

AWARD NUMBER: W81XWH-18-2-0049

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

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CONTRACTING ORGANIZATION: Oregon Health and Science University

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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:	52	69	56	
Screen fails:	14	8	12	
Enrolled mTBI:	9	23	20	52
Enrolled Controls:	10	25	16	51

15. SUBJECT TERMS mTBI, Rehabilitation, Brain Injury, Inertial Sensors, Balance, Concussion, Return To Duty					
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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	<i>6 months</i>	99% complete
Major Task 2: Recruitment and Testing	<i>28 months</i>	67% complete
Major Task 3: Data Analysis	<i>40 months</i>	17% complete
Specific Aim 3 (Responsiveness to Rehabilitation)		
Major Task 1: Launch Study Activities at Rehabilitation Sites	<i>30 months</i>	25% complete
Major Task 2: Data Collection	<i>42 months</i>	0% complete
Major Task 3: Data Analysis & Publications on Interventions	<i>48 months</i>	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; 99% complete; Fort Sam Houston has received funds and they are working with Geneva to sign the contract to disperse funds.*

Subtask 2: Prepare Technology for Study- *100% complete*

Subtask 3: Hiring and Training Personnel- *100% complete*

Major Task 2: Recruitment and Testing

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; 73% complete;* All academic sites are close to completion. Fort Sam Houston will begin recruiting early 2020.
- *Meet with primary sources of referral for logistics of recruitment; 73% complete;* All academic sites are close to completion. Fort Sam Houston will begin recruiting early 2020.
- *Finalize recruitment strategy; 73% complete;* All academic sites are done recruiting. At FSH, potential participants will be recruited by word of mouth and flyers will be posted around the AMEDDC&S and the Medical Education and Training Campus inviting potential participants to contact the study coordinator.
- *Phone screening of subjects; 73% complete;* This will be ongoing throughout the study. There have been 52 subjects screened at OHSU, 69 at CKRC, and 56 at UU.
- *Create screening logs; 73% 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.

Subtask 2: Data Collection and Management

- *Schedule neurocognitive testing at each site for data collection; 73% complete;* 103 of the anticipated 140 study participants have been tested. OHSU has enrolled 19 subjects, UU has enrolled 36 subjects, and CKRC has enrolled 48 subjects.
- *Schedule gait and balance testing for data collection at each site; 73% complete;* We have collected data on 103 of the anticipated 140 study participants at academic sites. We had one subject dropout at the OHSU site.
- *Data back-up onto server including manual data entry into Redcap; 65% 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; 60% complete;* Data quality checks will be executed regularly. Each site will perform their own data check, then OHSU the coordinating site, will do a larger data check. They will search and investigate outliers, missing data entry, and any other noticeable issues. Once this is completed and necessary changes are updated, OHSU will lock all forms to ensure no edits can be made. OHSU did a complete and thorough data check in January 2020. The next complete check will be done 10/2020 by OHSU once academic sites have completed all testing.
- *Validate and submit forms to FITBIR quarterly; 0% complete;* OHSU is submitting data for all sites and will do this annually (as required) by the end of September 2020.

Major Task 3: Data Analysis and Publications

Subtask 1: Data Analysis

- *Perform all analysis according to proposal and share all findings with investigators; 45% complete;* All academic sites are currently conducting data analysis and are in the process of disseminating findings.

Subtask 2: Reduction for Aim III

- *Reduce protocol for Aim III implementation; 0% complete;* We are awaiting the last participants from the academic sites before we begin this step. This is a priority for the next quarter to define the protocol for Aim III.

Subtask 3: Manuscripts and Presentations

- *Disseminate findings (abstracts, presentations, papers, DoD), including MHSRS and rehabilitation journals to share with clinicians; 20% complete;* We submitted 6 conference abstracts: 3 to Military Health System Research Symposium, 1 to American Society of Biomechanics, 1 to ACSM, and 1 to American Physical Therapy Association. In addition, we have two manuscripts in the late stages of preparation that we aim to submit in the next quarter (*see products section below*).

Specific Aim III (Responsiveness to Rehabilitation)

Major Task 1: Launch Study Activities at Rehabilitation Sites

Subtask 1: Prepare Technology and Assessments

- *Purchase APDM Mobility Lab systems; 100% complete*
- *Finalize written protocol; 0% complete;* The protocol will be determined (data reduction) once enrollment concludes and data from Aim I is analyzed.

Significant Results/ Key outcomes:

The primary analysis and outcomes have not been completed because data collection is ongoing. However, we have conducted preliminary analyses on the following milestones:

Milestone b. Determine clinically viable measures of turning based on clinometric properties. A preliminary analysis of the inter-site consistency of turning outcomes has been conducted. We have confirmed that turning outcomes are generally consistent across each academic site (Figure 1).

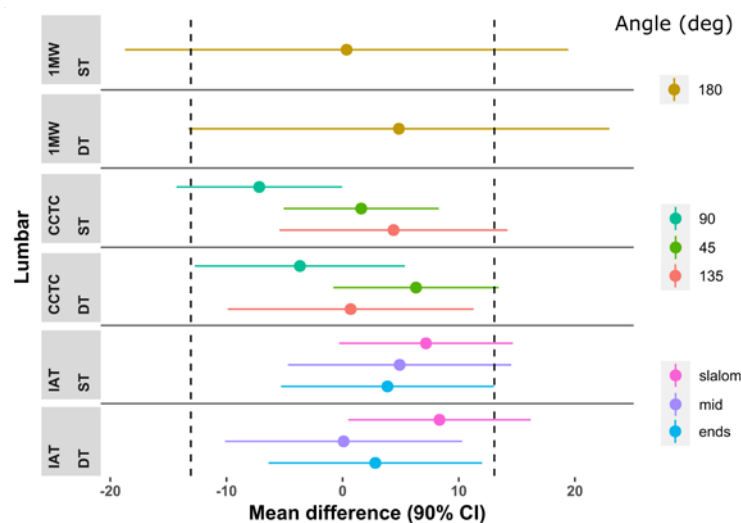


Figure 1. Mean difference between lumbar angular velocity collected during the 1-minute walk (1MW), the Custom Clinical Turns Course (CCTC) and the Illinois Agility Course (IAT) at University of Utah and Courage Kenny Rehabilitation Center. Values that sit within the vertical dashed lines are statistically equivalent.

This result supports the use of turning outcomes and our protocols as a viable clinical tool. Final analysis on the consistency of turning-related outcomes will be completed once all data collection has been completed at academic sites.

Milestone c. Assess the capacity of dual-task turning measures to predict performance in a military-relevant task. We conducted a preliminary analysis of the secondary outcomes of peak head and trunk turning velocity and head-body coordination during the simulated urban patrol task. We found individuals with mTBI exhibited similar trunk turning speeds, but slower head-on-trunk turning speeds compared to healthy control subjects (Figure 2). We also found that both lumbar turning speeds and head-on-trunk turning speed were associated with better overall performance on the task (Figure 3).

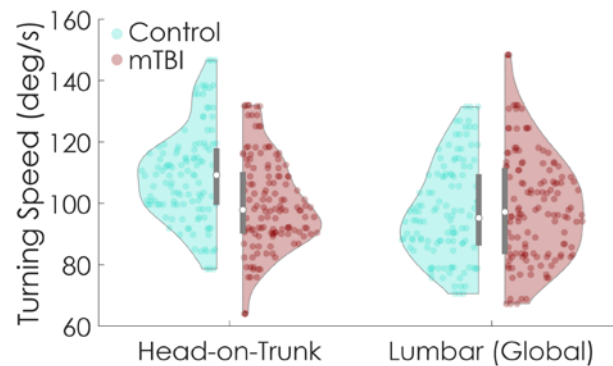


Figure 2. Peak head-on-trunk and lumbar turning speeds during the simulated urban patrol (SUP) task for healthy control subjects (cyan) and those with mTBI (red).

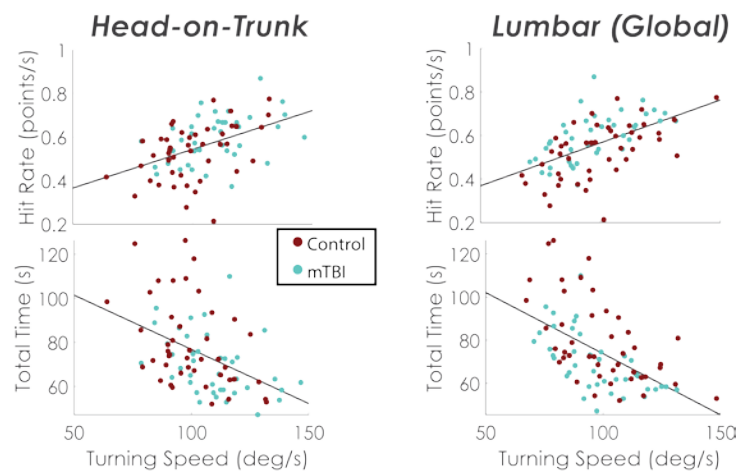


Figure 3. Correlations between peak head-on-trunk turning speeds and peak lumbar turning speeds with hit rate and task completion time during the simulated urban patrol task (SUP).

All other key outcomes and analysis will be performed once data collection is completed.

In addition to the specific milestones and evaluation of key outcomes, we have been exploring relationships between the vestibular/ocular motor screening symptoms scores and other measures. Using a subsample of the collected participants (mTBI only, $n = 42$, 21% male, 33 ± 10 years old, 1.7 ± 0.1 m, 75 ± 20 kg, 348 ± 282 days since concussion). We calculated the total post-item symptoms scores (i.e. sum across each symptom domain after each test condition), and the sum of all post-item symptoms. These measures were correlated against the dizziness handicap index (DHI) and the neurobehavioral symptom inventory (NSI). Correlations were assessed using Spearman's Rho, due to the ordinal nature of subjective symptom based data. We found that the DHI shared strong positive correlations with each of the post-item symptoms, as well as the sum of all post-item symptoms ($\rho = 0.66$ to 0.72). Additionally, the NSI exhibited moderate to large relationships with each of the post-item symptoms, as well as the sum of all post-item symptoms ($\rho = 0.45$ to 0.55). Our findings of stronger correlations between the DHI and VOMS symptom scores fit with the DHI being indicated for persons with vestibular disorders and in TBI in this population. It is also intuitive that the NSI may not share the same strength correlations with the VOMS symptom scores as the NSI, while indicated for TBI populations, is not specifically used to target vestibular dysfunction. These findings are being prepared within a manuscript for publication.

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 a military based conference, Military Health System Research Symposium (MHSRS). Due to COVID-19 restrictions this conference was canceled this year, but study team members plan to attend next year.

Members of our team meet monthly with multiple departments within our university and the Portland VA, including Family Medicine, Rehabilitation, and the National Center for Rehabilitation and Auditory Research (NCRAR).

Several members of the team attended a virtual conference where mTBI data was shared:
Brain Trust 2020 on May 1 2020: "New Research in Mild TBI Management"

Dr. Laurie King collaborated on the following article and it was recently published:
Theodoroff SM, Papesh M, Duffield TC, Novak M, Gallun FJ, King L, Chesnutt J, Rockwood R, Palandri M, Hullar TE. Concussion Management Guidelines Neglect Auditory Symptoms, Clinical Journal of Sport Medicine, 2020, September 15, 2020

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. We have also submitted a protocol manuscript to Frontiers of Neurology and six abstracts this reporting period.

The team from this project submitted an application for an 8 hour preconference at CSM 2021 called "Concussion subtypes; is it relevant for physical therapists?" This session was accepted as a preconference, although the meeting will be virtual we are unsure if we will proceed.

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

Aims I & II:

Aim 1: Our primary goal at the academic sites involves completing testing and finalizing enrollment and collection of data.

Unfortunately due to a combination of COVID-19 related restrictions to test participants in the laboratory and issues with hazardous air quality in Oregon due to wildfires, we were required to reschedule our remaining participants at the academic sites. These participants have been scheduled for the end of September- beginning of the October and correspond with the next reporting period.

Study goals for the next reporting period:

- Finish analysis of Aims I & II so we can refine the protocol for Aim III
- Get HRPO approval for Aim III
- Military IRB and HRPO approval for FSH
- Madigan and Fort Carson begin working on site specific addendums to get study approval
- Make training videos for the military sites
- Finalize the form to document physical therapy interventions for Aim III
- All three academic sites to complete enrollment
- CKRC send FSH all study materials that they no longer need

OHSU: The focus will be determining the clinometric properties of our turning outcomes. This will involve determining retest reliability of the measures and calculating the minimum detectable change (MDC). These values will be calculated on all turning outcome measures for control participants collected across the three sites. The primary product of this work will be a manuscript detailing the reliability and MDC findings. OHSU and CKRC are working collectively on analyzing the VOMS data which we will submit as a manuscript during the upcoming quarter. We also plan to submit FITBIR within the next quarter.

UU: Perform most data analysis of Aims I and II. Planned papers include those describing inter-site consistency of turning outcomes; minimum detectable differences of turning outcomes, and the primary papers for Aims I and II detailing the discriminatory capacity of turning outcomes, and the association of turning outcome with other relevant tasks. We will coordinate these papers with the other sites, and serve a primary lead on the latter two papers.

CKRC: Pending IRB approval to test VOMS normative data on 20 healthy control subjects. Planning to work on VOMS manuscript mentioned above with OHSU, as well as a normative VOMS paper in collaboration with FSH.

Aim II FSH: The contract with Geneva, to receive funds at the military sites, is currently processing and is expected to be approved by the end of September. Once this occurs, FSH will begin hiring a Research Physical Therapist. Dr. Fino is currently under travel restrictions from his university but will visit the site to train staff and setup the testing environment hopefully in early 2021. FSH plans to start recruitment early 2021.

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 virtually 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.

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

COVID-19 restrictions have limited finalizing data collection. We are working to finish data collection for Aim I and to begin Aim II.

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

Reported problems/delays from Year 2, Quarter 1:

Test retest on mTBI: We may have difficulty testing mTBI patients twice on the protocol due to increased symptoms. *We continued to perform test-retest on healthy controls instead of mTBI subjects.*

Reported problems/delays from Year 2, Quarter 2:

Fort Sam Houston funds: The funds are taking longer than expected to get approved. *The contract with FSH and Geneva should be approved by the end of September 2020.*

COVID-19: With restrictions due to COVID-19 all academic sites have been required to stop recruitment and enrollment indefinitely. *Sites are beginning to open up and we anticipate finishing testing soon.*

Reported problems/delays from Year 2, Quarter 3:

COVID-19: With restrictions due to COVID-19 all sites were required to stop recruitment and enrollment indefinitely. *We used this time to focus on publications/presentations and data analysis.*

Problems/delays from Year 2, Quarter 4:

FSH IRB & Funds: *The contract with FSH and Geneva should be approved by the end of September 2020. The IRB is in the final stage of approval and should be approved this next quarter.*

Changes that had a significant impact on expenditures

Due to COVID-19, we were unable to travel in 2020 due to institution travel bans. We were unable to have our in-person meeting with all sites, but we will reschedule as soon as travel restrictions are lifted.

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:

Manuscripts:

Fino PC, Weightman MW, Dibble LE, Lester ME, Hoppes CW, Parrington L, Arango J, Souvignier A, Roberts H, King LA. Objective dual-task turning measures for return-to-duty assessment after mild traumatic brain injury: The ReTURN study protocol. Submitted to *Frontiers in Neurology*

Manuscripts in preparation:

Parrington L, King LA, Weightman MW, Dibble LE, Lester ME, Hoppes CW, & Fino PC. Feasibility of collecting multi-site turning data. *Journal TBD.*

Parrington L, King LA, Hoppes CW, Klaiman MJ, Michielutti P, Fino PC, Dibble LE, Lester ME, & Weightman MW. Relationship between Vestibular Ocular Motor Screening and symptoms, clinical assessments, and higher-level motor ability in patients after mild Traumatic Brain Injury. *Journal TBD.*

Preconference Education Session:

Dibble LE, Lester ME, Hoppes CW, Weightman MM, Wilhelm JL, Leuty LK, Souvignier AR, Pelo RM, & King LA. Concussion Subtypes: Is It Relevant for Physical Therapists? 2021 Combined Sections Meeting, Orlando Florida. February 24 2021.

Abstracts:

Parrington L, Fino PC, Dibble LE, Weightman MM, & King LA. Upping the ante: Can agility performance differentiate previously concussed from healthy controls? To be presented at the ACSM 2020 Annual Conference, San Francisco, CA: May 26-30. (Podium) *Cancelled due to COVID-19

Fino PC, Dibble LE, Lester ME, Parrington L, Weightman MW, King LA. Turning speed and performance during a simulated urban patrol task in people with mild traumatic brain injury. American Society of Biomechanics Annual Meeting. Atlanta, GA, August 4-7, 2020. *Virtually held due to COVID-19

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. *Cancelled due to COVID-19

Fino PC, Dibble LE, Lester ME, Parrington L, Weightman MW, Hoppes CW, King LA. Turning speed and performance during two ecologically-relevant mobility tasks. Military Health Systems Research Symposium. *Cancelled due to COVID-19

Weightman MM, Parrington L, Hoppes CW, Michielutti P, Klaiman M, Fino PC, Dibble LE, Lester ME, King LA. Vestibular/Ocular Motor Screening (VOMS) assessment: Exploring use in adults with residual symptoms after mTBI. Military Health Systems Research Symposium. *Cancelled due to COVID-19

Weightman MW, Parrington L, Hoppes CW, Michielutti PG, Klaiman M, Fino PC, Dibble LE, Lester ME, King LA. Vestibular/ocular motor screening (VOMS) assessment: Relationship to clinical tests in adults after mTBI. American Physical Therapy Association Combined Sections Meeting. Orlando, FL, Feb 24-27, 2021.

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
Lee Dibble	UU	Co-I	1.2
Peter Fino	UU	Co-I	1.8

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

Margaret Weightman at CKRC went on a 30 day furlough beginning May 15th, 2020.

Holly Roberts's term at MAMC expired on May 30th, 2020. Holly is handing study oversight to Lisa O'Block, the lead PT at Intrepid Spirit.

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



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).

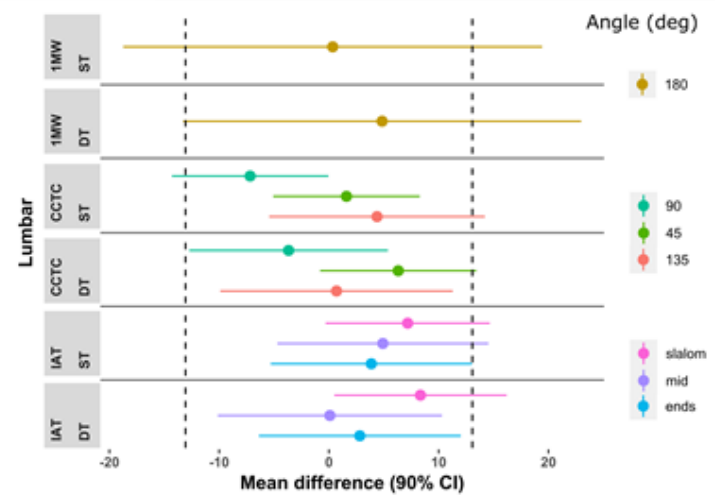


Figure 1. Mean difference between lumbar angular velocity collected during the 1-minute walk (1MW), the Custom Clinical Turns Course (CCTC) and the Illinois Agility Course (IAT) at University of Utah and Courage Kenny Rehabilitation Center. Values that sit within the vertical dashed lines are statistically equivalent.

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

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 sites have reopened.

Enrollment at all academic sites will be completed within the next quarter.

Budget Expenditure to Date

Projected Expenditure: \$556,403

Actual Expenditure: \$538,620