Predictors of Response to Physical Therapy Intervention for Plantar Heel Pain: A Secondary Analysis of Data from a Randomized Clinical Trial.

<table>
<thead>
<tr>
<th>Journal:</th>
<th>Foot &amp; Ankle International</th>
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<tr>
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<td>Manuscript Type:</td>
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<td>Exercise, Manual Therapy, Obese, Plantar Fasciitis, Prognosis</td>
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</table>

**Background:** Age, weight, and duration of symptoms have been associated with a poor response to treatment for plantar heel pain (PHP), but have not been examined in response to physical therapy (PT) intervention. The purpose of this investigation was to examine the influence of age, body mass index (BMI), and symptom duration on treatment response to PT intervention.

**Methods:** Sixty participants received 6 sessions of PT intervention over 4 weeks that included manual therapy and exercise or electrophysiological agents and exercise. Outcomes were assessed at 6 months using the Foot and Ankle Ability Measure (FAAM), Numeric Pain Rating Scale (NPRS), and Global Rating of Change Scale (GRC). Logistic regression was used to analyze age, BMI, and symptom duration as predictors of a successful response based on minimal clinically important changes in the FAAM, NPRS and GRC, or only the FAAM and NPRS.

**Results:** Improvement in NPRS was 3 points (95% CI; 2.4, 3.6) and FAAM improved by 22.5 points (95% CI; 16.8, 28.2). Individuals with symptoms less than 7.2 months were 4.2 (95% CI; 1.3, 13.8; p=.016) and 8.5 (95% CI; 2.5, 28.9; p=.001) times more likely to respond based on the NPRS/FAAM/GRC, and NPRS/FAAM success criteria, respectively. Age and BMI were not significant predictors.

**Conclusion:** Body mass was not associated with outcomes and obese individuals can achieve clinical success with the PT intervention used in the clinical trial. Individuals with PHP symptoms longer than 7 months require additional consideration and further investigation of effective strategies to improve treatment response.
Predictors of Response to Physical Therapy Intervention for Plantar Heel Pain: A Secondary Analysis of Data from a Randomized Clinical Trial.

Abstract

Background: Age, weight, and duration of symptoms have been associated with a poor response to treatment for plantar heel pain (PHP), but no studies were identified that examined predictors of response to physical therapy intervention. The purpose of this investigation was to examine the influence of age, body mass index (BMI), and symptom duration on treatment response to physical therapy intervention.

Methods: Sixty participants received 6 visits over 4 weeks of physical therapy intervention that included manual therapy and exercise or electrophysiological agents and exercise. Outcomes were assessed using the Foot and Ankle Ability Measure (FAAM), Numeric Pain Rating Scale (NPRS), and Global Rating of Change Scale (GRC). Logistic regression (p<.05) was used to analyze age, BMI, and symptom duration as potential predictors of a successful response based on the minimal clinically important difference of the outcome measures. Sensitivity analysis was used to assess the influence of success based on minimal clinically important changes in the FAAM, NPRS and GRC, or only the FAAM and NPRS. Receiver operating curves were used to determine the cut point for the significant predictor.

Results: At the 6 month follow-up to physical therapy intervention, NPRS was improved by 3 points (95% CI; 2.4, 3.6) and FAAM improved by 22.5 points (95% CI; 16.8, 28.2). Individuals with symptoms less than 7.2 months were 4.2 (95% CI; 1.3, 13.8; p=.016) and 8.5 (95% CI; 2.5, 28.9; p=.001) times more likely to
respond to treatment based on the NPRS/FAAM/GRC, and NPRS/FAAM success criteria, respectively. Age and BMI were not significant predictors (p ≥ .455 and p ≥ .450, respectively).

**Conclusion:** Age and BMI were not associated with outcomes and obese individuals did achieve a successful outcome with the physical therapy intervention used in the clinical trial. Individuals with PHP symptoms longer than 7 months require additional consideration and further investigation of effective strategies to improve treatment response.

**Level of Evidence:** Prognosis, level 2b

**Key Words:** Plantar Fasciitis, Prognosis, Obese, Manual Therapy, Exercise.

**Introduction**

Plantar heel pain (PHP), commonly referred to as plantar fasciitis, is a frequently occurring foot condition that results in disability and limited function in work, recreation, and daily activities. While plantar fasciitis has been reported as the most common cause of plantar heel pain, the term plantar heel pain is inclusive of other pathological and painful conditions of the plantar fascia and heel that are often difficult to discriminate via history and physical examination. Individuals with PHP incur approximately 800,000 to 1 million visits to physicians annually at an estimated cost of 192 to 376 million US dollars. In addition to physician visits, PHP was the most prevalent condition treated by podiatrists and the most common foot condition seen by physical therapists. Conservative (ie, non-surgical and non-extracorporeal shock wave therapy)
interventions are advocated initially to manage PHP and most patients respond positively to treatment.\textsuperscript{13, 42, 48, 61} Despite improvement in most who are treated conservatively for PHP, approximately 18-50\% of individuals continue to have symptoms after conservative treatment and 30\% have recurrent symptoms.\textsuperscript{5, 15, 39, 67}

Incomplete recovery or failure to respond to conservative treatment may be attributed to patient characteristics that affect treatment response. Age, body mass, and duration of symptoms have been identified as characteristics associated with a reduced response to conservative treatment for plantar heel pain (PHP).\textsuperscript{21, 30, 39, 51, 67} Recently, a randomized clinical trial demonstrated clinically meaningful improvement following multi-modal physical therapy intervention for PHP,\textsuperscript{8} but did not analyze the influence of age, body mass, or duration of symptoms on treatment response. No other evidence was found to indicate factors associated with treatment response to multi-modal physical therapy intervention. Knowledge of factors that can potentially affect outcome can help identify individuals less likely to respond to physical therapy intervention. Once identified, additional research can focus on strategies that may be more effective for subgroups of nonresponders and help to reduce the incidence of persistent or recurrent symptoms in individuals with PHP. Therefore, the purpose of this investigation was to identify if age, body mass, or symptom duration were predictors of outcome to physical therapy intervention in individuals with PHP.

Materials and Methods
Participants

The study population included 60 individuals who participated in a randomized clinical trial between October 2006 and January 2008. Participants included patients with PHP between the ages of 27 and 63 years that presented to physical therapy at 1 of 2 outpatient orthopaedic physical therapy clinics. The diagnosis of PHP was based on pain localized to at the medical calcaneal tubercle and pain worsened with during the first few steps in the morning after waking. Clinical presentation without additional imaging was not used to further discriminate the pathological conditions associated with the clinical presentation of PHP studies. Patients with precautions to manual therapy interventions (ie, tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, severe vascular disease, etc), prior surgery to the distal tibia, fibula, ankle joint, or rearfoot region (proximal to the base of the metatarsals), insufficient English proficiency to complete questionnaires, or inability to comply with treatment and follow-up schedules were excluded. Prior to participating in the clinical trial, patients reviewed and signed a consent form approved by The Human Investigations Committee, XXXXXX and the XXXXXX prior to participation in the clinical trial.

Measures

All participants in the clinical trial completed a standardized baseline examination at the outset that recorded age, sex, duration of symptoms, body mass index (BMI), and use of medications. In addition, the activities of daily living subscale of the Foot and Ankle Ability Measure (FAAM), the Lower Extremity Functional Scale (LEFS), the Beck Anxiety Index (BAI), and the 3-item (current, best, worst pain) Numeric Pain Rating Scale (NPRS) were completed at
baseline, 4 weeks, and 6 months after initiation of treatment. Also, the Global Rating of Change Scale (GRC) was completed at 4 weeks and 6 months after baseline. For the purpose of this secondary analysis, the variables selected included age, duration of symptoms, BMI, FAAM, NPRS, and GRC. The FAAM consists of 21 questions about the difficulty (range; 0 = unable to do, through 4 = no difficulty) of daily tasks due to foot and ankle problems. The total score is divided by the highest possible score and multiplied by 100, where 0 = no functional ability and 100 = highest state of functional ability. The FAAM has demonstrated content and context validity, an intraclass correlation coefficient (ICC) of 0.89, and a minimal clinically important difference (MCID) of 8 points. An 11-point NPRS, where 0 = no pain and 10 = worst imaginable pain was used to capture pain intensity. The NPRS with 3-items has demonstrated validity, a test-retest reliability of 0.61 to 0.88 and a MCID of 2 points. The GRC is a single item questionnaire that ranks patient-perceived improvement between −7 (a very great deal worse) to 0 (about the same) to +7 (a very great deal better). Scores of +5 (quite a bit better) have been used as an indicator of clinical success.

Procedures

Complete details of the clinical trial procedures are described by Cleland et al. Participants received 6 visits over 4 weeks of physical therapy intervention that included manual therapy and exercise or electrophysiological agents and exercise. Both groups received exercises that included stretching and self-mobilization of the plantar fascia, calf stretching with the knee flexed and extended, and ankle eversion self-mobilization. All patients were instructed to perform all activities of daily living that did not increase symptoms and to avoid...
aggravating activities. In the group that received manual therapy, intervention was based upon patient-specific impairments in the hip, knee, lower leg, ankle, and foot regions. Manual therapy included joint mobilization or manipulation to the aforementioned areas and soft tissue mobilization to the plantar fascia and flexor hallicus longus. In the group that received electrophysiological agents, ultrasound (3 MHz, 1.5 W/cm², 100-Hz, 20% duty cycle, 5 minute duration) was performed to the involved area followed by iontophoresis with dexamethasone (40 mA-min dose). Thirteen patients were taking anti-inflammatory medication at the start of the study and were instructed to continue usage as prescribed by their physician. Patients were limited to intervention provided within the clinical trial and did not receive any other intervention; eg, injections, night splints, anti-inflammatory medication (other than that taken prior to outset of the study), or immobilization were not utilized. Both groups were collapsed into one to determine response to physical therapy intervention that included exercise and modalities or exercise and manual therapy. The FAAM, LEFS, BAI, NPRS, and GRC were administered at 4 weeks and 6 months after the start of treatment.

Statistical Analysis

All data analyses and imputations were performed using SPSS, Version 22.0 (SPSS Inc., Chicago, IL, USA). Despite significant difference in outcomes between the 2 physical therapy intervention groups, significant, and clinically meaningful, improvement was observed in both groups. Therefore, to provide the most comprehensive analysis that included all responders to physical therapy intervention, participants from both treatment groups were included in the analysis consistent with multivariate prognostic modelling recommendations and procedures used by other responder analyses of randomized clinical trials.
This type of analysis allows a detailed analysis of whether age, body mass, or symptom duration should alter the decision to manage PHP with physical therapy interventions. Less than 12% of the original data was missing for the variables used in this investigation. Multiple imputation procedures were used to handle missing values after analysis of the missing data and observed absence of monotonicity. Five imputed data sets were generated using the Markov Chain Monte Carlo method and pooled estimates from the multiple imputations were used when reporting data. Patient characteristics and outcome variables were summarized using the mean and standard deviation for continuous measures and the frequency and percentages for categorical measures (Table 1).

Standard logistic regression (p < .05) was used to analyze age, BMI, and symptom duration as predictors of successful treatment response based on the minimal clinically important difference (MCID) of the outcome measures. Predictor variables were tested for multicollinearity and demonstrated variance inflation factor values greater than 10 and tolerance values less than 0.10 in all imputed data sets. A sensitivity analysis was conducted using 2 criteria to define successful response to physical therapy intervention. In the first scenario, participants were defined as having a successful response if they exceeded MCID thresholds for 3 outcome measures (NPRS, 2 points; FAAM, 8 points; and GRC, +5 or greater) at the 6 month follow-up similar to procedures used by Cleland et al. In the second scenario, successful response was defined only using the MCID of the NPRS and FAAM. Recent evidence has demonstrated concerns regarding the validity and stability of the GRC and therefore both analyses were conducted to assess the influence of a successful response criterion that does not include the GRC. Receiver operating curves were
used to determine the cut point for the significant predictor and the Nagelkerke $R^2$ was used to describe the amount of variation explained by the significant predictor. The odds ratio (95% CI) was reported to indicate the odds of a successful response to treatment based on the determined cut point of the significant predictor. Sensitivity, specificity, and positive and negative likelihood ratio values were calculated for the predictor variable. In addition, MANCOVA and Chi-square tests were used to compare the FAAM, NPRS, and GRC between individuals above and below the cut point for the significant predictor using baseline scores as the covariate.

Separate post hoc power analyses for logistic regression analyses were performed using G*Power 3.1.6 using the observed odds ratio, $\Pr(y = 1 \mid x = 1)$ H0 calculated from classification tables and $R^2$ obtained from both response criteria analyses, and $\alpha = .05$.  

Results

The characteristics of the sample included middle-aged participants who were, on average, obese (Table 1). Mean changes in NPRS and FAAM scores in response to physical therapy intervention at the 6 month follow-up exceeded the MCID of 2 and 8 points, respectively (Table 1). Also, the lower confidence interval of the FAAM and NPRS change score exceeded the MCID. In addition, 67% of participants reported a GRC of +5 (quite a bit better) or greater. The sensitivity analysis demonstrated different frequencies of successful response between the 2 criteria used. The NPRS/FAAM/GRC criteria resulted in 29 cases deemed a successful response and the NPRS/FAAM criteria defined a
successful response in 38 cases (Table 1). Duration of symptoms was the only significant predictor in logistic regression analyses using the NPRS/FAAM/GRC and the NPRS/FAAM criteria. Age and BMI were not significant predictors (p ≥ .455 and p ≥ .450, respectively) of successful treatment response. Analysis of the receiver operating curves for symptom duration identified a cut-point of 218 days (ie, 7.2 months) for both successful response criteria. Individuals with symptoms less than 7.2 months were 4.2 (p = .016) and 8.5 (p = .001) times more likely to respond to treatment based on the NPRS/FAAM/GRC, and NPRS/FAAM success criteria, respectively (Table 2). Sensitivity, specificity, and positive and negative likelihood ratio values for the accuracy of symptoms less than 7.2 months to predict a positive response to physical therapy intervention are listed in Table 2. Using the response rate of the sample and calculated likelihood ratios (Tables 1 and 2), the probability of successful response to physical therapy intervention if symptoms were present less than 7.2 months increased from 48% to 68% (95% CI 52, 81) using the NPRS/FAAM/GRC criteria and from 63% to 83% (95% CI 70, 91) using the NPRS/FAAM criteria. Differences in the FAAM, NPRS, and GRC between individuals with symptoms less than, and greater than, 7.2 months are provided in Table 3.

For the logistic regression analysis using the NPRS/FAAM/GRC criteria, the Nagelkerke $R^2$ ranged from 0.117 to 0.181 in the 5 imputed data sets and indicated that duration of symptoms predicted 18.1% of the variation, at best. The Nagelkerke $R^2$ using the NPRS/FAAM criteria range between 0.258 to 0.326 and therefore duration of symptoms explained 32.6% of the variation, at best.

Results of post-hoc power analysis indicated a power of 0.97 for the analysis including the NPRS/FAAM/GRC criteria and a power of 0.99 using the NPRS/FAAM criteria.
Discussion

In the clinical trial, 48% to 63% of individuals with PHP demonstrated a successful response to 6 sessions of multi-modal physical therapy intervention conducted over 4 weeks. If PHP symptoms were present for less than 7.2 months, the probability of a successful response increased to 68% and 83% for the NPRS/FAAM/GRC and NPRS/FAAM criteria, respectively. There were no other investigations found that examined success to intervention for PHP based upon the 2 criteria used in this investigation. The criteria and rate of success to conservative intervention for PHP varies widely between studies making direct comparison difficult. Some investigations have reported success rates ranging from 44% to 89% based upon patient reports of improvement of symptoms, no pain, total/100% relief, resolution of symptoms, good to excellent results, or 80% relief of symptoms. Other investigations have used outcome instruments to define success that included an 11-point visual analog scale (VAS) less than 5, GRC greater than +4, GRC greater than +5, or FAAM change greater than 8 points and have reported success rates ranging from 45% to 80%. When looking at the success rates of individual measures from the clinical trial (Table 1), rates of success were similar to other investigations that demonstrated 80% success based on FAAM change greater than or equal to 8 and 70% success based on GRC greater than or equal to +5. While no responder criteria was found to determine the cut point for successful response in individuals with PHP, responder criteria based on multiple measurement domains including pain, function, and patient's global rating of change has been developed and used in other populations. The
successful response criteria used in this investigation was chosen to minimize the possibility of deeming a response successful based on only 1 domain of response to treatment where unsuccessful responses may still be observed in other domains. As a result, the success rates observed in this investigation may be lower than investigations using only 1 measure to determine success. In addition to using criteria involving 3 measures of response to treatment, a parallel analysis was conducted only using the NPRS and FAAM criteria. While the NPRS/FAAM/GRC and NPRS/FAAM criteria produced similar results in logistic regression analysis, the NPRS/FAAM analysis resulted in an increased success rate and a higher odds ratio associated with the predictor variable. The increased success rate and odds ratio is likely attributed to the lower standards to achieve success in the NPRS/FAAM criteria; ie, 2 versus 3 measures used as the cut point for successful response. Despite evidence that the GRC lacked correlation with functional change measures, GRC may represent an important treatment response construct worthy of consideration when determining treatment success. In this study, a more conservative estimate of successful response to treatment was obtained when the GRC was added to the pain and function measures compared to the pain and function measures alone. Further consensus is needed to improve consistency in reporting of response to PHP conservative treatment so that better comparisons can be made between investigations.

A successful response to physical therapy intervention was found in this analysis despite a sample that included individuals who, on average, were obese (Table 1). Furthermore, high BMI was not a predictor of poor response to treatment in the logistic regression analysis. Previously, increased weight or obesity had been associated with an increased risk of PHP. In addition,
individuals who are overweight or obese were reportedly less responsive to conservative treatment for PHP. Because PHP often limits weight-bearing exercise, individuals with PHP are less able to use exercise to manage their weight. The results of this analysis are promising in that individuals who are overweight or obese can have a successful response to physical therapy intervention for PHP allowing them to reap the benefits of weight-bearing exercise.

Increased age is another factor that has been associated with PHP and decreased response to conservative treatment. In this analysis, age was not a significant factor that predicted successful response to treatment, but this sample was limited to individuals between the ages of 27 – 63. Because of the limited age range of this sample, it is unclear if individuals greater than 63 years of age have a different rate of success than individuals less than 63 years old. Approximately 15% of individuals with PHP are greater 65 years or older and therefore it is important to identify successful interventions for PHP in older adults.

The results of this analysis indicated that individuals with PHP symptom duration less than 7 months were more likely to respond to the physical therapy intervention included in the clinical trial. Two other studies were found that reported a reduced response to conservative intervention for PHP if symptoms were present for a longer duration; ie, 12 or more months. In a telephone survey of 100 patients treated conservatively by 3 orthopaedic surgeons, a good result (defined as no symptoms) was achieved in 14/22 (64%) with symptoms for 12 or more months compared to 68/78 (87%) with symptoms less than 12 months (p < .003). Conservative treatment was case-specific and included stretching, cushion or hard shoe inserts, anti-inflammatory medication or
injections, ice or heat, heel cup, night splint, or foot strapping. Similarly, in a mailed follow-up survey to 157 PHP patients that received conservative treatment from one orthopaedic surgeon, patients with symptoms greater than 12 months were less likely to have a good outcome defined as no pain (p < .04).\(^{39}\) Conservative treatment included anti-inflammatory medication or injection, night splint, at least one session of exercise instruction provided by a physical therapist, and a custom orthosis or heel cup. In the clinical trial that provided the sample for this analysis, patients received physical therapy intervention that included stretching and self mobilization exercises to the lower leg, ankle, and foot in addition to manual therapy or electrophysiological modalities. Despite the different conservative treatments provided to the participants that formed the sample for this analysis and in other studies that demonstrated reduced response with longer symptom duration, symptom duration appears to be a significant prognostic factor to consider in the conservative management of individuals with PHP.

Individuals with longer symptom duration may develop different pain mechanisms that contribute to their PHP experience and response to treatment. Individuals with a longer duration of pain demonstrated maladaptive psychosocial factors consistent with a central sensitization versus nociceptive pain mechanism.\(^{60}\) The reduced treatment response associated with longer duration of PHP symptoms and evidence of lower foot function in PHP patients with higher stress and depression indicates the potential for central sensitization mechanisms in patients with a longer duration of PHP.\(^ {12}\) Therefore, clinical reasoning models that integrate intervention with consideration of pain mechanism and clinical presentation may benefit individuals with longer PHP symptoms. Therapeutic pain neuroscience education is one intervention that is
recommended in the presence of central sensitization and has demonstrated positive effects on pain, disability, anxiety and stress in chronic musculoskeletal pain conditions. No evidence was found on the effects of therapeutic pain neuroscience education in individuals with PHP although a clinical trial is underway that includes this as one part of the conservative management plan.

In addition to therapeutic pain neuroscience education, other interventions directed at proximal inputs to PHP through central or peripheral neurodynamic mechanisms; eg, myofascial trigger points, may be of additional benefit. Myofascial trigger point manual and dry needling intervention has demonstrated significant improvement of PHP, pain pressure thresholds, and foot-related function. In investigations of myofascial trigger point therapy on PHP, only Cotchett et al included a sample of participants with an average duration greater than 7 months. Further research is needed to identify factors related to longer duration of PHP and to test the effects of pain neuroscience education and myofascial trigger point intervention on chronic PHP.

The results of this analysis indicated that symptom duration was a significant predictor of response to physical therapy intervention for PHP. While, the results of this analysis provide evidence of an improved response with a shorter duration of symptoms and a lesser response with a longer duration of symptoms, caution is warranted in generalizing the results. As indicated in Table 3, individuals with symptoms longer than 7 months had higher functional scores on the FAAM and lower pain on the NPRS at baseline that may have limited potential for improvement. Conversely, individuals with a lower duration of symptoms had lower functional scores and higher pain scores at baseline which may have contributed to greater potential for improvement. Therefore, because the responder criteria were based on the magnitude of response; ie, the MCID of
outcome measures, the effect of duration determined from logistic regression
may have been affected by the baseline differences between individuals above
and below the 7 month duration cut point. Despite the statistical significance that
demonstrated greater odds of successful outcome in individuals with symptoms
less than 7 months, clinically meaningful changes were also observed in
individuals with symptoms greater than 7 months based on the MCID of the
NPRS and FAAM (Table 3). In addition, an equal proportion of individuals with
symptoms greater and less than 7 months demonstrated GRC of +5 or greater
(Table 3). While further research is warranted to examine effective solutions in
individuals with a longer duration of symptoms, the physical therapy intervention
provided in this clinical trial resulted in clinically-meaningful changes regardless
of symptom duration and was still effective in individuals with symptoms greater
than 7 months.

In addition to duration of symptoms, there may be other factors that were
not recorded during the clinical trial or considered in this analysis that may
predict successful treatment response. Symptom duration explained 11.7 to
32.6% of the variation in the data, and therefore other factors are likely to
contribute to the remaining variability in treatment response. Few studies were
found that investigated factors related to response to conservative treatment
other than age, BMI, and symptom duration. Several other factors derived from
the history and physical examination including foot posture/mobility, ankle or
hallux dorsiflexion, daily weight-bearing duration, lower leg/foot strength,
neurodynamic dysfunction, stress, depression, and low back pain have
demonstrated an association with PHP or foot function and may contribute to the
response to physical therapy intervention. Additional
information derived from imaging including heel pad energy dissipation ratio,
hyperemia, thickened plantar fascia, and heel spurs may also contribute to prediction of response to treatment. While the historical, physical examination and imaging factors listed above may occur more commonly in some populations of PHP, they are also present in asymptomatic individuals and the impact of these factors on clinical management including prediction of successful response requires further investigation.

Conclusion

Individuals with PHP for less than 7 months were more likely to respond to the physical therapy interventions provided in the clinical trial, but age and BMI were not predictive of treatment response. Despite the improved response of individuals with symptoms less than 7 months, some individuals with symptoms greater than 7 months were still able to demonstrate clinically meaningful changes in response to physical therapy intervention. Participants in this trial were obese based on the average BMI, yet were responsive to physical therapy intervention despite previous reports of the associations of obesity with PHP and a poor treatment response. The upper age range in this sample was limited and further analysis is needed to assess the influence of age on treatment response in individuals greater than 63 years old. Further research is needed to elucidate additional strategies effective for PHP lasting longer than 7 months and matched to individual patient characteristics and preferences.

References


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Table 1: Participant characteristics and outcome measures at baseline and the 6 month follow-up (mean ± SD or frequency (%); n=60).

<table>
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<th>Variable</th>
<th>Baseline</th>
<th>6 month</th>
<th>Difference (95% CI)</th>
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<tr>
<td>Age in years (range)</td>
<td>48 ± 9 (27 - 63)</td>
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<tr>
<td>Female participants (%)</td>
<td>33 (55)</td>
<td>-</td>
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<tr>
<td>BMI in kg/m²</td>
<td>31.9 ± 7.5</td>
<td>-</td>
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<tr>
<td>Duration of symptoms in days</td>
<td>271.6 ± 212.7</td>
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<td>-</td>
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<td>NPRS</td>
<td>4.7 ± 1.7</td>
<td>1.7 ± 1.82</td>
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<td>Change ≥ 2 points (%)</td>
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<td>42 (70)</td>
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<td>FAAM</td>
<td>57.5 ± 14.9</td>
<td>80 ± 16.5</td>
<td>22.5 (16.8, 28.2)</td>
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<td>Change ≥ 8 points (%)</td>
<td>-</td>
<td>46 (77)</td>
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<tr>
<td>GRC ≥ +5 (%)</td>
<td>-</td>
<td>40 (67)</td>
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<tr>
<td>Successful response (%)</td>
<td></td>
<td></td>
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<tr>
<td>NPRS/FAAM/GRC criteria</td>
<td>-</td>
<td>29 (48)</td>
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<tr>
<td>NPRS/FAAM criteria</td>
<td>-</td>
<td>38 (63)</td>
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Abbreviations: BMI, body mass index; FAAM, Foot and Ankle Ability Measure; GRC, Global Rating of Change; NPRS, Numeric Pain Rating Scale.

Table 2: Odds ratio, sensitivity, specificity, and positive and negative likelihood ratio values of symptom duration less than 7.2 months as a predictor of successful response to physical therapy intervention.

<table>
<thead>
<tr>
<th>Successful response criteria</th>
<th>Odds Ratio (95% CI)</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>+ LR (95% CI)</th>
<th>- LR (95% CI)</th>
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<tr>
<td>NPRS/FAAM/GRC</td>
<td>4.2 (1.3, 13.8)</td>
<td>0.58 (0.41, 0.74)</td>
<td>0.75 (0.57, 0.87)</td>
<td>2.3 (1.2, 4.7)</td>
<td>0.56 (0.35, 0.89)</td>
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<td>NPRS/FAAM</td>
<td>8.5 (2.5, 28.9)</td>
<td>0.76 (0.6, 0.87)</td>
<td>0.73 (0.52, 0.87)</td>
<td>2.8 (1.4, 5.6)</td>
<td>0.33 (0.18, 0.62)</td>
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Abbreviations: FAAM, Foot and Ankle Ability Measure; GRC, Global Rating of Change; LR, likelihood ratio; NPRS, Numeric Pain Rating Scale.
Table 3: Outcome comparison of individuals with symptom duration above and below the 7.2 month cut point (mean ± SD or frequency (%); n=60). The p-values indicate the lowest value from MANCOVA for all imputed data sets unless otherwise indicated.

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Symptoms &lt; 7.2 months (n=35)</th>
<th>Symptoms &gt; 7.2 months (n=25)</th>
<th>Difference (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
</table>
| **FAAM**
  Baseline       | 53.3 ± 15.4                   | 63.2 ± 15                     | 9.9 (1.9, 18)       | <.001   |
  6 month         | 82 ± 17.2*                    | 77.2 ± 17.5*                  | 4.8 (4.3, 13.9)*    | > .19*  |
  Change score    | 24.5 ± 17.2*                  | 19.6 ± 17.5*                  | 4.4 (4.7, 13.5)*    | > .19*  |
| **NPRS**
  Baseline       | 5.5 ± 1.6                     | 3.7 ± 1.5                     | 1.8 (1, 2.6)        | <.001   |
  6 month         | 1.4 ± 2.2*                    | 2.1 ± 2.1*                    | 0.7 (1.8, 0.4)*     | > .08*  |
  Change score    | 4 ± 2.2*                      | 1.7 ± 2.1*                    | 2.3 (1.2, 3.4)*     | > .08*  |
| **GRC (%)**
  6 month        | 25 (68.6)                     | 16 (64)                       | -                   | > .36†  |

Abbreviations: FAAM, Foot and Ankle Ability Measure; GRC, Global Rating of Change; NPRS, Numeric Pain Rating Scale.

*Adjusted for baseline score.
†Calculated via Chi-square test.
Reviewer #1:

I'm still not satisfied with what disease state is being treated in this study. Plantar heel pain is not always plantar fasciitis. No imaging was attempted to discern a diagnosis outside of "plantar heel pain".

RESPONSE

In response to this comment and suggestions of the Associate Editor, the inclusion/exclusion criteria have been more explicitly defined in the Materials and Methods section.

In addition, further details have been added to the Introduction to provide upfront clarification that plantar fasciitis is one of many potential reasons for plantar heel pain, but is not the only condition that produces plantar heel pain.

Additional limitations were added at the end of the discussion to include consideration of factors that would be identified by imaging.

<table>
<thead>
<tr>
<th>COMMENT</th>
<th>RESPONSE</th>
<th>TEXT CHANGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
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<td>Please see response above. Please see text changes indicated above.</td>
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<td>Methods</td>
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<td>Please see response above. Please see text changes indicated above.</td>
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<td>Results</td>
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Discussion

I'm still not satisfied with what disease state is being treated in this study. Plantar heel pain is not always plantar fascitis. No imaging was attempted to discern a diagnosis outside of "plantar heel pain".

Conclusion

I'm still not satisfied with what disease state is being treated in this study. Plantar heel pain is not always plantar fascitis. No imaging was attempted to discern a diagnosis outside of "plantar heel pain".

Associate Editor: Campbell, John

Comments to the Author:

The authors should be congratulated on an outcome study that investigates a very common condition, plantar heel pain. I still share Reviewer #1's concerns which seem valid. The authors do not provide any inclusion/diagnostic criteria for PHP (our readers are mainly clinicians who treat numerous pathologies...PF? tarsal tunnel? Baxter’s nerve extrapment? fat pad atrophy?). I think the diagnostic criteria must be more explicitly defined. (this is what Reviewer #1 was getting at in asking about imaging)

Thank you for the additional clarification of Reviewer #1’s concerns. Please see the response to reviewer #1’s comment and text changes indicated above.

Were there any other treatment methods? NSAIDs? Night splint? Injections? Immobilization (boot or cast)? You must clarify this or it will be seen as an unspoken confounding factor.

No other interventions were provided other than those listed in the Materials and Methods section. Additional information has been added to indicate the number of participants who were taking medication at the start of the trial and to indicate that no other interventions were utilized. Please see lines 138 – 145.

Additionally, I still have trouble accepting the Methods, which treated the patients with two different regimens but then combined the data to look at correlation with BMI, age, etc. Although there may be some statistical precedence for this, I believe many of our readers
will look skeptically on this. This would likely need to be more clearly explained for my satisfaction.

Additional information has been added to the **Statistical Analysis** section to include references to recommended procedures for this type of analysis and other studies that have used similar procedures. Please see lines 150 – 159.