

AWARD NUMBER: W81XWH-15-C-0179

TITLE: "USASOC Injury Prevention/Performance Optimization Musculoskeletal Screening Initiative"

PRINCIPAL INVESTIGATOR: Kim Beals

RECIPIENT: Dr. Christie Vu

REPORT DATE: October 2016

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

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 current valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE 10-29-2016	2. REPORT TYPE Annual	3. DATES COVERED 30 Sep 2015 - 29 Sep 2016
4. TITLE AND SUBTITLE "USASOC Injury Prevention/Performance Optimization Musculoskeletal Screening Initiative"		5a. CONTRACT NUMBER W81XWH-15-C-0179
		5b. GRANT NUMBER
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S): Kim Beals, Erin Pletcher, Melessa Woehbler, Andy Simonson		5d. PROJECT NUMBER
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Pittsburgh Warrior Human Performance Research Center, 3860 South Water St Pittsburgh PA 15203 USASOC 1105 El Salvador St Building E-3323 Fort Bragg NC 28310		8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research Materiel Command Fort Detrick, Maryland 21702-50		10. SPONSOR/MONITOR'S ACRONYM(S)
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)
12. DISTRIBUTION / AVAILABILITY STATEMENT DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited		
13. SUPPLEMENTARY NOTES		
14. ABSTRACT One of the most important determinants of military readiness for USASOC is the health and well-being of its personnel as many suffer a multitude of preventable musculoskeletal injuries due to the daily rigors of physical training and preparation for tactical operations. Physical training remains the cornerstone of the weapons platform of USASOC personnel, yet a significant number of injuries are sustained during Command instructed physical training. The Tactical Human Optimization, Rapid Rehabilitation, and Reconditioning (THOR3) training program was established to improve functional performance and combat effectiveness, reduce lost manpower, and optimize recovery and reconditioning between deployments. As such, the purpose of this study is to measure the effectiveness of the THOR3 human performance training program to improve upon biomechanical, musculoskeletal, physiological, performance, tactical and injury mitigating characteristics and to reduce unintentional musculoskeletal injuries.		

15. SUBJECT TERMS

THOR3, Musculoskeletal injury prevention, Performance Optimization

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	SAR	19	19b. TELEPHONE NUMBER <i>(include area code)</i>

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

TABLE OF CONTENTS

	<u>Page No.</u>
1. Introduction	5
2. Keywords	5
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	10
6. Products	12
7. Participants & Other Collaborating Organizations	15
8. Special Reporting Requirements	18
9. Appendices	19

1. INTRODUCTION:

One of the most important determinants of military readiness for USASOC is the health and well-being of its personnel as many suffer a multitude of preventable musculoskeletal injuries due to the daily rigors of physical training and preparation for tactical operations. Physical training remains the cornerstone of the weapons platform of USASOC personnel, yet a significant number of injuries are sustained during Command instructed physical training. The Tactical Human Optimization, Rapid Rehabilitation, and Reconditioning (THOR3) training program was established to improve functional performance and combat effectiveness, reduce lost manpower, and optimize recovery and reconditioning between deployments. As such, the purpose of this study is to measure the effectiveness of the THOR3 human performance training program to improve upon biomechanical, musculoskeletal, physiological, performance, tactical and injury mitigating characteristics and to reduce unintentional musculoskeletal injuries.

2. KEYWORDS:

Injury prevention; Musculoskeletal Injury; Performance Optimization; USASOC, THOR3

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Administrative & Regulatory

- Milestone: University of Pittsburgh IRB Approval. Approved May 23, 2016. 100% Complete
- Milestone: Set up Data Use Agreement. UPitt has completed the DUA application and it is being sent to MRMC, SOCOM and USAOC POC's.
- Milestone: HRPO Approval. Approved July 28, 2016, 100% Complete

Major Task 2: Coordinate Logistics for the Research Trials

- Milestone: Research staff trained, 3 months. 2 Research staff trained and relocated to Fort Bragg. Hired 3rd person, however she has not relocated yet due to hold on the research account by USMRAA. 70% Complete
- Milestone: Pitt Remote Laboratory setup, 3 months. 100% Complete

Major Task 3: Subject Recruitment for the Research Trials

- Milestone: Recruit subjects for participation Phase 3 Aim THOR3 Trial, 4-12 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Recruit subjects for participation Phase 4 Aim 1 THOR3 USASOC wide Trial, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Recruit subjects for participation Phase 4 Aim 2 THOR3 Injury Mitigation Trial, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval

Major Task 4: Phase 3 Aim 1: Data Collection

- Milestone: Completion of baseline measures, 9-15 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Implement experimental protocol, 9-15 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Completion of Clinical Trial Data Collection, 15-18 months

Major Task 5: Phase 4 Aim 1 & 2: USASOC Wide Injury & Injury Mitigation Data Collection

- Milestone: Completion of baseline measures, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Implement experimental protocol, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval
- Milestone: Completion of USASOC Wide & Injury Mitigation Data Collection, 7-18 months. 0% Complete, awaiting USAMRMC/MRAA Revised SOW and Budget Approval

Major Task 6: Data Analysis for Research Aims 3 & 4

- Final Report provided to USASOC Command, 19-24 months
- Presentation of data at National Annual Conferences, 19-24 months
- Minimum of 5 manuscripts published in high impact journals, 19-24 months

What was accomplished under these goals?

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

UPitt remote faculty have worked with Ray Bear, Human Performance Coordinator for 3rd Special Forces Group, to learn how to administer the Operator Readiness Test and SOCOM Assessment.

How were the results disseminated to communities of interest?

Nothing to report

1. Administrative & Regulatory
 - a. Pending approval of revised statement of work and budget, modify IRB and HRPO documents and submit for approval.
 - b. Complete the Data Use Agreement
2. Relocate the final remote faculty position.
3. Coordinate Logistics for all 3 Research Trials (Phase 3 Aim 1 and Phase 4 Aim 1 & 2)
 - a. Identify which of the research aims require Pitt IRB modification, submit the modifications and await approval. Submit modifications to USAMRAA HRPO and await approval.
 - b. Plan a trip to USASOC to brief remote laboratory, USASOC personnel on the approved protocols and develop a recruiting strategy and study plan and timeline. Begin subject recruitment and testing.

4. IMPACT:

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

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

On June 7, 2016 the PI presented the protocol at an In-Progress Review to the JPC-5 at Fort Detrick. As a result of this meeting, CDMRP requested additional information with regard to the specifics of the proposed statement of work. The PI submitted a written response, including a revised statement of work addressing the concerns to Mr. Lance Nowell on June 21, 2016. Since this time, there have been several additional requests for information which Pitt provided either before or on the due date set by Mr. Lance Nowell. We are awaiting a response. As a result, there has been a delay (to date ~5 months) in initiating all research aims at Fort Bragg.

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

On June 7, 2016 the PI presented the protocol at an In-Progress Review to the JPC-5 at Fort Detrick. As a result of this meeting, CDMRP requested additional information with regard to the specifics of the proposed statement of work. The PI submitted a written response, including a revised statement of work addressing the concerns to Mr. Lance Nowell on June 21, 2016. Since this time, there have been several additional requests for information which Pitt provided either before or on the due date set by Mr. Lance Nowell. We are awaiting a response. As a result, there has been a delay (to date ~5 months) in initiating all research aims at Fort Bragg. Once we have the approval to proceed with the research, we will identify if modifications are required with the Pitt IRB and USAMRMC HRPO and submit these changes. We will initiate subject recruiting and testing on research aims that do not require regulatory modification/approval. Research Phase 4 Aim 2 is a 12-month trial and at this point, will require an extension to the contract end date in order to complete it.

On July 21, 2016 Mr. Ray Bear (THOR3) notified UPitt of a policy change by the new Commander at 3rd Special Forces Group mandating ORT for all Operators, increasing participation to THOR3 and difficulty getting subjects for the study cohorts as a result of this change. Due to the mandated change, Mr Bear and his team at 3rd group indicated they would not have the time to support research effort as originally planned. Proposed solutions to the problem include identifying another USASOC unit at Fort Bragg to participate in Phase 3 Aim 1, possibly the Special Warfare Center and School (SWCS) candidates for Special Forces. This proposed change was submitted within the revised SOW and we are still awaiting a response.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS:

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

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers, and presentations.

Nothing to report

- **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**

Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Operator Readiness Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Kim Beals
Project Role:	Principal Investigator
Nearest person month worked:	12
Contribution to Project:	Write IRB and IRB resubmission, Lab move and setup, Faculty Hiring, Data Use Agreement, In-Progress review, All planning of research aims

Name:	John Abt
Project Role:	Co-Investigator
Nearest person month worked:	9
Contribution to Project:	Write and review IRB, Involved in laboratory setup logistics, planning of research aims

Name:	Karen Keenan
Project Role:	Co-Investigator
Nearest person month worked:	12
Contribution to Project:	Write/review IRB and resubmission, Developing new templates for database to store data variables collected, Data collection forms, Development of Operator Readiness Report

Name:	Mita Lovalekar
Project Role:	Co-Investigator
Nearest person month worked:	12
Contribution to Project:	Write and review IRB and IRB Submission, Weekly meetings to discuss protocol development, TCONs with PHC, All planning of research aims study design and statistics, Development of USASOC wide survey

Name: Takashi Nagai
Project Role: Co-Investigator
Nearest person month worked: 12
Contribution to Project: Protocol development, Review IRB, Planning Research aims.

Name: Nick Heebner
Project Role: Co-Investigator
Nearest person month worked: 9
Contribution to Project: IRB and resubmission review, Protocol development, Lab setup,

Name: Scott Lephart
Project Role: Co-Investigator
Nearest person month worked: 9
Contribution to Project: Oversight on protocol development

Name: Andrew Simonson
Project Role: Co-Investigator
Nearest person month worked: 3
Contribution to Project: Planning all research aims, Laboratory setup, and operation.

Name: Meleesa Wohleber
Project Role: Co-Investigator
Nearest person month worked: 3
Contribution to Project: Planning all research aims, Laboratory setup, and operations.

Name: Meaghan Beck
Project Role: Research Coordinator
Nearest person month worked: 3
Contribution to Project: Meaghan Beck resigned her position at UPitt Dec. Assisted PI with IRB and with budget and administrative reports.

Name: Rob Koronosky
Project Role: Research Coordinator
Nearest person month worked: 3
Contribution to Project: Assisting the PI with budget and administrative reports.

Name: Thida San-Adams
Project Role: Database Analyst
Nearest person month worked: 5
Contribution to Project: Formatted UPittMED database to collect research data.

Name: Shawn Eagle
Project Role: Graduate Student Researcher
Nearest person month worked: 12
Contribution to Project: Write and review IRB and resubmission, Weekly meetings to discuss protocol modifications, remote laboratory move and equipment set up and calibration.

Name: Erin Pletcher
Project Role: Graduate Student Researcher
Nearest person month worked: 12
Contribution to Project: Write and review IRB and resubmission, Weekly meetings to discuss protocol modifications, remote laboratory move and equipment set up and calibration.

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

University of Kentucky informed Pitt that they would no longer be able to support their portion of the research work as per the original subcontract due to a change in the focus of their work. As such the University of Pittsburgh identified individuals at Pitt and requested approval to perform in-house the portion of work that would have been subcontracted to the UK from July 1, 2016 through September 30, 2017. This request was sent to Mr. Lance Nowell July 13, 2016. We are still waiting for a response/approval.

What other organizations were involved as partners?

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

<p>US Army Public Health Center, Aberdeen Proving Ground, MD 21010 Collaboration with Tyson Grier, Dr. Bruce Jones and MAJ Tanja Roy on the research aim study designs and development of the <i>USASOC Wide Physical Training and Injury Survey</i> used in Phase 4 Aim 1.</p>

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:



USASOC Injury Prevention and Human Performance Research

Background: Since April 2012, we have tested USASOC Operators at Fort Bragg with the purpose of identifying specific biomechanical, musculoskeletal, physiological, nutrition and performance characteristics that may be suboptimal and/or lead to a higher risk of injury and decreased physical performance

Key Findings to Date:

- Injury frequency- 18.9 injuries/100 subjects/year (76.9% preventable)
- Physical training was the most reported activity for preventable injuries.
- THOR3- 70.7% participation (3.3 ± 1.3 days for 12 months) (Award # W81XWH-11-2-0020)



Study Aims

Phase 3 Aim 1: To evaluate the THOR3 HP training program to modify injury mitigating and performance characteristics previously identified in Phases 1-2 of research.

Phase 4 Aim 1: To evaluate the THOR3 HP training program to mitigate musculoskeletal injuries USASOC-wide.

Aim 2: To evaluate the THOR3 HP training program to improve injury mitigating musculoskeletal characteristics.

Aim 3: To test changes in biomechanical, musculoskeletal, physiological, tactical, nutritional, performance and injury characteristics across the deployment of a USASOC Operator.

Deliverables:

- Validation of the THOR3 HP training program to mitigate musculoskeletal injury characteristics and optimize Operator readiness
- Increase the physical readiness of the Soldier by reducing the risk of musculoskeletal injury, optimizing performance, and ensuring a physically viable force for deployment
- Develop and validate an injury prevention and performance optimization program that is culturally specific and dynamically responsive to the unique tactical demands of USASOC

Appendices None