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 additional review and comments. Each comment 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.

Editor Comments:
Although the authors have adequately revised their manuscript for most of the comments of the reviewer's, the following comments should be taken into account more clearly:

1. Reviewer 1 had a remark on the natural course (recovery) of complaints. It should be stated more clearly in the following phrase whether the 80-90% individuals with recovery is related to the natural course or to the response at the local treatment approach: "A local treatment approach for PHP is more effective than placebo or no treatment (11), and it is estimated that 80-90% of individuals recover from the problem in 1 year (24-26)."

We apologize for the confusion. This statement was modified to clearly link localized treatment to the recovery statistic as follows (page 4, lines 18-24). “A local treatment approach for PHP is more effective than placebo or no treatment (11), and 80-90% of individuals recover or are satisfied with their outcome at 1 year following localized treatments (24-26)."

2. I agree with reviewer 1 that reporting the between group effect sizes (difference in change scores of groups divided by standard deviation of change score) has added value, as these numbers can easily be compared with other studies. Please provide these effect sizes in the Results section (in tekst or in Table).

Effect size calculations are now included in Table 3.
3. Reviewer 1 also mentioned the role of overweight/obesity. The authors therefore added literature concerning the impact of weight management by surgery (average BMI reduction of 10) on foot problems, but it would have added value to also mention the effects of weight loss interventions in primary care (diet or diet+ exercise) on foot problems. Please add this or if unavailable, mention that evidence on this is lacking.

Unfortunately, we could not find any evidence other than bariatric surgery that investigated the effects of other weight loss interventions for management of PHP or foot problems in general. We have been more explicit in indicating evidence is lacking in this area by modifying this section (pages 20, lines 4-32) as follows. “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). No evidence was found that demonstrated the effect of weight loss through diet and/or exercise on outcomes in individuals PHP or other foot conditions, but evidence for weight loss through bariatric surgery exists. An observational study found that 90% of obese individuals that reduced their BMI by an average of 10.2 kg/m2 after 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).”

4. Reviewer 2 has a good point that the control group used on average at least equal number of physiotherapy visits, which could be a plausible reason for not finding a difference in effects. Although the authors are correct that subgroup-analyses that have not been formulated a priori should be avoided, they should made some statements in the Discussion that unexpectedly, many people in the control group was provided physiotherapy and that this have reduced contrast between groups and therefore a plausible reason for not funding any difference in effects.

Thank you for the suggestion. Perhaps the table was misleading to include the total uPOD sample size at the top of the column and the last 3 rows to only include a subset of this sample. Therefore, to help clarify the extent that physical therapy treatment was present in the uPOD group, we have revised Table 1 to include the median number of PT visits for the entire uPOD sample and included the details about the 11 individuals allocated to uPOD that also received treatment from a PT as a footnote in this table and added specifics to the results section on page 13, line 45 – page 14, line 5, “Eleven of 12 participants in the uPOD group referred to a physical therapist attended at least 1 visit with a physical therapist and, when compared to participants in the uPOD+PT group, had more median number of visits with a physical therapist (uPOD = 6 [IQR 3-10], uPOD+PT = 4 [IQR 2.3-5.8]), more days until the first visit with a physical therapist (uPOD = 24.5 [IQR 13.5-43.8], uPOD+PT = 14.5 [IQR 7-27]), and longer median duration of physical therapy visits (uPOD = 60 [IQR 7.3 – 125.5], uPOD+PT = 33 [20.1 – 61]).” In addition, we added information to the discussion on page 17, line 55 – page 18, line 10; and page 18 lines 40-49. “Other explanations for the lack of difference in the primary outcome of this study may the pragmatic design that resulted in 11 participants in the uPOD group receiving physical therapy treatment over the course of the study. Although, it is possible that this muted between-group contrasts, post-hoc subgroup analyses were avoided to due lack of power and the high risk of spurious findings (52)….. Further investigation is required to determine unbiased estimates of uPOD+PT treatment effects including subgroups of persons that may benefit most from interventions provided by a physical therapist and less pragmatic designs that restrict participants in the comparison group from physical therapy treatment.”