

AWARD NUMBER: W81XWH-21-2-0036

TITLE: Improved Training Method for Advanced Rehabilitation of Warfighters with Lower Extremity Trauma

PRINCIPAL INVESTIGATOR: Kenton Kaufman, PhD, PE

CONTRACTING ORGANIZATION: Mayo Clinic, Rochester, MN

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14. ABSTRACT <p>With the current military healthcare rehabilitation approach, not all trauma patients achieve the high-level functional skills that enable them to return to active duty or pursue pre-injury activities. Lower limb trauma patients often spend 6 to 18 months in rehabilitation, yet only a small number (13%) of all Service members with amputation return to Active Duty with a mere two percent being able to return to their original occupation. More than half of military amputation patients are deemed fully disabled following extensive rehabilitation.</p> <p>The primary goal of lower limb rehabilitation is to help the patient walk in an energy efficient and symmetrical pattern without the use of an assistive device. Yet, after standard rehabilitation for amputation or limb salvage, many Service members struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. The objective of this program is to augment existing conventional rehabilitation by providing fall-prevention training, to help Service members return to full high-level functional capabilities and emotional wellness, and to shorten the time required to return to active duty or to a productive, active civilian life. Over the initial year of this project, we have created the infrastructure to perform the project.</p>						
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1. INTRODUCTION

With the current military healthcare rehabilitation approach, not all trauma patients achieve the high-level functional skills that enable them to return to active duty or pursue pre-injury activities. Lower limb trauma patients often spend 6 to 18 months in rehabilitation, yet only a small number (13%) of all Service members with amputation return to Active Duty with a mere two percent being able to return to their original occupation. More than half of military amputation patients are deemed fully disabled following extensive rehabilitation.

The primary goal of lower limb rehabilitation is to help the patient walk in an energy efficient and symmetrical pattern without the use of an assistive device. Yet, after standard rehabilitation for amputation or limb salvage, many Service members struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. Following a trip or slip, many warfighters are still likely to fall and injure themselves, despite advances in rehabilitation care. Adaptations due to the loss of function, while necessary, may also limit physical performance and reduce quality of life.

The **objective** of this program is to augment existing conventional rehabilitation by providing fall-prevention training, to help Service members return to full high-level functional capabilities and emotional wellness, and to shorten the time required to return to active duty or to a productive, active civilian life.

2. **KEYWORDS:** Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy

3. ACCOMPLISHMENTS

• **What were the major goals of the project?**

This project has three main goals.

- (1) Improve the user interface of the task-specific rehabilitation program to facilitate clinical use
- (2) Determine functional improvement from perturbation training during and following the initial post-injury acute rehabilitation period
- (3) Create the educational materials needed for clinical implementation

• **What was accomplished under these goals?**

The primary goals in this first year of the study were to establish the project infrastructure and obtain regulatory review of the study protocol.

The postural disturbances are provided by a microprocessor-controlled treadmill. Work was done to validate the Treadmetrix Fall Mitigation system. Key kinematic variables of overall belt displacement, peak belt velocity, and average initial belt acceleration were recorded by motion capture (200Hz) and were compared to expected to assess accuracy and precision of the perturbation movements. Representative curves of the belt velocity are shown in Figure 1. Relative error and coefficient of variation in the belt displacement, belt peak velocity, and average initial acceleration were assessed at each perturbation magnitude in both the anterior (positive displacement, peak velocity) and posterior (negative displacement, peak velocity) directions (Figures 2). These results demonstrate that the perturbations provided by the treadmill system are accurate. This work is being done in conjunction with Award Number W81XWH-20-C-0104 (Proposal Number 20000082).

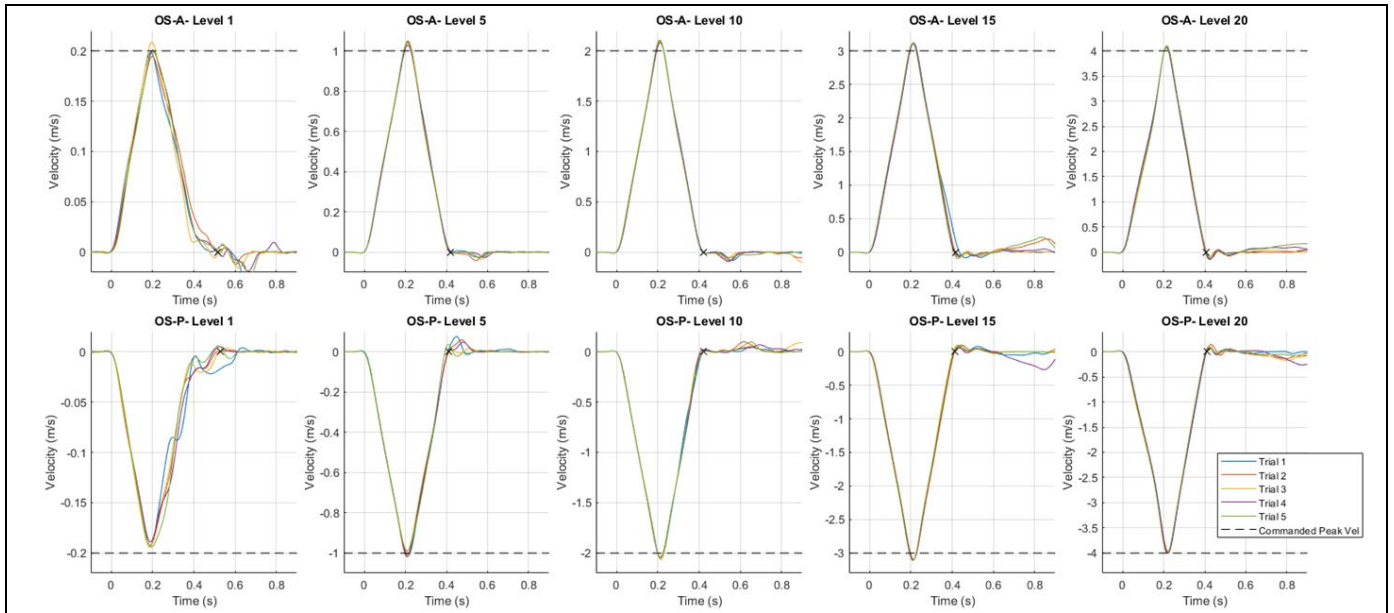
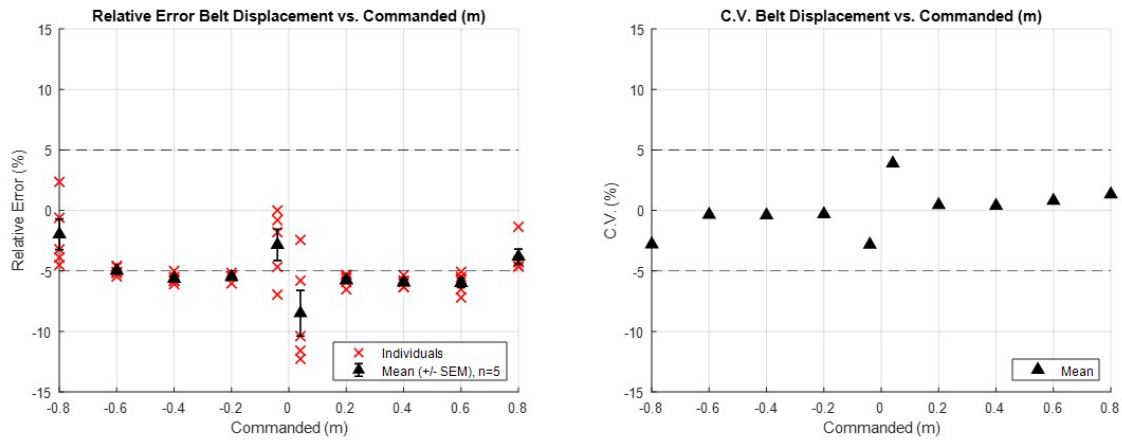


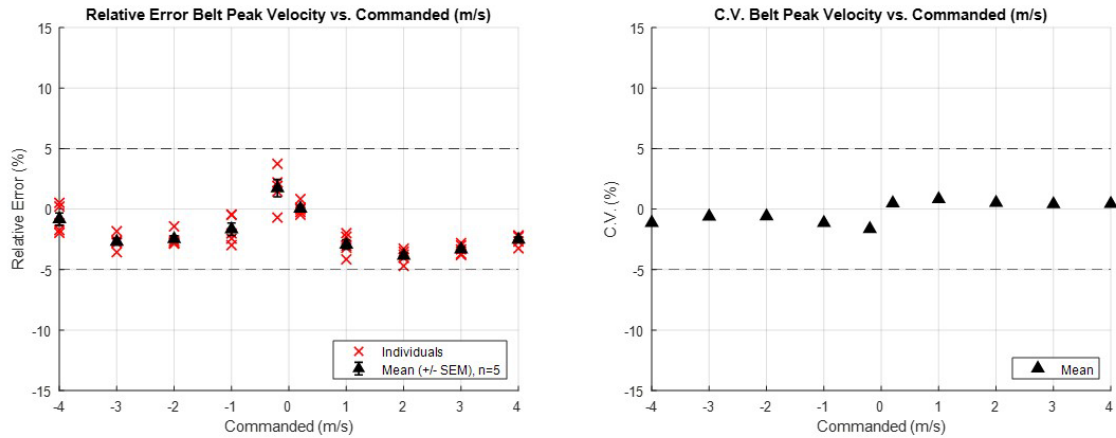
Figure 1. Representative treadmill belt velocity profiles.

Treadmill Belt Kinematics- Overall Displacement



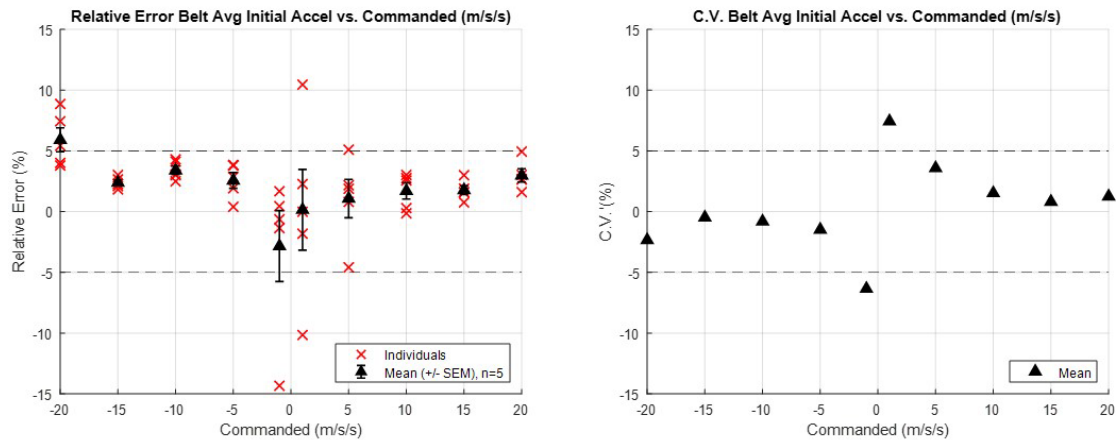
$(\text{Expected} - \text{Observed}) / \text{Expected} * 100\%$

Treadmill Belt Kinematics- Peak Velocity



(Expected – Observed)/Expected *100%

Treadmill Belt Kinematics- Avg. Initial Acceleration



(Expected – Observed)/Expected *100%

Figure 2. Relative Error (%) and coefficient of variation (%) in treadmill belt (a) displacement, (b) velocity, and (c) acceleration.

Work has begun graphical user interface (GUI) (Figure 3). The GUI will provide a simple user interface with the Treadmetrix Fall Mitigation system. User interviews suggest that a streamlined interface, minimizing button clicks in administering fall mitigation protocols is essential for the full software.

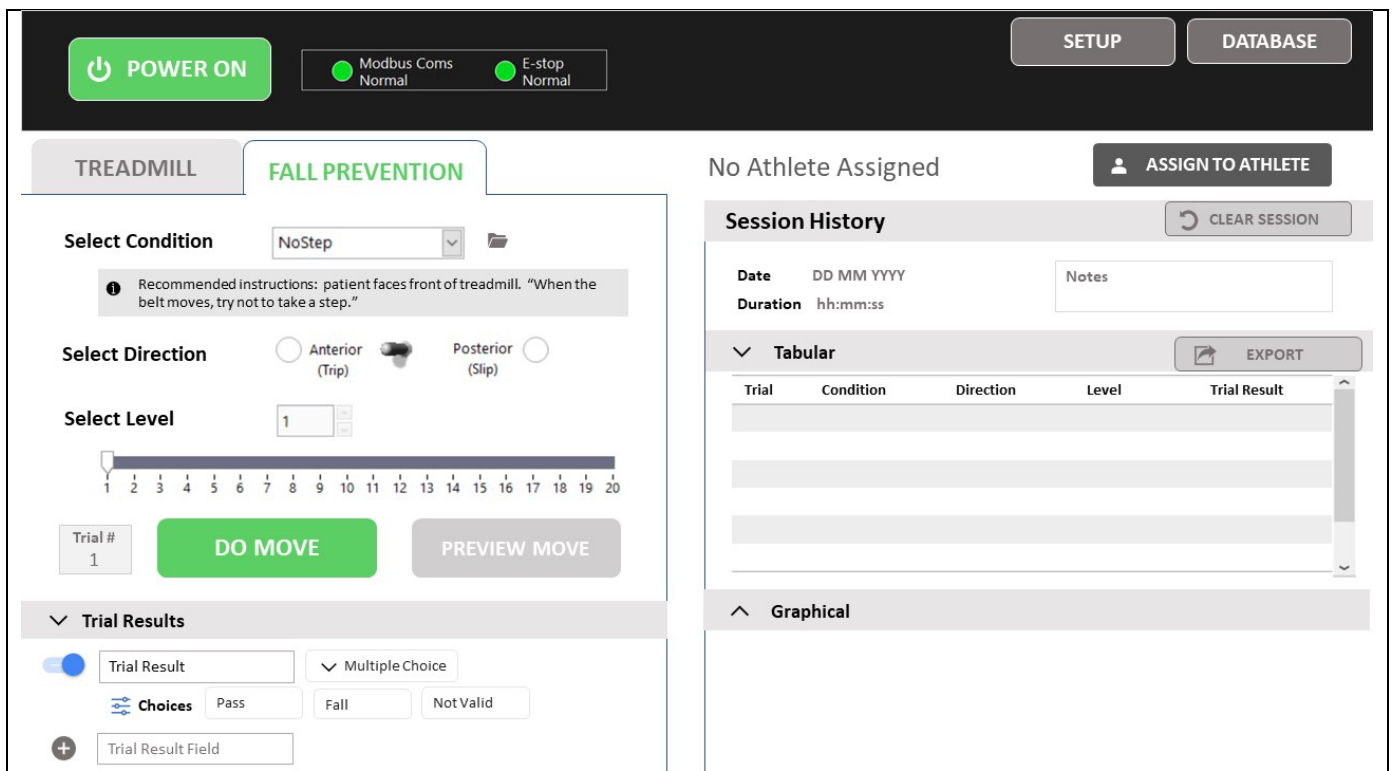


Figure 3. Graphical User Interface (GUI) interface for the treadmill controller.

The study team met in person to discuss the project and plan the study. Data will be collected before and after training (Figure 3). After the subject is enrolled, a baseline assessment will be performed. Next, at least six training sessions will be completed with at least one day of rest between sessions. A post-training assessment will be completed at 6 weeks post-baseline assessment. To assess skill retention, additional post-training assessments were performed at three and six months after completion of the training. At each test session, multiple assessment tools will be used. The narrow beam walking test and the L-test have been created and are ready for use.

Study data will be stored and managed using REDCap (Research Electronic Data Capture) tools hosted at Mayo Clinic. REDCap is a secure, web-based software platform that meets HIPAA compliance standards for data capture. The data collection platform has been created and is ready for use (Figure 4).

The protocol has been approved by the Mayo IRB. We are waiting for HRPO approval to begin data collection.

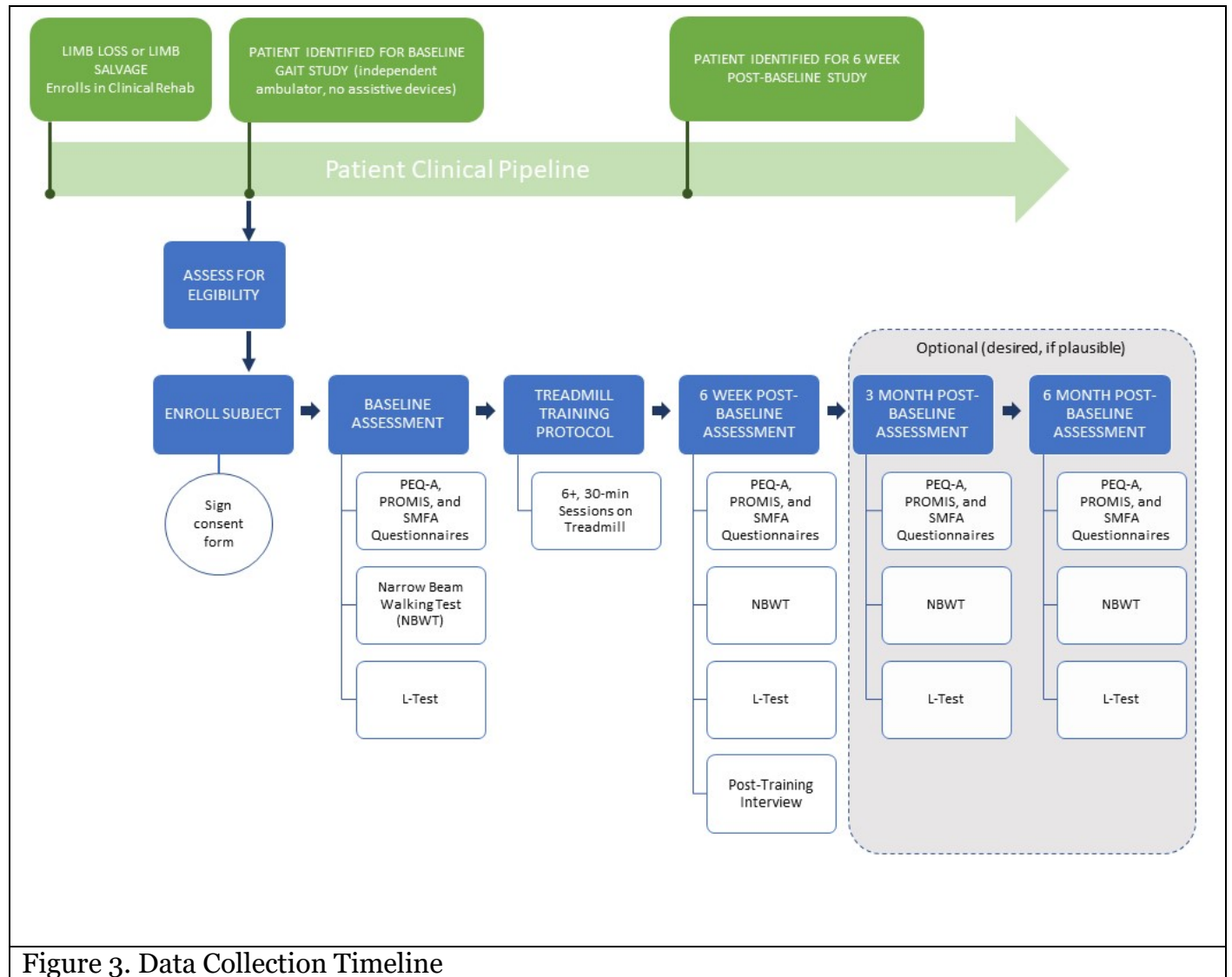


Figure 3. Data Collection Timeline

IIIRR Improved Training Method for Advanced Rehabilitation of Warfighters with Lower extremity Trauma PID 2614

Project Home | Project Setup | Online Designer | Data Dictionary | Codebook

Create snapshot of instruments | VIDEO: How to use this page
Last snapshot: 07/11/2022 2:17pm

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

[+ Create](#) a new instrument from scratch
[Import](#) a new instrument from the official [REDCap Instrument Library](#)
[Upload](#) instrument ZIP file from another project/user or [external libraries](#)

Form options:
[Form Display Logic](#)

Survey options:
[Survey Queue](#) | [Survey Login](#)
[Survey Notifications](#)

Automated Survey Invitation options:
[Upload or download Auto Invitations](#)
[Re-evaluate Auto Invitations](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Gait Lab Summary Sheet	32		Enable	Choose action	
Patient History (initial)	31		Enable	Choose action	
Ltest	6		Enable	Choose action	
NBWT Narrow Beam Walking Test	14		Enable	Choose action	
Short Musculoskeletal Function Assessment (SMFA) Scored	51		Enable	Choose action	
Post Training Interview	9		Enable	Choose action	
PEQ A	18			Choose action	Survey settings + Automated Invitations
PROMIS SF v1.1 - Global Health	10		Enable	Choose action	

Figure 4. Data Collection Platform

- **What opportunities for training and professional development has the project provided?**
Nothing to report.
 - **How were the results disseminated to communities of interest?**
Since this was the first year of this project, no results have been disseminated at this time.
 - **What do you plan to do during the next reporting period to accomplish the goals?**
 - Obtain HRPO approval
 - Install the microprocessor-controlled treadmill
 - Begin data collection
- 4. IMPACT**
- **What was the impact of 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

- **Changes in approach and reasons for change**

No changes to report.

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

We are having supply chain issues with receipt of the motor drive for the treadmill. If the motor is not delivered by the time that HRPO approval is granted, we will remove a motor from another treadmill and use it in the treadmill at NMCSD for the project.

- **Changes that had a significant impact on expenditures**

Nothing to report.

- **Significant changes in use or care of human subjects**

None.

6. PRODUCTS

- **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:	Kenton Kaufman, PhD, PE
Project Role:	Principal Investigator, Mayo Clinic
Nearest person month worked:	1
Contribution to Project:	Dr. Kaufman has held regular meetings with the study investigators. He has prepared materials for submission to the Mayo IRB and HRPO. He has worked to develop the standard operating procedures for the research protocols. He has served as the liaison with the Grants Officer's Representative and has proved the required quarterly and annual reports.
Funding Support:	

Name:	Cecilia Streff, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	1
Contribution to Project:	Ms. Streff has attended regular meetings with Co-Investigators. She has conducted equipment tests and provided design input for the graphical user interface being implemented in the postural perturbation treadmill.
Funding Support:	

Name:	Christine Huyber, CCRP
Project Role:	Study Coordinator, Mayo Clinic
Nearest person month worked:	2
Contribution to Project:	Ms. Huyber has attended regular meetings with Co-Investigators. She has prepared materials for submission to the Mayo IRB. She has developed data collections tools for use across institutions with REDCap as the data management tool for this project.

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

No.

- **What other organizations were involved as partners?**

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

- **Quad Chart**

9. APPENDICES