AWARD NUMBER: W81XWH-17-2-0046

TITLE: POrtable WARrior Test Of Tactical AgiLity: POWAR-TOTAL

PRINCIPAL INVESTIGATOR: Karen L. McCulloch

CONTRACTING ORGANIZATION: University of North Carolina at Chapel Hill CB 7135 Bondurant Hall 3024 UNC Chapel Hill, Chapel Hill, NC 27599-7135

REPORT DATE: OCTOBER 2019

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

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14. ABSTRACT					
	his project an	re to establish	project infras	structure a	nd regulatory approvals,
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compare POWAR-TOTAL performance in healthy controls (n=60) to those with concussion (n=100)					
recruiting from Fort Bragg and Madigan Army Medical Center (MAMC), and examine how POWAR-					
TOTAL scores o	change with reb	abilitation re	covery for thos	se with con	cussion. We had inordinate
delays in regulatory approval at both sites, beginning data collection at Fort Bragg in May					
of 2018, with the MAMC approval in November of 2018. As of September 2019 we have collected					
data on 60/60 healthy control participants and 50/100 individuals with mTBI using the POWAR-					
TOTAL, (32 pre- post-test). We have completed all infrastructure tasks (procedures,					
personnel, equipment, training, database establishment, FITBIR, ongoing regulatory					
approvals). We obtained a no cost extension to complete the project given the regulatory					
delays.					
15. SUBJECT TERMS					
mTBI, concussion, return to duty					
			19a. NAME OF RESPONSIBLE PERSON		
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			Unclassified		code)
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1. INTRODUCTION:

This project plans to translate components of the Assessment of Military Multitask Performance (AMMP) to a clinic-ready test providing real-time feedback about highlevel mobility and dual task performance with the use of smartphone based sensor technology. Similar tasks from the AMMP project empirically demonstrated that service members with persistent symptoms after mTBI have movement characteristics that are not clearly discernible to the naked eye but that differ from healthy active duty service members. Expensive laboratory equipment and analyses were used in the AMMP proofof-concept project to document these subtle movement differences. This project combines the most sensitive elements of two AMMP tasks in a clinical test that is time efficient, uses inexpensive wearable sensors, is more clinically feasible, and that will have the ability to provide immediate performance feedback to the clinician. This dualtask assessment is innovative as it is the first and currently only military postconcussion standardized, externally valid multi-domain functional assessment that is time, space, and cost efficient for clinic use. The data collection and analysis is innovative, as data collection will be done via smartphone and immediately following collection, uploaded to a computer that uses healthy control data to compare performance. Data are analyzed using vector analysis to provide the clinician with quick results regarding a SMs mobility during simulated tactical maneuvers. These additional data points for evaluating abilities are clearly related to functional demands associated with warfighting and can aid the clinician in verifying that a SM is not only symptomfree but duty ready.

2. KEYWORDS:

Mild traumatic brain injury, mTBI, concussion, military, vestibular, functional assessment, return to duty, movement analysis, dual-task

3. ACCOMPLISHMENTS:

Project Percent completed month Major Task 1: Establish infrastructure, procedures 100% Coordinate with Sites for CRADA submission 1-3 100% Refine eligibility criteria, exclusion criteria, screening protocol 1-3 100% Finalize consent form & human subjects protocol 1-3 Coordinate with Sites for IRB protocol submission, ISC-FB first, UNC to rely on WAMC. Obtain ORP/HRPO review for ISC-FB. 100% 1-3

+ What were the major goals of the project?

Pilot test with 3-5 healthy controls and 2-3 patients with concussion to confirm planned methods are appropriate.	4-5	100%
Coordinate activities for healthy control recruitment with DVBIC Education Outreach coordinator.	3-6	100%
Initiate MAMC IRB approval process, obtain ORP HRPO approval	3-5	100%*
Milestone: IRB and HRPO approval at all sites.	1-6	100%
Submit amendments, adverse events and protocol deviations	PRN	ongoing
Coordinate annual IRB report for continuing review	annually	ongoing
Create manual of procedures, finalize instruments for use in study, build RedCap database.	1-3	100%
Clarify return to duty indicators in common use across sites, and indicators unique to ISC-FB or MAMC.	2-4	100%
Coordinate with Sites for job descriptions design	1-2	100%
Advertise and interview for project related staff (Ft Bragg hire first, then MAMC hire once IRB is in process there)	3-6	100%
Coordinate for space allocation, credentialing, and training necessary to obtain access to MTF and patients.	1-6	100%
RedCap database ready for use by project staff	4-6	100%
Conduct training with ISC-FB RA, revise training procedures and manual as necessary.	4-6	100%
Conduct training with MAMC RA (RA to travel to ISC-FB)	5-7	100%
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	4-7	100%
Milestone Achieved: Research staff trained	4-8	100%
Major Task 2: Compare POWAR-TOTAL scores between cohorts; examine change in performance after intervention		
Subtask 1: Data collection initiated at both sites (ISC-FB first, followed by MAMC).	5-9	75%
Complete healthy control data collection	4-15	100%
Complete post-intervention assessments after completion of intervention.	6-24	32%
Subtask 2: Preliminary accelerometry data analysis with first 20 subjects in each group.	9-15	100%
Confirm custom algorithm is functioning as expected.	9-10	100%
Assess 10 concussion patients for change in POWAR-TOTAL response post-intervention.	12-13	100%
Determine need to repeat test healthy control subjects based on post-intervention testing.	13-14	100%
	1	

Tested additional healthy control subjects 2 nd time (n=10)		100%
Major Task 3: Planning for translation		
In conjunction with T2 collaborators/consultants, develop a plan for transition of technology use toward clinical practice.	3-6	50%
Seek feedback from clinicians about the test procedure, interface, administration and feedback screens.	3-24	ongoing
Seek feedback from patients tested about the test process and feedback screens.	8-24	ongoing
Develop plans to translate the test and application to practice, as appropriate	18-24	50%
Major Task 4: Data analysis		
Coordinate with Sites & database manager for monitoring data collection rates and data quality	4-24	Ongoing/in progress
Perform all analyses according to specifications, share output and findings with all investigators	12-24	Ongoing/ in progress
Dissemination and reporting of findings (abstracts, presentation, publications, DOD)	12-24	planned

+ What was accomplished under these goals?

We finally obtained IRB approval at our second testing site and have been working to collect data for the project. We have made good progress with our data collection efforts, with all of our healthy control subjects having completed testing. Based on initial analysis of pre- post-test performance of the first 20 mTBI subjects, we determined that we did need to collect additional test-retest reliability data on some of our healthy control subjects. At the point when this was determined, we had 10 more healthy controls to test for the 60 that were targeted, therefore we did 2nd tests on the final 10 subjects, avoiding the need for an IRB modification to request more subjects.

Our mTBI recruitment continues, but at a slower than hoped rate, although we have recruited half of the subjects we intend for the study. Retesting after therapy has occurred with 32 of the mTBI subjects, although our lost to follow-up rate is ~15% at both sites. This will result in fewer than the 100 that would be ideal for our 3rd study aim (that involves regression analysis), but we have discussed plans to modify the extent of that analysis with our statistician. We will still do the analysis, but may have to

incorporate fewer variables in the analysis.

In order to continue to recruit for the study, we requested and were granted a no-cost extension for an additional year. This additional time should allow us to collect sufficient data to complete the project given the remaining funds available for use by our Geneva subcontract.

Dr McCulloch travelled to Fort Dietrich October 9, 2019 to provide an in progress review of the study, which did not result in any specific suggestions for implementation for the no-cost extension year of the study. Our team has also been awarded another DoD grant that will allow us to continue to test the POWAR-TOTAL task as part of a larger test battery that incorporates 3 tasks.

Although methods for POWAR-TOTAL continue as initially designed, we are identifying ways in which the test could be improved in the next project. We had hoped that we might be able to determine that the head sensor was not necessary for the test, as mounting the head sensor is occasionally challenging given the size of the phone. We have confirmed that we do in fact need to retain the head sensor, so we are testing smaller inertial sensors that are now reasonably affordable and could avoid the occasional difficulty our testers have with the head sensor for the "next generation" of the test.

We have healthy control data that is sufficient to offer prototype feedback screens that we are using to evaluate best options for display for patient and clinicians and are accelerating our efforts to get clinician feedback about this through screenshots that will be shared at our upcoming poster presentations at APTA Combined Sections meeting. This meeting is attended by active duty military therapists who are target end users of our test.

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

Our group has been active in providing presentations to share preliminary results of our work in the past year, sharing results in numerous professional meetings that allow us to interact with professionals who treat concussion and therapists

who serve the US military.

+ How were the results disseminated to communities of interest?

CSM 2019 (American Physical Therapy Association)

Scherer MR, Lester M, Weightman MW, King L, McCulloch KL: Functional Return to Duty Decision Making Post mTBI and Musculoskeletal Injury, APTA Combined Sections Meeting, Federal Section Plenary, Washington, DC, January 2019

IBIA (International Brain Injury Association)

- McCulloch KL , Cecchini A , Prim J. Characteristics of Service Members with Concussion Referred to Physical Therapy Who Seek to Return to Active Military Duty, International Brain Injury Association, Toronto, CA, March 2019
- McCulloch KL, Favorov O, Cecchini A, Prim J. Individuals with Concussion Perform More Slowly on a Test of Tactical Agility Designed to Assist with Military Return to Duty Decision Making, International Brain Injury Association, Toronto, CA, March 2019

USPHS (US Public Health Service)

Prim JH, Cecchini AS, Krok M, Favorov O, McCulloch KL. Portable Warrior Test of Tactical Agility. US Public Health Service Scientific and Training Symposium, Minneapolis MN, May 2019.

MHSRS 2019 (Military Health Service Research Symposium)

- Prim J, Favorov O, Cecchini A, McCulloch KL. Individuals with Concussion Perform More Slowly on a Test of Tactical Agility Designed to Assist with Military Return to Duty Decision Making, Military Health Services Research Symposium, Kissimee, FL, August 2019
- McCulloch KL, Prim J, Petrenko LM, Cecchini AS. Characteristics of Service Members with Concussion Referred to Physical Therapy Who Seek to Return to Active Military Duty, Military Health Services Research Symposium, Kissimmee, FL, August 2019
- Adams K, Prim J, Cecchini A, McCulloch KL. Characterization of healthy control group in the development of the powar-total- a test of return to duty readiness following concussion, Military Health Services Research Symposium, Kissimmee, FL, August 2019
- Petrenko L, Prim J, Adams K, Cecchini A McCulloch KL. Comparison of subjects with mTBI and healthy controls in the development of the POWAR-TOTAL: a test of return to duty readiness following mTBI. Military Health Services Research Symposium, Kissimmee, FL, August 2019

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

gouis.

We will be presenting two abstracts at American Congress of Rehabilitation Medicine in November, and a collaborator will present at AMSUS for Federal Health Professionals in December. In addition we have gotten notification that we will present 2 abstracts for the Federal American Physical Therapy Association in Denver, CO. These presentations allow us feedback from a range of therapists who are active duty to share our results and share screenshots of feedback screens to get their input about how to configure information from tests.

Since we are approaching an equal number of individuals with mTBI to compare to data

from our 60 healthy control subjects, we will write our first papers sharing results that provide evidence for the value of the POWAR-TOTAL test in discriminating between those with mTBI and comparable healthy controls. We will likely need to share this data in several papers as there are numerous variables that could be the focus of papers. One paper will cover basic psychometric characteristics of the test (reliability, validity) while an additional paper will focus on group differences.

We will also use this first 60 mTBI sample to draft a paper that details the characteristics of this group that present to physical therapy (similar in focus to a poster presentation shared at MHSRS), that provides a profile of various comorbidities that are present in this group in addition to impairments that are illustrated by vestibular, balance and mobility tests.

We plan to draft a paper that describes change that occurs with physical therapy on the measures we collected, this paper may also include information about return to duty, or depending on the findings, may be an additional paper that is written with that as its main focus.

The work that we do on the patient and therapist interface will be directly integrated into the project that has been funded on the Complex Assessment of Military Performance, which will allow us to further refine the testing procedures and methods to improve clinical feasibility.

- 4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:
 - 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? We have decided to move in the direction of using a laptop for collecting and displaying test data, as we are planning for the Complex Assessment of Military Performance project, where we have need for additional Bluetooth physiologic measurement that is better handled with a laptop vs. a tablet.
 - What was the impact on society beyond science and technology? Nothing to report.

5. CHANGES/PROBLEMS:

+ Changes in approach and reasons for change

Based on work with other projects at Fort Bragg, we have a greater understanding of the difficulty in obtaining information about return to duty. Our original intention was to use therapist recommendation about ability to return to duty as the variable (recommended for return to duty or not) as the value we intended to predict in our 3rd aim (using regression). We thought that we would be able to access a brain injury team decision for those patients who were being seen for intensive outpatient services, and PT recommendations for those who are only being seen for single services vs. an intensive program. We have discovered that very few of the mTBI subjects that we recruit are in the intensive OP program (these individuals typically are much more chronic post-injury, are not being treated with full return to duty as a goal, or sometimes are being seen prior to retirement from military service). In addition, those who are seen for single services often do not return for a final PT session so data about return to duty status is missing (or the final note describes PT goals being met without specific reference to duty status). Our most consistent information about return to duty comes from the self-report a service member provides when they participate in post-testing after they are finished with PT services. It is our plan to use this information as a variable we predict in our Aim 3 analysis, as we don't have reason to suspect that this self-report is inaccurate.

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

We may not meet our overall recruitment goal of 100 subjects with mTBI. We expect that we will test 50 individuals at Fort Bragg, given they have 3 therapists who are working in PT in their Intrepid Spirit Center. At MAMC, we are not confident we will test 50 subjects in part b/c their tempo is slower given there is only one PT and no plans to increase staffing. Our intention to continue

to collect data in both sites as we await IRB approval for the CAMP project that has been funded. Approval for that study will occur first at Ft Bragg, and we will shift our focus to CAMP when that approval is obtained. We will then initiate the process to add MAMC and an additional site for CAMP, and when that approval is obtained and we have accomplished project staff training, shift to CAMP from POWAR, so we are not competing with our own project to recruit subjects. CAMP will allow us to gather additional data on the POWAR task, but in conjunction with other tests and additional physiologic markers that will further validate its use. For our future studies we include target numbers overall, but don't specify numbers by site, since it is difficult to assure that all sites will have the same level of access to potential subjects.

Changes that had a significant impact on expenditures

The tempo of recruitment and testing at Fort Bragg does not necessitate full time coverage, therefore our project manager has reduced her hours (by her choice) to accommodate personal work priorities. This has allowed us to reserve funds to continue funding on the project to continue to try to reach our recruitment goals.

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

- 6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."
 - + Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

- + Journal publications. Nothing to report
- + Books or other non-periodical, one-time publications. Nothing to report

+ Other publications, conference papers, and presentations.

CSM 2019 (American Physical Therapy Association)

Scherer MR, Lester M, Weightman MW, King L, McCulloch KL: Functional Return to Duty Decision Making Post mTBI and Musculoskeletal Injury, APTA Combined Sections Meeting, Federal Section Plenary, Washington, DC, January 2019

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- +
- + Website(s) or other Internet site(s) Nothing to report
- + Technologies or techniques Nothing to report
- + 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:	Karen McCulloch
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-4228-0517
Nearest person month worked:	2.4
Contribution to Project:	Dr. McCulloch is the project PI, coordinating the efforts of the research team on the project, troubleshoot project challenges and identify recruitment strategies based on site specific needs. Writing reports and drafting abstracts, coordinating writing efforts and soliciting feedback onr display for clinical use of the measure.
Funding Support:	N/A
Name:	Amy Cecchini
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	9
Contribution to Project:	Dr. Cecchini has managed the project at Ft Bragg including recruitment and data collection, established project procedures,

	taken the lead on regulatory efforts, coordinated training of the MAMC staff to ready them for data collection, assisted with report writing, and provide ongoing guidance for Dr. Oh at MAMC.
Funding Support:	
Name:	Annabell Oh
Project Role:	Project Manager
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5
Contribution to Project:	Dr. Oh has been trained to recruit and collect data at the MAMC site, coordinating efforts with Dr. O'Block. She is assuming responsibility for regulatory efforts at MAMC, and will initiate data collection as soon as we get IRB approval.
Funding Support:	
Name:	Julianna Prim
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Researcher Identifier (e.g.	3
Researcher Identifier (e.g. ORCID ID): Nearest person	
Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to	3 Ms. Prim has set up the RedCap database, coordinated ongoing research team conference calls and record keeping, and worked with Dr. Favorov on data analyses for poster presentations,
Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to Project: Funding	3 Ms. Prim has set up the RedCap database, coordinated ongoing research team conference calls and record keeping, and worked with Dr. Favorov on data analyses for poster presentations,
Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Contribution to Project: Funding Support:	3 Ms. Prim has set up the RedCap database, coordinated ongoing research team conference calls and record keeping, and worked with Dr. Favorov on data analyses for poster presentations, assisted with presentations and development of posters.

Nearest person month worked:	4.8
Contribution to Project:	Dr. Favorov takes the lead on motion sensor analyses, including supervision of a research assistant who set up the procedures for use of the the cell phone sensors for the project.
Funding Support:	
Name:	Wanqing Zhang
Project Role:	Co-investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Zhang has worked with RA support on the RedCap database development and has taken primary responsibility for FITBIR data sharing agreement and administration
Funding Support:	
Name:	CDR Scott Klimp
Project Role:	Site PI – Fort Bragg
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	CDR Klimp works with project staff as the site PI at Ft Bragg to assist with recruitment and involvement of his staff (physical therapy) to identify potential subjects for the study. He meets with Dr. McCulloch quarterly to assure the project is going smoothly.
Funding Support:	
Name:	Lisa O'Block

Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. O'Block serves as the site PI for MAMC. She initiated the IRB protocol for their site, hired and assisted with training an RA to administer the project. She provides ongoing guidance to the project team related to feasibility and clinical utility.
Funding Support:	
Funding Support:	
Name:	Timothy Challener
Project Role:	Research Assistant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Mr. Challener is a post-doc working with Dr. Favorov on sensor data colletion, offering technical support if difficulties arise with data collection. He has developed interactive screens/guidance for our testers in the field and is also testing smaller sensors to validate them for future applications of the POWAR test.
Funding Support:	

Name:	Olcay Kursun
Project Role:	Consultant
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	Dr. Kursun works in collaboration with Dr. Favorov on the analsysis of accelerometry/gyroscopic data to develop custom or deep learning algorithms to differentiate those with mTBi from healthy controls.
Funding Support:	

- Has there been a change in the active other support of the PD/PI (s) or senior/key personnel since the last reporting period? Nothing to report
- + What other organizations were involved as partners?
 - + Organization Name: Geneva Foundation
 - + Location of Organization: Tacoma, WA
 - + Partner's contribution to the project Subcontractor for personnel at Ft Bragg and MAMC
 - Financial support; support provided to Geneva to hire personnel and administer project at local military treatment facilities
 - + In-kind support Facilities N/A
 - + Collaboration N/A
 - + Personnel exchanges N/A
 - + Organization Name: Fort Bragg Intrepid Spirit Center
 - + Location of Organization: Fayetteville, NC
 - Partner's contribution to the project local site for subject recruitment and data collection
 - + Financial support N/A
 - In-kind support partner has made office space, computer, phone available to project staff, and also provides access to a pool of healthy control subjects through the DVBIC Newcomer's briefing that occurs at Ft Bragg
 - + Facilities Data collection takes place in the physical therapy treatment area

during non treatment hours (lunch time, late afternoon, meeting times)

- + **Collaboration** CDR Klimp and physical therapists Shaun Carlson and Michael Krok are collaborators to assist with recruitment, provision of feedback to project staff on testing feasibility and preferences to improve clinical utility.
- + Personnel exchanges N/A
- + Other.
- + Organization Name: MAMC
- + Location of Organization: Tacoma WA
- Partner's contribution to the project Provision of site PI and additional physical therapist collaborator, access to former staff of the T2 to assist with translation questions
 - + Financial support N/A
- + In-kind support Partner allows project RA space, laptop computer, that she can use in office space at the Intrepid Spirit Center
- Facilities Partner allows testing to occur in the physical therapy treatment space during non-treatment hours;
- Collaboration Provision of physical therapist (Lisa O'Block, site PI, Holly Roberts) and psychologist collaborations (for translation issues)
- + Personnel exchanges N/A
- + Other.

8. SPECIAL REPORTING REQUIREMENTS

- + COLLABORATIVE AWARDS: N/A
- + QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments) Provided on following page.

POrtable **WAR**rior **T**est **O**f **T**actical **A**giLity (POWAR-TOTAL): A dual-task test to aid return-to-duty (RTD) decision making after military concussion Focus area: Sensory systems, military relevance for return to duty assessment



PI: Karen McCulloch, PT, PhD, NCS Org: UNC-Chapel Hill/Geneva Foundation Award Amount: \$1,000,150

AMMP elements **Study/Product** Aim(s) **POWAR-TOTAL** Test via • Compare POWAR TOTAL responses of healthy control participants to those mobile with concussion Improved smartphone •Examine changes in POWAR-TOTAL performance as a result of outpatient feasibility application intervention at Intrepid Spirit Centers at Fort Bragg and Joint Base Lewis-ROLL RUN McChord (JBLM) • Examine the relationship between POWAR-TOTAL scores and return to duty space, GRID indicators used in clinical practice. COORDINATE **Real time** MEMORY expense Approach (DUAL TAS Our goal is to assess the performance-based POWAR-TOTAL, that requires TRANSITIONS for SM & tactical mobility skills in a dual-task scenario. We will improve clinical WITH POST-TEST clinician feasibility over similar validated AMMP test components by requiring less space & time while using less expensive smartphone technology to measure movement. This will provide a portable clinical test to inform RTD decision The POWAR-TOTAL uses the most sensitive elements from a recently validated dual- and multi-task battery, the Assessment of Military Multitask Performance (AMMP), that making and provide clinician and SM feedback in real time. challenges cognitive and motor performance simultaneously. This testing approach proved effective in detecting differences between ADSM and SM with symptoms post-concussion. **Goals/Milestones** Timeline and Cost CY17 Milestones - IRB and HRPO at Fort Bragg; Research staff trained, standardized procedures established (1-13 months) 1-6 7-12 13-18 19-36 Activities months Healthy control data collection began month 8 at Ft Bragg - 30/50 subjects Concussion data collection began month 8, 6/50 subjects at Ft Bragg) Seek iterative clinician feedback on protocol and test feedback. Project infrastructure/procedures CY18 Milestones – Preliminary data analysis with first 20 subjects per group indicated need for test-retest reliability analysis with HC subjects (n=10) Data collection for Aims 1 & 2 Transition and clinical use plan Iterative data analysis &

Estimated Budget (\$1000K)

dissemination

\$550K

Inititiated data collection at MAMC as of 11/2018, Data collected on 60/60 HC, 50/100 mTBI Obtained no cost extension, In Progress Review

CY19 Goals - Complete data collection, analyze/disseminate results Finalize means of transition with clinician guidance/assistance.

Comments/Challenges/Issues/Concerns – mTBI numbers at MAMC lagging behind expected. May need to modify Aim 3 to include fewer variables if 100 subjects not obtained in data collection.

9. APPENDICES: Abstracts presented at meetings in 2019

IBIA (International Brain Injury Association)

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Characteristics of Service Members with Concussion Referred to Physical Therapy Who Seek to Return to Active Military Duty

Individuals who sustain concussion in military service are commonly managed by primary care acutely, only seeking additional levels of care if symptoms are persistent. Concussion complaints have been described in clusters of signs and symptoms, yet the presentations seen for physical therapy in military treatment facilities are not well studied.

Study Aim: The purpose of this abstract is to describe the characteristics of individuals referred for physical therapy with the intent to return to active duty, who were participating in an observational study of a performance based test of tactical agility. Subjects: Our current sample of 13 will be expanded prior to presentation to include a larger n. Participants were on average 29.5 years (SD 7.3), all male, having served in the military on average for 7.8 years (SD 6.1) and completed a mean number of deployments of 2.8 (SD 2.8). Self-reported number of prior concussions ranged from 2-40 (median 6). Referral to therapy occurred on average 7.5 months post-injury (range 3-16 months), with all participants reporting multiple symptoms and complaints. Self-reported Neurobehavioral Symptom Inventory scores were 35.9 (SD 13.8), with stress related responses on the PCL-5 averaging 22.8 (SD 18.5) and 23% of the sample reporting scores above the 33 red flag level. Self-reported pain on the Defense and Veterans Pain Rating Scale was 4.5/10 on average (SD 2.1). A very high level of headache complaint was reported with the Headache Impact Test-6. All of the participants reported a level of sleep dysfunction on the Pittsburgh Quality Sleep Index that was indicative of poor sleep quality (average 14.1, SD 2.7), reference value >5 as target for referral. Connor-Davidson Resilience Scale scores averaged 73.2 (SD 18.0), consistent with prior studies of primary care patients. Dizziness Handicap Inventory subscale scores were on average as follows: a-function: 10/28 (SD 7.8), b-physical: 9.4/28 (SD 4.4), c-emotion: 6.9/36 (SD 6.4). Dynamic visual acuity testing demonstrated an average of 2.7 lines lost during head movement (range 1-5 lines). Sensory Organization Test (SOT) composite scores were on average 72.8 (SD 12.4). The Head Shake SOT was performed to challenge balance to a greater degree, but 46% of participants could not tolerate this test because of dizziness.

Summary: This group of military service members demonstrated multiple somatic, vestibular and balance related complaints that may respond to physical therapy. The chronicity of service member complaints, on average more than 6 months, was notable. It is possible intervention sooner after injury could reduce problems that were prevalent including chronic pain, sleep dysfunction and lack of ability to return to duty. Service members may manage their symptoms without seeking additional care as a result of military cultural norms and an expectation of resilience.

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Individuals with Concussion Perform More Slowly on a Test of Tactical Agility Designed to Assist with Military Return to Duty Decision Making

Individuals who sustain a concussion in military service may demonstrate subtle impairments in motor function that are important for combat related activities. A tactical agility test, based on test items in the Assessment of Military Multitasking Performance, was designed to challenge these

abilities in a portable clinical test that could be administered in typical therapy space. In this abstract we report on preliminary findings comparing the first 10 individuals with concussion to the first 10 control group subjects in our ongoing POWAR-TOTAL project. The task begins with the service member prone, holding a simulated weapon. A rapid transition to standing is followed by a short distance run, transition to a combat roll, transition back to standing and back pedaling to the start position. Rolls are completed in both directions over trials. Movement is measured with the use of tri-axial accelerometry and gyroscopes in cell phones attached at the lumbar area and on the head of each subject.

Subjects: Healthy controls (n=10) included 7 men, were on average 23.6 years (SD 4.8), with 2.9 years (SD 3.7) in service and only 1 had deployed. Healthy controls reported an average of 6.2 hours (SD 1.1) of sleep per night. Individuals with concussion (n=10) were all men, on average older 30.4 years (SD 7.6), with 9.3 years (SD 9.3) in service and 3.3 deployments (SD 3.0). Those with concussion reported an average of 4.9 hours (SD 1.0) of sleep per night.

Methods: Accelerometry and gyroscope data are displayed with each of 3 axes labelled as red, green and blue in RGB color display. This allows us to identify stepping cycles (via accelerometer readings) and combat rolls (via gyroscopic readings) and illustrates high frequency oscillatory patterns of running as well as low frequency oscillatory patterns of turning. Using a network of Radial Basis Function units we can identify individual running steps and turns in order to time precise segments of the task in a portable test.

Results: Healthy control and individuals with concussion differed significantly (at alpha=.05) in the time of an agility trial, with slowdowns in performance observed in all phases of the task (forward running, clock-wise roll, running backward, counter-clockwise roll) but the slowing was more prominent in the second half of the task.

Conclusion: Differences in movement observed in our preliminary analysis could have multiple causes. The injured group was older, had more time in service, self-reported a history of more concussions and less sleep, all of which could contribute slower movement. Reduced speed in the later half of the task could reflect a fatigue effect in the concussion group. As the project continues, our healthy control recruitment will target older participants to provide more valid comparisons.

USPHS (US Public Health Service)

Prim JH, Cecchini AS, Krok M, Favorov O, McCulloch KL. Portable Warrior Test of Tactical Agility. US Public Health Service Scientific and Training Symposium, Minneapolis MN, May 2019.

Introduction: Physical and occupational therapists are important in assessing for return to duty in concussed service members (SM) and are currently challenged to objectively assess spectrum of vulnerabilities associated with mild traumatic brain injury (mTBI). A recently completed validation study of the Assessment of Military Multitasking Performance (AMMP) included challenging cognitive/motor tasks that detected performance decrements in injured service members with mTBI as compared to active duty SMs. The POWAR-TOTAL combined the most sensitive elements of two AMMP tasks into a clinical test that involves high level mobility (running, obstacle avoidance, combat roll, rapid changes of position) with a concurrent cognitive task. The combined cognitive challenge and rapid movement requirements highlighted cognitive and vestibular deficits following mTBI. Instead of expensive laboratory grade accelerometers and gyroscopes, POWAR-TOTAL uses readily available smartphone technology to augment observational testing and aid in making return to duty decisions. Objective: To perform comprehensive field-testing of the POWAR-TOTAL task, assessing its feasibility, and to evaluate the effectiveness of the data analysis approaches. Methods: A single session, cross sectional study design. Participants were healthy ROTC cadets and pilot testing included both single motor, single cognitive, and dual task trials as well as a trial with the use of clinical blurry glasses to simulate concussive symptoms. The POWAR-TOTAL task was performed while wearing a smartphones attached to the head and to the torso, each outputting 13 sensor measurements using built-in 3-axial linear accelerometer, gyroscope, gravity, and orientation at a rate of 100Hz. The 26-dimensional time-series data were converted into frequency domain and a profile of dominant frequency bands was used to express the task

performance of each tested individual. Also, a deep-learning multilayer convolutional neural network (CNN) was designed and trained to extract most discriminative high-order features from the collected 26-variable data, which were then used for binary classification. Results: The POWAR-TOTAL was found feasible as it was time and space efficient and easily understood. Wearing blurry glasses or adding a cognitive load significantly altered the task performance frequency-domain profiles. Cross-validated using a leave-one subject- out approach, the CNN classifier was able to discriminate between performing the POWAR-TOTAL task with vs. without a cognitive load at 87% accuracy.

Conclusions: The observed condition-dependent variations in the POWAR-TOTAL task performance suggest that it has high sensitivity to CNS functional state and thus might prove useful in evaluating various neurological disorders including mTBI.

MHSRS 2019 (Military Health Service Research Symposium)

Individuals with Concussion Perform More Slowly on a Test of Tactical Agility Designed to Assist with Military Return to Duty Decision Making

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Individuals who sustain a concussion in military service may demonstrate subtle impairments in motor function that are important for combat related activities. A tactical agility test, The Portable Warrior Test of Tactical Agility (POWAR-TOTAL), based on test items in the Assessment of Military Multitasking Performance, was designed to challenge these abilities in a portable clinical test that could be administered in typical therapy space.

Objective: Preliminary analysis to examine between-group differences (mTBI vs. healthy control) in performance on POWAR-TOTAL and assess components that can act as classifiers between these groups.

Subjects: 19 Active duty servicemmebers (ADSM) with mTBI and 42 ADSM Healthy controls.

Methods: The POWAR-TOTAL begins with the service member prone, holding a simulated weapon. A rapid transition to standing is followed by a short distance run, transition to a combat roll, transition back to standing and back-pedaling to the start position. Rolls are completed in both directions over trials. A subject's motor performance on the test is measured using tri-axial accelerometry and gyroscopes in 2 smartphones attached to the head and lumbar area. Stepping cycles and combat rolls are identified using a self-organized network of Radial Basis Function units in order to precisely time each phase of the test.

Results: Age-matched healthy controls and individuals with concussion differed significantly (at alpha<0.025) in the task execution time, with slowdowns in performance observed in all phases of the task (forward running, clock-wise roll, running backward, counter-clockwise roll, and prone-to-standing transitions). The most mTBI-sensitive measure of a subject's POWAR-TOTAL performance is the total duration of the two rolls (ROC AUC = 0.83). The roll components also had the lowest magnitude of inter-individual variability in healthy controls.

Conclusion: The performance on POWAR-TOTAL test, and in particular the roll components that perturb the vestibular system, provide a sensitive method for identifying deficits associated with mTBI. This test is easily conducted in typical clinical space, challenging motor and vestibular functions in a task that is relevant for military training. This may provide a sensitive measure of performance that will be found useful in return-to-duty decision making.

Characteristics of Service Members with Concussion Referred to Physical Therapy Who Seek to Return to Active Military Duty

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Introduction: Individuals who sustain concussion in military service primarily receive acute treatment with primary care providers, typically only seeking additional levels of care if symptoms are persistent. Concussion complaints have been described in clusters of signs and symptoms, yet specific clinical presentations seen for physical therapy in military treatment facilities are not well studied.

Purpose/Objective: The purpose of this abstract is to describe the characteristics of individuals referred for physical therapy intending to return to full active duty, who were participating in an observational study of a performance-based test of tactical agility.

Methods: As a part of a larger study, we collected demographic data for the recruited participants who were receiving post-concussion care at military treatment facilities.

Results: Our current sample of 23 will be expanded prior to presentation to include a larger n. Participants were all male, an average of 28.6 years old (SD 6.9), with an average of 7.8 years (SD 6.1) of military service and 3.4 (SD 2.4) deployments. Self-reported number of prior concussions ranged from 1-40 (median 3). Referral to therapy occurred on average 5.1 months post-injury (range 1-15 months), with all participants reporting multiple symptoms and complaints. Self-reported Neurobehavioral Symptom Inventory scores were 35.2 (SD 14.9), with stress related responses on the PCL-5 averaging 21.3 (SD 18.1) and 20% of the sample reporting scores above the 33 red flag level. Self-reported pain on the Defense and Veterans Pain Rating Scale was 4.2/10 on average (SD 2.2). A very high level of headache complaint was reported with the Headache Impact Test-6, with an average of 59.0 (SD 7.8). All of the participants reported a level of sleep dysfunction on the Pittsburgh Quality Sleep Index that was indicative of poor sleep quality (average 14.1, SD 3.2), reference value >5 as target for referral. Connor-Davidson Resilience Scale scores averaged 76.2 (SD 17.7), consistent with prior studies of primary care patients. Dizziness Handicap Inventory subscale scores were on average as follows: a-function: 9.5/28 (SD 8.1), b-physical: 9.4/28 (SD 5.0), c-emotion: 7.9/36 (SD 5.6). Dynamic visual acuity testing demonstrated an average of 2.9 lines lost during head movement (range 1-7 lines). Sensory Organization Test (SOT) composite scores were on average 72.5 (SD 11.3). The Head Shake SOT was performed to challenge balance to a greater degree, but 40% of participants could not tolerate this test because of dizziness.

Conclusions: This group of military service members demonstrated multiple somatic, vestibular and balance related complaints that may respond to physical therapy. The chronicity of service member complaints, on average more than 5 months, was notable. It is possible intervention sooner after injury could reduce problems that were prevalent including chronic pain, sleep dysfunction, and lack of ability to return to duty. Service members may manage their symptoms without seeking additional care as a result of military cultural norms and an expectation of resilience.

CHARACTERIZATION OF HEALTHY CONTROL GROUP IN THE DEVELOPMENT OF THE POWAR-TOTAL- A TEST OF RETURN TO DUTY READINESS FOLLOWING CONCUSSION

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Introduction: Clinicians evaluating for readiness to return-to-duty (RTD) in servicemembers postconcussion are faced with challenges in objectively assessing the various impairments associated with mild traumatic brain injury. This is in part due to limited validated assessments that are feasible in the clinic setting. Dual task deficits are common among this population and may lead to decreased performance upon RTD. The Portable Warrior Test of Tactical Agility (POWAR-TOTAL) is a dual-task performance-based assessment that requires less space, time, and technology than previously validated laboratory-based RTD assessments. It has a high external validity and provides immediate feedback to clinicians regarding patient status. In order to validate this measure, POWAR-TOTAL performance in healthy controls must be compared to those with concussion.

Objective: We aim to characterize and measure performance of the healthy control group to understand how healthy subjects prioritize motor vs. cognitive tasks during a dual-task assessment.

Methods: This study utilized a single session, cross-sectional study design. 45 healthy active-duty participants performed the POWAR-TOTAL, which consisted of a single task (ST) motor component, ST cognitive component, and dual-task (DT) component. Data was collected using an accelerometer smartphone application. The motor component included running, combat rolling, and side shuffling. The cognitive component consisted of a working memory task of grid coordinates. DT condition included both the motor and cognitive ST components. The subjects were required to repeat the grid coordinates in the correct order after completion of the agility task. Multiple trials of ST and DT conditions were completed to compare performance and prioritization of motor vs. cognitive tasks.

Results: 45 subjects with a mean age of 28.39 (SD= 7.09) years completed the POWAR-TOTAL and demonstrated prioritization of motor performance over cognitive performance. Of those subjects that prioritized motor performance, there was a concurrent dual task cognitive cost in 13 subjects, while 21 subjects performed better in dual task conditions for both cognitive and motor performance. **Table 1** shows averages for all conditions.

Conclusions: Understanding how healthy active-duty individuals prioritize attention in dual-task situations provides a comparison for servicemembers recovering from concussion. This data will help establish guidelines for the determination of RTD readiness using the POWAR-TOTAL.

Table 1. Results		
Single Task Cognitive	6.93 (SD= 1.37) coordinates	
Single Task Motor	13.87 (SD= 1.98) seconds	
Dual-Task Cognitive	6.23 (SD= 1.42) coordinates	
Dual-Task Motor	13.78 (SD= 2.13) seconds	
Dual-Task Motor Cost	0.006 (SD= 0.06) seconds	
Dual-Task Cognitive Cost	-0.10 (SD= 0.29) coordinates	

COMPARISON OF SUBJECTS WITH mTBI AND HEALTHY CONTROL GROUP IN THE DEVELOPMENT OF THE POWAR-TOTAL: A TEST OF RETURN TO DUTY READINESS FOLLOWING mTBI

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Introduction: Return-to-duty (RTD) readiness assessments for servicemembers following mTBI requires complex clinical considerations of a myriad of impairments.^{1–6} Following a concussive event, many servicemembers present with deficits in dual-tasking activities that prevent an individual servicemember's deployability and overall task-force readiness particularly in combat situations which

require cognitive clarity and motor agility.^{4,5} At this time, there are limited validated or clinically feasible measures to assess dual-task changes in the military population, who have unique cognitive and physical demands in typical military duty tasks.^{3,5,7} The Portable Warrior Test of Tactical Agility (POWAR-TOTAL) is a performance-based, dual-task assessment which requires less time, space, and technology than previous laboratory-based RTD assessments. Pulling from components of the previously validated Assessment of Military Multitask Performance (AMMP) conducted by Radomski et al, the POWAR-TOTAL combines two of the most sensitive elements of the AMMP, specifically the run-roll-aim motor/agility task and grid coordinate memorization/cognitive task.^{7,8} The POWAR-TOTAL also demonstrates high external validity, as it is comprised of familiar components to the military population.² In order to determine the sensitivity of the POWAR-TOTAL to identify dual-task deficits in servicemembers following a mTBI, we compared performances between subjects with mTBI and healthy controls.

Objective: Compare preliminary results of healthy control group vs. mTBI group on the POWAR-TOTAL task to determine differences in performance of motor vs. cognitive components of dual-task assessment.

Subjects: 23 Active-Duty Servicemembers (ADSM) with mTBI and 50 ADSM Health Controls

Methods: The POWAR-TOTAL includes a physical and cognitive component. The physical component includes handling a simulated weapon, and begins with the service member in prone, with a rapid transition to standing, diagonal 10m run, transition to a combat roll, rapid transition back to standing, and back pedaling to the starting position. The task is then repeated with a diagonal run and combat roll in the opposite direction. The cognitive component consists of a working memory task, with the servicemember retaining grid coordinates and then repeating them back to the researcher after 15-seconds. In the Dual-Task activity, the ADSM is read coordinates, then completes the agility activity, and is then required to repeat the grid coordinates in the proper order. The Single-Task Motor, Single Task Cognitive, and Dual-Task were repeated over multiple trials to compare performance and prioritization of cognitive vs. motor task. Each ADSM's results of the POWAR-TOTAL were recorded, with components consisting of a Single-Task Motor (ST-motor) activity, Single-Task Cognitive (ST-cognitive) activity, and a Dual-Task (DT) activity.

Results: 4 out of the 23 mTBI participants could not complete the POWAR-TOTAL due to becoming symptomatic after the first trial (i.e., dizzy, nauseous, etc.) and were not included in the final analysis, while 50 out of 50 healthy controls completed the full task. During the motor component of the assessment, mTBI participants (Mean=15.48-seconds, SD=3.26) were significantly slower than healthy controls (Mean=13.73-seconds, SD=1.96) during the single task condition (p=0.023). mTBI participants (Mean=5.61coordinates, SD=1.53) also performed significantly worse in the single cognitive task when compared to the healthy controls (Mean=6.94 coordinates, SD=1.39) (p=0.001). During the dual task conditions, mTBI participants were slower (Mean=15.27-seconds, SD=3.31, p=0.044) and remembered less (Mean=4.92 coordinates, SD=2.04, p=0.008) when compared to healthy controls (Mean=13.66-seconds, SD=2.09; Mean=6.29 coordinates, SD=1.48). There were no significant differences between groups on dual tasks costs.

Conclusions: The POWAR-TOTAL was sensitive to detect differences between the mTBI and healthy controls. Ability to complete the POWAR-TOTAL was significantly lower in the mTBI group. Individuals in the mTBI group also performed worse on the single task physical and cognitive components and dual-task physical and cognitive components. These findings are in agreement with previous studies noting changes in dual-task motor or cognitive performance following a concussion, such as decreased gait speed, increased center-of-mass sway, and worsened cognition beyond typical return-to-activity parameters.^{1,9–13} While there were no dual task cost differences between the groups, the POWAR-TOTAL observational components can still detect group differences. This preliminary analysis supports the need for performance-based measures in RTD assessments.³ Furthermore, the findings also support the need for implementing interventions addressing dual-task needs specific to military occupational demands in preparing for return-to-duty.¹⁴ Further assessment of findings in this on-going study is imperative in further validating the POWAR-TOTAL in identifying dual-task deficits in the military population and supporting its utilization in RTD assessment.