

Orthopaedic Section of the APTA
Grant Program
Annual Progress Report

Date: 6/16/2014 (amended 7/08/2014)

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

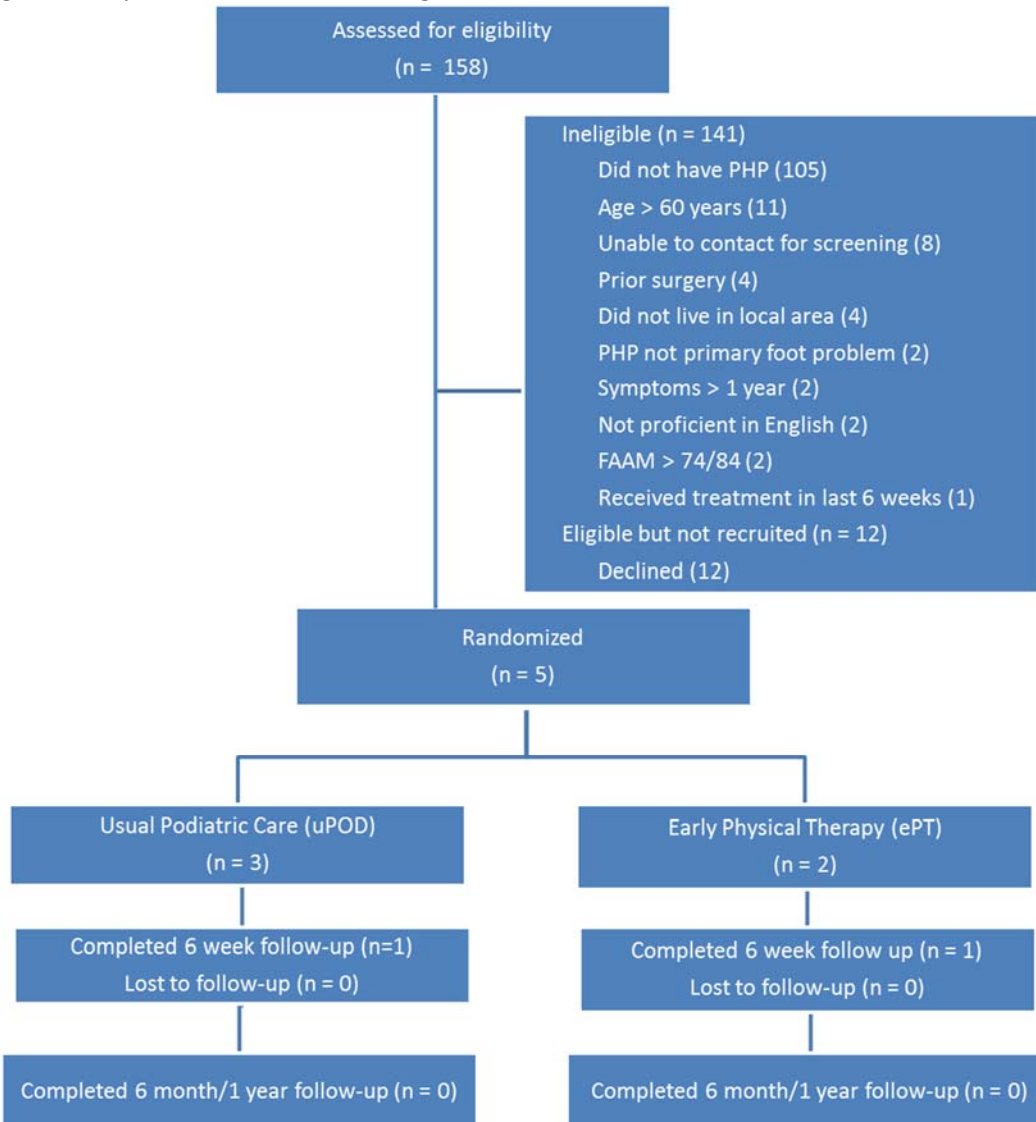
Award Date: 6/18/2013

Current Year of Award: 1

1. Summary of accomplishments in the past year:

- a. Protocol paper was written and published.
- b. Institutional Review Board approval was received from Des Moines University and Rocky Mountain University of Health Professions.
- c. Educated and trained support staff involved in patient recruitment.
- d. Educated and trained clinical staff that will provide treatment.
- e. Randomization process was created and tested.
- f. Participant recruitment efforts
 - i. Recruitment process was tested and implemented.
 - ii. Videos produced
 1. Marketing for plantar heel pain patients to access the Des Moines University Clinic
 2. Informational video about the study
 - iii. Informational flyer created and distributed
 - iv. Presentations provided, local newspaper and magazine advertisements were run, and information about plantar heel pain added to the Des Moines University website to increase visibility of the Des Moines University Clinic for treatment of plantar heel pain.

g. Participant enrollment flow diagram (December 9, 2013 – June 11, 2014)



Abbreviations: FAAM, Foot and Ankle Ability Measure; PHP, plantar heel pain

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. 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, 112 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

*McClinton SM, Flynn TW, Heiderscheid BC, et al. Comparison of usual podiatric care and early physical therapy intervention for plantar heel pain: study protocol for a parallel-group randomized clinical trial. *Trials*. 2013;14:414. doi:10.1186/1745-6215-14-414.

Manuscript in preparation

McClinton SM, Cleland J, Flynn TW. Investigation of age, body mass index, and duration of symptoms as predictors of response to physical therapy intervention for plantar heel pain: A retrospective cohort analysis.

Accepted abstracts

Vincent E, Collazo C, McClinton SM. Comparison of the modified paper grip test and rocker board test in individuals with and without plantar heel pain. Des Moines University Research Symposium. December 2013. †Winner of the best movement science poster.

Collazo C, Vincent E, McClinton SM. Reliability and minimal detectable difference of the modified paper grip test and rocker board test for clinical assessment of foot and lower leg muscle performance. Des Moines University Research Symposium. December 2013.

Submitted abstracts

McClinton SM, Cleland J, 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. Submitted for platform presentation at the APTA Combined Sections Meeting, February 2015.

McClinton SM, Vincent E, Cleland J, Flynn TW, Heiderscheid BC. Prevalence of low back pain in individuals with plantar heel pain: A retrospective case control analysis. Submitted for platform presentation at the APTA Combined Sections Meeting, February 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 2-3	TOTAL		
<u>Supplies</u>						
Printing and copying	\$400.00	\$270.00 (\$50.59)	\$130.00	\$400.00	\$219.41	\$349.41
Mailing/Postage	\$375.00	\$250.00 (\$0.00)	\$125.00	\$375.00	\$250.00	\$375.00
<u>Fees and software</u>						
Database	\$1,555.00	\$1,555.00 (\$0.00)	\$0.00	\$1,555.00	\$1,555.00	\$1555.00
<u>Participant compensation</u>	\$6,500.00	\$3,300.00 (\$40.00)	\$3,200.00	\$6,500.00	\$3,260.00	\$6460.00
<u>Personnel</u>						
Principle investigator	\$14,410.27	\$2,250.00 (\$1500.00)	\$2,250.00	\$4,500.00	\$750.00	\$3,000
Research assistant	\$1,670.00	\$835.00 (\$278.00)	\$835.00	\$1,670.00	\$557.00	\$1392
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	\$15,000.00	\$6591.00	\$13,131.41

a. Rationale for deviation

- i. Enrollment has been lower than expected which has shifted the cost burden for supplies and participant compensation from year 1 to year 2. In addition, efforts in year 1 have been focused on enrollment and therefore database development has been shifted to year 2.
- ii. Payment to personnel reflects payment over only 8 months due to time required to receive IRB approval from both institutions. Payment of personnel for only 8 months during year 1 also allows funds to be distributed over the entire award period projected through 9/30/2015.

5. Objectives for the next year

- a. Conduct marketing to increase volume of patients with plantar heel pain at the Des Moines University Clinic and enhance participant recruitment.
- b. Provide information to the community about the study to facilitate participant recruitment.
- c. Collect 6 week and 6 month outcome data.
- d. Create and test database.
- e. Perform preliminary data analysis once at least 30% of the sample is acquired.
- f. Submit abstract to at least 1 APTA national conference.

6. Methods to increase subject recruitment

- a. Increase the upper limit of the age range from 60 to 70 to capture individuals who consume the majority of visits because of plantar fasciitis based on further observations of clinic census and reports of similar findings.¹ Based upon clinic numbers to date, this will increase the number of participants with PHP who are eligible by 20%.
- b. Marketing efforts are underway to increase the volume of patients with plantar heel pain seen at the Des Moines University Clinic. Marketing is taking place through social media, web and newspaper articles/advertisements, and recent release of a video. Flyers have been created and are currently being distributed in the local community in addition to major corporations in the area. In addition, I will be offering to present on the topic of plantar fasciitis to local corporations and offering interested individuals the opportunity to enroll in the study.
- c. Team building will continue on a monthly basis with the Podiatry department to improve participant flow through the informational and enrollment process. This will include more meetings with the providers, clinical staff, and students who are regularly rotating through the Podiatry department. It is anticipated that these efforts will help to increase the recruitment rate.
- d. The increased recruitment rate through increased number of individuals eligible and Podiatry department team building in addition to increased volume of PHP patients will increase the number of participants enrolled in the study as depicted in the timeline below (**FIGURE**).

REFERENCE

1. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. *Foot Ankle Int.* 2004;25(5):303-310.