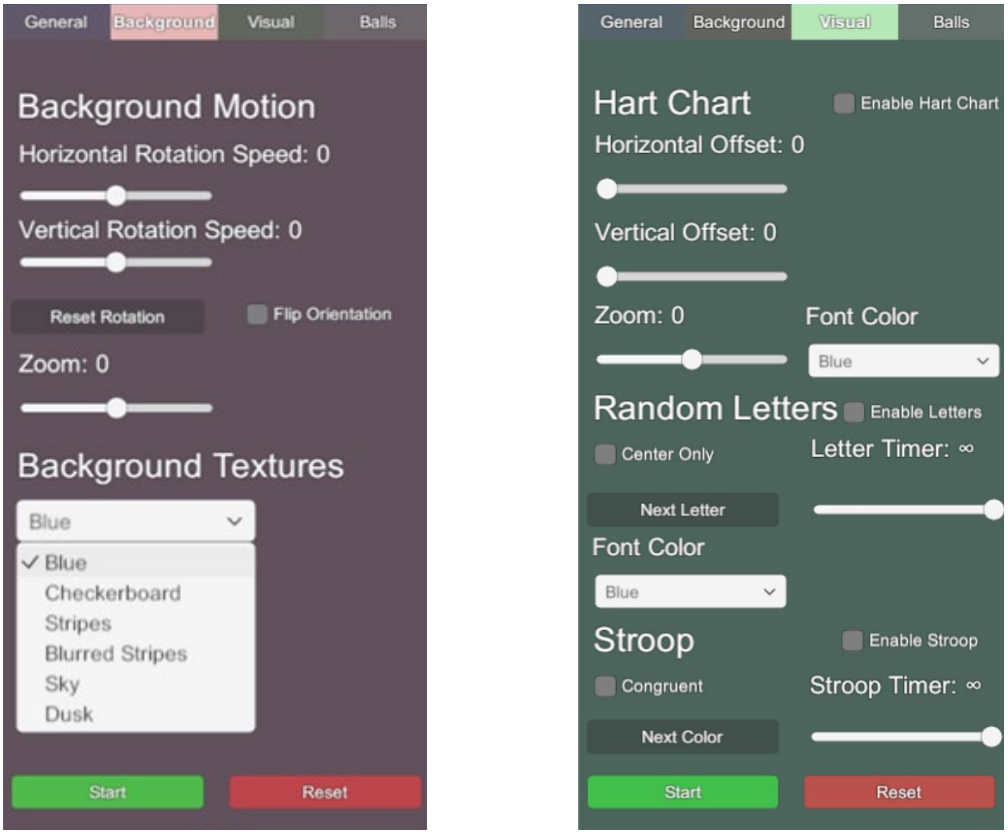


Figure 1: *Examples of the Unity user interface tabs which visually display 'Background' settings and 'Visual' cognitive task parameters that can be changed by the clinican/operator as the user carries out the virtual application.*

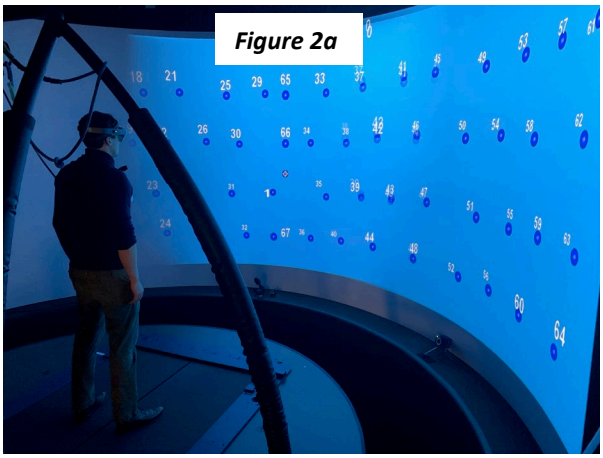
SSC-PAC created several different AR-based pilot applications and demonstrated them for NHRC to ensure that basic requirements needed for vestibular applications (i.e., decision making, head turning, etc.) are functioning. These applications included a Stroop test for HoloLens and DAQRI systems and a speech-based cognitive test developed for HoloLens. These pilot applications were helpful to discuss capabilities of the current systems and needs of the therapist. SSC-PAC continues to provide mobile visual and audio equipment for evaluation including DAQRI and Magic Leap to NHRC. This is being tested by NHRC engineers and therapists to determine if these devices will meet requirements for VR therapy. Other efforts that SSC-PAC is working on for this project will include ability to see and interact with a real object (i.e. pointer or weapon) within an AR space. Creare LLC, another technical consultant on the project, is working on improved versions of speech-based cognitive tasks to use in the rehabilitation portion of the study (second, upcoming protocol for Aim 2). They have provided a draft of two applications to use for the HoloLens that incorporates speech and head turning. MIT LL recreated the aurally aided visual search task (AAVS) in Unity and provided versions to WRNMMC/NICoE and NHRC for feedback.

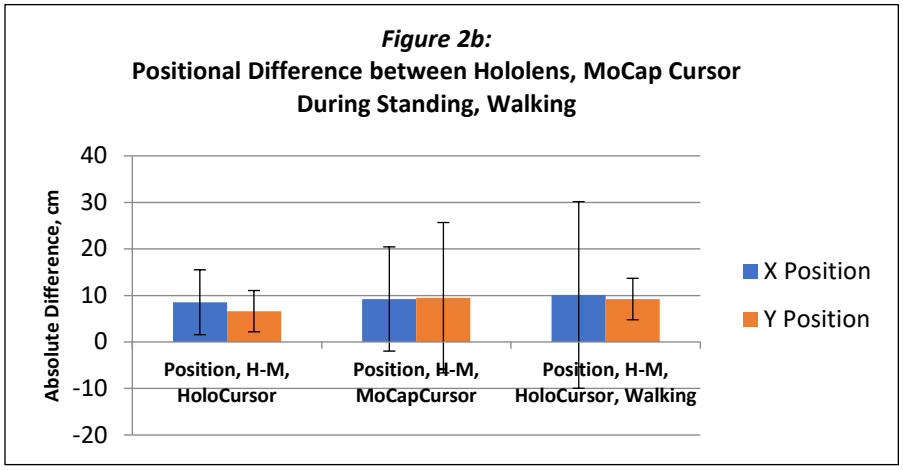
Several hardware components were purchased and installed at WRNMMC/NICoE to build a system capable of running Unity as well as mobile 3D audio within their existing CAREN infrastructure. NHRC and MITLL staff provided assistance in the install of this hardware in December 2018. Some technical details are being finalized and we expect the enhanced system to be working at WRNMMC/NICoE by the end of Year 2, Q1.

Task 3: Establish secure data storage location and create study in FITBIR (12 months; 100% completion). Data will be stored on approved servers at project sites (NHRC and WRNMMC/NICoE). 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.

Task 4: Collect and analyze data for validation with enrolled research subjects (27 months; 0% completion). In preparation for this task, draft applications were created by NHRC in order to start testing and identifying visual display issues between the CAREN screen projection and the HoloLens. Pilot testing was conducted at NHRC to assess differences between Motion Analysis Corp (MAC) optical motion capture used in the CAREN and the HoloLens Inertial Sensor for tracking a cursor and head rotation. No large differences were found between the two capture methods in standing or walking (see Figures 2 and 3). Additionally, data storing techniques were developed for both HoloLens and CAREN D-Flow applications for use in data collection.

The AAVS task is one of the primary testing applications for Aim 1 of this study and has historically been used in D-Flow, the CAREN's native software. Implementing the AAVS in Unity, a robust gaming engine, is intended to provide an enhanced immersive environment as well as improved testing capabilities. MITLL has developed the Unity-based AAVS task for this project, has provided a copy to NHRC and WRNMMC/NICoE, and is preparing a technical report on how this capability can be installed and utilized.





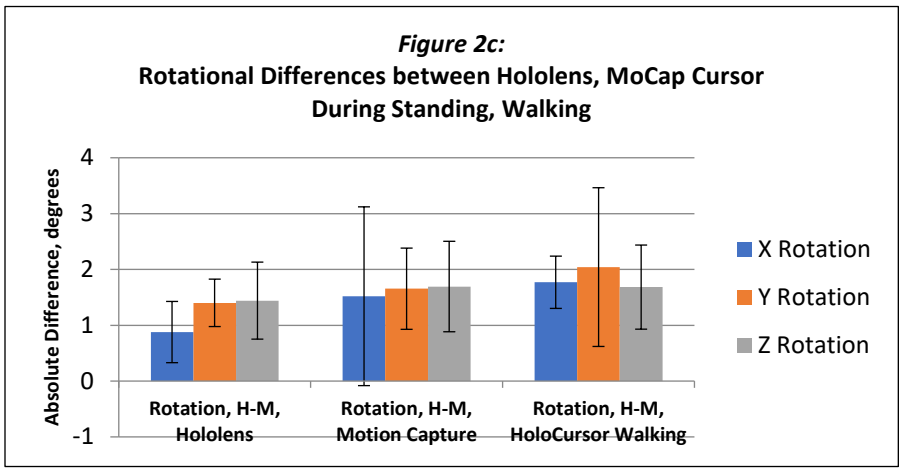


Figure 2: *Testing HoloLens on the CAREN to compare cursor position for data collection between systems (Fig. 2a). Mean differences in cursor position (Fig. 2b) and rotation (Fig. 2c) between the HoloLens and MAC optical motion capture methods for each of the 67 points tested across the CAREN screen. H-M is the difference between the HoloLens and Motion Capture measured values while [HoloCursor] and [MoCapCursor] refer to the cursor type used to highlight the points on the array as feedback to the user during testing. Four subjects were used in this collection.*

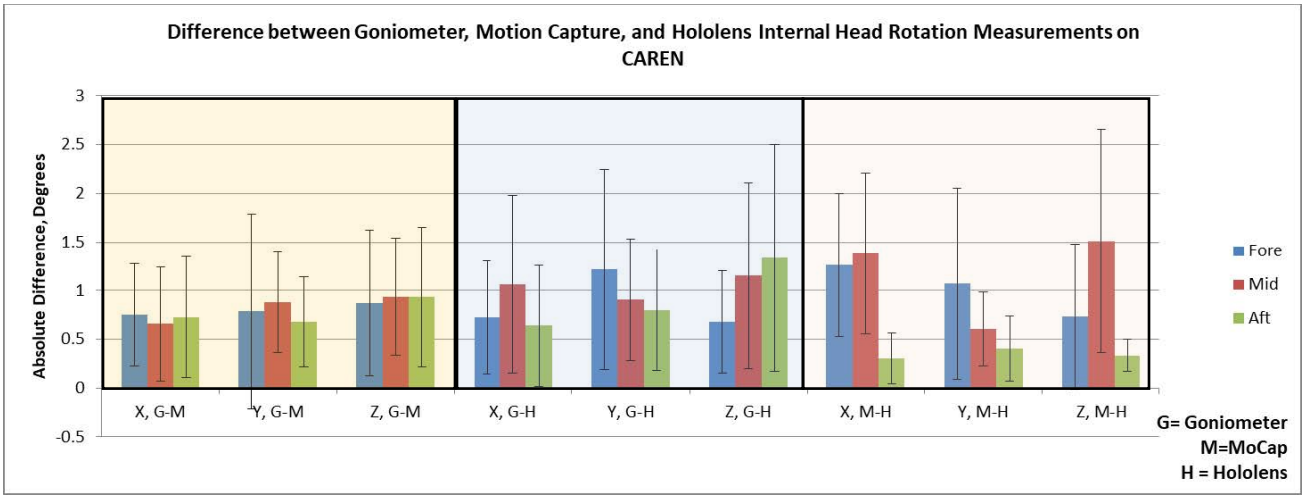


Figure 3: *Head rotation angle differences between the goniometer and motion capture (G-M), goniometer and HoloLens (G-H), and motion capture to HoloLens (M-H) in absolute degrees difference for X head rotation (-30 to 30 degrees), Y head rotation (-80 to 80 degrees) and Z head rotation (-60 to 60 degrees).*

The following tasks for Aim 2 (randomized clinical trial for TBI patients undergoing vestibular therapy) have not yet been initiated:

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.

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

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

Task 8: Data analysis and interpretation.

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

  Clinicians have been able to attend several meetings and educational training sessions through this project. This includes the Hearing Center of Excellence Collaborative Auditory and Vestibular Research Network (CAVRN) annual meeting in Dayton, OH, April 2018; Military Health Systems Research Symposium (MHSRS) in Kissimmee, FL, August 2018; and the first annual International Conference for Vestibular Rehabilitation in Chicago, IL, August 2018. Researchers also attended several meetings related to this project including the Augmented World Expo in Santa Clara, CA, June 2018 and Technical Exchange on Augmented

Reality in Maintenance and Material Management (TEAR 3M) in San Diego CA, February 2019.

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

  Discussions and overview presentations were made at the 2018 CAVRN meeting.

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

  NHRC's IRB protocol will be reviewed by WRNMMC's IRB at the end of this quarter and submitted to HRPO for 2nd level review by the end of next quarter. Any modifications or requests will be made in a timely manner to obtain approval as soon as possible. This quarter we will also seek guidance from the FDA regarding the use of the AR head mounted devices in the setting of physical therapy as requested by NHRC's IRB. Testing of MITLL's final version of the AAVS application for use on the CAREN system at WRNMMC/NICoE and NHRC will continue this quarter. Modifications based on operator and physical therapist feedback are expected. SSC-PAC will continue to design software that allows a user interface to be displayed when using AR devices, making it possible to allow for remote controlling of therapy application parameters by the physical therapist. Continued evaluation of new AR/VR devices and associated components (e.g., heart rate monitoring, controllers, etc.) is expected. Additionally, continued development of a test battery for the CAREN and mobile audio comparison will occur collaboratively between project sites. NHRC will coordinate an in-person meeting at MITLL (June 2019) or at the MHSRS meeting (August 2019) with most study sites represented.

4. IMPACT:

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

  Nothing to report.

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

  Nothing to report.

- **What was the impact on technology transfer?**

  Nothing to report.

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

  Nothing to report.

5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**.

  Nothing to report.

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

  At the request of NHRC's IRB, we are requesting FDA's guidance and approval for use of AR devices during therapy for Aim 2 and the timeline of this approval is unknown. Additionally, there is a new requirement to have the study protocol uploaded into the eIRB system at NHRC as well as recent common rule changes for which the protocol needs to be modified. FY19 funding has not yet been received. WRNMMC/NICoE does not have approval for use of FITBIR for central data entry though this is currently under discussion. Finally, filling the vestibular physical therapist position at WRNMMC/NICoE could take several months as candidates are just recently being sought and need to be credentialed at WRNMMC.

- **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 resulted in the development of Unity virtual applications for use in virtual reality (VR) HMDs (e.g., HTC Vive) to perform vestibular tests. These include: 1) Balance Cubes; 2) Walking; 3) AAVS task, mimicking application previously developed in the CAREN and used for patient testing. In addition, applications were also developed in Unity for use with augmented reality (AR) HMDs (e.g., HoloLens) to include the Stroop and speech-based cognitive tasks. Finally, an application was developed to test and compare outputs from the AR HMD and CAREN system, specifically head tracking with built-in gyro versus gaze position versus optical motion capture markers.

- **Publications, conference papers, and presentations**

  Nothing to report.

- **Website(s) or other Internet site(s)**

  Nothing to report.

- **Technologies or techniques**

  This project will develop a new technical capability to utilize both D-Flow and Unity software on the CAREN system to perform the AAVS test and other relevant applications to allow for enhanced vestibular assessment for TBI patients. This technology can potentially be used in other military patient populations for 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:	4
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 been directing the development of the technical infrastructure needed to perform the research studies required for the project as well as the protocol documents for IRB approval.*

Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	Dawn Bodell, DPT
Project Role:	*Co-Investigator (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*TBD*
Nearest person month worked:	3
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:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Paula Poh, PhD*
Project Role:	*Data Core Manager (NHRC)*
Researcher Identifier (e.g. ORCID ID):	0000-0003-0915-6119
Nearest person month worked:	4
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:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Amanda Markham, MPH*
Project Role:	*Project Manager/Coordinator (NHRC)*
Researcher Identifier (e.g. ORCID ID):	0000-0002-5761-4068
Nearest person month worked:	3
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:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Jacob VanDehy, MSE*
Project Role:	*Biomedical Engineer (NHRC)*
Researcher Identifier (e.g. ORCID ID):	0000-0003-2471-0528
Nearest person month worked:	4
Contribution to Project:	*Jacob Van \Dehy is the biomedical engineer/CAREN Operator at NHRC. He has been creating software applications for use in the VR systems. He has attended all study meetings and coordinates the hardware and software components needed for the project with the other collaborating sites.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological*

	Health and Traumatic Brain Injury Research Program (PH/TBIRP)

Name:	*Jeff Pawelek, BS*
Project Role:	*Project Manager (NHRC)*
Researcher Identifier (e.g. ORCID ID):	*0000-0003-1419-6131*
Nearest person month worked:	1
Contribution to Project:	*Jeff Pawelek has begun transitioning into the role of Project Manager on this project at NHRC. He has attended two meetings and two teleconferences since his start date of 28JAN2019 and will provide multiple support roles for this project.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

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 evaluated some of the mobile head mounted devices. She will continue to support the project by speaking with other clinicians and providing her subject matter expertise.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Kerry Rosen*
Project Role:	*Research Assistant (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	TBD
Nearest person month worked:	1
Contribution to Project:	*Kerry Rosen has participated in regular project meetings and has been conducting extensive literature reviews to familiarize herself with vestibular rehab and the patient population. She has also reviewed the grant and protocol in preparation for submission to the WRNMMC IRB.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Kyle Fitzgibbons*
Project Role:	*Application Developer (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	TBD
Nearest person month worked:	4
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 virtual reality-based head mounted displays. He has also been developing support documentation for these applications. Additionally, he has been investigating the integration of new hardware (i.e. eye tracking) and has provided technical insight about the integration of Unity with the NICoE CAREN system.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

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 I protocol and facilitated the approval of support agreements and contracts in preparation for IRB submission at NICoE/WR. She continues to supervise the development of the technical infrastructure at NICoE, procuring hardware and directing software development efforts. She has also been coordinating with MIT LL and AFRL on the virtual audio and Unity integration efforts.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Donielle Brasure, DPT*
Project Role:	*Research Physical Therapist (WRNMMC/NICoE)*
Researcher Identifier (e.g. ORCID ID):	TBD
Nearest person month worked:	3
Contribution to Project:	*Dr. Brasure participated in regular meetings about the project. She worked collaboratively with the other PTs on the project to refine the eligibility criteria, as well as the screening and data collection procedures for the rehabilitation portion of the project. She also conducted literature reviews about biometric devices that may be incorporated with the mobile system. She worked with Mr. Fitzgibbons on the development of new virtual environments and associated documentation.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

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:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Josh Kvavle, PhD*
Project Role:	*Project Manager (SSC-PAC)*
Researcher Identifier (e.g. ORCID ID):	0000-0001-9528-0700
Nearest person month worked:	1
Contribution to Project:	*Dr. Kvavle is the Project Manager at SSC-PAC for this project and will be responsible for managing the tasks required by SSC-PAC for this project. He has attended all study meetings. He supervises the technical team for SSC-PAC's contribution, consisting of Garrison Price, Matthew Hemker, Richard Capewell, Jake Ramirez and Gautham Dixit.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Heidi Buck*
Project Role:	*Project Director (SSC-PAC)*

Researcher Identifier (e.g. ORCID ID):	TBD
Nearest person month worked:	1
Contribution to Project:	*Heidi Buck manages the staffing team that is responsible for evaluating new mobile visual equipment that could be used within this study. She has attended study meetings and coordinates with NHRC regarding any new hardware and software components that are being evaluated.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Delsey Sherrill* *Christopher Smalt* *Paul Calamia*
Project Role:	*Sherrill: Project Manager (MIT LL)* *Smalt: Audio Development (MIT LL)* *Calamia: Audio Development (MIT LL)*
Researcher Identifier (e.g. ORCID ID):	Sherrill: 000-0002-7633-4328 Smalt: 000-0002-3467-5888 Calamia: 000-0002-0401-6996
Nearest person month worked:	4
Contribution to Project:	*Delsey Sherrill is the site project manager at MIT LL and is overseeing the development of the AAVS task for Unity, and the delivery of the task to NICoE. She has attended regular phone meetings for this project.* *Chris Smalt is a researcher at MIT LL and is responsible for assisting with the virtual audio development for this project. He regularly attends monthly phone meetings and has supported on-site deployment to NICoE.* *Paul Calamia is a researcher at MIT LL and is responsible for assisting with the virtual audio development for this project. He regularly attends monthly phone meetings.*

Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

Name:	*Chris Gengler* *Harvey Edwards*
Project Role:	*Gengler: Software Development (MIT LL)* *Edwards: Operations (MIT LL)*
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	6
Contribution to Project:	*Chris Gengler is assisting with software development for the AAVS task in Unity and has supported on-site deployment to NICoE.* *Harvey Edwards is assisting with operations for the development of the AAVS task in Unity. He regularly attends monthly phone meetings.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

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.*
Funding Support:	*Joint Program Committee-8, Clinical and Rehabilitative Medicine Research Program (JPC-8 CRMRP), Psychological Health and Traumatic Brain Injury Research Program (PH/TBIRP)*

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

  Dr. Donielle Brasure left her position as the physical therapist at WRNMMC/NICoE and recruitment for her replacement is currently underway. Jeffrey Pawelek was hired as a project manager for this project at NHRC.

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

  1. **Organization Name:** Creare LLC
  2. **Location of Organization:** Hanover, NH
  3. **Partner's contribution to the project:** Enhanced audio capabilities for applications.

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

  b. **In-kind support**: Will provide several speech-based cognitive task applications within Unity to use in the rehabilitation portion of the study.

  c. **Facilities:** N/A

  d. **Collaboration**: N/A.

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

  f. **Other:** N/A

8. SPECIAL REPORTING REQUIREMENTS

- QUAD CHART *(see attached)*

9. APPENDICES

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

ERMS/Log Number: PT160118 Task Title: DoD JPC8/CRMRP, PH/TBI Research Program, Complex Traumatic Brain Injury Rehabilitation Research Award W81XWH-16-PHTBIRP-CTRRA

PI: Pinata Sessoms, Ph.D. **Org:** Naval Health Research Center **Award Amount: $** 4.8M

Study/Product Aim(s)

To improve TBI neurosensory symptoms in patients who may be nonresponsive to prescribed traditional rehabilitation treatments, through use of mobile technologies that can be transitioned to clinics and the home.

- Aim 1: To test the hypothesis that mobile visual and auditory technologies provide similar feedback to the user (healthy controls and patients with mTBI) when compared with CAREN-based visual and auditory inputs.
- Aim 2: To conduct a clinical trial to evaluate the efficacy of mobile visual and auditory technologies for patients with TBI participating in vestibular therapy. This group will be compared with treatment groups 1) utilizing standard CAREN sytem and 2) participating in traditional vestibular physical therapy.

Approach

Head mounted mobile technology will be incorporated with augmented reality and 3D spatial audio. Healthy controls will validate mobile system and establish baseline measurements. Patients with TBI will be randomized to therapy groups.

Accomplishments: Project infrastructure established. All agreements are in place for project teams. Project kick-off meeting was held and team continues to hold teleconference meetings every two weeks. Application development and testing is ongoing. Project timeline and cost is on track. HoloLens testing on the CAREN shown above.

Timeline and Cost

Activities / CY	18	19	20	21
Approvals and Hardware Implementation				
Mobile System Validation				
Intervention testing of TBI patients				
Analysis and dissemination				
Estimated Budget ($K)	**$4600K**	**$50K**	**$50K**	**$50K**

Updated: (02/20/2019)

Goals/Milestones

CY18 Goal – Approvals and Hardware Implementation

- X Agreements approvals (7600s and subcontracts)
- X Coordinate study staff and equipment
- X IRB approval for Aim 1

CY19 Goals – Mobile System Validation

- ☐ Collect and analyze Aim 1 data on healthy controls and TBI group
- ☐ Development of treatment applications in CAREN and HMD for complex TBI
- ☐ IRB approval for Aim 2

CY20 Goal – Intervention testing of TBI patients

- ☐Collect Aim 2 data (TBI population) for comparison of treatment groups

CY21 Goal – Data collection, analysis, and dissemination

- ☐Data analysis and interpretation for Aim 2
- ☐Presentations and publications

☐**Comments/Challenges/Issues/Concerns**

- If there is not a correlation between systems, must implement new hardware or software strategy

Budget Expenditure to Date

Projected Expenditure:$4.7M by FY21

Actual Expenditure: $928K disbursed ($3.9M obligated)