

Orthopaedic Section of the APTA Grant Program Annual Progress Report Form

Date: 9/26/2016

Name of Investigators:

Name of Grant:

Award Period: 5/28/2013 to 9/30/2015 (Initial award date is the date that the award was made to your institution)

Current Year of Award completed (circle one): 1st, 2nd no-cost extension year (3rd)

Progress reports are due no later than 1 year plus 10 days after the initial award date. Failure to submit a timely progress report may result in the termination of your award.

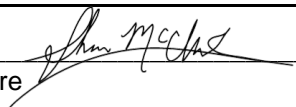
1. Summary of accomplishments in the past year:

2. Provide a one-paragraph summary of results or abstract suitable for posting on the Orthopaedic Section website.

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications supported by Orthopaedic Section funding.

4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was $\geq 25\%$ deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale.

5. Objectives for the next year:

Your Signature 

9/26/2016
Date

Return to:

Tara Fredrickson, Executive Associate
Orthopaedic Section, APTA, Inc.
2920 East Avenue South, Suite 200
LaCrosse, WI 54601-7202

Orthopaedic Section of the APTA
Grant Program
Annual Progress Report: Year 3

Date: 9/26/2016

Name of Investigators: Shane McClinton, Timothy Flynn, Bryan Heiderscheit

Name of Grant: Comparison of Usual Podiatric Care and Early Physical Therapy for Plantar Heel Pain

Award Period: 5/28/2014 to 9/30/2015

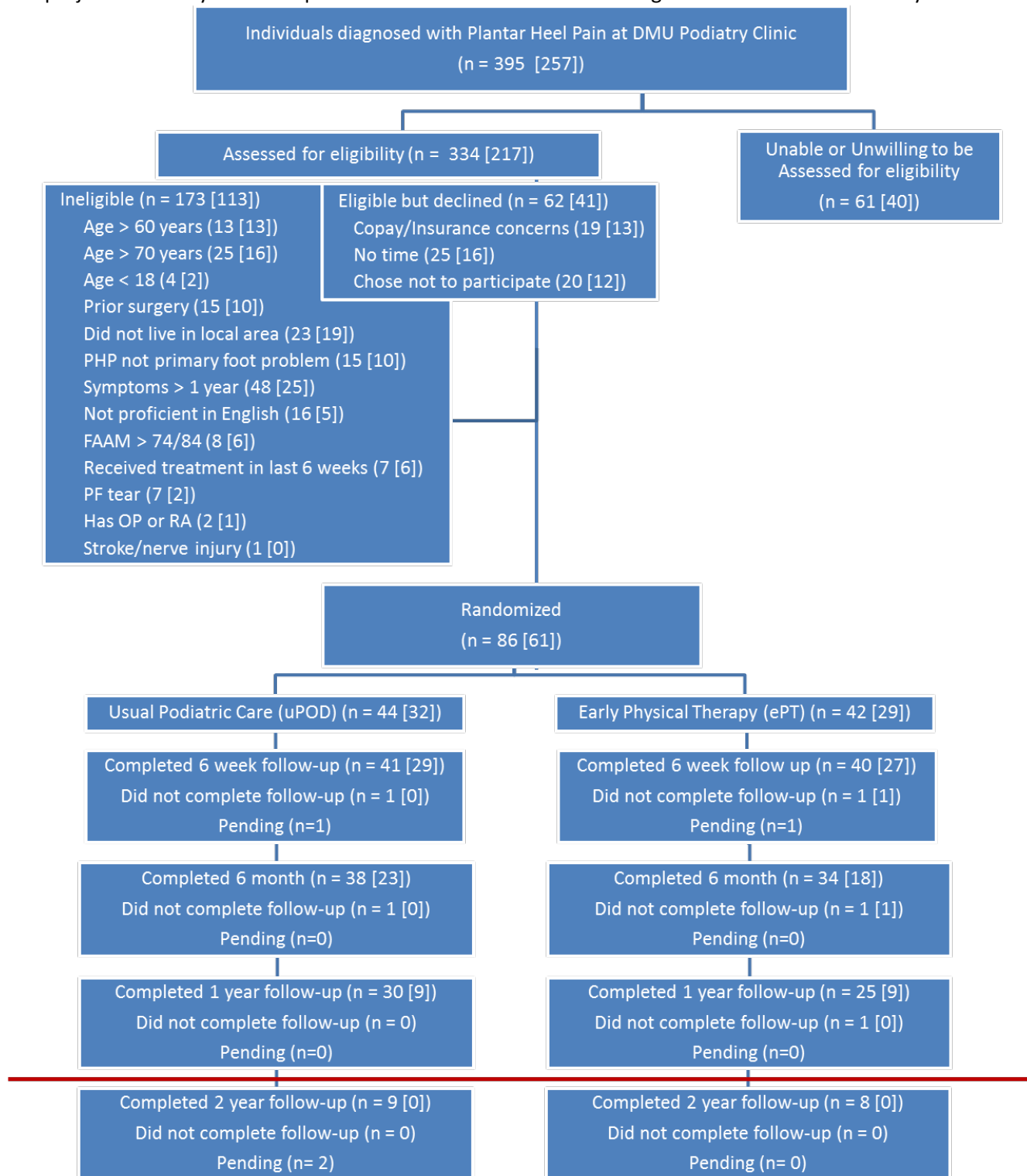
Award Date: 6/18/2013

Current Year of Award: 3

1. Summary of accomplishments in the past year:

- a. Patients screened daily from appointment lists and billing report.
- b. Increased enrollment from 61 to 86 (**FIGURE 1** and 2).
- c. Collected data – participant completion of follow-ups has been dramatically better than predicted. Only 2 out of 72 participants (3%) that were enrolled have failed to complete the 6 month follow up compared to the 30% rate of loss accounted for in the original power analysis)(**FIGURE 1**).
- d. Power analysis has been re-run using preliminary data and confirmed that the original power analysis and last year's interim analysis was on target. The recent analysis identified a total sample of 86 required to power a between-group comparison of the FAAM at the 6 month follow up. Therefore, when factoring in the 3% drop-out rate, the total enrollment target will remain at 88, which was established after last year's power analysis.
- e. Database has been created and tested. Data is currently being entered by a collaborator who is blinded to the group assignment and the database is up-to-date.
- f. Marketing efforts have continued in the local community including flyers, social media efforts, and presentations (see "Presentations" below).
- g. Team building has continued with quarterly meetings with the Podiatry department (clinicians, staff, and students) and weekly meeting with students in the Podiatry Clinic to improve participant flow through the informational and enrollment process.
- h. Preliminary funding was obtained through the Research Department at Des Moines University to extend outcome collection to 2 years and up to 5 years. Approval for this extension has been approved by the Des Moines University IRB. Follow-up has been completed for 17 individuals. Full funding for this portion of the project is currently under review.

FIGURE 1. Participant enrollment flow diagram (September 19, 2015 – September 21, 2016). Brackets indicate numbers from the second year progress report. The red line indicates the end of the part of the project funded by the Orthopaedic Section and the start of funding from Des Moines University.



Abbreviations: FAAM, Foot and Ankle Ability Measure; OA, osteoarthritis; OP, osteoporosis; PHP, plantar heel pain; PF, plantar fascia; RA, rheumatoid arthritis.

2. Provide a one-paragraph summary of results or abstract suitable for posting on the Orthopaedic Section website.

A blind analysis is planned and therefore we are unable to perform analysis until all data is collected. The lay language summary previously submitted and included below with additional information of the projects status would be appropriate at this phase of this research.

Plantar heel pain (PHP) is one of the most common foot conditions in podiatry and physical therapy practice. Chronic symptoms and prolonged disability associated with PHP results in a burden on the healthcare economy. Currently, there is wide variation in treatment, cost, and outcomes of care for PHP. Two practice guidelines are available to direct management patterns, but the guidelines and recent evidence of PHP interventions are unclear about the timing and influence of physical therapy in the multidisciplinary management of PHP. The purpose of this investigation is to compare the outcomes and costs associated with early physical therapy (ePT) following initial presentation to podiatry versus usual podiatric care (uPOD) in individuals with PHP. It is hypothesized that there will be greater improvement and/or reduced costs associated with either ePT or uPOD. In this study, 88 individuals with PHP will be randomized to receive uPOD or ePT after an initial visit with a podiatrist. The uPOD group will receive treatment determined by a podiatrist according to usual management patterns. The ePT group will receive treatment determined by a physical therapist that will focus on impairment-based manual therapy and exercise to the lower half of the body in addition to evidence-based pain modulating modalities. Comparisons will be made between groups in the Foot and Ankle Ability Measure, Numeric Pain Rating Scale, Global Rating of Change (GROC), and costs of treatment at 6, 26, and 52, weeks. Additional considerations within the outcome analysis will include factors related to patient expectation and preference. The results of this investigation will help to determine the impact of ePT to inform practice, update existing guidelines to reduce practice variation, and identify the most cost-effective treatment for patients with PHP. Currently, 86 individuals have been enrolled in this clinical trial and 72 have completed the 6 month follow-up.

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications supported by Orthopaedic Section funding.

Published Manuscript

McClinton S, Collazo C, Vincent E, Vardaxis V. Impaired Foot Plantar Flexor Muscle Performance in Individuals With Plantar Heel Pain and Association With Foot Orthosis Use. *J Orthop Sports Phys Ther.* 2016;46(8):681-688. doi: 10.2519/jospt.2016.6482.

Heiderscheit B, McClinton SM. Evaluation and Management of Hip and Pelvis Injuries. *Phys Med Rehabil Clin N Am.* 2016;27(1):1-29. doi: 10.1016/j.pmr.2015.08.003.

Submitted Manuscripts

Phillips A, McClinton SM. Gait Deviations association with Plantar Heel Pain: A Systematic Review. Under revision with *Clin Biomech.*

McClinton SM, Luedke L, Clewley D. Non-Surgical Management of Mid-Substance Achilles Tendinopathy. Invited submission to *Clin Podiatr Med Surg*.

Poster Presentations

*Barton E, McClinton SM. The Role of patient expectations in plantar heel pain treatment outcomes. Des Moines University Research Symposium. December 2015. Updated version also submitted to the Iowa Podiatric Medical Society Heartland Foot and Ankle Conference. September/October 2016.

Standiford A, Weber C, McClinton SM. Effect of a prior history of plantar heel pain on treatment outcome. Submitted to the Iowa Podiatric Medical Society Heartland Foot and Ankle Conference. September/October 2016.

Presentations

Rationale for Manual Therapy Amidst Trending Techniques. Mountain Land Running Summit. September 2016.

Exercise Design for the Distance Runner. Mountain Land Running Summit. September 2016.

Practical Gait Retraining for the Injured Runner. Mountain Land Running Summit. September 2016.

McClinton SM, Wille CM, Gallow A. *Practical Gait Analysis and Retraining Methods for the Injured Runner.* Combined Sections Meeting. February 2016

Interventions for the foot and ankle that don't stink: Evidence and hands-on application. IPTA Fall Conference. November 2015.

Fundamental manual physical therapy interventions. Des Moines University Continuing Medical Education. October 2015.

4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was > 25% deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale.

EXPENSE CATEGORY	PROJECTED COST	AMOUNT REQUESTED (ACTUAL AMOUNT SPENT)				AMMOUNT REMAINING	PROJECTED EXPENDITURE
		YEAR 1	YEAR 2	YEAR 3	TOTAL		
<u>Supplies</u>							
Printing and copying	\$400.00	\$270.00 (\$50.59)	\$130.00 (\$18.79)	\$330.62 (\$262.88)	\$400.00 (\$332.26)	\$67.74	\$67.74
Mailing/Postage	\$375.00	\$250.00 (\$0.00)	\$125.00 (\$45.22)	\$329.78 (\$160.23)	\$375.00 (\$205.45)	\$169.55	\$169.55
<u>Fees and software</u>							
Database	\$1,555.00	\$1,555.00 (\$0.00)	\$0.00 (\$1,555.00)	\$0.00	\$1,555.00 (\$1,555.00)	\$0.00	\$0.00
<u>Participant compensation</u>	\$6,500.00	\$3,300.00 (\$40.00)	\$3,200.00 (\$1,760.00)	\$4,700.00 (\$2,970.00)	\$6,500.00 (\$4,770.00)	\$1,730.00	\$1,730.00
<u>Personnel</u>							
Principle investigator	\$14,410.27	\$2,250.00 (\$1500.00)	\$2,250.00 (\$3,000.00)	\$0.00	\$4,500.00 (\$4,500.00)	\$0.00	\$0.00
Research assistant	\$1,670.00	\$835.00 (\$278.00)	\$835.00 (\$1392.00)	\$0.00	\$1,670.00 (\$1670.00)	\$0.00	\$0.00
Investigators	\$0.00	\$0.00 (\$0.00)	\$0.00	\$0.00	\$0.00 (\$0.00)	\$0.00	\$0.00
TOTAL: Original Proposal Progress Report	\$24,910.27	\$8,460.00 (\$1,868.59)	\$6,540.00 (\$7771.01)	\$5,360.40 (\$3,393.11)	\$15,000.00 (\$13,032.71)	\$1967.29	\$1967.29

a. Rationale for deviations

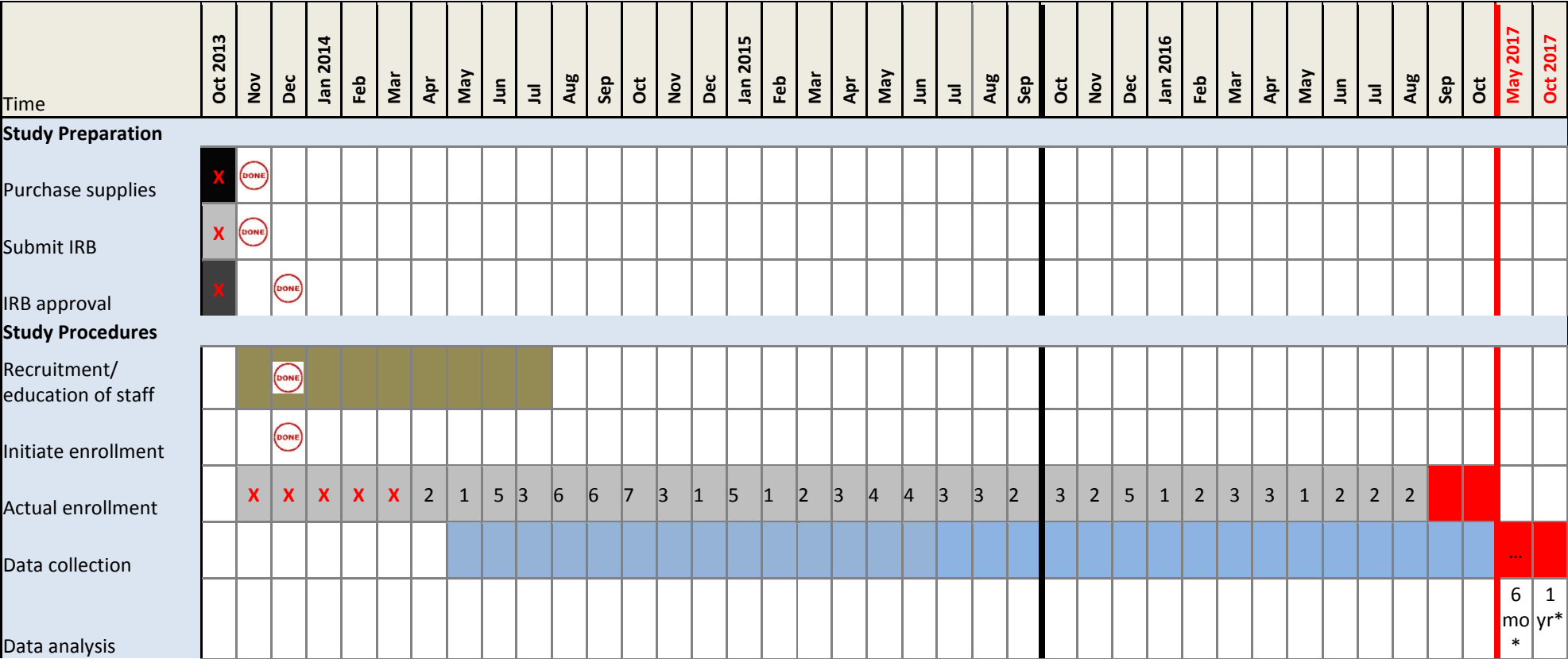
- i. Enrollment rate has been slower than originally projected which has shifted the cost burden for supplies and participant compensation from year 1 and 2 to years 2-4.

5. Objectives for the next year

- a. Continue marketing efforts to increase volume of patients with plantar heel pain at the Des Moines University Clinic and enhance participant recruitment. This will include weekly meeting and an email update to students rotating in the clinic, Clinical, and non-clinical staff.
- b. Continue to provide information to the community and promote the study via social media outlets to facilitate completion of enrollment recruitment.
- c. Complete enrollment (see **FIGURE 2** for projected timeline).
- d. Collect 6 week, 6 month, and 1 year outcome data.
- e. Continue to enter data into database
- f. Submit abstract to Combined Sections Meeting.
- g. Complete case series providing details of interventions in the ePT group.

6. Revised Timeline

FIGURE 2: Timeline including actual enrollment and projected enrollment from the first year progress report. Extended predictions for data enrollment and collection are indicated by the red-shaded cells. The extended enrollment period is based on the average enrollment to date. A red “X” indicates planned event/procedures that did not take place as anticipated. The bold, black vertical line represents the end of the original grant award period. The bold, red vertical line represents the end of the first 1 year no cost extension. The end of the graph would be the second 1 year no-cost extension. The fulfillment of this project as indicated by the below timeline is contingent upon a second 1 year no cost extension to include extension of remaining funding to complete the 1 year participant compensation.



*6mo and 1yr, refers to data analysis of the outcome data up to the indicated time frame (eg, 6 month will include data analysis of the 6 week and 6 month data).