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Award Number: W81XWH-11-2-0170

TITLE: Reduction of Risk for Low Back Injury in Theater of Operations

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REPORT DATE: October 2013

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE October 2013		2. REPORT TYPE Annual		3. DATES COVERED 30 September 2012 – 29 September 2013	
4. TITLE AND SUBTITLE Reduction of Risk for Low Back Injury in Theater of Operations				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-11-2-0170	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) William S. Quillen, PT, DPT, Ph.D., FACSM John Mayer, DC, Ph.D., CCRP E-Mail: wquillen@health.usf.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of South Florida Tampa, FL 33620-9951				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 Specific aim: The specific aim of this project is to assess the effectiveness of a high intensity progressive resistance exercise training program targeting the lumbar extensors to improve lumbar extensor muscular strength and endurance (the desired physiological responses) in US Army Soldiers. Hypothesis: A high intensity progressive resistance exercise for the lumbar extensors will result in a 25% increase in lumbar extensor muscular strength and endurance compared with control following the 12-week intervention. Design: A mixed methods, two-arm, controlled clinical trial with cluster randomization will be conducted. The sampling frame will be soldiers training to become combat medics from 12 platoons, within 3 companies of one domestic US Army base (Fort Sam Houston, TX). Soldiers (n = 592 from 12 platoons) will be randomly assigned (by platoon) to one of two interventions - experimental (n = 296 soldiers from 6 platoons) or control (n = 296 soldiers from 6 platoons). All participants at a given platoon will receive the same intervention and all interventions will be carried out at the US Army base, in addition to the soldiers' usual physical fitness training program. Participants randomized to the experimental group will perform lumbar extensor muscle progressive resistance exercise using standardized protocols. Exercise training will consist of 1 set of high intensity, progressive resistance exercise for lumbar extensors on specialized equipment. Participants in the control group will perform 5 minutes of low intensity core stabilization exercises on the floor. Interventions will be carried out 1X/week for 12 weeks. Outcome measures that will be utilized to test the hypothesis include validated physical fitness tests for lumbar extension muscular strength and endurance. Fitness tests will be conducted at baseline and following the 12-week intervention period.					
15. SUBJECT TERMS Prosthetics, performance optimization					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	7	19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION

Specific aim: The specific aim of this project is to assess the effectiveness of a high intensity progressive resistance exercise training program targeting the lumbar extensors to improve lumbar extensor muscular strength and endurance (the desired physiological responses) in US Army Soldiers.

Hypothesis: A high intensity progressive resistance exercise for the lumbar extensors will result in a 25% increase in lumbar extensor muscular strength and endurance compared with control following the 12-week intervention.

Design: A mixed methods, two-arm, controlled clinical trial with cluster randomization will be conducted. The sampling frame will be soldiers training to become combat medics from 12 platoons, within 3 companies of one domestic US Army base (Fort Sam Houston, TX). Soldiers (n = 592 from 12 platoons) will be randomly assigned (by platoon) to one of two interventions - experimental (n = 296 soldiers from 6 platoons) or control (n = 296 soldiers from 6 platoons). All participants at a given platoon will receive the same intervention and all interventions will be carried out at the US Army base, in addition to the soldiers' usual physical fitness training program. Participants randomized to the experimental group will perform lumbar extensor muscle progressive resistance exercise using standardized protocols. Exercise training will consist of 1 set of high intensity, progressive resistance exercise for lumbar extensors on specialized equipment. Participants in the control group will perform 5 minutes of low intensity core stabilization exercises on the floor. Interventions will be carried out 1X/week for 12 weeks. Outcome measures that will be utilized to test the hypothesis include validated physical fitness tests for lumbar extension muscular strength and endurance. Fitness tests will be conducted at baseline and following the 12-week intervention period.

BODY

The research accomplishments associated with the tasks outlined in the approved Statement of Work (SOW) are described in this section.

A. Pre-Study Procedures (months 1-9)

Task A.1. Complete pre-enrollment regulatory and human subjects protection assurances.

A.1.a. Prepare and submit Institutional Review Board (IRB) applications.

IRB application 1: USF IRB

IRB application 2: Brooke Army Medical Center IRB, AMEDD C&S

Milestone 1: IRB approvals - obtained (month 2)

A.1.b. Prepare and submit DOD human subjects and regulatory documents.

Milestone 2: DOD regulatory approval - obtained (month 6)

Task A.2. Implement facilities and train staff.

A.2.a. Conduct strategic meetings with battalion officers and non-commissioned officer (NCO) cadre.

A.2.b. Prepare exercise facilities.

A.2.c. Train study personnel.

Milestone 3: Site, facilities, personnel - established (month 9)

Accomplishments - SOW section A:

All tasks in the SOW section A have been successfully completed.

B. Specific Aim 1 (months 10-18): In a controlled clinical trial, assess the effectiveness of a progressive resistance exercise training program to improve lumbar extensor muscle strength and endurance in US Army Soldiers from the 232nd Medical Battalion at Fort Sam Houston, TX training to become combat medics.

Task B.1. Carry out recruitment, consent, enrollment, and screening, and baseline assessment procedures.

B.1.a.1. Recruit subjects.

B.1.a.2. Consent and enroll subjects.

Milestone 4: Recruitment, consenting, and enrollment - completed (month 15)

B.1.a.3. Conduct screening procedures.

B.1.a.4. Conduct baseline fitness tests assessing lumbar muscle strength and endurance.

Milestone 5: Screening and baseline fitness tests - completed (month 15)

Task B.2. Administer interventions in experimental and control groups.

Task B.3. Conduct post-training fitness tests assessing lumbar muscle strength and endurance.

Milestone 6: Exercise training intervention and post-training fitness tests - completed (month 18)

Accomplishments - SOW section B:

All tasks in the SOW section B have been successfully completed.

Recruitment and data collection were initiated in June 2012 and completed in August 2013. Participants were enrolled from 12 platoons within 6 companies. Final enrollment figures as of October 29, 2013 are shown in Table 1. Analysis of reasons for withdrawals / drops at each phase of the study is currently underway.

Table 1. Subject enrollment figures through various phase of the study.

Enrollment Figures	Control (Core)	Experimental (MedX)	Total
Consented:	--	--	649
Completed baseline tests / Randomized:	284	298	582
Initiated Exercise Training:	257	265	522
Completed Follow Up Tests:	221	231	452

Exercise interventions: Overall compliance to the exercise program was lower than expected, particularly in the first company. The research team identified issues and implemented a corrective course of action, which appeared to reduce these compliance issues in subsequent companies.

Safety: No occurrences of definitely related or possibly related serious adverse events have been reported. Definitely related or possibly related minor adverse events or expected side effects (for example, muscle soreness) have occurred at the expected frequency and severity. These adverse events were minor, temporary, and self-limiting, and did not affect physical function or active duty status.

Confidentiality: No known breaches in confidentiality have occurred.

IRB regulatory status:

BAMC IRB provided annual continuing review and approved the continuation of the study on September 17, 2013.

USF IRB provided annual continuing review and approved the continuation of the study on April 27, 2013.

Potential obstacles that may preclude completing all tasks defined in the statement of work: With the completion of data collection and processing, we do not foresee any serious obstacles that may impede completion of all tasks defined in the statement of work by the end of the study period (September 29, 2014).

C. Data Analysis and Dissemination (months 19-24)

Task C.1. Analyze data.

Task C.2. Prepare and disseminate final reports, manuscripts, and presentations.

Milestone 7: All study procedures - completed (month 24)

Accomplishments - SOW section C:

As of October 29, 2013, all data have been entered into a database with a data structure developed by our group, verified, and audited. A final database has been prepared and is ready for submission to the biostatistician for analysis of primary outcomes in Task C.1.

KEY RESEARCH ACCOMPLISHMENTS

- All regulatory and IRB approvals have been obtained and updated.
- Recruitment, enrollment, and baseline tests have been completed in 582 subjects from 12 platoons within 6 companies.
- Exercise interventions have been initiated and completed.
- End-of-trial tests have been completed in 452 subjects.
- Initial data management procedures have been completed with a final database ready for analysis of primary outcomes.

REPORTABLE OUTCOMES

No reportable outcomes regarding the primary variables are available at this time. See Data collection and management is complete and data ready for primary analysis.

CONCLUSION

Data collection for this study has been successfully completed. The study now enters the data analysis, results reporting, and dissemination phases. We received approval for a 12-month no

cost extension of the study period. The study period ends on September 29, 2014, which gives us 12 months to complete these tasks.

REFERENCES

See approved study protocol.

APPENDICES

None.