Author’s response to reviews

Title: Foot Exercise plus Education versus wait and see for the Treatment of plantar heel pain (FEET Trial): A protocol for a feasibility study.

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Author’s response to reviews:

Dear Professor Rome,

We would like to thank the reviewers for their comments and suggestions, and the opportunity to revise our manuscript. We have itemised each of the reviewer comments below, followed by our response which includes a description of the subsequent change in manuscript (and refers to line numbers within the revised manuscript). Within the manuscript file, changes have been highlighted with blue text.

REVIEWER REPORTS

Reviewer #1:

This a very well designed study protocol, that convinces of a high level of research competence. There is a good attention to detail in relation to all aspects, from overall conceptualisation to selection of study variables and definitions of terms, to the reporting standard. I have some points to raise for consideration:

Reviewer comment:
1. The anchoring of the 12 week time period to the inadequacy of previous studies at 6 weeks and the funding envelope available is useful. It may strengthen this decision if it were anchored to a bit more detail on the timeframe for physiological response to the exercise regimen.

Author response: Thank you for this comment, it has highlighted a lack of clarity regarding our reasons for our exercise program and the primary outcome time. We have revised the background section of the manuscript to clarify the limitations of the existing evidence of exercise programs in PHP, which were regarding the physiological response to parameters of intensity, volume and the foot exercise used (Lines 129-160). Based on existing evidence, The American College of Sports Medicine[1] recommends that progressive overloading is necessary for maximal muscle recruitment and consequently muscle hypertrophy. We selected a 12-week time period for measuring outcomes to allow an adequate timeframe to capture adaptations. Our exercise programme design has included a (a) 2-week lead in period of familiarisation and movement competency training, (b) 8-week strengthening programme, (c) graduated progression of exercise, and (d) integration into functional tasks. We included both clinic and home-based exercise to inculcate exercise behaviours that the patient would be confident in continuing after clinical interaction was completed (i.e. period of 2 weeks following session 8 / week 10 of the intervention). We have provided further clarity in lines 371-374.


Reviewer comment:

2. Are there criteria for interpretation of the results obtained in relation to the battery of outcome measures selected? For example, how will the decision be made on which to take forward? The ambition would seem to be to adopt a comprehensive set of measures in the feasibility study with the intention of refining this on the basis of the results. A comment on how this will be achieved would be useful.

Author response: In the absence of a defined core outcome set for PHP, our intention by adopting this comprehensive set of measures was to include outcome measures that evaluate different aspects of the condition. For example, pain (numeric rating scale for first step pain, worst pain and average pain), disability (Foot and Ankle Ability Measure), foot related quality of life (Foot Health Status Questionnaire), psychological (Pain Self-Efficacy Questionnaire), physical activity level (Active Australia Survey) and structure and function (foot muscle morphology, foot posture index, foot mobility, toe flexion strength, ankle dorsiflexion, ankle plantarflexor strength). The outcome measurements that go forward will depend on a number of factors: for example, the aims of the main trial, effect size in this feasibility trial, are they feasible, and are there satisfactory completion rates. For measures that capture a similar aspect of the condition (e.g. first step/worst/average pain on numeric rating scale, ultrasound imaging and MRI determined intrinsic foot muscle size), the decision of what goes forward will be guided by effect sizes. We have modified the manuscript to provide clarity of outcome measure selection and interpretation (lines 423-432).
Reviewer comment:

3. The adoption of the SPIRIT guidelines, and commitment to report using CONSORT standards is entirely appropriate, as is the inclusion of a study flowchart.

Author response: Thank you, no response required.

Reviewer comment:

4. Details and definitions of measures, measurements techniques, and minimum differences is excellent for all measures.

Author response: Thank you, no response required.

Reviewer comment:

5. The appendices / additional files are excellent. I do wonder about the clarity and ease of use of the data collection diaries. Their layout and spacing, reading age, and language clarity could be objectively considered as all measures have to reduce the risk of poor completion. As an example, I felt that the pain location maps were small and close together, and that it might be easy for errors in location to be made. With the attention to detail applied, establishing diary quality would be a worthwhile addition.

Author response: We appreciate the reviewers concern regarding layout and ease of use of the documentation such as the patient diary (logbook) and pain location maps, and agree that these are aspects with potential to influence utility. As data collection has now been completed (as at 31st January 2020), we are unable to modify documentation at this point in time. The acceptability of this documentation is part of our primary outcome of feasibility, and will inform design of these materials in the follow-up trial. We also have several processes in place that aim to facilitate accurate use/completion of study documentation:

- During data collection (completion of pain maps and patient reported outcomes) the chief investigator (tester) inspects documentation for completion of each item and verifies accuracy (e.g. pain map completion versus patient description of location).

- Treating clinicians were instructed at training sessions to review study documentation, such as the logbook, with patients and to review the use and accuracy of completion of these documents at each session.

We will also have the opportunity to identify issues with documentation at the close-out of the study by reporting aspects such as logbook completion, and explore feasibility and acceptability of study documentation during patient interviews at completion of the trial.
Reviewer comment:

6. The adoption of SPIRIT and CONSORT is good. Further anchoring of design to efforts to minimise risk of key biases would be useful too. For example, there seems to be an effort to afford participants in each group a comparable level of attention, to reduce performance bias. Explicit consideration and mention of this may be worth the effort. I did feel that there was a disconnect between the 'brief information' and the question in their diary regarding how they managed any issues that they experienced. The brief information focuses on understanding of the condition and doesn't provide many ideas for treatment. I would wonder about contamination effects and how these could be controlled for. A bit more information on treatment options might be useful, and reduce potential placebo effects related to performance bias, due to very limited interaction for the brief information group.

Author response: The information provided in the handout for the brief advice group was designed to provide reassurance and minimal information related to treatment with the intention of a wait-and-see approach (Lines 338-350 and Lines 703-712). The question in the diary regarding how they managed any issues that they experienced was included as a record of action related to brief information provided (e.g. ice application, start with activities that don’t aggravate symptoms and gradually increase activity level as pain lessens), as well as any treatments sought outside of the study protocol (Line 338-350). We have modified the manuscript to include discussion of study limitations, including performance bias due to the structure of the interventions (Lines 703-712).

Reviewer comment:

7. Is 12 weeks a long enough time period, and is the use of 2 sets of exercises - a daily and the other 3x weekly a necessary complexity?

Author response: The evidence suggests that 12 weeks is a sufficient time period as muscle hypertrophy is reported to be evident within the first 6 weeks of resistance training[1]. Previous studies in healthy adults[2,3] have reported increased cross-sectional area of intrinsic foot muscles following eight weeks of a foot strengthening program.

In terms of the use of 2 sets of exercise, we developed our program consistent with The American College of Sports Medicine position stand1. Their evidence statement and recommendation for increasing muscle hypertrophy suggests that program design targeting both neural (daily low load, low intensity foot and toe movements) and hypertrophic (moderate-high load and intensity 3 weekly exercises) factors may be most beneficial for maximising muscle hypertrophy. Furthermore, the daily exercises are designed to provide an opportunity for familiarisation and movement competency throughout the programme.

Semi-structured interviews conducted at the end of each participant’s intervention period will provide an opportunity to explore their perspectives regarding the composition of the program.


Reviewer comment:

This study will make an important contribution to the field. Very best of luck with it.

Author response: Thank you very much for your recognition of our work and encouraging words.

Reviewer #2:

Review

Thank you for the opportunity to review this protocol. PHP is clearly a condition that has a significant impact on the community and there is a need for high quality trials to add to the evidence base. Overall, I don't have any major issues for the authors to review but rather some minor suggestions.

The protocol is a well written and well-designed trial that has been registered; will adhere to the CONSORT guidelines for a feasibility trial and will attempt to minimise the influence of major forms of bias (i.e selection, allocation, and detection bias). Performance bias is clearly an issue but cannot be overcome in this type of trial.

Minor considerations

Reviewer comment:

1. The authors have been open about issues relating to the cross-sectional nature of the study by Cheung that evaluated rearfoot muscle volume. The authors proposed a hypothesis for how IFM atrophy contributes to the development of PHP, although the authors have focused on the implications for the plantar fascia and heel fat pad. The evidence has revealed that calcaneal oedema is also common in people with PHP, which might be contributing to the noxious stimulus in this population. Can the authors highlight that the PF and heel pad are not the only tissues under stress but also
hypothesise how IFM atrophy might be associated with calcaneal oedema (if at all) with PHP? I think it is important for the reader to recognise that PHP is not just a 'tendinopathy' or 'heel pad issue' that might respond to an exercise program.

Author response: We agree with the reviewer that PHP can involve many potential underlying sources, including calcaneal oedema, and we did not intend to infer otherwise within the manuscript. The plantar fascia and fat pad were provided as examples, but not intended as an exclusive list. As suggested by the reviewer, we have modified the manuscript to clarify this for the reader (see Lines 98 and 124).

“During walking and running the foot dissipates, recycles and produces mechanical energy [11]. This involves contributions from both the passive (i.e. plantar fascia, heel fat pad, ligaments, bone) and active (i.e. intrinsic and extrinsic muscles) structures of the foot.”

“For example, atrophy of these muscles may compromise the energetic function of the foot with implications (e.g. modified loading) for passive structures such as the plantar fascia, heel fat pad and calcaneus.”

Reviewer comment:

2. Foot exercise plus education: this is more of a comment. The 30-minute consultation might not be sufficient to address patient education and the prescription of the exercise program, although I understand that the primary aim of the trial is to determine the feasibility of the program. Would the authors consider asking the treating physiotherapists to record the duration of their consultations, especially the initial consult?

Author response: Although we have not instructed physiotherapists to record consultation time, physiotherapists will provide treatment notes for each consultation and this aspect of feasibility (challenges in adhering to the intervention) will be explored in semi-structured interviews with treating physiotherapists at the close-out of the study (see line 416-420).

Reviewer comment:

3. Foot exercise plus education (handout) - the authors suggested that the most common trigger is a change (sudden increase) in weightbearing. I would be inclined to remove this statement or just state that it is a 'common trigger'. I don't think anyone can truly say that it is the most common factor as there are an unknown percentage of people with PHP that have not overloaded the tissue.

Author response: In hindsight, we agree with the reviewer that “common trigger” is probably more appropriate terminology than “most common trigger”. As data collection has now been completed (31/1/2020) we are unable to modify the patient handout for this study, but the recommendation will be considered in refinement of resources for the main trial.
Reviewer comment:

4. Outcome measures: The outcome measures are very appropriate, but can the authors explain why the focus on physical measurements? Did the authors consider evaluating any psychological factors (e.g. depression, anxiety, fear etc) especially given the references made to the psychological impact of the condition?

Author response: Yes. We considered a range of measures when planning this study and decided that we would like to focus mainly on the putative mechanism of effect of exercise, e.g., hypertrophy and strength adaptations. This was because of the identified gap in previous studies of exercise, e.g., questions regarding an adequate dose to achieve hypertrophy or strength adaptations; lack of measures to test strength and hypertrophy of the targeted foot muscles. We did indicate that there were impacts on psychological status of the person with PHP (e.g., anxiety and depression) in our background, but this was more to highlight the gravity of the condition’s impact.

In terms of clinical efficacy, we note that there is an absence of a defined core outcome set for PHP. In this absence, we aimed to include outcome measures that evaluate different aspects of the condition. This includes pain (numeric rating scale for first step pain, worst pain and average pain), disability (Foot and Ankle Ability Measure), foot-related quality of life (Foot Health Status Questionnaire), psychological features (Pain Self-Efficacy Questionnaire), physical activity (Active Australia Survey) and structure and function (foot muscle morphology, plantar fascia thickness, foot posture index, foot mobility, toe flexion strength, ankle dorsiflexion, ankle plantarflexor strength). Inclusion of other psychological factors (e.g., anxiety and depression) will be an important consideration to take forward in development of the main trial. We have modified the manuscript to provide this clarity around outcome measure selection (Lines 423-432).

Reviewer comment:

5. Qualitative interview: would the authors consider also interviewing clinicians about their perspectives of implementing the program? What were some of the barriers they faced in the provision of the program? I think the combination of the patient and clinician voice would tell a great story.

Author response: Yes, as indicated on Lines 416-420, semi-structured interviews will be conducted with treating physiotherapists at the close-out of the study. We have modified additional file 8 to include the question guide used for physiotherapists.

Reviewer comment:

I wish the team (and participants) all the best with the trial. Thanks again for the opportunity to review this well designed trial.
Author response: Thank you very much for your positive comments on our trial.

Reviewer #3:

A well written research protocol. The study is novel and addresses and area of practice where there is a paucity of evidence to guide practice.

I have the following general questions and comments:

Reviewer comment:

1. Regarding eligibility - is the link that potential participant will respond to potentially limiting and a potential source of bias. Will those who are in remote areas or experience deprivation whereby access to the internet is limited or non-existent have the ability to participate. Does this mechanism also limit inclusion to only those who are computer literate?

Author response: Thank you for highlighting an oversight in the description of our recruitment process. Advertisements will provide two options for interested individuals: (1) an online survey link that participants can provide their contact details and undergo preliminary screening, and (2) contact details of chief investigator (phone, email) to contact directly. We have modified the manuscript to clarify the recruitment process (see Lines 211-216).

“The advertisement will direct volunteers to an online survey link (Google forms) or to contact the chief investigator (email, phone). The online survey link will assess preliminary eligibility criteria (age, pain characteristics, concomitant conditions, see Additional File 1). For volunteers who directly contact the chief investigator, the preliminary eligibility criteria will be covered within the telephone interview.”

Reviewer comment:

2. Regarding physical screening, you will you palpation during physical screening. Recent research (Menz) has questioned the usefulness of palpation as a discriminatory test.

Author response: Our inclusion criteria of pain on palpation and plantar fascia thickness greater than 4mm aimed to recruit a group of individuals with similar presentation of PHP. Palpation is one part of a routine clinical examination[1] and if we have interpreted the Menz[2] paper correctly, their results reported that palpation was not able to differentiate between presence of calcaneal heel spur and plantar fasciitis. That differentiation was not the reason for including palpation in our selection criteria.


Reviewer comment:

3. Regarding physical screening how will you rule out other heel pathologies as you are only assessing fascial thickness. Do you feel screening for other heel pathologies (fat pad oedema, bone marrow oedema, neural based pain) would be of benefit.

Author response: As mentioned above in response to Reviewer comment #2, our selection criteria aimed to recruit individuals with a similar presentation profile, but did not aim to determine the specific underlying diagnosis.

Reviewer comment:

4. Regarding inclusion criteria I am interested why a level of 3/10 the week prior to testing has been chosen. The nature of PHP is quite intermittent, if it is only 2/10 why would they be excluded?

Author response: The criteria of minimum 3/10 pain is related to the sensitivity to change of the numeric rating scale measures of pain (the reported minimal clinically important difference is 2 points out of 10 [1]).


Reviewer comment:

5. Again, I am unsure why you would exclude a participant who does not have palpable pain. What if their fascia is thickened (&gt;4mm) but no pain, do they not have PHP?

Author response: Palpation is one part of a routine clinical examination [1] and the combination of these selection criteria (palpation, plantar fascia thickness &gt;4mm) is related to our recruitment of individuals with a similar presentation.
Reviewer comment:

6. Regarding the exclusion criteria, can you be more specific surrounding exclusion for foot surgery. Why must all foot surgeries lead to exclusion. It may have been a digital surgery that has increased the efficacy of foot function.

Author response: We acknowledge that it is possible that foot surgery improved foot function, but were unable to determine that for the participant presenting at the later point in time. We decided that it was more robust to exclude all surgeries given the unknown (undocumented) effects.

Reviewer comment:

7. Why only excluded pain in the lower limb that caused an activity reduction. Should lower back pain be considered as well?

Author response: We did consider lower back pain/injury as part of our exclusion criteria. We have modified the manuscript to state this more explicitly (Line 244).

Reviewer comment:

8. Regarding allocation, will the number of clinics that participate be limited to ensure accuracy? There is the potential for the 20 participants to receive the intervention form 10-15 different practitioners.

Author response: Seven clinics were recruited for the trial with 14 physiotherapists trained in delivery of the interventions for the study. The manuscript has been modified to indicate that the study will be conducted in seven clinics across Brisbane (Line 2775-276). We considered that it was more appropriate to offer patients a variety of clinic locations, as well as involve a greater number of physiotherapists, to increase generalisability rather than accuracy.

“The interventions will be delivered by registered physiotherapists, who regularly treat musculoskeletal conditions, in seven private practices across Brisbane.”

Reviewer comment:

9. Once a participant is enrolled into the study how will they be allocated to a professional to receive the intervention?
“As treating physiotherapy clinics are located in various suburbs of Brisbane, participants may select the most convenient practice for them to attend.”

Reviewer comment:

10. It would be great to see some additional information in the background section surrounding MRI and foot morphology. This seems like it will form a large part of demonstrating the effectiveness of the intervention. Just a few sentences on how imaging has been used to quantify muscle morphology in the foot would suffice.

Author comment: As suggested by the reviewer, we have modified the manuscript to provide additional detail in the background section surrounding previous MRI methods used to quantify muscle morphology (see lines 107-120).

Reviewer #4:

I congratulate the authors on planning this project. This manuscript is on a topic which I expect will be of great interest to readers of JFAR. The study is well designed, and the manuscript is very well written. The additional files are also very detailed and support the manuscript well. As the trial has been registered my suggestions largely relate to providing greater clarity regarding the study's methodology and areas that I believe warrant further discussion.

Major Essential Revisions

Reviewer comment:

1) Discussion: The authors have presented strengths of the proposed trial but have not presented or discussed any limitations. Please present/discuss study limitations.

Author response: Thank you for highlighting this oversight. We have added a discussion of study limitations to the manuscript, see lines 703-712.

Reviewer comment:

2) Twenty participants with PHP will be randomly allocated to one of two groups for a 12-week intervention period: (i) foot exercise plus education (includes 8 physiotherapy sessions and detailed education), or (ii) brief advice (includes 1 physiotherapy session and brief advice). Given the vastly different hours of treatment received between the two groups, I feel the authors must acknowledge and discuss the potential contextual effects
that may affect the results of this study (i.e. could any observed differences in patient outcome measures be attributed to contextual effects and not the actual interventions being compared).

Author response: Thank you for highlighting this oversight. We have added a discussion of study limitations to the manuscript, see lines 703-712.

Reviewer comment:

3) Further to the above comment, have the authors considered that there may be differences between the groups based on the level of education received between the two groups. If the control group also received 'detailed education' then any benefits could be attributed to foot exercises and differences in contextual effects, but at present any difference can be attributed to foot exercises, education, and differences in contextual effects. Please discuss.

Author response: We acknowledge the reviewer’s comment and understand that any differences between groups may be attributed to foot exercise, education and differences in contextual effects. It is important to acknowledge that the primary aim of this study is to establish the feasibility of conducting a full-scale RCT, rather than to establish treatment effects. We selected our comparator group (brief advice) to best reflect a wait-and-see approach, given the lack of studies in the literature that compare interventions for PHP to a wait-and-see or minimal intervention. The brief advice provided is deliberately intended to provide minimal information for that reason. We have modified the manuscript to provide a discussion of study limitations (Lines 707-712).

Reviewer comment:

4) Reference is made to intrinsic foot muscles throughout the manuscript, yet several tests and exercises will also strengthen/test extrinsic muscles. Can the authors discuss this issue or consider reviewing terminology to ensure most accurate terminology is used? See line 485 as an example.

Author response: We agree with the reviewer that it is not possible to definitively exclude extrinsic muscle contributions from several tests and exercises that are involved in the study. That being said, we have attempted to design exercises that are intrinsic focussed. For example, during the ‘long toe push’ exercise participants are instructed to keep interphalangeal joints of the toes extended and produce flexion at the metatarsophalangeal joints in an attempt to bias intrinsic foot muscle contributions (e.g. flexor digitorum brevis, flexor hallucis brevis, quadratus plantae and lumbricals) and minimise extrinsic muscle contributions (flexor digitorum longus and flexor hallucis longus) that would also produce flexion of interphalangeal joints (Additional file 4 – exercise protocol). Although the ‘seated’ and ‘standing heel raise’ exercises undoubtedly recruit the extrinsic (calf) muscles, we instruct this exercise with an intrinsic focus (participants maintain doming and isometric long toe push into floor during the exercise). Patients with PHP
performing a heel raise or squat may naturally perform these tasks with interphalangeal joint flexion or even with their toes off the ground. The foot focus aims to maximise intrinsic muscle contribution to these tasks. This explanation/instruction is provided within The Foot Exercise Protocol (Additional file 4). We have also attempted to provide clarification within the manuscript by adding the term foot muscle focussed and foot focused exercise where appropriate (Line 297, 682).

With regard to line 485 (now line 606 of revised manuscript) – toe flexion strength testing – again, we agree that it is not possible to definitively exclude extrinsic (long toe flexor) contributions from this test. Similar to the exercises, we have attempted to bias contribution from the intrinsic muscles by instructing patients to keep interphalangeal joints of the toes extended and by positioning the dynamometer under the proximal phalanx of the toes. We have provided additional clarification of test procedures within the manuscript, see lines 606-614. During IFM Motor Performance tasks, part of the rating of performance is taking into account excessive extrinsic muscle contribution, which might be observed for example by flexion of the interphalangeal joints (long toe flexors), pronation or supination of the foot (tibialis posterior, tibialis anterior, peroneals). The manuscript has been modified to provide additional detail (Lines 564-567).

Minor Essential Revisions

Reviewer comment:

1) Keywords: consider adding 'Plantar Fasciitis' (MeSH term)

Author response: The manuscript has been modified to add ‘plantar fasciitis’ as a keyword.

Reviewer comment:

2) Please ensure British English or American English (not both) is used throughout the manuscript. For example, on page 5 (line 100) you have used 'characterized' (American English) and on page 10 (lines 229 & 254, respectively) you have used 'randomised' and 'programme' (British English). Other examples exist, so please amend throughout. I suggest that British English is preferred as the authors are from Australia, and the Journal of Foot and Ankle Research is the official journal of the Australian Podiatry Association and The College of Podiatry (UK).

Author response: Thank you for highlighting this oversight. The manuscript has been revised to use British English throughout.

Reviewer comment:
3) Throughout the manuscript. There are several instances where examples are listed but they don't have an 'and' before the last listed item or don't have an 'etc.' at the end. For example (line 216), '(e.g. metal implants, pacemaker).' Please either change to 'or pacemaker' or 'pacemaker, etc.'. Please amend this issue throughout the manuscript. Also, when listing only some examples I suggest using 'e.g.' at the start of the list to indicate it is not a complete list. See line 185.

Author response: As suggested by the reviewer, the manuscript has been modified throughout.

Reviewer comment:

4) Please check abbreviations. Plantar heel pain is abbreviated early in the manuscript and then it appears intermittently in full (not abbreviated) later in the manuscript. The same applies to 'RCT'.

Author response: Thank you for highlighting this oversight. Abbreviations throughout the manuscript have now been defined in full at first appearance and then abbreviations used subsequent to that.

Reviewer comment:

5) Line 201: Will 'first step pain during the previous week' indicate the average first step pain for the previous week, the worst first step pain for the previous week, the best first step pain for the previous week, etc. Please clarify what data will be used.

Author response: Worst first step pain for the previous week will be used. The manuscript has been modified to clarify this (see line 234).

“Report worst first step pain during the previous week of greater than 3/10 on a numerical rating scale (0 = no pain; 10 = worse pain imaginable).”

Reviewer comment:

6) Exclusion criteria. I think it would be beneficial to indicate that participants will be excluded if they 'report' a history of X, Y, Z, etc. as it appears that you won't be testing for the presence/absence of these conditions and you will rely on participants reporting them.

Author response: The manuscript has been modified as suggested by the reviewer, see line 240.

Reviewer comment:
7) Allocation: "Following baseline assessment, participants will be randomised via concealed allocation....." Can you clarify what will be known about the participants following baseline assessment (is it just whether they are eligible or not)? Could any information that has been obtained at baseline compromise allocation concealment?

Author response: The study investigator who is responsible for managing the randomisation schedule will be blinded to any information regarding baseline assessment. We have modified the manuscript to clarify this process, see lines 268-270.

“A study investigator (RM) who is not involved in recruitment or outcome assessment will manage the randomisation allocation and liaise with the treating physiotherapist regarding group allocation. As treating physiotherapy clinics are located in various suburbs of Brisbane, participants may select the most convenient practice for them to attend. Participants will be informed of group allocation by the treating physiotherapist.”

Reviewer comment:

8) Check the consistent use of hyphens throughout. E.g. '12-week' vs '12 week' vs '30 minutes'.

Author response: The manuscript has been revised throughout to ensure consistency. When the phrase is used adjectively, we have used a hyphen.

Reviewer comment:

9) Line 236: Can you please comment on the length of the training session and if knowledge transfer to the physiotherapists was measured (i.e. how do you know that they left this session knowing what to do?)

Author response: Two training sessions were conducted, one week apart, each of 90 minutes duration. This detail has been added to the manuscript, see line 276-279.

At the end of the second session, study investigators (MMFS, AG) observed physiotherapists’ ability to teach and correct the exercises to check knowledge transfer regarding the foot exercise intervention.

Reviewer comment:

10) I assume data collection hasn't started. However, if it has, please state this.

Author response: We have added a statement at the end of the manuscript regarding trial status, see line 723-726.
“The study was registered on 11 July 2019. Enrolment of the first participant was 2 August 2019. Data collection commenced on 2 August 2019. The final follow-up measurement was conducted on 31 January 2020.”

Reviewer comment:

11) What will you use as a definition of an 'adverse event'? Please include.

Author response: We have modified the manuscript to include a description of adverse events (Line 354-365).

Reviewer comment:

12) Line 261: what will the clinician use as a guide to determine whether IFMs are recruited without excessive extrinsic foot muscle contribution. What is consider 'excessive' and how will this be determined?

Author response: Based on their anatomical configuration (insertion), intrinsic foot muscle contributions are expected to produce movement at the metatarsophalangeal joint, but not the interphalangeal joints which are only acted on by the extrinsic muscles (flexor digitorum longus and flexor hallucis longus). Therefore, signs of excessive extrinsic muscle contribution would include flexion of the interphalangeal joints, or unintended movements of the foot and ankle (e.g. pronation and supination by extrinsic muscles like tibialis posterior, tibialis anterior and peroneals). We have provided clarification in the manuscript at line 304-311.

“When the indicated repetitions and sets are reached for a stage, progression is made provided that:

(i) the therapist considers that the patient can adequately recruit the IFMs without excessive extrinsic foot muscle contribution (e.g. able to maintain extension of the interphalangeal joints of the toes) or perform local joint motion at the foot and ankle with optimal control (i.e. smooth motion through the intended plane of action without unintended overflow into adjacent planes or joints, such as, pronation or supination of the foot and ankle);”

Reviewer comment:

13) Lines 273-274: Please outline the rationale used to underpin the advice provided regarding footwear, posture and gait.

Author response: We are not aware of direct evidence that has evaluated these elements of advice (posture, gait, avoiding barefoot, try a cushioned sole) in this population. Anecdotally, these are common components of ‘load management’ found to be effective by health
professionals and have a plausible rationale. Accordingly, with a pragmatic approach in mind, we thought it a good opportunity to incorporate into our study education component. Gait advice was underpinned by reference to current expert opinion [1] to “Consider strategies to reduce overstride and impact loading variables (e.g. vertical loading rate), increasing step rate”. We believe it is logical that load on the symptomatic foot could be reduced by ensuring patients are standing in postures with their weight evenly spread across both feet, in comparison to a posture that places more weight bearing load on their symptomatic foot (such as leaning their weight onto that leg). We are aware that the 2014 Clinical Practice Guidelines for Heel Pain [2] states that “clinicians may prescribe a rocker-bottom shoe construction in conjunction with a foot orthosis”, however in the scope of this study, we wanted to provide general advice about existing footwear selections/choices, rather than prescribe a new item that they would need to purchase (it is possible that any new footwear purchased may have had an effect on symptoms which was not the aim of the study).


Reviewer comment:

14) Check spacing consistency. E.g. '0-5 / 10' (line 264) vs '&lt;5/10' (line 265).

Author response: As suggested by the reviewer we have made revisions throughout the manuscript.

Reviewer comment:

15) One-on-one semi-structured interviews: have these questions been established? If so, what are they?

Author response: Additional file 8 provides the question guide for semi-structured interviews. We have revised this file to also include the question guide for physiotherapist, which was omitted from the initial submission file.

Reviewer comment:

16) Line 376: An Oxford comma has been used here. This is not the case elsewhere in the manuscript. Please check for consistency throughout.
Author response: As suggested by the reviewer we have made revisions throughout the manuscript.

Reviewer comment:

17) Line 448: when will the video recordings be taken, and what planes will the recordings be taken in?

Author response: As indicated at line 370, outcome measures will be evaluated at baseline and 12-week time-points. For great toe extension, lesser toe extension and toe spread tasks, the camera will be positioned in front of the participant (frontal plane view). Pilot testing demonstrated that this was the view that allowed movement of all 5 toes to be best observed. For the doming task, the camera will be positioned at the mid-point between the frontal and sagittal plane to allow view of both the medial longitudinal arch and the interphalangeal joints all 5 toes. We have not modified the manuscript but would be happy to provide further detail within the manuscript if the reviewer considers it necessary.

Reviewer comment:

18) Line 461: fix spacing issue.

Author response: The manuscript has been modified as suggested (now line 576).

Reviewer comment:

19) Line 470: Please either use a '-' or 'to' between the numbers consistently. I prefer 'to' as '-' can sometimes make a positive number look 'negative'.

Author response: We have modified the text (now line 591) to use ‘to’ and ensure consistency with the rest of the manuscript.

Reviewer comment:

20) Line 480 and 482. Here the distances have been reported in cms and then mm. I suggest that a consistent unit of measure is used.

Author response: The manuscript has been modified to use millimetres (line 603).

Reviewer comment:

21) Line 490: What is a 'make test'?
Author response: A make test means that the tested individual exerts an increasing force against the dynamometer over a period of several seconds while the tester (or external fixation e.g. in our case the ground) holds the dynamometer steady against the effort of the tested individual [1]. To minimise any confusion caused by terminology, we have removed use of the term ‘make test’ and instead just described the process (see line 614-615).


Reviewer comment:

22) Line 514-518: A sample size of 20 has been used. Please justify/use reference that this is an adequate sample size to address the aims of the study. If recruitment is going well will you stop recruiting at 20 or keep going? At present it sounds like you will stop at 20 (which is fine), but if it isn't then please indicate this.

Author response: We will stop at 20. This is partly due to budget constraints (e.g. MRI costs, physiotherapy costs), but also because we deemed 20 participants to be sufficient to address both the primary and secondary aims of the study. Sample sizes of this magnitude will best provide estimate parameters for determining a clinical trial that seeks to identify large standardised effect sizes [1]. The manuscript has been modified to provide justification (lines 648-651).


Reviewer comment:

23) Line 543: A criticism of previous research is that exercise programs were not adequate (volume, progressions, etc.). What makes the strengthening programme used in this study adequate? Although it seems very adequate, was it based on existing strengthening guidelines?

Author response: We developed our programme consistent with The American College of Sports Medicine position stand1. Their evidence statement and recommendation for increasing muscle hypertrophy suggests that program design targeting both neural and hypertrophic factors may be most beneficial for maximising muscle hypertrophy. Hence, our programme includes daily exercises that are low load, low intensity foot and toe movements, as well as exercises that are moderate-high load and intensity performed three times per week. Other features of our programme that are consistent with recommendations include:

- concentric, eccentric and isometric muscle actions
- moderate loading for 8-12 repetitions per set for one to three sets
• single- and multiple-joint exercises
• slow to moderate velocities
• frequency 2-3 days per week

Our programme provides progressive overload by increasing the demands placed on the body via alteration in intensity (3 stages of each exercise using progressions of load through body weight variations and resistance tubing) and volume (number of repetitions/set working towards 3 sets of 12 repetitions). Variation of volume and intensity is most effective for long-term progression [1]. Finally, the evidence suggests that 12 weeks is a sufficient time period as muscle hypertrophy is reported to be evident within the first 6 weeks of resistance training [1]. Previous studies in healthy adults [2,3] have reported increased cross-sectional area of intrinsic foot muscles following eight weeks of a foot strengthening program. Our 12 week time period for measuring outcomes allows an adequate timeframe to observe adaptations. Our exercise programme is aimed to (a) have a 2 week lead in period of familiarisation and movement competency training, (b) have a 8 week strengthening programme, (c) graduated progression of exercise, and (d) integration into functional tasks. We included both clinic and home-based exercise to inculcate exercise behaviours that the patient would be confident in continuing after clinical interaction was completed (i.e. period of 2 weeks following session 8 / week 10 of the intervention).


Reviewer comment:

24) Line 548: Add hyphen for consistency to 'single leg', as earlier in the sentence you use 'two-leg'.

Author response: Thank you for identifying this oversight, the text has been modified as suggested by the reviewer, see line 693.

Discretionary minor revisions

Reviewer comment:
1) Methods, design: when I was reading this section, I was questioning whether stratification occurred, what were the random permuted block sizes, etc. I later read some of this information was provided under 'allocation'. I wonder if it is worth adding to the 'design' section something like 'see 'allocation' for more detail regarding randomisation).

Author response: Thank you for this suggestion to add clarity to the methods. The manuscript has been modified, see line 176.

Reviewer comment:

2) I note that the authors have elected to use the term 'randomised clinical trial' in preference to 'randomised controlled trial'. Is there a reason for this?

Author comment: First we note that reference to randomised clinical trial is for future trials and not this current feasibility trial. This is salient in so far as a randomised clinical trial should be powered to test efficacy of the different arms of the study, which our feasibility trial does not. Future trials will be clinical trials, which may or may not have a control arm. The term randomised clinical trial covers both possibilities whereas a randomised control trial is usually more specific to those trials that have a control group/arm.