AWARD NUMBER: W81XWH-18-2-0049

TITLE: “Objective Dual-Task Turning Measures for Return-to-Duty Assessment”

PRINCIPAL INVESTIGATOR: Dr. Laurie King

CONTRACTING ORGANIZATION: Oregon Health and Science University
Portland, OR 97239

REPORT DATE: Sept 2019

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE
Sept 2019

2. REPORT TYPE
Annual report

3. DATES COVERED
1 SEP 2018 - 31 AUG 2019

4. TITLE AND SUBTITLE
"Objective Dual-Task Turning Measures for Return-to-Duty Assessment"

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-2-0049

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S) Dr. Laurie King; Shelby Martin; Dr. Peter Fino; Dr. Margaret Weightman; Ben Cassidy

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES)

Oregon Health & Science University 3181 SW Sam Jackson Park Road Portland, Oregon 97239

Courage Kenny Research Center, University of Utah, Fort Sam Houston, Warrior Recovery Clinic, Madigan Army Medical Center

8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 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

Objectives: Our overall objective is to expand our prior preliminary work on wearable sensors to evaluate objective dual-task turning measures for use as rehabilitative outcomes and as tools for RTD assessments. Our central hypothesis is that objective measures of dual-task turning will have high diagnostic accuracy, predictive capacity, and responsiveness to intervention in people with mTBI. Deficits in dual-task turning may measurably reflect impairments in sensory, vestibular, ocular, motor, and cognitive systems following mTBI that are not detected when assessed in isolation.

Plan: OHSU will serve as both a participating site for Aims I and II and the coordinating center for the entire study. We plan to enroll 10 subjects with persistent symptoms from mTBI and 10 health controls at OHSU for Aims I and II. Across all sites, Aims I and II will include 50 civilians with persistent symptoms from mTBI, 50 civilian healthy controls, and 40 active duty SM healthy controls in total. Three non-military sites (OHSU, UU, CKRC) will test civilians. A fourth military site (FSH) will enroll and test 40 healthy active duty SMs across a range of military experience and ability levels. Recruitment, inclusion criteria, and methods will be identical across the three non-military sites (OHSU, CKRC, UU). Recruitment, inclusion criteria, and methods for healthy active duty SM controls at FSH will be identical to those used for civilian healthy control subjects at the non-military sites. Recruitment, inclusion criteria, and power calculations are common to both Aims I and II.
OHSU will serve as the coordinating center for Aim III; OHSU will not be a participating site for Aim III. Subjects for Aim III will include 40 active duty SMs with persistent symptoms from mTBI who are referred for physical therapy due to their symptoms. Participants will be recruited from two military medical centers specializing in the rehabilitation of active duty personnel after mTBI, WRC at Fort Caron and MAMC at Joint Base Lewis-McChord. Each site will recruit 20 participants for Aim III.

Aims and Hypotheses: Aim 1 (Diagnostic Accuracy): To assess the added value of objective dual-task turning measures over standard clinical assessments. Hypothesis 1A: We hypothesize that objective turning measures, performed in dual-task contexts, will improve the diagnostic accuracy relative to standard clinical assessments of physical function to SMs with mTBI. Hypothesis 1B: We hypothesize that objective turning measures, performed in a dual-task contexts, will be associated with impairments in International Classification of Function and Disability (ICF) model, including body structure/function, activity level, and participant level domains. Aim 2 (Predictive Capacity): To determine if objective dual-task turning measures predict functional performance in civilian and military relevant tasks. We hypothesize that objective turning measures, performed in dual-task contexts and obtained in the clinic, will predict functional performance in (A) ecologically valid civilian environments and in (B) ecologically valid, simulated high-demand battle drills. Aim 3 (Responsiveness to Intervention): To assess the responsiveness of objective dual-task turning measures to standard vestibular rehabilitation in active duty SMs with residual mTBI-related symptoms. We hypothesize that objective turning measures, performed in dual-task contexts, will measurably improve over the course of rehabilitation.

Methods: OHSU will serve as the coordinating center for Aim III; OHSU will not be a participating site for Aim III. Subjects for Aim III will include 40 active duty SMs with persistent symptoms from mTBI who are referred for physical therapy due to their symptoms. Participants will be recruited from two military medical centers specializing in the rehabilitation of active duty personnel after mTBI, WRC at Fort Caron and MAMC at Joint Base Lewis-McCord. Each site will recruit 20 participants for Aim III.

Results: Recruitment at academic sites is in progress and will be ongoing.

	OHSU	CKRC	UU	Total	
Screened:	24	20	22		
Screen fails:	2	2	6		
Enrolled mTBI:	5	1	6		**12**
Enrolled Controls:	3	8	1		**12**

15. SUBJECT TERMS mTBI, Rehabilitation, Brain Injury, Inertial Sensors, Balance, Concussion, Return To Duty					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified	Unclassified	15	19b. TELEPHONE NUMBER *(include area code)*

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

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1. INTRODUCTION:

Our long-term goal is to improve function, recover combat readiness, and restore quality of life by advancing assessment and rehabilitative care after mTBI. Our overall objective is to expand our prior preliminary work on wearable sensors to evaluate objective dual-task turning measures for use as rehabilitative outcomes and as tools for RTD assessments. Our central hypothesis is that objective measures of dual-task turning will have high diagnostic accuracy, predictive capacity, and responsiveness to intervention in people with mTBI. Deficits in dual-task turning may measurably reflect impairments in sensory, vestibular, ocular, motor, and cognitive systems following mTBI that are not detected when assessed in isolation. We plan to test our central hypothesis with the following specific aims:

Aim 1 (Diagnostic Accuracy): To assess the added value of objective dual-task turning measures over standard clinical assessments. Hypothesis 1A: We hypothesize that objective turning measures, performed in dual-task contexts, will improve the diagnostic accuracy relative to standard clinical assessments of physical function to SMs with mTBI. Hypothesis 1B: We hypothesize that objective turning measures, performed in a dual-task contexts, will be associated with impairments in International Classification of Function and Disability (ICF) model, including body structure/function, activity level, and participant level domains. Aim 2 (Predictive Capacity): To determine if objective dual-task turning measures predict functional performance in civilian and military relevant tasks. We hypothesize that objective turning measures, performed in dual-task contexts and obtained in the clinic, will predict functional performance in (A) ecologically valid civilian environments and in (B) ecologically valid, simulated high-demand battle drills.

Aim 3 (Responsiveness to Intervention): To assess the responsiveness of objective dual-task turning measures to standard vestibular rehabilitation in active duty SMs with residual mTBI-related symptoms. We hypothesize that objective turning measures, performed in dual-task contexts, will measurably improve over the course of rehabilitation.

OHSU will serve as both a participating site for Aims I and II and the coordinating center for the entire study. We plan to enroll 10 subjects with persistent symptoms from mTBI and 10 health controls at OHSU for Aims I and II. Across all sites, Aims I and II will include 50 civilians with persistent symptoms from mTBI, 50 civilian healthy controls, and 40 active duty SM healthy controls in total. Three non-military sites (OHSU, UU, CKRC) will test civilians. A fourth military site (FSH) will enroll and test 40 healthy active duty SMs across a range of military experience and ability levels. Recruitment, inclusion criteria, and methods will be identical across the three non-military sites (OHSU, CKRC, UU). Recruitment, inclusion criteria, and methods for healthy active duty SM controls at FSH will be identical to those used for civilian healthy control subjects at the non-military sites. Recruitment, inclusion criteria, and power calculations are common to both Aims I and II.

OHSU will serve as the coordinating center for Aim III; OHSU will not be a participating site for Aim III. Subjects for Aim III will include 40 active duty SMs with persistent symptoms from mTBI who are referred for physical therapy due to their symptoms. Participants will be recruited from two military medical centers specializing in the rehabilitation of active duty personnel after mTBI, WRC

at Fort Caron and MAMC at Joint Base Lewis-McChord. Each site will recruit 20 participants for Aim III.

2. KEYWORDS:

mTBI, Rehabilitation, Brain Injury, Inertial Sensors, Balance, Concussion, Return To Duty

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Goal	Target Completion Date	Percentage of Completion/ Date of Completion
Specific Aim 1 & 2 (Diagnostic Accuracy Predictive Capacity)		
Major Task 1: Launch Study Activities	*6 months*	97% complete
Major Task 2: Recruitment and Testing	*28 months*	23% complete
Major Task 3: Data Analysis	*40 months*	0% complete
Specific Aim 3 (Responsiveness to Rehabilitation)		
Major Task 1: Launch Study Activities at Rehabilitation Sites	*30 months*	0% complete
Major Task 2: Data Collection	*42 months*	0% complete
Major Task 3: Data Analysis & Publications on Interventions	*48 months*	0% complete

What was accomplished under these goals?

Specific Aims I & II

Major task 1: Launch Study Activities

Subtask 1: Prepare Regulatory Documents and Research
Set up sub award across sites; 65% complete; All sub awards for academic sites are setup, however there has been a delay in setting up sub awards at the military sites. See details in the delayed section below.

Finalize consent form and human subject protocol; refine eligibly criteria, exclusion criteria and screening protocol; ~~100% complete~~; All study documents have been finalized and submitted to the IRB for approval.
Prepare testing protocol; ~~100% complete~~; The testing protocol has been finalized. Testing is underway at all academic sites.
Prepare screening and testing forms for database; ~~100% complete~~; Screening and testing forms have been finalized and entered into REDCap.
Create RedCap database to store screening and testing forms, 100% complete; The REDCap database is live and data has been entered by all academic sites.
Prepare forms for FITBIR; ~~100% complete~~; All forms have been received by FITBIR, however the study and forms have not been created in the FITBIR database yet.
Prepare IRB approved forms; ~~100% complete~~; All forms have been IRB approved at academic sites. If there are changes, all sites will submit them to their site's IRB for approval.
Prepare petty cash/log to track payments of research subjects; ~~100% complete~~; Petty cash has been issued at University of Utah and Courage Kenny Research Center. ClinCards are being used to compensate subjects at OHSU. Payment logs are being kept at each site.

Subtask 2: Prepare Technology for Study
Purchase computers for data collection and set up with APDM Sensors; ~~100% complete~~; Identical computers and sensors have been ordered and received by all academic sites.
Order equipment for simulated combat task; ~~100% complete~~; All equipment has been ordered and received by all academic sites.
Prepare turning course for clinic assessment: build simulated combat task, dual task; ~~100% complete~~; The turns course has been setup and implemented at all academic sites.
Meet with all sites to finalize protocol; ~~100% complete~~ All sites met at University of Utah on March 6-8th 2019. This meeting allowed study team members from each site to observe a mock testing session and revise the protocol as needed. We have another in-person meeting scheduled at Courage Kenny Research Center November 13-15th 2019 to prepare for Aim III to begin.

Subtask 3: Hiring and Training Personnel
Hire staff including research assistants and post-doctoral fellows;~~100% complete~~; Hiring has been completed at each site.
Staff completes research compliance training; ~~100% complete~~; All study team members have completed the required research trainings and have been trained on protocol procedures.
Train RA's in data collection and protocol; 100% complete; Dr. Peter Fino, Co-I, attended each academic site to train post-doctoral fellows and research assistants on data collection and protocol procedures.

<u>Major Task 2: Recruitment and Testing</u>

Subtask 1: Recruitment
Prepare brochures for subject recruitment; ~~100% complete~~; Brochures have been designed and approved by the IRB at all academic sites.
Make contacts with sources of referrals through Primary Care, Family Medicine, and other clinics; 25% complete; All academic sites have been collaborating with internal and external referral sources for recruitment.

Meet with primary sources of referral for logistics of recruitment; 25% complete; All academic sites have been collaborating with internal and external referral sources for recruitment.
Finalize recruitment strategy; 20% complete; OHSU's most successful recruitment method has been contacting participants recorded in a research database, that expressed interest in participating in future studies. Also, OHSU has been working closely with the OHSU Concussion Clinic staff and they are referring eligible patients to us. Courage Kenny Research Center employs two separate methods – one for each subject type (HC vs. case). For healthy control subjects, their most effective method has been a system-wide outreach for employees of the hospital. For mTBI subjects, they have a registry of research-eligible patients (either current or former) that they use. University of Utah primarily uses two different recruitment resources which have been, Physical Therapists at the University of Utah Sugar House Clinic, and Dr. Colby Hansen, MD and Lara Haynes, DNP who are in the PM&R Department at the University of Utah and have a Concussion Specialty Practice. They have had success with both methods. The PTs at Sugar House have provided them with the majority of subjects but Dr. Colby Hansen and Lara Haynes' Clinic has increased over the last few weeks.
Phone screening of subjects; 17% complete; This will be ongoing throughout the study. There have been 24 subjects screened at OHSU, 20 at CKRC, and 22 at UU.
Create screening logs; 17% complete; Screening information is kept at each site in paper form. Once a subject has enrolled in the study their screening information is entered into REDCap. Each site will only have access to their site's study participants in REDCAp and no PHI (except dates) will be stored.

Subtask 2: Data Collection and Management
*Schedule neurocognitive testing at each site for data collection; 17% complete; 2*4 of the anticipated 140 study participants have been tested. OHSU has enrolled 8 subjects, UU has enrolled 7 subjects, and CKRC has enrolled 9 subjects.
Schedule gait and balance testing for data collection at each site; 17% complete; We have collected data on 24 of the anticipated 140 study participants at academic sites.
Data back-up onto server including manual data entry into Redcap; 10% complete; Data is being saved at each site on their secure server. Also, research assistants at each site are manually entering data into the REDCap database. This will be ongoing throughout the study.
Screen and verify data on server; check for accuracy; 15% complete; Data quality checks will be executed each quarter. Each site will perform their own data check, then OHSU the coordinating site, will do a larger data check. Once this is completed, OHSU will lock all forms to ensure no edits can be made. All academic sites completed data checks September 2019.
Validate and submit forms to FITBIR quarterly; 0% complete; OHSU will begin submitting data quarterly to FITBIR once the study has been approved and is open for submissions. OHSU will be responsible for submitting data for all sites.

Significant Results/ Key outcomes:
Our significant results to date center around verifying the feasibility of our simulated urban patrol task (SUP) and civilian ambulatory task (CAT). Using an initial sample of 12 subjects, we compared the turning speed exhibited during the One Minute Walk Test (1MW), the Illinois Agility Test (IAT), the Custom Clinical Turning Course (CCTC), the CAT, and the SUP. Specifically, we extracted the peak angular velocity of the head and lumbar for each turn throughout every test. Subsequently, we averaged the peak angular velocities for each trial, yielding one average peak

angular velocity per trial. We also calculated the 95th percentile turning velocity for each trial. Comparing these two outcomes, we found the CAT had slower mean and 95th percentile lumbar angular velocities than all other tasks. While the mean lumbar angular velocities were fastest in the 1MW likely because of the sharp 180° turn angle, both the 1MW and the SUP task had equivalent 95th percentile angular velocities (Figure 1).

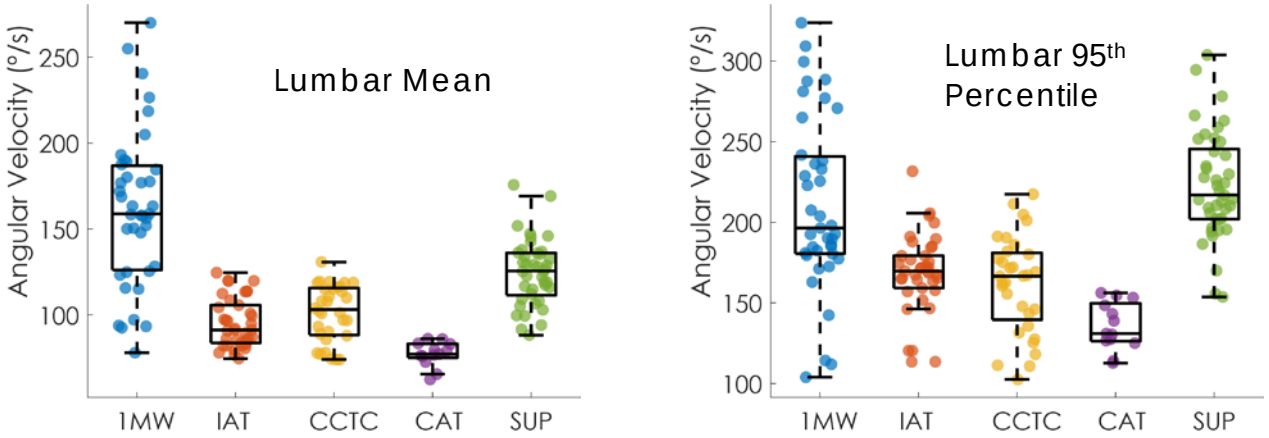

Figure 1. Lumbar angular velocities for each task. Individual dots represent different trials. Left: Mean peak lumbar angular velocities for each task. Right: 95th percentile peak lumbar angular velocities for each task. Please note the difference y-axis scales between the two figures.

When comparing the peak head angular velocities, the CAT had similar mean head velocities as the CCTC. The SUP had mean head velocities that were faster than the IAT, CCTC, and CAT, but slightly slower than the 1MW. Comparatively, the 95th percentile head velocities were fastest in the SUP. Additionally, the 95th percentile head velocities in the CAT were similar to those exhibited in the 1MW. These results suggest ecologically-valid tasks such as the CAT and SUP require a small amount of very fast head rotations that are not captured in the clinical tasks. These results provide the appropriate ground-work to continue with Aim II to determine the degree to which the 1MW, the IAT, and the CCTC are associated with performance on the CAT and SUP.

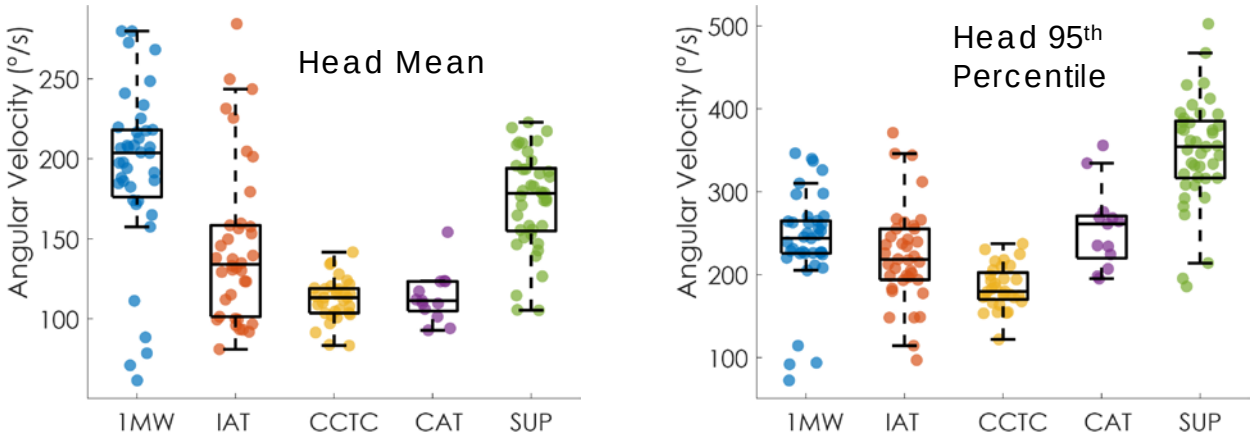

Figure 2. Head angular velocities for each task. Individual dots represent different trials. Left: Mean peak head angular velocities for each task. Right: 95th percentile peak head angular velocities for each task. Please note the difference y-axis scales between the two figures.

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

Members of the research team had the opportunity for training and professional development through attendance at specific military based conference. Dr. King, Dr. Weightman, and Dr. Fino attended the Military Health System Research Symposium (MHSRS) in August 2019. This meeting offered the opportunity to listen and engage with experts in the field of research. More specifically, the attendees at MHSRS were invited to attend a session about return to duty decisions and allowed the opportunity to continue to build countrywide networks with other experts who are conducting research in the area. Dr. Fino presented the results detailed above at this conference.

How were the results disseminated to communities of interest?

We have registered this study at ClinicalTrials.gov, which is available to the public. At this site potential subjects can get information about the study as well as contact the study team to participate as either a healthy control or mTBI if they are eligible.

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

OHSU will continue to recruit and plans to enroll the final 12 subjects in the next reporting period. Once the aim III protocol is finalized, OHSU will get IRB approval and will design the REDCap project for data collection.

CKRC will be hosting the next all site in-person training in November 2019 and they will be disseminating planning for this. In the next reporting period, in regards to recruitment, they will continue to recruit off the patient registry. Since they have enrolled more HC subjects than mTBI, it is likely that word of mouth will be sufficient for healthy subject recruitment. However, if this is not the case, they are able to run a similar system-wide notice again to recruit healthy subjects.

UU plans to continue its recruitment and enroll the remaining 33 subjects before the end of May 2020. They are going to expand recruiting efforts at the University of Utah Emergency Departments, Urgent Cares and with non-operative Sports Medicine Physicians.

All academic sites will need to do test-retest reliability on half of their enrolled subjects. This will be implemented in the next reporting period and will be ongoing.

FSH plans to finalize and submit the Aim III protocol and get HRPO approval.

4. IMPACT:

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

This project will influence the base knowledge of return to duty for individuals who suffer from mTBI. This project will give insight on combat readiness using objective dual task turning measures and rehabilitative care after mTBI. Clinical practice may also be impacted through the

implementation of wearable sensors to more accurately measure and assess gait and balance during both at-home activity, as well as in clinical and rehabilitative settings.

What was the impact on other disciplines?

Our research team has continued to meet once per month with mTBI treating doctors, physical therapists and athletic trainers, and affiliated clinicians from other clinics. We have found that these meetings allow an open discussion between researchers and clinicians, to discuss research findings, and work towards translating research knowledge into clinical practice.

OHSU is planning a regional TBI symposium where we plan to discuss the study in December 2019.

What was the impact on technology transfer?
Nothing to Report.

What was the impact on society beyond science and technology?

Our research team has continued to help mentor the development of young researchers completing undergraduate and high-school programs of education. Specifically, we have had students help write the operational manual, develop study documents, and build the testing environment. We also are expanding and improving public knowledge on TBIs using a variety of methods, including community outreach, meeting with health professionals, engaging in direct discussion with patients, and distributing fliers.

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

Reported problems/delays from Year 1, Quarter 1:
1) Due to delay in HRPO approval, Dr. King's effort for this reporting period was .08 calendar months.
Resolution: Due to the minimal effort of Dr. King in the first quarter, and the anticipated effort for the remainder of this project year at 1.3 calendar months, her total effort for year 1 will be decreased by more than 25% from what was budgeted. We expect that she will still be able to carry out the scope of work as approved. In year 2, we anticipate her effort to be as budgeted.

Reported problems/delays from Year 1, Quarter 2:
1) Working on distribution of funds to military sites
Resolution: We are working closely with Grant Specialist, Lucinda Keeney, at Ft. Detrick and the Office of Proposal and Award Management (OPAM) at OHSU to move forward

Reported problems/delays from Year 1, Quarter 3:
1) The military sites are still awaiting the sub award to be setup
Resolution: The interagency agreement (IAA) between CDMRP and Fort Sam Houston is currently being staffed at the AMEDD center for signature by the commanding general. The IAA is pending signature.

Problems/delays from Year 1, Quarter 4:
1) The IAA still remains unsigned
Resolution: As per the ACSRM, "the IAA will be signed against FY20 dollars in the new Fiscal Year/October". This agreement replaces the now cancelled FY18 document and combines the FY18 and FY19 budget periods for a current amount of $141,720.00 (CDMRP FY19 RDT&E, funds expiring 09/30/2020). Once the agreement has been fully signed we will proceed with the MIPR." Once Dr. Lester has provided his feedback, Carrie Hoppes will send the new IAA back for a signature.

Overall, our largest obstacle has been getting the military sites setup to accept funds. Therefore, we cannot proceed with the military aspect of the study until this occurs.

Changes that had a significant impact on expenditures

Our study start up took longer than expected due to awaiting HRPO approval, which also prolonged setup of the sub awards. In addition, OHSU has not received final invoices from the sub award sites. The current total expenditures do not reflect the total Year 1 sub award costs. OHSU has only paid invoices from University of Utah for costs through June 2019 and Courage Kenny (Allina) through May 2019.

The estimated expenditures for Year 1 were $490,329 per the awarded budget. The actual expenditures to date are $192,915. Pending charges are still expected.

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

6. PRODUCTS:

Platform Presentation:

1. Fino PC, Dibble LE, Weightman MM, Lester ME, King LA. (2019). Development of a simulated urban patrol task and its relation to clinical assessments of turning. *Military Health Research Symposium*. Kissimmee, FL, August 19-22.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Site:	Role:	Cal Month
Laurie King	OHSU	PI	1
Shelby Martin	OHSU	Study Coordinator	4.8
Margaret Weightman	CKRC	Co-I	2.6
Max Klaiman	CKRC	RA	5.2
Patrick Michielutti	CKRC	Research PT	2
Lee Dibble	UU	Co-I	1.2
Peter Fino	UU	Co-I	1.8
Benjamin Cassidy	UU	RA	4.5

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

MAJ Mark Lester has recently retired from Fort Sam Houston, but remains active on the study. Carrie Hoppes will be taking over his role, as Co-I, at Fort Sam Houston. She will be at our all site in-person meeting in November for onboarding.

What other organizations were involved as partners?
Organization Name: APDM Wearable Technologies
Location of organization: 2828 SW Corbett Avenue, Portland, OR 97201
Partner's contribution to project: Partners have developed the Opals, which are the wearable sensors that detect movement, gait, and balance.

8. SPECIAL REPORTING REQUIREMENTS

9. APPENDICES

See Quad Chart Below

Objective Dual-Task Turning Measures for Return-to-Duty Assessment
PT170106
W81XWH-18-2-0049

PI: Laurie King, PhD, PT **Org:** Oregon Health and Science University **Award Amount:** $1.6 million

Study/Product Aim(s):

Our long-term goal is to improve function, recover combat readiness, and restore quality of life by advancing assessment and rehabilitative care after mTBI. Our overall objective is to expand our prior preliminary work on wearable sensors to evaluate objective dual-task turning measures for use as rehabilitative outcomes and as tools for RTD assessments.

Aim I: Cross-sectional assessment of head and trunk coordination and velocity during turning tasks with a simultaneous cognitive overlay in a clinical setting.
Aim II: Cross-sectional assessment of civilian and warrior tasks to assess how measures of dual-task turning predict functional performance in daily tasks.
Aim III: Pre-post assessments of dual-task turning in active duty SMs before and after rehabilitation for mTBI to assess the responsiveness of dual-task turning measures to change.

Approach:

We will collect data from 50 civilian mTBI patients, 50 civilian healthy controls, and 40 active duty SM healthy controls to determine diagnostic accuracy (Aim I) and predictive capacity (Aim II). Then pre-post rehabilitation assessments will be analyzed from 40 active duty SMs with mTBI to determine responsiveness to intervention (Aim III).

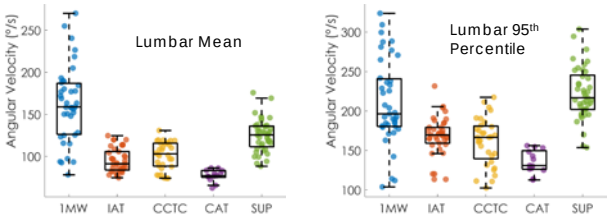

Figure 1. Lumbar angular velocities for each task. Individual dots represent different trials. Left: Mean peak lumbar angular velocities for each task. Right: 95th percentile peak lumbar angular velocities for each task. Please note the difference y-axis scales between the two figures.

These results provide the appropriate ground-work to continue with Aim II to determine the degree to which the 1MW, the IAT, and the CCTC are associated with performance on the CAT and SUP.

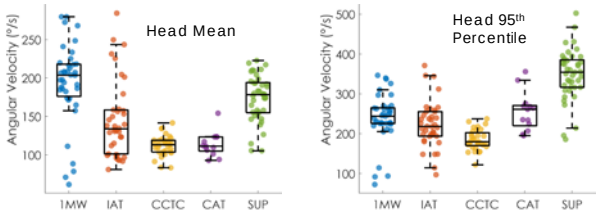

Figure 2. Head angular velocities for each task. Individual dots represent different trials. Left: Mean peak head angular velocities for each task. Right: 95th percentile peak head angular velocities for each task. Please note the difference y-axis scales between the two figures.

Timeline and Cost

Activities CY	18	19	20	21
Study setup, Hiring, Training, Purchasing, IRB, Site Coordination				
Recruitment for Aims I and II				
Aims I and II: Diagnostic Accuracy and Predictive Capacity in 75 mTBI, 105 healthy controls				
Aim III: Responsive to Rehabilitation in Active Duty Service Members				
Data Analysis				
Manuscript Preparation and Submission				
Estimated Budget ($K) $2,000	$558	$558	$512	$372

Updated: 27 September 2019

Goals/Milestones:

CY18 Goal
☒ Launch study activities

CY19 Goal
☒ Recruitment and testing (Aims I & II)

CY20 Goal
❑ Launch study activities at rehabilitation sites
❑ Data analysis and publications (Aims I & II)

CY21 Goal
❑ Data analysis and publications (Aim III)

Comments/Challenges/Issues/Concerns: All academic sites are recruiting and enrolling participants. We are concerned that the military sites have not been setup to accept funds.

Budget Expenditure to Date
Projected Expenditure: $490,329 Actual Expenditure: $192,915