AWARD NUMBER: W81XWH-15-1-0470

TITLE: The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited

Community Ambulators

PRINCIPAL INVESTIGATORS: Phyllis A. Richey,PhD.

CONTRACTING ORGANIZATION: UNIVERSITY OF TENNESSEE
MEMPHIS TN 38103-4903

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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 microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6-month period of time in addition to receiving physical therapy training. All outcome measures will be evaluated three times during the 6 month study period. Once HRPO approval for the project was received in April 2016, recruitment efforts via Partner Prosthetic clinics was undertaken to identify over 700 potentially eligible individuals, 40 of whom were veterans. Similar efforts with the Regional DAV have also been undertaken. Active recruitment began in July 2016 and has yielded 77 individuals responding to recruitment efforts, 76 of whom have been screened for eligibility. Of those, 32 (42%) met eligibility criteria to qualify for evaluation of Medicare Functional Classification Level (MFCL) using the Amputee Mobility Predictor-Prosthesis (AMP-Pro). Five (15.6%) of those individuals (who comprised 7% of the total 76 screened) met the K-Level 2 classification as a "community ambulator" and were eligible for randomization to group assignment. Recruitment, enrollment/randomization, intervention and followup assessments will continue in the coming quarter/year.

15. SUBJECT TERMS
Trans-tibial amputee (TTA), microprocessor controlled prosthetic foot (MPF), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, community ambulator

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and 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 the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6 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 current foot, strengthening and stretching based on published guidelines for TTA, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 6 month study period: At baseline, at the 3-month follow up visit and at the 6 month follow up visit. We believe the immediate benefit of this project will determine if an innovative MPF, designed to facilitate toe clearance by optimizing ankle angle and foot position, will improve functional performance, ambulatory safety (risk of falls), and quality of life in the typical veteran amputee. This study will also have significant long term benefit for all typical amputees, 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:** Provide a brief list of keywords (limit to 20 words).
Trans-tibial amputee (TTA)
Microprocessor controlled prosthetic foot (MPF)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Community ambulator

3. **ACCOMPLISHMENTS:** The 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.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

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, Phone (Pre-) Screening, Screening Eligibility Baseline Randomization Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Microprocessor Foot; Intervention Group (N=27; Months 7-24)
6. Physical Therapy Sessions and Prosthesis Accommodation Period (N=54; Months 7-24)
7. 3-Month Follow Up Visit and Prosthesis Accommodation Period (N=54; Months 10-27)
8. 6-Month Follow Up Visit and subject closure (N=54; Months 10-30)
9. Data Analysis/Dissemination of Findings (Months 28-36)
10. Assess Prosthesis related quality of life (N=54; Months 7-36)

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. Perform Preliminary Study Requirements
    a. Prepare study documents and apply for Local IRB (UTHSC) and USAMRM Human Research Protection Office (HRPO) approval- Complete, HRPO approval received Apr 5, 2016.
        - Updated consent form submitted Apr 26, 2016- Approved May 5, 2016
    b. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – completed May 2, 2016
    e. Develop database management system – completed May 26, 2016
    f. Develop and finalize all study data collection forms – completed May 2, 2016
    g. Submit amendments, adverse events and protocol deviations – In progress.
    h. Maintain, update and perform data integrity test on study DBMS – In progress.

2. Train Study Personnel for Clinical Trial
   a. Train staff, evaluation physical therapist, treating physical therapist and prosthetists for project – completed May 27, 2016
      - Trial run through of Screening and Baseline visits for the study
      - Eligibility and Randomization training – Completed March 31, 2016
      - Adverse Events Training with Dr. Mihalko, MD – Completed April 1, 2016
   b. Develop participant recruitment materials – completed May 13, 2016
      - Participant Flyer - Completed Mar 16, 2016
      - Participant Flyer with Tear-offs – Completed Mar 16, 2016
      - Business Card – Completed Mar 16, 2016

3. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit– In Progress
   a. Participant recruitment – In progress, have performed initial targeted recruitment via Partner Prosthetic clinics,Regional DAV, VA and local area hospitals and physician practices, to identify targeted mailings to prospective participants.
      - Identify prospective participants for targeted recruitment
      - Perform phone (pre-) screening, schedule qualifying participants to baseline session – In Progress
   b. Confirm pre-screening at in person Screening Eligibility Visit – In Progress
      - Sign informed consent
      - Evaluate functional level of participant
      - Evaluate fit of current prosthesis
   c. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Evaluations – In Progress
   d. Baseline Randomization Evaluations – In Progress

4. Participant Randomization – In Progress

5. Participant Fit with Microprocessor Foot; Intervention Group – In Progress

6. Physical Therapy Sessions and Prosthesis Accommodation Period– In Progress

7. 3-Month Follow Up Visit and Prosthesis Accommodation Period- In Progress

8. 6-Month Follow Up Visit and subject closure- In Progress

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and

experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

During this reporting period we offered the annual 6 CEU professional development seminar for physical therapists and prosthetists in the Memphis area conducted by Ossur trainers at our study facilities at the University of Tennessee Health Science Center (UTHSC). Additionally, we presented a guest lecture on improving mobility opportunities for below-the-knee amputees at the UTHSC Endocrinology Division spring meeting. Finally, we have engaged faculty of the UTHSC Department of Surgery, Division of Vascular Surgery interested in publication opportunities with the VALOR dataset to submit proposals for presentation and publication.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

As described above, during this reporting period we initiated outreach to both the UTHSC Department of Medicine, Division of Endocrinology and Department of Surgery, Division of Vascular Surgery, through guest lecture and journal club meetings to inform physicians of the opportunities the VALOR Study provides for their patients' participation as well as professional publication opportunities with the VALOR dataset.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

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

1. 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
2. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit
3. Participant Recruitment
4. Identify prospective participants for targeted recruitment
5. Confirm pre-screening at in person Screening Eligibility Visit
    a. Sign Informed Consent
    b. Confirm pre-screening in person

c. Perform screening evaluation including evaluation of functional level of participant
d. Evaluate prosthetic fit

6. Participant Randomization
    a. Randomize participants into Intervention (N=27) or Comparison (N=27) Groups
    b. Schedule visits for prosthetic clinics (Intervention group) and physical therapy visits
7. Participant Fit with Microprocessor Foot
    a. Provide participants randomized into Intervention group new prosthetic foot and train on use of foot during 2-4 prosthetic clinic over 2 week period

8. Physical Therapy Sessions and Prosthesis Accommodation Period 1
    a. Provide all participants 2 sessions per week of physical therapy for 4 weeks
    b. Provide weekly phone visits during 8-week accommodation period 1 to all participants in both groups

9. Perform 3-month evaluation and Prosthesis Accommodation Period 2
    a. Perform repeat of all baseline evaluation measures
    b. Provide weekly phone visits during 12-week accommodation period 2 to all participants in both groups

10. Perform 6-month evaluation and subject closure
    a. Perform repeat of all baseline evaluation measures
    b. Provide participants randomized into Intervention group prosthetic foot finishing of the Microprocessor foot or return and finish original prosthetic foot to participant

11. Perform data analysis of primary outcomes
    a. Mine data and prepare data sets for analyses
    b. Perform all analyses according to specifications, share output and findings with all investigators.

12. Perform data analysis of prosthesis-related quality of life outcomes
    a. Mine data and prepare data sets for analyses
    b. Perform all analyses according to specifications, share output and findings with all investigators

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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge,

theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *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:** 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
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

During this reporting period an amendment to the award was granted to (1) change the Principal Investigator from Dr. Audrey Zucker-Levin to Dr. Phyllis Richey, (2) incorporate, by reference, a revised SOW dated 10 April 2018 and (3) provide a 12-month extension to CLIN 0001 (through 31 August 2019) at no additional cost to the government.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

As referenced above an Extension Without Funds was granted during the current reporting period to allow for additional time to fulfill the recruitment goal of 54 participants.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

As described above carryover from previous reporting periods has enabled an extension of the project period through August 31, 2019 to be accomplished without need for additional funds.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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:** 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.

  Nothing to Report

- **Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

- **Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  Nothing to Report

- **Other publications, conference papers, and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

  Nothing to Report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

  Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to Report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. 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.*

During the current reporting period study data continued to be collected that will inform the project results and ultimately providers and patients. Results from data analyses will be shared via dissemination at professional conferences and through publication.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

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 continuing to fulfill the role providing the physical therapy intervention for participants and insuring consistency in delivery of the intervention protocol as outlined in the SOW. Additionally, as described in the change of PI request and revised SOW (Apr, 10, 2018), Dr. Singhal has been performing the Joint-PI duties as the acting "Intervention PI," previously assigned to Dr. Zucker-Levin, following her departure from the University as a full-time employee.

Name:	Kristen Leone
Project Role:	Study Coordinator
Research Identifier:	3
Nearest person month worked:	6
Contribution to Project:	Ms. Leone has worked with IRB submissions, data collection, participant recruitment, retention, screening, conducting evaluation visits, performing phone visits, and scheduling, as well as PT visit scheduling and prosthetic clinic communication and 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/maintenance, participant recruitment, screening, conducting evaluation visits, retention, and scheduling, prosthetic clinic communication and scheduling.

Name:	William Mihalko, MD, PhD
Project Role:	Co-Investigator
Research Identifier:	5
Nearest person month worked:	12
Contribution to Project:	Dr. Mihalko is fulfilling the role of co-investigator overseeing intervention safety and adverse event reporting as outlined in the SOW.

Name:	Catherine Womack, MD
Project Role:	Co-Investigator
Research Identifier:	6
Nearest person month worked:	12

Contribution to Project:	Dr. Womack is fulfilling the role of co-investigator adjudicating any participant eligibility determinations in which medical history and/or current health habits (e.g. medication and/or substance abuse, depression status, etc) are in question.
Name:	E Shannon Hughes, PT
Project Role:	Co-Investigator
Research Identifier:	7
Nearest person month worked:	12
Contribution to Project:	Ms. Hughes is fulfilling the role of co-investigator performing the physical therapy evaluations and other primary outcome measurements during the in-person evaluation visits (baseline, 3-month and 6-month) the as outlined in the SOW.
Name:	Richard Kasser, PhD, PT
Project Role:	Staff Evaluation PT
Research Identifier:	8
Nearest person month worked:	4
Contribution to Project:	Dr. Kasser is fulfilling the role of staff evaluation PT needed for the expanded screening physical therapy evaluations and other primary outcome measurements during the in-person evaluation visits (baseline, 3-month and 6-month) the as outlined in the SOW.
Name:	Jim Wan, PhD
Project Role:	Co-Investigator
Research Identifier:	9
Nearest person month worked:	12
Contribution to Project:	Dr. Wan is fulfilling the co-investigator role as Statiscian outlined in the SOW.
Name:	Audrey Zucker-Levin, PhD, PT
Project Role:	Investigator
Research Identifier:	10
Nearest person month worked:	6
Contribution to Project:	Dr. Zucker-Levin role has changed dramatically since her departure from the University March 1, 2017. She has continued on the project contributing up to 2% effort and her previous duties being redistributed to Dr. Richey and Dr. Singhal (Joint-PIs) as outlined in the approve revised SOW dated April 10, 2018.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Effective March 1, 2017, Dr. Audrey Zucker-Levin (Joint-PI) left the University as a full-time employee. This change in personnel was reported and a revised SOW submitted March 1, 2017. As a result of this personnel change, Dr. Richey (Joint-PI) has assumed the majority of Dr. Zucker-Levin's duties and Dr. Singhal (Co-I), being a physical therapist like Dr. Zucker-Levin, assumed her primary "Intervention PI" duties. Dr. Zucker-Levin remained on the project contributing up to 10% effort until April 2018. An additional revised SOW (Apr, 10, 2018), was submitted last quarter requesting the lead PI be changed to Dr. Richey and Dr. Singhal, who has been performing the duties of acting "Intervention PI" that were previously assigned to Dr. Zucker-Levin, be designated as Joint PI. Approval of this PI change was received July 12, 2018.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
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.*

Organization Name:	CFI Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Human Technology Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Precision Prosthetics, Inc.
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Spears Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
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

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

Not Applicable

QUAD CHARTS: N/A

9. APPENDICES:

Not Applicable