

AWARD NUMBER: W81XWH-20-2-0056

TITLE: A Proprioceptive Training Program Using an Uneven Terrain Treadmill for Patients with Ankle Instability

PRINCIPAL INVESTIGATOR: Elizabeth Russell Esposito

CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Bethesda, MD

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14. ABSTRACT Lower limb sprains and strains are three-times more prevalent than any other acute injury in the Armed Forces, with lateral ankle sprains being the most common injury sustained during active-duty. Forty percent of individuals who experience an ankle sprain will go on to develop chronic ankle instability. Training and rehabilitation programs that incorporate proprioceptive training are particularly effective at improving outcomes and reducing re-injury rates. Proprioceptive training targets how the body receives sensory information from the environment to produce a movement. However, current techniques (Bosu balls, foam mats, etc.) do not help individuals "train to the tasks" they will encounter once they leave physical therapy and re-injury rates remain high. The proposed intervention uses a rocky uneven terrain treadmill that specifically targets aspects of the real-world environment to restore and improve short-term function and performance and reduce the long-term risk of re-injury. We aim to (1) compare the effectiveness of a targeted proprioceptive and physical rehabilitation intervention against standard of care physical therapy for persons with ankle sprains and chronic ankle instability. The intervention will use a rocky uneven terrain treadmill as part of a progressive intervention for these individuals. Two groups will be studied. Seventy-eight individuals with ankle sprains and chronic ankle instability will participate. Half of individuals will receive physical therapy as normal and will be in the control group. The other half will be in the experimental group and will receive the rocky terrain treadmill intervention in addition to their normal physical therapy. The intervention involves tasks while moving on the uneven terrain such as walking with head turns, low light conditions, and walking without being able to see the ground. The intervention will be progressive and participants will perform more challenging tasks as their recovery progresses. Patient-reported outcomes, performance tests, and biomechanical measures of muscle activity and foot pressures will be investigated to compare differences between the groups. We aim to (2) identify the predictors and mediators of clinical benefits and successful outcomes in individuals who did and did not receive standard of care incorporated with the uneven terrain progressive rehabilitation program. The ability to identify individuals who have a high probability of success with the intervention can help us develop customized programs that better meet the needs of the individual patient. We aim to (3) compare long-term outcomes and re-injury rates. Participants who received the rocky terrain rehabilitation intervention will be compared to those who received the standard of care physical therapy over an 18 month period after they leave physical therapy. Patient-reported outcomes and re-injury rates will then be tracked for 18 months after discharge from physical therapy. Our study has approvals to begin data collection at two of our sites.						
15. SUBJECT TERMS lateral ankle sprains, chronic ankle instability, proprioceptive rehabilitation, rocky treadmill, uneven surface, physical therapy						
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1. INTRODUCTION:

Lateral ankle sprains are the most ubiquitous musculoskeletal injury sustained in the military. We are limited in our ability to successfully rehabilitate Service members to a full, unlimited return to active duty after a destabilizing ankle injury. The intervention uses a novel rehabilitation strategy (a rocky terrain treadmill) that specifically targets aspects of the military training environment to restore and improve short-term function and performance and reduce the long-term risk of re-injury for retention on duty. It also has the potential to improve performance beyond even baseline levels for enhanced force readiness post-injury. We aim to (1) compare the effectiveness of a progressive rehabilitation intervention against standard of care, (2) identify predictors and mediators of clinical benefits, and (3) compare long term outcomes and re-injury rates in Service Members and Veterans with lateral ankle sprains and chronic ankle instability.

2. KEYWORDS:

lateral ankle sprains, chronic ankle instability, proprioceptive rehabilitation, rocky treadmill, uneven surface, physical therapy

3. ACCOMPLISHMENTS:

What were the major goals of the project?

***Specific Aim 1.** Compare the effectiveness of a targeted proprioceptive and physical rehabilitation intervention against standard of care physical therapy for destabilizing ankle injuries.*

***Specific Aim 2:** Identify the predictors and mediators of clinical benefits and successful outcomes.*

***Specific Aim 3:** Compare long-term outcomes and re-injury rates.*

What was accomplished under these goals?

Prepare regulatory documents and research protocol for study.

***Milestone 1:** Research and Data sharing agreements established.*

All Research and Data Sharing/Use Agreements are either approved, or awaiting submission pending IRB approval. CRADA documents for Madigan are prepared and will be finalized upon receipt of local IRB approval. Cooperative Research Agreements for Ft. Sam Houston are prepared and will be routed for signature upon receipt of local IRB approval. CRADA and Research Agreements are not required for NMCSO or NHRC/CP. A DHA-level DSA is in review. Lastly, our study is registered on ClinicalTrials.gov (NCT04999904)

Milestone 2: Approvals or deferred approvals from local IRB

NMCS D (IRB of record) was approved 2/10/2021. NHRC and NHCP deferrals have been approved. VAPSHCS received an exemption to the single IRB mandate and approved the study on 10/8/2020. MAMC received an exemption to the single IRB mandate and study documents were submitted for the October 2021 IRB meeting. Advarra received an exemption to the single IRB mandate and study documents were approved for HJF employees to conduct research at the VAPSHCS.

Milestone 3: Approval from HRPO

HRPO Approvals received at the NMCS D (9/27/2021, E01628.1c), NHRC (10/5/2021, E01628.1d), and NHCP (10/7/2021, E01628.1f). HRPO documents submitted for VAPSHCS and Advarra. Documents will be submitted for MAMC and FSH upon local IRB approval.

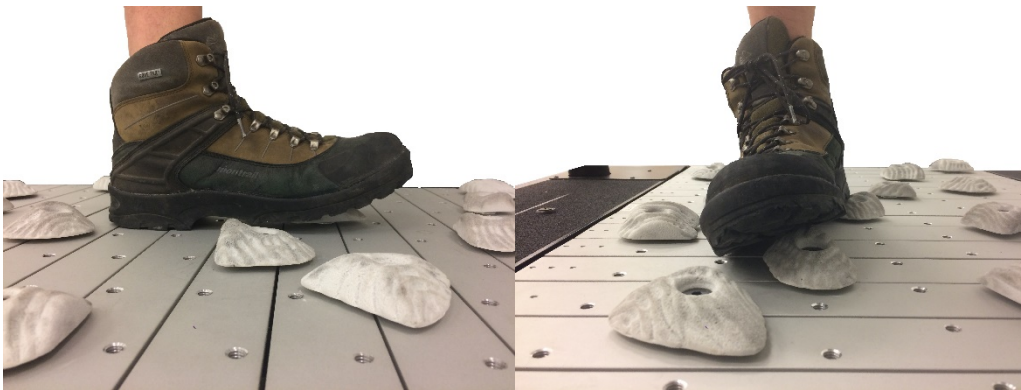
Equipment purchases

Milestone 1: All equipment purchased in time for regulatory approval start date

All equipment has been purchased and evaluated for data quality assurance. Rocky treadmills delivered and installed at MAMC, NMCS D, and NHCP sites. Delivery of FSH treadmill is expected by 11/11/2021.

Evaluation of the data processing procedures to be used by all the sites has been rigorously completed at VAPSHCS.

As part of this milestone we defined the rock geometry in collaboration with clinical teams. This included trialing various geometries, and densities to elicit appropriate ankle perturbations in a broad variety of footwear types.



Ankle perturbations during walking on the uneven treadmill.



Finalized rock treadmill.

Hiring and training of study personnel

Milestone 1: Research personnel hired and trained

Personnel are hired at all sites with approval to initiate data collection. Positions are currently being hired for sites pending IRB/HRPO approval to initiate data collection. Trainings are prepared and will be coordinated to occur with recruitment.

Data analysis and quality control

Milestone 1: Recruitment and retention procedures optimized to ensure target enrollment is met

Recruitment will begin by the end of 2021 at the NMCS and NHCP sites. Other sites will begin as regulatory approvals are met.

Milestone 2: Target enrollment achieved

Nothing to report

Milestone 3: 18 month follow up data from target sample

Nothing to report

Data Analysis & Quality Control

Milestone 1: Quarterly data quality checks complete with revisions made, as required.

Local sites have collected test electromyography (EMG) and pedography data which has been analyzed for quality and conformance to study standards. The study team meets biweekly to ensure quality control. A catalog of all the data collection and evaluation activities has been created for consistency across sites. Examples include low visibility (a), obscured foot placement (b), uphill/downhill carrying load, and distracted walking



(a)



(b)



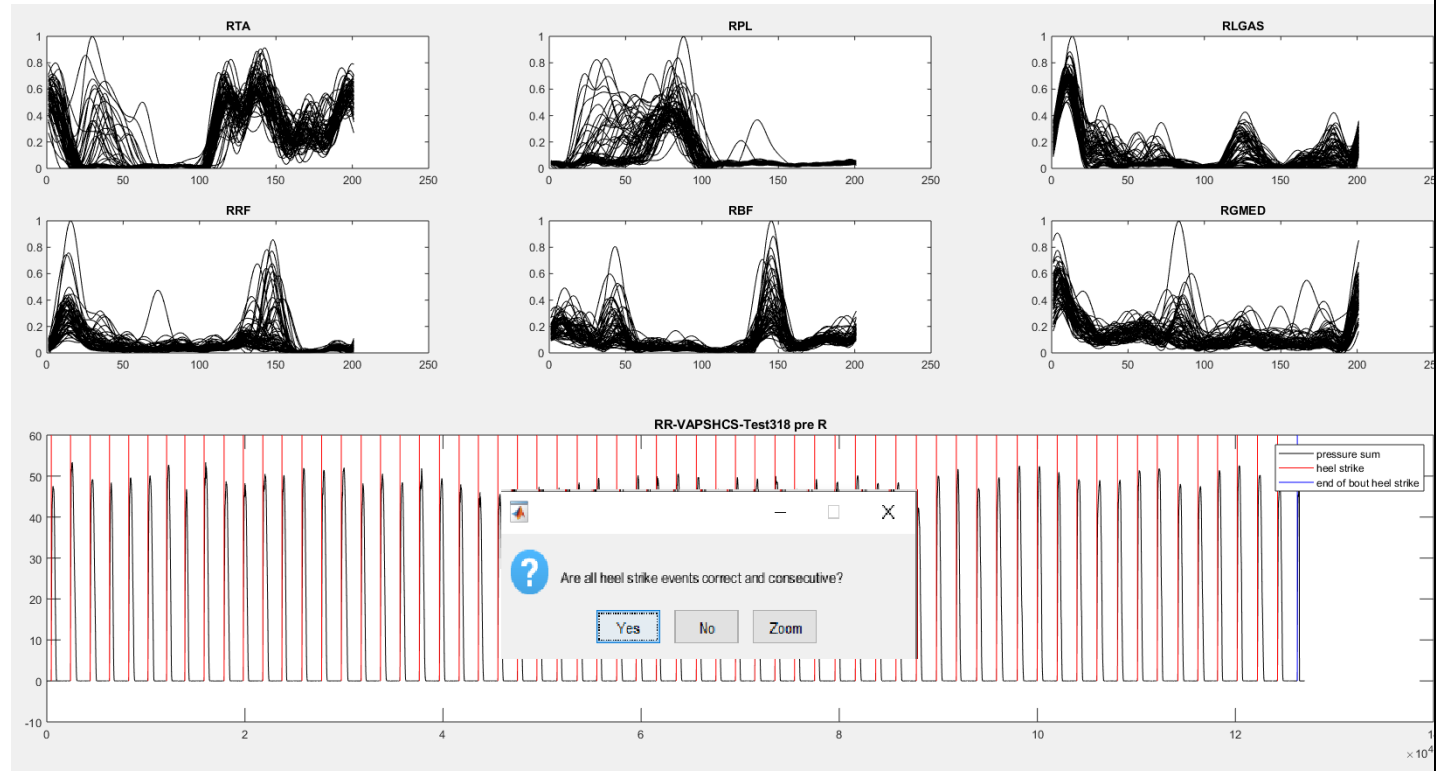
(c)



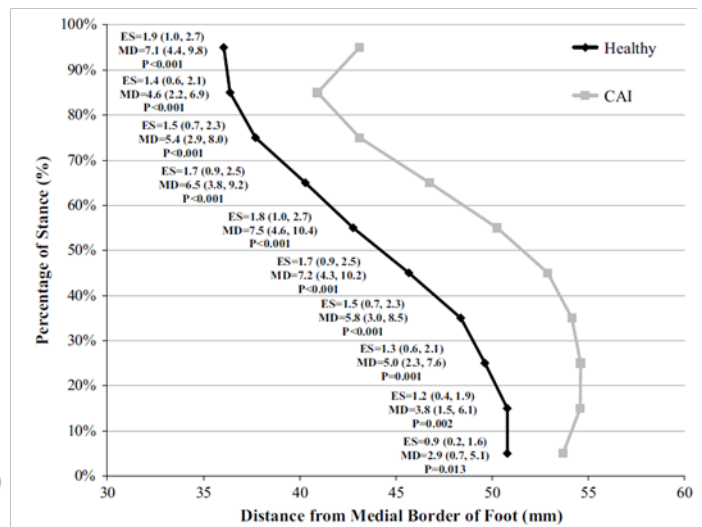
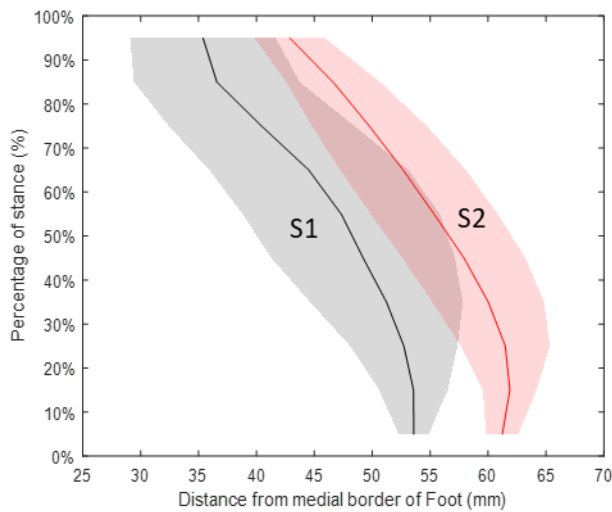
(d)

Milestone 2: Consensus on final analysis procedures

All outcome measures and data collection procedures have been rigorously evaluated at each site. Data analysis pipelines to process EMG and pedography data has been completed and adjusted for site specific differences in equipment to ensure uniform calculation of biomechanical outcome variables.



Custom GUI for data quality analysis.



(Left) Sample test outcome data for mediolateral center of pressure progression throughout the gait cycle compared to literature data (Right) Ref: Koldenhoven, et al. Knee Surg Sports Trammatol Arthrosc 2016.

Milestone 3: Final dataset compiled and analyzed for Specific Aims
Nothing to report

Distribution of Findings

Milestone 1: Report and distribute results from data compilation and analyses

Our protocol paper had been drafted for submission to Journal of Medical Internet Research and is in review by the authors. In addition, two conference presentations, highlighting the upcoming study have been presented (see results dissemination section below).

Milestone 2: Identify follow-on studies and funding

An AMTI-funded study will identify the dose response of this rocky treadmill intervention and evaluate the biomechanical response to walking on the rocky treadmill in different footwear. This information will make it possible to replicate the treadmill design at different facilities and discuss the study findings in the context of the magnitude of the perturbation imposed. Data collection has begun on this research study. Discussions are currently underway with the FSH team to expand this intervention to patients with TBI.

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

Nothing to report

How were the results disseminated to communities of interest?

Previews of this project have included as part of the following conference presentations:

- 1) Fraser J. *It's not "just an ankle sprain."* Clinical management of the athlete with lateral ankle sprain & chronic ankle instability. American Medical Society for Sports Medicine National Online Fellow Lecture Series. Aug 2021. Online.
- 2) Fraser J. *Change is afoot in the management of lateral ankle sprains and chronic ankle instability.* 2021 American College of Sports Medicine Annual Meeting. Jun 2021. Online. doi: 10.6084/m9.figshare.14700825.v1

A proprioceptive training program using an uneven terrain treadmill for patients with ankle instability

This proposal addresses the Peer Reviewed Orthopaedic Research Program's FY19 focus area: "Retention on Duty Strategies: Validation of battlefield-feasible diagnostic capabilities, decision support tools, interventions, and/or rehabilitation strategies that can facilitate retention on duty for common combat-related musculoskeletal injuries."



Objective: To assess a progressive proprioceptive rehabilitation and training program intervention using a rocky terrain treadmill to augment the standard of care physical therapy for ankle sprains and chronic ankle instability to improve force readiness and reduce re-injury rates.



Presentation slide previewing the goals of this study.

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

Throughout the next reporting period, we intend to initiate enrollment at our approved sites: NMCS D and NHCP. We anticipate IRB approvals at FSH and MAMC. Staff at NMCS D will continue to train all study therapists at the other data collection sites. Trainings will be held as needed to maintain personnel readiness and data quality checks will be performed on an ongoing basis as data is collected. Recruitment procedures will be reviewed quarterly to ensure good retention and site collection rates.

4. IMPACT:

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

Rehabilitation practices targeting proprioception in ankle sprains and chronic ankle instability have improved outcomes and long-term recovery rates. However, re-injury rates are still high and existing rehabilitation methodologies do not "train to the task". Prior research has shown that military kit can obscure foot placement and load carriage can impact an individual's stability, exacerbating the injury and re-injury rate and highlighting the need to incorporate task relevant training that may challenge a patient's ankle into the rehabilitation paradigm. The rocky treadmill replicates the rough, uneven terrain encountered by Service personnel and lends itself to incorporating a variety of military relevant activities including load carriage, high impact activities, low visibility conditions, and fatigue all in a controlled physical therapy setting. By providing task relevant

training as part of the rehabilitation strategy, this research aims to improve outcomes and decrease re-injury rates following ankle injuries.



Evaluation of the rocky treadmill. The condition shown demonstrates low visibility via dark sunglasses, load carriage via a backpack, and a partially obstructed view of the ground via the weapon.

What was the impact on other disciplines?

While the rocky treadmill was developed for this project and is targeted at rehabilitation in ankle sprains and chronic ankle instability there are applications with a wider variety of patients for whom proprioceptive rehabilitation is common. Potential populations include lower limb amputees and individuals with TBI.

What was the impact on technology transfer?

If successful at improving rehabilitation outcomes, the rocky treadmill provides an accessible platform that could be broadly incorporated in clinical settings. This would constitute an attractive rehabilitation or training tool as the treadmill does not require specialist training to operate or maintain. Its incorporation into existing virtual reality-based rehabilitation programs is also an attractive feature that our study team is pursuing.

What was the impact on society beyond science and technology?

If successful at improving rehabilitation outcomes, the rocky treadmill will improve the physical readiness of Service men and women, and may both improve the quality of life, and reduce the cost of care in both Service Members and Veterans. Successful results open the door to applying similar practices to other Service member and civilian populations

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Issue: Information Security at NMCS D would not review the use of REDCap for a study where NMCS D is the prime. However, NMCS D has numerous (50+) studies using HJF's REDCap platform for studies in which another site is the lead IRB. This was an unforeseen issue. In addition, HJF's REDCap platform is used in over 100 DHA level DSAs. This item represented the a key bottleneck to the project's progress.

Resolution: IRB documents have been modified to not require the use of REDCap and all data collection will start on paper forms. There have been several requests associated with this project and others for approval at NMCS D. Our navy collaborators have worked to add REDCap to the list of external service offerings to be reviewed by DHA for its security features and potential to use in DoD studies.

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

Issue: Regulatory. The timeliness of regulatory approvals has delayed the start of data collection from the anticipated start of the third project quarter. Madigan Army Medical Center unexpectedly declined deferral to NMCS D to comply with the single IRB mandate. In addition, an external IRB (Advarra) was used to cover Henry Jackson Foundation employees working at the VA site. HRPO determined that Advarra would additionally need a waiver of the single IRB mandate. The DSA was submitted upon receipt of NMCS D IRB approval and we are waiting on approval.

Resolution: Both Madigan Army Medical Center and Advarra received a waiver of the single IRB mandate from DHA. Sufficient regulatory approvals have recently been received to initiate data collection at NMCD

and NHRC/CP sites. Data collection at these sites is slated to begin in the next quarter. Other sites will follow as approvals are finalized. We have removed all data sharing requirements from the IRB protocol associated with the need for the DSA. The DSA will be needed in the later years of the study and we will add those components in once we have our approved agreement.

Issue: Vendor delays. Issues with the treadmill design (as it came from the manufacturer) delayed purchase of the rocky treadmills for the DoD data collection sites.

Resolution: Study personnel at VAPSHCS dedicated substantial effort towards the research and development of aspects of the rocky treadmill design which were expected to be finalized by the vendor. Study personnel initiated and completed new tasks to determine rock geometry. All treadmills have since been ordered and either delivered or shipped.

Issue: Relocation of key personnel. Dr. Elizabeth Russell Esposito expects to be intermittently on site at VA Puget Sound and temporarily located at FSH starting November 2021. LCDR John Fraser was expected to be reassigned to Ft. Sam Houston, which spurred opening Ft. Sam Houston as a data collection site, but he has since been reassigned back to NHRC. As active duty personnel, MAJ Szymanek (site PI at MAMC) and MAJ Halle (CO-Investigator at MAMC), are not guaranteed to remain at MAMC throughout the entirety of the period of performance and Dr. Brian Hatler (Co-Investigator at MAMC) was reassigned to a different PT clinic at Joint Base Lewis McChord.

Resolution: VAPSHCS will no longer participate in active recruitment of subjects for this study so that Dr. Russell Esposito can facilitate recruitment at the FSH site. Data processing can still occur at VAPSHCS using established pipelines and personnel. Dr. Russell Esposito expects to be permanently back in Seattle prior to the study's conclusion. LTC Carrie Hoppes will remain the Site PI at Ft. Sam Houston to support the study efforts there in LCDR Fraser's absence. Dr. Russell Esposito will additionally support study efforts at Ft. Sam Houston. A new civilian PT researcher (Chelsea Jordan) has replaced Dr. Brian Hatler at Madigan and has been identified as a replacement for MAJ Szymanek's role as Site PI in the event of her departure.

Issue: COVID-19 presents an ongoing concern for the safety of study personnel and participants. Data collection may be delayed or limited at each site depending on implementation of local restrictions or on-site patient visits

Resolution: Potential mitigation strategies may include focusing study recruitment efforts on less impacted sites as conditions permit. The study team will continue to stay abreast of and follow the local guidance at each site to abide with COVID-19-relation policies. Patient throughput at each site will continue to be evaluated each quarter as the pandemic progresses.

Changes that had a significant impact on expenditures

Issue: Research staff billing. The timeline for regulatory approvals has delayed the start of data collection. As a result, in an effort to reserve funds for their intended use of data collection efforts, Research Physical Therapists are either not billing to this study (NMCSO, MAMC) or are will be hired in time for data collections (NHRC/CP, FSH).

Resolution: We are constantly evaluating options for PT recruitment and evaluating the time required for credentialing of new PTs. This allows us to back calculate when we would need to initiate hiring actions.

Issue: Funding transfer. The Year 1 transfer of funds has not been received by NHCR and it has not been possible to hire staff for this project to support that site. All current staff have been working in kind of the project without funding.

Resolution: Year 2 funds have been received but we are still awaiting the transfer of Year 1 funding. Our project is being supported by MRDC to resolve this.

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

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

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

Journal publications.

Russell Esposito, E, et al. "Rocky Treadmills for Proprioceptive Rehabilitation of Destabilizing Ankle Injuries: A Randomized, Controlled, Pragmatic Clinical Trial." *Journal of Medical Internet Research*.
In Preparation
Acknowledgement of federal support: Yes

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

Nothing to Report

Other publications, conference papers and presentations.

- 1) Fraser J. *It's not "just an ankle sprain."* Clinical management of the athlete with lateral ankle sprain & chronic ankle instability. American Medical Society for Sports Medicine National Online Fellow Lecture Series. Aug 2021. Online.
- 2) Fraser J. *Change is afoot in the management of lateral ankle sprains and chronic ankle instability.* 2021 American College of Sports Medicine Annual Meeting. Jun 2021. Online. doi: 10.6084/m9.figshare.14700825.v1

- **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**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Elizabeth Russell Esposito, PhD
Project Role: Primary Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Dr. Russell Esposito provided the lead project management for this project.
Funding Support: EACE

Name: Benjamin R. Shuman
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 10
Contribution to Project: Dr. Shuman developed the data processing pipelines, developed the rocky treadmill, completed all purchases, conducted data quality checks, and served as a scientific project manager on this award.
Funding Support: Award

Name: LTC John Fraser
Project Role: NHCP Site PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Site PI, clinical leader in the finalization of the progressive intervention protocol
Funding Support: US Navy

Name: Dr. Shawn Farrohki
Project Role: NHMCS D Site PI

Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Site PI, IRB of record PI, clinical leader in the finalization of the progressive intervention protocol
Funding Support: EACE

Name: LTC Carrie Hoppes
Project Role: FSH Site PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0
Contribution to Project: Site PI, initiated study start-up activities for bringing FSH on as a data collection site
Funding Support: US Army

Name: MAJ Eliza Szymanek
Project Role: MAMC Site PI
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.2
Contribution to Project: Site PI, initiated study start-up activities at MAMC
Funding Support: US Army

Name: MAJ Brian Halle
Project Role: MAMC Site Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0
Contribution to Project: Co-Investigator, facilitated study start-up activities at MAMC
Funding Support: US Army

Name: Pinata Sessoms, PhD
Project Role: NHCP Site Co-I
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Site PI on protocol; facilitated all local data quality checks and study start-up activities at NHCP.
Funding Support:

Name: Robert Smetanka
Project Role: NMCS D Protocol Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Facilitated regulatory approvals for the entire study
Funding Support: Award

Name: Laura Bechard
Project Role: NMCS D Research PT
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Evaluated all study procedures, initiate training procedures for PTs at all other sites
Funding Support: Award

Name: Rachel Mayhew
Project Role: MAMC Research PT

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 2

Contribution to Project:

Facilitated submission of all regulatory documents at MAMC

Funding Support:

Award

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

Dr. Russell Esposito received two new awards (no overlap):

W81K0221P0085 - A predictive musculoskeletal modeling and simulation framework for individuals with above knee amputation

W81XWH2120049 - Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy

Dr. Hatler was reassigned to an H2F unit and is no longer participating in this study.

Dr. Pinata Sessoms assumed the protocol site PI role at NHRC to accommodate the pending move of LCDR John Fraser

LTC Carrie Hoppes was added as a Site PI at FSH.

Dr. Benjamin Shuman was added as a Co-Investigator at VAPSHCS.

What other organizations were involved as partners?

Organization Name: Veterans Affairs Puget Sound Health Care System (VAPSHCS)

Location of Organization: Seattle, WA

Partner's contribution to the project: Facility, Collaboration, and Personnel support.

Site provides main administration of the project, developed data analysis pipelines, and will be the main data analysis site.

Organization Name: Naval Medical Center San Diego (MAMC)

Location of Organization: San Diego, CA

Partner's contribution to the project: Facility, Collaboration, and Personnel support.

Data collection site. IRB of record.

Organization Name: Madigan Army Medical Center (MAMC)

Location of Organization: Joint Base Lewis McChord, WA

Partner's contribution to the project: Facility, Collaboration, and Personnel support.

Data collection site.

Organization Name: Naval Health Camp Pendleton (NHCP)

Location of Organization: Marine Corps Base Camp Pendleton, CA

Partner's contribution to the project: Facility, Collaboration, and Personnel support.

Data collection site.

Organization Name: Fort Sam Houston (FSH)

Location of Organization: Joint Base San Antonio, Tx

Partner's contribution to the project: Facility, Collaboration, and Personnel support.

Data collection site.

Organization Name: The Henry Jackson Foundation for the Advancement of Military medicine (HJF)

Location of Organization: Bethesda, Md

Partner's contribution to the project: Collaboration, and Personnel support.

Project administration and statistical analyses.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: