Author’s response to reviews

Title: Effectiveness of physical therapy treatment in addition to usual podiatry management of plantar heel pain: A randomized clinical trial

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Author’s response to reviews:

Please consider the attached revised manuscript entitled “Effectiveness of physical therapy treatment in addition to usual podiatry management of plantar heel pain: A randomized clinical trial.”

Thank you for the thorough review and comments from the initial submission. After careful deliberation of the comments from the review team, changes were made to improve the manuscript. Each comment from the initial review is addressed below including the corresponding page and line number(s) followed by text that was changed or added.

Thank you for your time and consideration of this submission.

Reviewer reports:
Marike van der Leeden (Reviewer 1): General remark Optimizing treatment for plantar heel pain, which is a highly prevalent condition, is of importance. This RCT studies the effect of physical therapy in addition to usual podiatry management in PHP.

Specific comments
Introduction
1. Rational: The authors write ’A local treatment approach for PHP works well and some studies estimate that 80-90% of individuals recover from the problem in 1 year (24-26)’. Can the authors be more specific on the natural course of PHP? What is the benefit of conservative treatment in accelerating recovery from PHP compared to the natural course of recovery?

A systematic review has recently assessed comparative effectiveness of common local treatments for plantar heel pain and was referenced earlier in this paragraph; but, did not indicate the comparison to no treatment/placebo. Therefore, indication that no treatment is less effective than treatment was added in page 4, lines 16-20: “A local treatment approach for PHP is more effective than placebo or no treatment (1), and it is estimated that 80-90% of individuals recover from the problem in 1 year (2-4).”

2. Purpose: In the purpose of their study the authors write that they aim to examine the effects of
interdisciplinary care for PHP. For care to be interdisciplinary the patients' goals and treatment aims must be coordinated between the both disciplines. In the intervention it is not clearly described whether this is the case. Please clarify.

Thank you for the comment. This is an important point and additional details are now included in the methods (page 9, Lines 18-39) to elucidate how care was coordinated between providers: “Physical therapy intervention was provided as an extension of care received from the podiatrist…. Participants in the uPOD+PT group followed-up with their podiatrist as per the podiatrist’s recommendations and the physical therapist sent progress notes to the podiatrist prior to each follow-up appointment. The physical therapist and podiatrist discussed the care plan or any issues in person or via telephone on an as-needed basis.”

Methods
The RCT was carried out in accordance with the CONSORT statement. Participants and therapists were not blinded, but the results were analyzed blindly.

3. Primary outcome measure: is the FAAM validated for people with PHP? Please add information on the validity of the FAAM specific for this patient population.

Additional details about the validity of the FAAM including in persons with PHP was added to page 7, lines 9-17: “The FAAM has been examined in individuals with lower leg, foot, and ankle-related disorders (approximately 10% with PHP) and demonstrated high content and construct validity, has a test-retest reliability equal to ICC = 0.89, and an MCID of 8 points (43).”

4. Treatment fidelity: how was it checked that the therapists were working according to the protocols?

Additional details were added to page 9, lines 50-59: “After initial training, therapists consulted the lead author as needed for clarification of treatment procedures or progression. All treating physical therapists and the lead author worked in the same clinic which supported consistency of treatment and assessment of treatment fidelity.”

Results
5. Reporting of results (table 3): It would give additional insight in the results to calculate and present between-group effect sizes for the outcomes measures used.

Table 3 includes the mean difference between groups including the 95% confidence interval which is consistent with CONSORT recommendations for reporting parallel group RCTs (2).

Discussion
6. High BMI is predictive factor in the development and maintenance of PHP as stated in the Discussion. Please explain why BMI is not a target of treatment.

Thank you for the comment and this brings up a good point. While we did not list specific weight loss interventions, many patients had goals of returning to exercise or an activity that were based on their desire to lose weight. Further details are provided in our case series (3) and we have expanded the discussion of this issue on page 19 line 38 – page 20, line 5: “Specific weight management strategies were not implemented in this study, but weight management was promoted by goals focused on increasing activity levels and returning to regular exercise (49). An observational study published after the start of the current study found that 90% of obese individuals that reduced their BMI by an average
of 10.2 kg/m2 after having bariatric surgery required less treatment visits and modalities for their PHP (66). In addition, 2 other studies of patients with foot pain not specific to plantar heel pain, support improvement in foot function or pain following bariatric surgery (67, 68). Despite limited randomized clinical trials to determine efficacy, clinical guidelines recommend weight loss strategies within the management of PHP and these strategies may improve the outcomes achieved in this study (2).”

7. As this is a pragmatic trial, it does not contribute to unraveling the mechanisms behind the success of treatment. More knowledge on mechanisms is needed to further optimize the effects of treatment and to select the right patient for the right intervention. Please elaborate on this topic in your Discussion.

We agree that there is a lot more work to be done and hopefully our work can help advance the basic and clinical science of plantar heel pain management. We have expanded our statement regarding the limitations of this pragmatic trial in the limitations section, page 21, lines 35-46: “The pragmatic design of this study limits conclusions regarding specific interventions (e.g. manual therapy, stretching or strengthening exercises, injections, etc), and precise duplication of specific interventions. Because treatment was multimodal and pragmatic, further research is needed to elucidate the mechanisms of specific interventions and to identify factors that predict patient response to specific treatments or treatment approaches.”

Todd E. Davenport (Reviewer 2): Thank you for the opportunity to review this interesting manuscript. The manuscript describes a randomized clinical trial, which compared clinical outcomes of patients with plantar heel pain who received usual podiatric care with a group of patients with plantar heel pain who received physical therapy intervention in addition to usual podiatric care. The manuscript was free of major errors in diction and grammar, was easy to understand, and appeared formatted appropriately for the submission type indicated by the journal. The topic is important because plantar heel pain is a relatively common and severe source of morbidity among people with foot and ankle pain. Identification of appropriate interventions and health service provision seems important to ensure appropriate and cost-effective clinical outcomes for patients.

MAJOR COMMENTS

1. It seems notable that physical therapists do not "own" all the interventions that patients received as part of the study, and some may have been provided by podiatrists during usual care. The authors may comment on the extent to which the profession matters who provides the care, relative to patients being provided the evidence-based care itself.

Thank you for the comment and this is a good point. We agree that the intervention provided by the physical therapists is not exclusive to physical therapists and similarly, intervention provided by podiatrists is not exclusive to podiatrists. We have elaborated on this in the limitations section on page 20, line 57 – page 21, line 12: “The usual practice patterns and interdisciplinary collaboration within this study may not represent practices in other health systems or countries. The physical therapy and podiatry interventions used in this study may not be discipline-specific, but provider-specific terms (podiatrist and physical therapist) were used throughout this study to clearly depict the providers of the interventions.”

2. Practice patterns for podiatrists likely vary in terms of referral to physical therapists. Thus, some evidence to support the moniker "usual podiatric care" seems warranted, because there seemed to be
substantial variation in this study.

At the outset of this study, we chose to avoid imposing changes to the podiatrists’ current referral practices because we are not aware of evidence that determines when a podiatrist should refer a patient to a physical therapist. The term “usual podiatric care” was used from study inception and was maintained for consistency. We feel this is the best term to refer to this treatment group and the methods and supplemental files provide additional details regarding what was considered “usual” in this trial. Practice patterns of the podiatrists in this trial are consistent with podiatrist-based guidelines (4, 5) which helps to affirm their practice patterns and we are unaware of more specific evidence that indicates “usual” practice. We do realize that practice patterns in different parts of the world may be different and were careful to clarify the location of the trial and discuss limitations regarding the single location of enrollment (page 20, lines 55-58) to allow interpretation of generalizability. We also added a comment to indicate that practice patterns were consistent with American-based clinical guidelines (page 21, lines 4-24): "Generalizability of this investigation is limited because it was conducted at one clinic by a limited number of providers. The usual practice patterns and interdisciplinary collaboration within this study may not represent practices in other health systems or countries. The physical therapy and podiatry interventions used in this study may not be discipline-specific, but provider-specific terms (podiatrist and physical therapist) were used throughout this study to clearly depict the providers of the interventions. Physical therapy and podiatry practice patterns were consistent with American-based professional associations’ practice guidelines (5, 6). Further research of interdisciplinary treatment approaches in other health systems and regions is needed, however the outcomes of uPOD+PT group were similar to those achieved in a separate investigation that included 6 physical therapists from 2 different clinics in 2 different countries (6).”

3. Building on the previous point, the mean number of visits with a physical therapist actually was greater in the uPOD group compared to the uPOD+PT group (difference not statistically significant). However, it appears the mean was potentially influenced by outliers, because only 11 patients in the uPOD group received physical therapy. The authors should comment on the potential effects of frequency of physical therapy in the uPOD and uPOD+PT groups, because the groups do not seem mutually exclusive. The authors also may consider presenting the results of a subgroup analysis in which the 11 patients who resemble the uPOD+PT group within the uPOD group are excluded, although the reviewer acknowledges this analysis may be underpowered based on the authors' sample size calculation.

This point is something we have discussed extensively and after completing the primary analysis, we have explored the data around the 11 participants in the uPOD group that received physical therapy treatment. As you indicated, any subgroup analysis would be underpowered and likely to produce spurious findings. In accordance with CONSORT guidelines (2), “Because of the high risk for spurious findings, subgroup analyses are often discouraged. Post hoc subgroup comparisons (analyses done after looking at the data) are especially likely not to be confirmed by further studies. Such analyses do not have great credibility,” we have chosen not to include a subanalysis. Additional, and less pragmatic investigation is warranted to improve the precision of the estimated effect of physical therapy treatment.

4. The authors helpfully cite their clinical trial protocol (https://clinicaltrials.gov/ct2/show/NCT01865734). It appears there is a deviation from protocol that may be reasonable but not discussed. In the protocol, reference is made to "early physical therapy." However, this reference was dropped from this manuscript, so it is unclear whether the deviation was just semantic or may have more substantively influenced the study hypotheses or interpretation. The
authors should explain this and any other deviations from their proposed protocol.

After discussion, we appreciated that the timing of physical therapy intervention was not an independent variable of this study and therefore felt it may be misleading. We decided uPOD+PT is the most accurate description of this treatment group. We have indicated this change from the protocol and the reason on page 9, lines 20-29: “In our protocol paper (6), this was referred to as early physical therapy intervention; but because timing of physical therapy intervention was not manipulated in this study, the term uPOD+PT was felt to be more appropriate and is used in this paper.”

5. The authors clearly define the definition for "completers" of uPOD+PT, but the definition applied for uPOD is unclear. The authors should clarify this definition.

Further clarification of the completer criteria was added to page 11, lines 23-51. “In both groups, participants were considered to complete treatment if they attended clinic appointments or follow-up according to the plan mutually set by the participant and provider as indicated in the participant’s medical record (53-55). In addition, for participants assigned to the uPOD+PT group, they were considered to complete treatment if they attended at least 4 visits with a physical therapist regardless of adherence to recommended follow-up appointments. Participants that did not complete treatment failed to follow-up as planned and, in the uPOD+PT group, attended fewer than 4 visits. The completer criteria of 4 visits in the uPOD+PT group was used to represent the average number of visits with a physical therapist for PHP of 4.9-5.1 (40, 56), to assure that care continuity was established (57), to reduce the potential for diminished response with fewer than 4 visits (58), and to reduce the likelihood of removing participants that did not follow-up due to lack of response to treatment.”

6. A value of CPT data is the potential to associate direct costs of evaluation/interventions with the respective groups. However, cost effectiveness was not addressed in this study. The authors may consider inclusion of cost effectiveness analysis as part of the study, or could indicate where, in the presence of statistically similar results for the primary outcome measure between groups, cost effectiveness analysis could further assist in treatment and referral decisions based on the data presented in this study.

We agree with this wholeheartedly and are underway with our cost-effectiveness analysis. We acknowledge the need to consider the results relative to costs and impact on participation on page 16, lines 18-27: “Further research is needed to elucidate the importance of pain and functional improvements that considers the cost-effectiveness and the impact of uPOD or uPOD+PT on a person’s participation in domestic, work, and community, social and civic life.”

MINOR COMMENTS

7. Page 8, line 7: Please change "principle" to "principal."

Thank you for catching this. The change has been in all instances (page 8, lines 8-10; page 10, lines 45-47): “The envelopes were only accessible to the principal investigator…” “Therefore enrollment was terminated by the principal investigator…”

REFERENCES


