Reviewer's report

Title: Non-surgical treatment of Pes Planovalgus associated pain: study protocol of a randomized clinical trial

Version: 1 Date: 2 December 2014

Reviewer: Szu-Ping Lee

Reviewer's report:

Comment to the authors:
• The background is riddled with excessive information that is not relevant to the main purposes of this research. It reads like a compilation of information related to PTTD and pes planovalgus, without a clear focus on developing the research. It should be pared down extensively.
• The inclusion criteria may be too restrictive. In particular the radiographic evidence of arch flattening and the “too many toes” sign. Also, “eligibility for non-surgical treatment” needs to be elaborated (or removed) as a criterion.
• The biomechanical testing collects lower extremity kinetic and kinematic information, however the authors do not present hypotheses of how the lower extremity biomechanics may respond to the intervention or sham treatment. For example, what changes in the biomechanical parameters during walking will be considered as “improvement” or “treatment effects”?
• Significant improvement regarding the writing in English language needs to be made before the manuscript can be considered. In the current form, this manuscript is understandable by the reviewer who has content expertise. However, it is not ready to be published without substantial refinement.

Specific comments:

Abstract
1. Line 29-30: this opening sentence doesn’t make sense. Pes planovalgus is a deformity, and this foot deformity sometime comes with certain symptoms.
2. Line 39: change “missing” to “lacking”.
3. Line 42: what specifically are the inclusion criteria? This information should be included, at least briefly, in the abstract.
4. Line 49-51: it is unclear what the “dosed foot load management” is.
5. Line 54-55: it is unclear how the kinematic data and neuromuscular activity data will be used, and during what activities.
6. Line 56-57: one-factor ANOVA will not be able to identify group effects (FOO vs. FOS vs. FOE), and hence is not appropriate for this experimental design. This is in contradiction to what was described in line 514-516.

Background
1. Line 78: depending on the stage of tibialis posterior dysfunction, the deformity can be flexible or rigid. This was pointed out by the authors in line 106-110.

2. Line 80-82: this statement is unclear and did not accurately reflect the findings of the cited research. Furthermore, the reviewer do not see the rationale of this sentence being inserted here.

3. Line 86-88: this statement is true, however it does not seem to be relevant to the main purposes of this research.

4. Line 99-106: this information on radiographic imaging doesn’t seem to be relevant to the purposes of the research.

5. Line 111-112: what types of patients are typically considered to be eligible for non-surgical treatment?

6. Line 141: what is “optimization of foot loading management”? 

Methods

1. Line 247: what specific standardized biomechanical measurements?

2. Line 259: what complains? How severe should the symptoms be? Location of the pain?

3. Line 271: the “too many toes” sign is very subjective, the result can be variable due simply to the angle of view and the distance of observation. The test needs to be standardized.

4. Line 284: define “acute physical therapy”

5. Line 303-305: please explain what this means: “The experimental situations of biomechanical testing (standing, walking and walking down a stairway) will be administered in a fixed sequence since standing posture serves as calibration for dynamic measurements”

6. Line 333: it might be helpful to have a mid-intervention assessment (at 6 weeks)

7. Line 333-334: details of intervention should be given in the following section to avoid repeat of information.

8. Line 363-364: explain what this means: “This might lead to changes in afferent input triggering neuromuscular control in the course of a longer lasting intervention”.

9. Line 370-372: this procedure of exercise should be described better.

10. Line 367-386: how will the exercise intensity be progressed over the 12 weeks?

11. Line 390-392: not sure why the orthoses will be sham if they also have the functional elements? This needs to be described better.

12. Line 482-484: it is possible that some individuals may not have “preactivation before initial touchdown”.

13. Line 493-495: explain what this means: “the electronic database will then be checked for plausibility”, and “all measures will be checked by range checks to
Discussion

1. Line 543-545: it is important to recognize that pes planovalgus, symptoms, and PTTD do not necessarily present in all patients simultaneously. It is possible to have pes planovalgus without any symptoms. It should be stated clearly that the treatment is aimed to address symptoms and not structural changes.

2. Line 550-573 and 600-605: in terms of the treatment provided to the patients, what makes this study any different then the Kulig et al. RCT? The authors should elaborate on the additional insights that conducting this study provides to the knowledge base of treating patients with the pathology.

3. Line 569: what is the meaning of the exclamation mark?

4. Line 583-599: this argument of not performing indwelling EMG on the tibialis posterior is valid. However, there are other methods to investigate tibialis posterior activation level. For example, Kulig et al. demonstrated that MR imaging can be used to evaluate acute muscle activation (Kulig et al. 2004, Selective Activation of Tibialis Posterior: Evaluation by Magnetic Resonance Imaging; Medicine and Science in Sports and Exercise)

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests.