

Orthopaedic Section of the APTA Grant Program Annual Progress Report Form

Date: 9/21/2015

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

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

Award Period: 5/28/2013 to 9/30/2015 (Initial award date – date on contract as start date)

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:

Please see pages 3-4 of this document.

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

Please see page 5 of this document.

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.

Please see page 5-6 of this document

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. (See example below)

EXPENSE CATEGORY	Budgeted Amount for Year 1	Actual Amount Spent in Year 1	Amount Remaining in Year 1 budget	Budgeted for Year 2	Projected Expenditure in Year 2
TOTAL					

Please see page 7 of this document.

5. Objectives for the next year:

Please see page 7 of this document.

Your Signature

Date

Return to:

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Orthopaedic Section of the APTA
Grant Program
Annual Progress Report: Year 2

Date: 9/21/2015

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

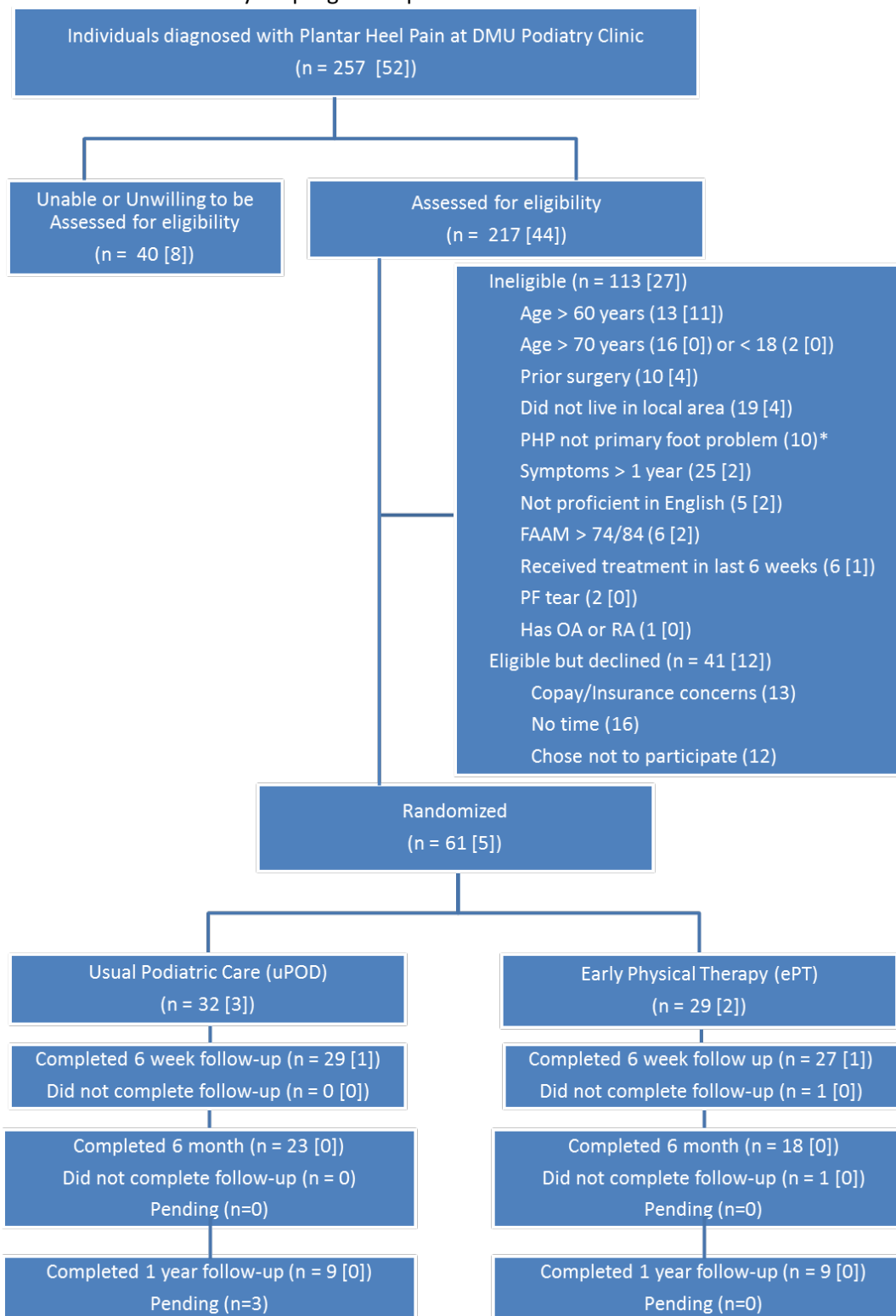
Award Date: 6/18/2013

Current Year of Award: 2

1. Summary of accomplishments in the past year:

- a. Patients screened daily from appointment lists and billing report.
- b. Increased enrollment from 5 to 61 (**FIGURE 1 and 2**).
- c. Collected data – participant completion of follow-ups has been dramatically better than predicted (only 3% have not completed follow-ups vs. 30% accounted for in power analysis)(**FIGURE 1**).
- d. Power analysis has been re-run using preliminary data and confirmed that the original sample determination was more than adequate (ie, N=84). Because of the completion rate of follow ups and confirmed power analysis, the enrollment can be reduced from 112 to 88 to expedite completion of the project.
- 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. Modifications made and approved by both IRBs
 - i. increased the upper limit of the age range from 60 to 70
 - ii. created and disseminated flyers to the local community
 - iii. created and used PHP website for recruitment <https://www.dmu.edu/dose/2015/01/heal-heel-pain-plantar-fasciitis/>
 - iv. used social media to direct individuals to the website and the podiatry clinic
- g. Marketing efforts have continued. In addition to the items in “b” above, flyers have been replenished in the community and presentations have been provided to the community (see “Presentations” below).
- h. Team building has continued with quarterly meetings with the Podiatry department (clinicians, staff, and students) to improve participant flow through the informational and enrollment process.

FIGURE 1. Participant enrollment flow diagram (December 9, 2013 – September 18, 2015). Brackets indicate numbers from the first year progress report.



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

*Compared to 1st progress report, only individuals confirmed to have PHP are counted in this category.

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

Currently, not enough data has been collected to produce an abstract. In addition a blind analysis is planned and therefore unable to be performed until all data is collected. The lay language summary previously submitted and included below 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.

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 SM, Cleland JC, Flynn TW. Predictors of response to physical therapy intervention for plantar heel pain: A secondary analysis of data from a randomized clinical trial. *Foot Ankle Int.* 2015;36(4):408-416. doi:10.1177/1071100714558508.

Submitted Manuscripts

Heiderscheit BC, McClinton SM. Evaluation and management of hip and pelvis injuries. Accepted for publication in *Phys Med Rehabil Clin N Am.*

McClinton SM, Collazo C, Vincent E, Vardaxis V. Intrinsic and Extrinsic Foot Muscle Performance and Association with Orthotic Use in Individuals with Plantar Heel Pain: A Matched Case-control Study. Submitted to *J Orthop Sports Phys Ther.*

Manuscript in final preparations

Phillips A, McClinton SM. Gait Deviations association with Plantar Heel Pain: A Systematic Review. In preparation for submission to *Clin Biomech*.

Published abstracts/CSM Platform Presentations

McClinton SM, Vincent E, Cleland JC, Flynn TW, Heiderscheid BC. Prevalence of low back pain in individuals with plantar heel pain: A retrospective case-control analysis [abstract]. *J Orthop Sports Phys Ther*. 2015;45(1):A22-A23.

McClinton SM, Cleland JC, Flynn TW. Investigation of age, body mass index, and symptom duration as predictors of response to physical therapy intervention for plantar heel pain: A retrospective cohort analysis [abstract]. *J Orthop Sports Phys Ther*. 2015;45(1):A23.

Platform Presentations

*Bartin E, McClinton SM. The Role of patient expectations in plantar heel pain treatment outcomes. Des Moines University Mentored Student Research Program. July 2015. †Selected for student keynote.

Poster Presentations

Wolf J, Rivera J, McClinton SM, Vardaxis V. *Differences in the kinematic breakdown of foot support pattern in patients with plantar fasciitis*. Des Moines University Research Symposium. December 2014.

Kindred K, Gardner J, Feilmeier M, McClinton SM. *Inter-rater reliability of ankle plantar flexor isokinetic testing*. Des Moines University Research Symposium. December 2014.

Phillips A, McClinton SM. *Gait deviations association with plantar heel pain: A systematic review*.

- Des Moines University Research Symposium. December 2014.
- Iowa Podiatric Medical Society Heartland Podiatry Conference. October 2014.

Presentations

*McClinton SM. *In Search of the Ideal Walking/Running Form: Considerations for the Everyday Walker and Endurance Athlete*. Wells Fargo. June 2015.

*McClinton SM. *Demystifying the Pieces of the Plantar Fasciitis Puzzle*. IPTA Fall Conference. November 2014.

*McClinton SM. *How to deal with plantar fasciitis that disrupts your exercise plans*. Des Moines University Clinic Power Hour Series. April 2014.

*McClinton SM. *Plantar heel pain: Physical therapist management considerations*. Rural Medicine Educational Pathway; Friday night lights. March 2014.

Accepted Conference Presentations

*McClinton SM. Interventions for the foot and ankle that don't stink: Evidence and hands-on application. Accepted at the Iowa Physical Therapy Association Fall Conference. November 2015.

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

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	TOTAL		
<u>Supplies</u>						
Printing and copying	\$400.00	\$270.00 (\$50.59)	\$130.00 (\$18.79)	\$400.00 (\$69.38)	\$330.62	\$330.62
Mailing/Postage	\$375.00	\$250.00 (\$0.00)	\$125.00 (\$45.22)	\$375.00 (\$45.22)	\$329.78	\$329.78
<u>Fees and software</u>						
Database	\$1,555.00	\$1,555.00 (\$0.00)	\$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)	\$6,500.00 (\$1,800.00)	\$4,700.00	\$4,700.00
<u>Personnel</u>						
Principle investigator	\$14,410.27	\$2,250.00 (\$1500.00)	\$2,250.00 (\$3,000.00)	\$0.00	\$0.00	\$0.00
Research assistant	\$1,670.00	\$835.00 (\$278.00)	\$835.00 (\$1392.00)	\$0.00	\$0.00	\$0.00
Investigators	\$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)	\$15,000.00 (\$9,639.60)	\$5360.40	\$5,360.40

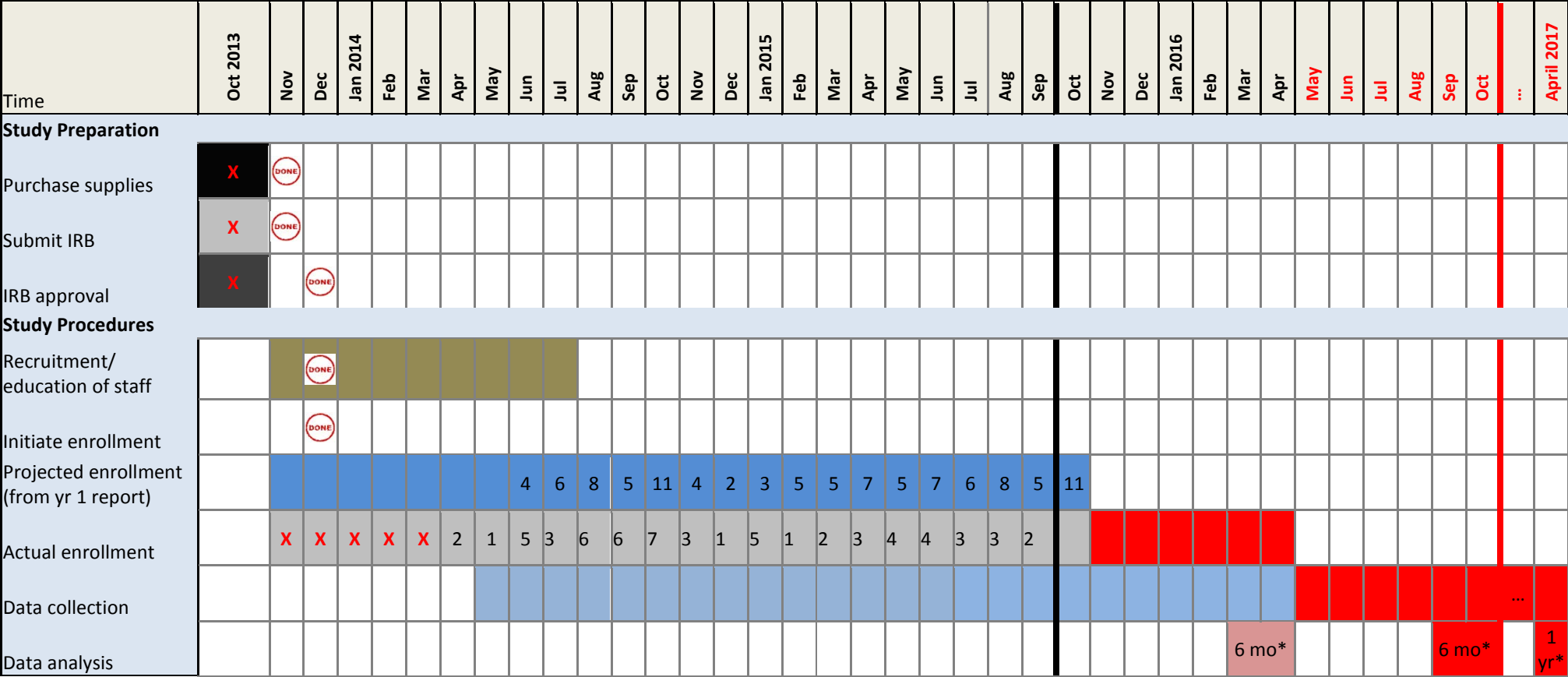
- a. Rationale for deviations
- i. Enrollment was lower than expected for the first year which has shifted the cost burden for supplies and participant compensation from year 1 to years 2 and 3.
 - ii. Because of the original end date of the grant (9/30/2015) is 4 months later than the month of the start date and therefore the first year period, the second year payment to personnel reflects payment over only 16 months.
 - iii. Minimal costs for supplies have taken place to date because of use of pre-existing supplies (envelopes, etc.). Additional costs are expected in this are to replenish existing supplies and to support reprinting of flyers and recruitment material.

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.
- b. Continue to provide information to the community about the study to facilitate participant 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 M.

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 a 1 year no cost extension. The fulfillment of this project as indicated by the below timeline is contingent upon a 1 year no cost extension and further extension or funding to complete the 1 year participant compensation. Based on projected enrollment and a June abstract date, the first presentation of results at CSM would be in year 2017.



*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).