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
                               Chapel Hill, NC 27599-7135

REPORT DATE: October 2018

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*

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2018	2. REPORT TYPE Annual	3. DATES COVERED 15 Sept 2017-14 Sept 2018
4. TITLE AND SUBTITLE Portable Warrior Test of Tactical Agility: POWAR-TOTAL		**5a. CONTRACT NUMBER**
		5b. GRANT NUMBER W81XWH-17-2-0046
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) Karen McCulloch (PI), Amy Cecchini (Project manager) E-Mail: kmac@med.unc.edu		**5d. PROJECT NUMBER**
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of North Carolina at Chapel Hill Chapel Hill, NC 27599-7135		**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

The goals of this project are to establish project infrastructure and regulatory approvals, 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 change with rehabilitation recovery for those with concussion. We had inordinate delays in regulatory approval at both sites, beginning data collection at Fort Bragg in May of 2018. MAMC is still not approved. We have collected data on 30/60 healthy control participants and 6/50 individuals with mTBI using the POWAR-TOTAL, (2 pre- post-test). We have completed all infrastructure tasks that we have control over (procedures, personnel, equipment, training, database establishment, FITBIR), but are limited by software glitches in the eIRB system that continue to delay MAMC approval. We are implementing additional recruitment strategies at Ft Bragg given mTBI renrollment has been slower than planned. We will likely require a no cost extension to successfully complete the project given the regulatory delays.

15. SUBJECT TERMS
mTBI, concussion, return to duty

16. SECURITY CLASSIFICATION OF: U			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	19	19b. TELEPHONE NUMBER *(include area code)*

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

Table of
Contents

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 high-level 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 proof-of-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 dual-task assessment is innovative as it is the first and currently only military post-concussion 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 automatically uploaded to a database via Bluetooth, allowing real time calculation 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 symptom-free but duty ready.

2. **KEYWORDS:**

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

3. **ACCOMPLISHMENTS:**

▪ **What were the major goals of the project?**

	Project month	Percent completed
Major Task 1: Establish infrastructure, procedures		
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	100%
Coordinate with Sites for IRB protocol submission, ISC-FB first, UNC to rely on WAMC. Obtain ORP/HRPO review for ISC-FB.	1-3	100%

Task	Months	% Complete
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	75%*
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	50%
Complete healthy control data collection	4-15	50%
Complete post-intervention assessments after completion of intervention.	6-24	4%
Subtask 2: Preliminary accelerometry data analysis with first 20 subjects in each group.	9-15	80%
Confirm custom algorithm is functioning as expected.	9-10	30%
Assess 10 concussion patients for change in POWAR-TOTAL response post-intervention.	12-13	20%
Determine need to repeat test healthy control subjects based on post-intervention testing.	13-14	
If necessary, test additional healthy control subjects 2nd time.	14-18	
Major Task 3: Planning for translation		

In conjunction with T2 collaborators, 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	0%
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?**

One of the most significant activities for this annual reporting period include completion of an arduous process of regulatory approval through the newly established Regional Health Command-Atlantic IRB as well as MRMC HRP0. This process took significantly longer for several reasons which are described in more detail in section 5. In addition, a Manual of Procedures was created for all aspects of the study including recruitment, consenting and testing procedures, data collection, data management and data storage procedures, and timelines and guidance for all regulatory reporting. Finally, data collection was initiated at Ft. Bragg for both healthy control and for mTBI patient cohort groups. Healthy control recruitment and enrollment is progressing as expected with the planned recruitment strategy yielding sufficient positive responses to support the planned number of subjects to be tested (n=60). Current enrollment for this group is 30 subjects having completed testing. Patient participant recruitment and enrollment has lagged significantly behind expected numbers to date and additional recruitment strategies have been explored and are in the process of being implemented. Total patient enrollment at Ft. Bragg is planned for 50, with 6 participants having completed initial testing and 2 having completed final testing.

The performance site protocol has been completed and submitted to MAMC IRB for HPA approval however, due to eIRB technical factors it has not yet been reviewed and approved preventing planned initiation of MAMC data collection. It is the only major task that has not been met for this reporting period and is more fully described in section 5 below. The RA for the MAMC arm of the project has travelled to Ft. Bragg for training on all study procedures and the study PI has travelled to MAMC to ensure clinical operations and staff are able to fully support the project (at the time of project funding, the MAMC Intrepid Spirit Clinic was not completed). The REDCap database is fully operational and data for all subjects has been entered for preliminary analysis which is being initiated in the next quarter. Biweekly phone calls with the study team members at Ft Bragg and MAMC have been underway since the training of the MAMC RA to troubleshoot and attempt to facilitate IRB approvals there. In addition, sensor data has been shared with the BME staff (Dr. Favorov and his assistant) for preliminary analysis. Data entry is progressing with the use of a RedCap database that has been thoroughly tested. Hard copies of all data forms were hand delivered to the PI, Dr. McCulloch, for data entry quality assurance and for permanent storage per the core protocol. Dr. Zhang has worked to develop the link with the FITBIR database for sharing of study data. Smartphone sensor data collection has been flawless with zero occurrences of technology failure or data loss. Due to the early state of overall data collection, major conclusions regarding the POWAR-TOTAL test cannot yet be formulated.

Study methods include the completion of several pages of questions regarding the participants' demographics, educational and military background, as well as deployment and injury history, and for patient participants, questions regarding the interventions they are currently receiving for their concussion symptoms. In addition, several self-report questionnaires are completed including those related to pain, dizziness, sleep, anxiety, overall health, neurocognitive symptoms, and post-traumatic stress related symptoms. All subjects then complete a previously validated measure of high level mobility followed by the POWAR-TOTAL test. Patient participants may also complete computerized dynamic posturography testing if they did not do so during their initial Physical Therapy evaluation.

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

  Given the delays in our ability to start data collection with the military population, we sought military cadets for data collection to begin to address some of the methodological aims of the study. The results of this data collection effort were shared at two meetings in a poster presentation by Julianna Prim, HMSC doctoral student who is assisting with the project. We had submitted an abstract to share the preliminary analysis of 10 in each group to the Military Health Services Research Symposium, but withdrew that abstract since we did not have sufficient data collected to analyze in August of 2018.

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

  Poster presentation shared at Federal Interagency Conference on TBI, Washington DC, June 2018 and Military Health Services Research Symposium, Kissimmee, FL, August 2018.

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

  The next reporting period will focus on early completion of regulatory approval to bring the MAMC performance site on board for data collection. MAMC personnel and equipment are in place and ready to begin testing as soon as regulatory approval is confirmed. Effective recruitment strategies are in place at both sites with on-site research staff and close collaboration with clinical staff in order to ensure timely progress with subject recruitment, enrollment and testing. It is anticipated that all healthy control subject data collection and all initial testing concussion subject data collection will be completed within the next reporting period. It is anticipated that a no cost extension will be required in order to complete final testing concussion data collection, due to the protracted regulatory approval period for this project.

  We also plan to submit abstracts to the International Brain Injury Association conference scheduled in March of 2019, and will resubmit for MHSRS for 2019 as well.

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 are beginning to test the use a tablet for administration of the testing protocol with the intention of gathering further information from our research team and local clinicians about preferences for testing with that device vs. the use of a computer.
   - **What was the impact on society beyond science and technology?** Nothing to report.
5. **CHANGES/PROBLEMS:**
   - **Changes in approach and reasons for change**

     There have been two changes in approach, one with respect to recruitment and one with respect to procedures. The procedural change involves removing two of the self-report intake forms from the initial and final concussion patient participant intake packets (BSI-18 and WHO-QoL) and removal of one self-report measure from the final intake packet (CDRS). These changes were made to reduce the amount of time needed to complete the self-report paperwork which was longer than anticipated due to concussion associated symptoms including difficulty concentrating and headache. It was determined that the information gained from these two measures was not sufficiently informative beyond that obtained from the remaining measures to continue to justify their inclusion. No changes in procedures were made for healthy control participants.

     The recruitment change expanded the number of potential patients who could be recruited for the mTBI cohort. Initially, the study team wanted to focus on recruiting only patients who had received a physical therapy evaluation and were being treated by the physical therapist. A secondary aim of this study was to determine if the test showed sensitivity to change as a result of intervention therefore study methods included a post intervention POWAR-TOTAL test. The study team initially felt that the test would elicit a more significant change in performance for patients being treated by the PT team for problems associated with dizziness and

balance. This resulted in a substantial percentage of patients who are undergoing intervention at the Intrepid Spirit Center who may be appropriate for inclusion not even being approached about the study. After extensive discussion and consultation with clinical partners, it was decided to include patients who were receiving any rehabilitation treatment for their symptoms, including vision or cognitive rehab, as long as they at least had received a PT evaluation. This change is in accordance with the recruitment and eligibility language in the protocol. It was anticipated that perhaps current PT assessments were not sensitive enough to detect the need for services and therefore eligible patients were not being seen for PT treatment. This is an important assessment gap that the POWAR-TOTAL test aims to fill and is the primary aim of the study. The change in recruitment strategy has recently been initiated at Ft. Bragg.

Ongoing discussion with our MAMC PI, who is a physical therapist, suggests that we may have fewer difficulties recruiting patients in their setting given the nature of their referral streams. We hope to have data collection occurring there by the end of October.

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

There have been extensive and ongoing delays related to regulatory oversight for this project. Although the initial protocol was submitted to Womack Army Medical Center IRB August 30, 2017, final approval did not occur until March 30, 2018. This was due to several reasons: a recent turnover in Scientific Review Committee personnel with novice reviewers taking over this role; transition from WAMC IRB authority to Regional Health Command-Atlantic IRB authority with several weeks of delay as personnel learned new roles and RHC-A institutions adjusted to a new documentation format and new procedures, timelines and responsibilities; and, implementation of a new electronic IRB format that has and continues to have extensive infrastructure and utilization anomalies requiring frequent downtime and need for technical support and troubleshooting assistance. It then required an additional six weeks to receive MRMC HRPO written approval to initiate study procedures at Ft. Bragg. On July 10, 2018 the performance site addendum for MAMC was submitted to the eIRB system however, a post hoc change in procedures

for the invitation of a performance site to the core protocol necessitated that the submission be withdrawn, a core protocol modification to key personnel be submitted to RHC-A, and, upon approval of that modification, a resubmission of the performance site protocol, which was completed on August 15, 2018. This submission was reviewed administratively, returned with stipulations, and resubmitted on September 5. It was returned again with additional stipulations and was attempted to be resubmitted on September 21 however a technical error in the software has not allowed the submission to move forward in the eIRB workflow and therefore it remains stuck in the system. The local RA, Ft. Bragg RC, site PI and study PI have all engaged with technical support and local MAMC HRP staff to come to a resolution in order for the submission to be approved and study procedures to be initiated at MAMC.

- **Changes that had a significant impact on expenditures**

  Due to the delay in onboarding the RA for MAMC, there are personnel funds that will not be used in the first year of the study. In addition, the fulltime Research Coordinator at Ft. Bragg reduced her hours to 80% in June. Due to the anticipated need for a no-cost extension unused personnel funds for year one funds will be able to be re-allocated to personnel expenses for additional time that will be needed for data collection and other study procedures.

- **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.**

Prim JH, Favorov OV, Kursun O, McCulloch KL. The development of the Portable Warrior Test of Tactical Agility (POWAR-TOTAL). Federal Interagency Conference on TBI, Washington, DC, June 2018.

McCulloch KL, Prim JH, Favorov OV, Kursun O. Portable Warrior Test of Tactical Agility – Validation with a ROTC cadet population. Military Health Services Research Symposium, Kissimmee, FL, August 2018.

- **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, including conducting visits to both sites during this project year to assure staff training was progressing, troubleshoot project challenges and identify recruitment strategies based on site specific needs.*
Funding Support:	*N/A*
Name:	*Amy Cecchini*
Project Role:	*Project Coordinator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*10*
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:	*3*
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):	
Nearest person month worked:	*3*
Contribution to Project:	*Ms. Prim has set up the RedCap database, performed data collection with ROTC cadets to initiate project aims, coordinated ongoing research team conference calls and record keeping, and worked with Dr. Favorov on data analyses for poster presentations.*
Funding Support:	
Name:	*Oleg Favorov*
Project Role:	*Co-investigator*
Researcher Identifier (e.g. ORCID ID):	

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*
Project Role:	*Site PI - MAMC*

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:	
Name:	*Holly Roberts*
Project Role:	*Co-investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Roberts serves in a part-time PT role at MAMC, but participates in our biweekly conference calls about the project as she is able, providing guidance about test feasibility and clinical utility.*
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 graduate student working with Dr. Favorov on developing the means by which we collect data with the phones as sensors. He has developed interactive screens/guidance for our testers in the field and serves as technical support for any problems that arise with the equipment.*
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 projec**t 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 projec**t 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 projec**t 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 WARrior Test Of Tactical AgiLity (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*

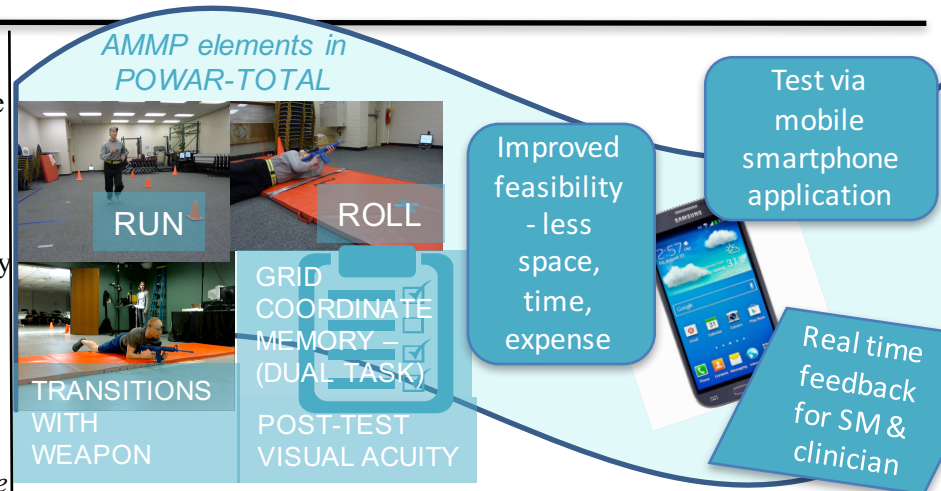**PI:** Karen McCulloch, PT, PhD, NCS   **Org:** UNC-Chapel Hill/Geneva Foundation **Award Amount:** $1,000,1500

Study/Product Aim(s)

• Compare POWAR TOTAL responses of healthy control participants to those with concussion

•Examine changes in POWAR-TOTAL performance as a result of outpatient intervention at Intrepid Spirit Centers at Fort Bragg and Joint Base Lewis-McChord (JBLM)

• Examine the relationship between POWAR-TOTAL scores and return to duty indicators used in clinical practice.

Approach

Our goal is to assess the performance-based POWAR-TOTAL, that requires tactical mobility skills in a dual-task scenario. We will improve clinical 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 making and provide clinician and SM feedback in real time.

AMMP elements in POWAR-TOTAL: RUN, ROLL, TRANSITIONS WITH WEAPON, GRID COORDINATE MEMORY – (DUAL-TASK), POST-TEST VISUAL ACUITY. Improved feasibility - less space, time, expense. Test via mobile smartphone application. Real time feedback for SM & clinician

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 challenges cognitive and motor performance simultaneously. This testing approach proved effective in detecting differences between ADSM and SM with symptoms post-concussion.

Timeline and Cost

Activities months	1-6	7-12	13-18	19-24
Project infrastructure/procedures	███	███		
Data collection for Aims 1 & 2		███	███	
Transition and clinical use plan		███	███	
Iterative data analysis & dissemination			███	███
Estimated Budget ($1000K)	**$450K**		**$550K**	

Updated: (10/15/2018)

Goals/Milestones

CY17 Milestones –IRB and HRPO at Fort Bragg; Research staff trained, standardized procedures established (1-13 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.

CY18 Goals –Preliminary data analysis with first 20 subjects per group (initial test) and pre-post test for concussion subjects
Inititate data collection at MAMC
Additional healthy control testing if needed
Request no cost extension

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

Comments/Challenges/Issues/Concerns

• Our project has been hampered by incredible regulatory delays and software glitches with the new eIRB system, in addition to lower than expected mTBI recruitment at Ft Bragg. Strategies to reduce these problems are in place, but our project will likely require a no cost extension to complete project goals.

9. APPENDICES: Two abstracts presented at meetings in 2018

Federal Interagency Meeting, Washington DC, June 2018

THE DEVELOPMENT OF THE PORTABLE WARRIOR TEST OF TACTICAL AGILITY (POWAR-TOTAL): A PILOT STUDY

Julianna H. Prim[1,2], Tim D. Challener[1,3], Oleg V. Favorov[1,3], and Karen L. McCulloch[1,2]

[1]The University of North Carolina at Chapel Hill, [2]Human Movement Science Curriculum, [3]Department of Biomedical Engineering

Topic: Performance and Movement Analysis

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, the POWAR-TOTAL will use 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 2 smartphones attached to the head and 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.

Abstract for MHSRS 2018

Karen L. McCulloch, PT, PhD, NCS[1]
Julianna Prim, MS[1]
Oleg V. Favorov, PhD[1]
Olcay Kursun, PhD[2]

[1]University of North Carolina at Chapel Hill, Chapel Hill, NC
[2]University of Central Arkansas, Conway, AR

Portable Warrior Test of Tactical Agility – Validation with a ROTC cadet population

There is a need for a performance-based tests of higher level mobility to inform return to duty decision making following concussion that approximate the true physical demands of active duty in the military. The Portable Warrior Test of Tactical Agility is a modification of the Run-Roll-Aim task from the Assessment of Military Multitasking Performance (AMMP). While AMMP tasks took an important step toward combining cognitive and motor tasks in military related activities, many of the tasks required laboratory equipment and analyses. The POWAR-TOTAL is designed to be more clinician friendly using smartphone sensors to provide movement feedback about task performance with immediate clinician feedback. POWAR-TOTAL requires less space and time, comparable to resources of clinical settings, and requires multiple fast position changes similar to tactical training activities that are common in the military.

Objectives: Assess feasibility and effectiveness of data analyses approaches of the POWAR-TOTAL with a cross-sectional sample of 28 ROTC cadets.

Subjects: 28 ROTC cadets all 18 or older, all without any history of concussion.

Methods: The POWAR-TOTAL maneuver combined the most sensitive elements of two previously validated AMMP tasks in a clinical test that requires running, obstacle avoidance, combat rolls and multiple rapid position changes) in a single task condition as well as in dual-task conditions while remembering a grid coordinate sequence (sequences of two words from NATO phonetic alphabet and 6 numbers). Single task cognitive performance was also measured. Since all of the subjects in this study were healthy, we simulated the effects of a concussion by adding a condition with the use of blurry glasses. During all POWAR-TOTAL trials, a smartphone was attached to the head and torso, allowing 13 sensor measurements using the built-in tri-axial accelerometry, gyroscope, gravity and orientation at a rate of 100Hz.

Data analysis: The 26-dimensional time series data were converted into the frequency domain and a profile of dominant frequency bands was used to express the task performance of each tested individual. A deep learning multilayer convolutional neural network (CNN) was designed and trained to extract the most discriminative higher order features from the 26-variable data, then used for binary classification. Calculated cognitive task accuracy and dual-task costs for this healthy control group provides reference values for optimal cognitive task performance in the dual-task condition.

Results: The POWAR-TOTAL test is feasible and is time and space efficient. Wearing blurry glasses or adding a cognitive load significantly altered the task performance frequency-domain movement profiles. Cross-validation with a leave one out approach demonstrated the CNN classifier discriminated between single and dual-task conditions at an 87% accuracy. On average the cadets in this sample did well with single task cognitive performance (7.1/8 memory element recalled), with reductions in average cognitive task recall (6.5/8, 7.1/8, and 6.6/8 elements) in the dual-task condition. The POWAR-TOTAL motor task on the other hand demonstrated slight increase in speed over time of 7% on average. An analysis of dual-task interference patterns

showed variability in responses, with the 60% demonstrating some reduction in cognitive performance, and 53% demonstrating some slowing in motor performance. A portion of the sample (21%) showed no reduction in performance on either task in the dual-task condition (or improved performance over the single task condition).

Conclusions: Dual-task tradeoffs favored motor performance slightly over cognitive performance occur in this task, but differences in single and dual-task performance were small in this non-injured collegiate group. Cognitive performance of individuals at lower education levels and who are recovering from concussion is expected to be lower in the dual-task challenge. The use of sensor-based technology is likely necessary to detect the potentially subtle movement changes associated with concussion. The condition dependent variation detected with the frequency-based analyses in this healthy group supports further use of this approach to contrast healthy control and injured populations. Additional study of the POWAR-TOTAL is planned with individuals who are active duty (healthy control compared to those recovering from concussion).