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TITLE: The Effect of a Powered Ankle Foot Orthosis (PAFO) on Function, Safety, and Quality of Life in Military Service Members and Veterans Who Wear a Prescribed Orthosis

PRINCIPAL INVESTIGATORS: Phyllis A. Richey, PhD.

CONTRACTING ORGANIZATION: University of Tennessee

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a powered ankle foot orthosis (PAFO), that assists with toe clearance and provides push-off power when taking a step, will translate into enhanced function in individuals who walks with a prescribed AFO. We will assess these outcomes in 64 veterans who walk with a prescribed AFO by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in both groups will receive new shoes to be worn with their orthosis to eliminate any confounding variables presented by worn or inadequate shoes. Participants in the intervention group will be provided enhanced training opportunities to use a PAFO while the comparison group will continue with their currently prescribed orthosis. All participants will be followed with weekly contact over a 7-month period of time and receive physical therapy training. All outcome measures will be evaluated three times during the 7-month study period. Recruitment resources via Partner Orthotic clinics, Regional DAV ,Memphis VAMC, local area health care agencies and physician practices have been identified and approval to contact potential study volunteers is currently in progress. Recruitment, enrollment/randomization, intervention is in progress and follow-up assessments will take place during in the coming quarters/year.

15. SUBJECT TERMS
Ankle foot orthosis (AFO), powered ankle foot orthosis (PAFO), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, gait symmetry, foot drop, stroke, spinal cord injury (SCI), traumatic brain injury (TBI), peripheral injury.

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

STANDARD FORM (SF) 298: A sample SF 298 is provided at https://mrmc.amedd.army.mil/rrpindex.asp. The abstract shall be provided in Block 14 and shall state the purpose, scope, and major findings and be an up-to-date report of the progress in terms of results and significance. Abstracts will be submitted to the Defense Technical Information Center (DTIC) and shall not contain proprietary information. Subject terms are keywords that may have been previously assigned to the proposal abstract or are keywords that may be significant to the research.

Pages shall be numbered. The number of pages shall include all pages that have printed data (including the front cover, SF 298, table of contents, and all appendices). Page numbers must match the numbering shown on the Table of Contents.

14. ABSTRACT

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15. SUBJECT TERMS

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TABLE OF CONTENTS

1. INTRODUCTION:

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to quantify functional performance, gait symmetry, ambulatory safety, and quality of life in 64 veterans who walk with a prescribed AFO. The cohort will be randomized in a 1:1 ratio into an intervention or a comparison group. The blocked randomization schedule will be generated by a computer program with a block size of 4; this will guarantee that we have approximately the same number of participants in each treatment group throughout the trial. Participants in both groups will receive new shoes to be worn with their orthosis to eliminate any confounding variables presented by worn or inadequate shoes. Participants in the intervention group will receive enhanced training opportunities with the PAFO while the comparison group will continue with their currently prescribed orthosis. All participants will be followed with weekly contact over a 7-month period of time and receive physical therapy training to minimize deviations resulting from habit or lack of training, education to maximize use of the mechanical properties of their currently prescribed AFO, strengthening and stretching based on published guidelines, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 7-month study period: At baseline, at the 4-month follow up visit and at the 7-month follow up visit. We believe the immediate benefit of this project will determine if an innovative PAFO, designed to assist with toe clearance and provide push off power when taking a step, will improve functional performance, gait symmetry, ambulatory safety (risk of falls), and quality of life in the typical veteran with lower extremity impairment. We will also study whether the same variables/constructs show evidence of any carry over effect of the PAFO when the patients are not wearing an AFO. This study will have significant long-term benefit for all people who depend on an AFO to walk, both veterans and the general public, as they face medical, social and psychological complications associated with falling (broken bones, head trauma, depression, social isolation and death), decreased function and poor quality of life that directly impacting their families and caregivers.

2. KEYWORDS:

Ankle foot orthosis (AFO)
Powered ankle foot orthosis (PAFO)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Gait symmetry
Foot drop
Stroke
Spinal cord injury (SCI)
Traumatic brain injury (TBI)
Peripheral injury.

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goals of this project as stated in the approved SOW are as follows:

1. Perform Preliminary Study Requirements (Months 1-6)
2. Recruit, Coordinate and Train Study Personnel for Clinical Trial (Months 3-6)
3. Participant Recruitment, Screening Eligibility and Baseline Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Powered Ankle Foot Orthosis (PAFO); Intervention Group (N=32; Months 7-24)
6. Physical Therapy Sessions and Orthosis Accommodation Period (N=64; Months 7-25)
7. 4-Month Follow Up Visit and Prosthesis Accommodation Period (N=64; Months 10-30)
8. 7-Month Follow Up Visit and subject closure (N=64; Months 13-30)
9. Assess Secondary Aims (N=64; Months 7-36)
10. Data Analysis/Dissemination of Findings (Months 28-36)

What was accomplished under these goals?

1. Perform Preliminary Study Requirements
   a. Prepare study documents and apply for Local IRB (UTHSC) – Approved 08/06/2018
   b. Apply for USAMRM Human Research Protection Office (HRPO) Approved 09/28/2018
   c. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – Completed
   d. Develop database management system – Completed
   e. Develop and finalize all study data collection forms – Completed
   f. Submit amendments, adverse events and protocol deviations – None to report.
   g. Maintain, update and perform data integrity test on study DBMS – None to report

2. Train Study Personnel for Clinical Trial
   a. Train staff, evaluation physical therapist, treating physical therapist for project – Completed
   b. Trial run through of Screening and Baseline visits for the study – Completed
   c. Eligibility and Randomization training – In Progress
   d. Adverse Events Training with Dr. Johnson, MD – Completed
   e. Develop participant recruitment materials – Completed

3. Participant Recruitment
   a. Establish participant recruitment resources with partner Orthotic Clinics, healthcare agencies, physician practices and Regional DAV – Completed
   b. Identify targeted mailings to prospective participants – Completed

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

During this reporting period another annual professional development seminar for all study personnel and physical therapists was conducted by ReWalk Restore engineers trainers at our study facility at the University of Tennessee Health Science Center (UTHSC) on the Restore PAFO.

How were the results disseminated to communities of interest?

Nothing to Report

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

During the next reporting period we will continue to perform the following actions to accomplish the goals and objectives listed:

1. Continue to identify prospective participants for targeted recruitment- specifically at the Memphis VA Medical Center

2. Participant Recruitment and enrollment, phone (pre-) screening, schedule in-persion screening eligibility visit

3. Confirm pre-screening information at in-person Screening Eligibility Visit
    a. Sign Informed Consent
    b. Confirm pre-screening information
    c. Perform screening evaluation including evaluation of functional level of participant
    d. Evaluate orthotic fit

6. Participant Randomization
    a. Randomize participants into Intervention (N=32) or Comparison (N=32) Groups
    b. Schedule physical therapy visits
    c. Provide all participants new pair of shoes

7. Participant Fit with PAFO
    a. Conduct physical therapy sessions
    b. Provide all participants 2 sessions per week of physical therapy for 4 weeks
    c. Provide weekly phone visits during 8-week following completion of PT sessions to all participants in both groups

8. Perform 3-month evaluation
    a. Perform repeat of all baseline evaluation measures
    d. Provide weekly phone visits during 12-week following completion of 3-month follow-up visit to all participants in both groups

9. Perform 6-month evaluation and subject closure
    a. Perform repeat of all baseline evaluation measures

10. Continue to perform ongoing study requirements
    a. Submit amendments, adverse events and protocol deviations as necessary
    b. Maintain, update and perform data integrity test on study DBMS

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?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

As previously reported, we were forced to change the study device to the Restore Exosuit after manufacturer discontinuation of the originally proposed device. ReWalk Robotics Inc. is providing the study with their new product, Restore Exosuit PAFO to carry out the study intervention. Upon staff training by the ReWalk engineers and deliver of the device it was determined that due to the extensive donning and doffing procedures required to use the device as well as the detailed instructions to operate the device that it would not be appropriate to send home with the study participants. Therefore, we have changed our approach to the accommodation periods for the intervention group and are providing each participant randomized to the intervention group enhanced training opportunities twice a week throughout both accommodation periods at UTHSC where study staff will assist the participant with donning and doffing of the Exosuit as well as monitored "enhanced" exercise sessions beyond that received during the preliminary physical therapy sessions all participants, in both groups, receive following randomization.

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

As referenced above, a delay in executing our timeline was incurred while a substituted device was found. We also experienced a delay acquiring the device from ReWalk Robitics. We finally received the device during quarter three of this reporting period. We have since

performed staff training with the device and have opened the study up for enrollment. Additionally, during the fourth quarter of this reporting period we have received WOC status with the local Memphis VAMC. Therefore, given the current momentum and approval to recruit directly out of the VA we anticipate during the next reporting period we will continue as planned with study recruitment.

Changes that had a significant impact on expenditures

None to Report

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

None

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**
  Nothing to Report

- **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**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Phyllis Richey, PhD
Project Role:	Joint-Principal Investigator
Research Identifier:	1
Nearest person month worked:	12
Contribution to Project:	Dr. Richey is fulfilling the role of co-Principal Investigator as outlined in the SOW.

Name:	Kunal Singhal, PhD, PT
Project Role:	Co-Investigator
Research Identifier:	2
Nearest person month worked:	12
Contribution to Project:	Dr. Singhal is fulfilling the role of co-Principal Investigator as outlined in the SOW.

Name:	Kristen Leone
Project Role:	Study Coordinator
Research Identifier:	3
Nearest person month worked:	12
Contribution to Project:	Ms. Leone has worked with IRB submissions, HRPO submissions, recruitment materials, participant recruitment, retention, screening, conducting evaluation visits, performing phone visits, and scheduling, as well as PT visit scheduling and intervention group enhanced PAFO training session scheduling

Name:	Matt Hood
Project Role:	Study Coordinator/Informatics
Research Identifier:	4
Nearest person month worked:	12
Contribution to Project:	Mr. Hood has worked with IRB submissions, HRPO submissions, database development, data collection form design, staff development and training

Name:	Lindsey Siegfried
Project Role:	Study Coordinator
Research Identifier:	5
Nearest person month worked:	10
Contribution to Project:	Ms. Siegfried has assisted Ms. Leone with data collection, participant recruitment, retention, screening, conducting

evaluation visits and performing phone visits, measurement visit scheduling, as well as PT visit scheduling and intervention group enhanced PAFO training session scheduling.

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:	CFI Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Orthotic Clinic
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Human Technology Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Orthotic Clinic
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Spears Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Orthotic Clinic
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Disabled American Veterans (DAV)
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Methodist Healthcare
Location of Organization:	Tennessee

Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Region One Healthcare
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None
Organization Name:	Memphis Veterans Administration Medical Center
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:
Not Applicable

QUAD CHARTS:
Attached

9. APPENDICES:
Not Applicable

The effect of a powered ankle foot orthosis (PAFO) on function, safety & quality of life in military service members and veterans who wear a prescribed orthosis

OP160076

Joint PI's: Richey, P.A. & Singhal, K. **Organization:** University of Tennessee Health Science Center **Budget:** $1,998,325

Study Aim: Primary (1)

To determine if a PAFO with greater range of motion and active power improve functional performance while wearing the PAFO, as well as carry over to improved functional performance when the PAFO is not worn..

Secondary Aims (3):

To determine if use of a PAFO, with greater range of motion and active power, will improve (SA:1) gait symmetry, (SA:2) ambulatory safety (reduce risk of falls), and (SA:3) general quality of life and orthotic-related quality of life while wearing the PAFO, as well as carry over to improved gait symmetry when the PAFO is not worn.

Approach:

We will randomize 64 patients with neurologic impairment who have significant weakness of the foot and ankle musculature in a 1:1 ratio to either the intervention or comparison condition. The study is a 2-arm, parallel, randomized, controlled clinical trial.

Accomplishment: We are currently enrolling Veteran trans-tibial amputees in the DoD funded "Veterans Leading pRostetic Research" (VALOR) study. This study is contributing to the improved rehabilitation of amputees classified as "community ambulators" to enhance their function and quality of life.

3 Year Timeline and Cost

Activities	Year 1	Year 2	Year 3
Process/Approvals			
Recruitment/Evaluation			
Intervention			
3-month follow up			
6-month follow up			
Analysis/Dissemination			
Estimated Budget ($K)	$736,000	$800,000	$462,000

Updated September 2019

Goals/Milestones

Year 1– Project Planning, Start-Up, Recruitment, Enrollment, Intervention and Follow-Up Evaluation

☒ Define processes/obtain all approvals for safety and compliance. Begin participant recruitment and baseline evaluation and randomization treatment condition.

☒ Begin intervention including orthotic fitting period (2 weeks) and physical therapy sessions.

❑ Begin follow-up evaluations and retention including 3 month follow up visits and accommodation phase 1 with weekly phone visits

Year 2– Continue, Enrollment, Intervention and Follow-Up Evaluation

❑ Complete participant recruitment and baseline evaluation, complete orthotic fitting period and physical therapy sessions

❑ Continue 3 month and begin 6 month follow up visits and retention.

❑ Complete accommodation phase 1 and begin accommodation phase 2

Year 3– Project Completion and Close Out

❑ Complete 3 and 6 month follow up visits and accommodation phase 2

❑ Complete data analyses

❑ Disseminate findings in journal and conference venues