Author's response to reviews

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

Authors:

Angela Blasimann (angela.blasimann@bfh.ch)
Patric Eichelberger (patric.eichelberger@bfh.ch)
Yvonne Brühlhardt (yvonne.bruehlhart@bfh.ch)
Isam El-Masri (isam.elmasri@hirslanden.ch)
Gerhard Flückiger (gerhardflueckiger@sonnenhof.ch)
Lars Frauchiger (lars.frauchiger@spitalstsag.ch)
Martin Huber (martinhuber58@hotmail.com)
Martin Weber (Martin.Weber@spitalnetzbern.ch)
Fabian G Krause (FabianGoetz.Krause@insel.ch)
Heiner Baur (heiner.baur@bfh.ch)

Version: 2 Date: 6 March 2015

Author's response to reviews: see over
Point-by-Point-Response

MS: 2060532141459754
Non-surgical treatment of Pes Planovalgus associated pain: study protocol of a randomized clinical trial [clinicaltrials.gov ID NCT01839669]

Reviewers' comments:

Reviewer #1:
Comments:
Major Compulsory

Methods
Interventions
Foot orthoses only

i. It would help if the authors provide more detail about the orthotic to be prescribed including the type of material (e.g. EVA or polypropylene); thickness or density, and if a rearfoot post will be added to the “bowl-shaped heel”. It would also be helpful to provide an image of a typical orthotic to be prescribed;
->The material for sham as well as for the treatment foot orthoses is EVA (shore 40) with a thickness at the basis of approximately 4mm. A medial-longitudinal arch support resulting in a rearfoot correction (“rearfoot post”) is used in combination with the bowl-shaped heel. We now provide a picture of sham and treatment orthoses (and positive from 3D-foam impression. The picture hopefully gives a good impression of the treatment orthoses as well as the manufacturing process (we put less emphasis on the sham in the picture – more pics are certainly possible).

ii. The authors will need to provide a reference for casting the foot in neutral with partial weightbearing.
->This is a very common method in European orthopaedic technicians paradigms. The 3D-foam imprint of the “corrected” (neutral) position of the foot under partial weightbearing serves as the basis for implementing corrections (like medial longitudinal arch support) via software (CAD). The following reference can serve as a suitable reference:
This information is now added to the manuscript.

iii. What materials were used to cast the foot? Will the neutral position be captured using plaster or a foam box impression?
->A “foam box impression” is used to cast the foot. A 3D scanner scans this impression. Afterwards corrections (treatment orthoses: medial longitudinal arch support, bowl-shaped heel) or no corrections (sham) will be implemented with a CAD-software. Then, the foot orthoses will be cut out in 3D shape out of EVA-blocks. Finally a top layer (Alcantara) is glued on top of the three-dimensional foot orthoses. This information is now added to the manuscript.

iv. Could the authors provide more detail about how the dynamic barefoot plantar pressure results will affect the amount of medial arch posting? In addition, are the authors considering other variables during the prescription process (e.g. BMI; activity levels; current footwear; bony or soft tissue prominences)?
->The dynamic plantar pressure distribution helps to provide information on foot progression angle and forefoot abduction, both influencing the amount of medial post. Moreover medial loading on the foot also affects the amount of medial arch support.
This information is now added to the manuscript.
Activity level and current footwear is also implemented in the thoughts on foot orthoses design. For example: if the last design of the shoe is convex at the plantar surface, then the orthoses will fill out the convex space of the...
midsole). Depending on bony or soft tissue prominences, the amount and extent of medial arch supports will be adjusted.

v. How will the authors deal with any modifications that need to be made to the orthoses, particularly during the issuing stage? Will the researchers modify the orthoses to overcome any fitting/tolerance issues?
The orthoses will be slightly modified in cases where the participants will have obvious fitting problems. The orthopaedic technician will do these modifications if necessary right after first use (at least before measurement 1).

vi. Are participants permitted or encouraged to contact the researchers if they have any concerns (e.g. difficulty tolerating the orthoses)?
Yes, all participants receive written information with contact details of several members of the research team (postal address, telephone number, e-mail address). They are encouraged to contact the researchers or the orthopaedic technician in case of difficulties tolerating the orthoses, other upcoming problems or if they have questions. Our Ethics Committee which is a legal authority in Switzerland requires a phone number with a 24-7(!) availability.

vii. Will this group receive an activity booklet to record all accompanying activities? It appears that Group 2 and 3 will receive a booklet but it is unclear if group 1 are treated the same.
Yes, all three groups receive an activity booklet to record the length of wearing the orthosis and accompanying activities. This is clarified in the manuscript.

Foot orthoses and eccentrics
In the body of the text, it appears that the exercise group will receive more attention than the orthoses only and Sham orthotic groups (i.e. monitoring calls at one, four and eight weeks). This is not stated for the other two groups although Figure 1 suggests that all groups will receive monitoring calls. Could the authors confirm, in the body of the text, that the orthoses only and sham orthotic groups will also be monitored to ensure that the non-specific effects of the interventions are similar across groups?
All three groups get the same amount of monitoring calls, reminders in electronic or conventional form as Figure 1 suggests. We corrected the manuscript accordingly and hope that the procedures are now clear.

Sham orthoses
i. The description of the sham orthotic is unclear. Could the authors provide specific details of this device (material; thickness; density; shape etc)?
->Please see also our description above. The sham orthoses is also made from a 3D foam impression but no corrections are implemented in this orthoses. It is a one-to-one copy of the foot resulting in no potential to correct or alter static or dynamic alignment/neuromuscular control.

ii. Has the sham orthotic been validated as a credible sham? The authors might benefit from the following article, which evaluated the effect of different sham orthoses on plantar pressures.
->Internal test measurements showed that sham orthoses did not alter plantar pressures (total foot or on specific foot regions) compared to standard shoes alone. We therefore think that we provide a reasonable sham treatment.

Outcome measurements
The authors have not stated the pre-specified time point of primary interest (i.e. the primary endpoint). I assume this is 12 weeks but this needs to be specifically stated for the primary outcome measure (refer to Item 6a of the CONSORT statement).
Thank you for this point. Your assumption is right; the primary endpoint is 12 weeks. We added one sentence in the revised manuscript.

Minor Essential Revisions
i. The study flow diagram (Figure 1) is not referred to in the body of the text. Maybe a reference to Figure 1 could be placed on page 10.

Thank you for your suggestion. We mentioned now the flow diagram in the body of the text (section “Methods” under the subheading “Study design”).

ii. In the opening paragraph of page 4, tibialis posterior is referred to as an extensor of the foot, when it should referred to as a plantarflexor and invertor of the foot.

Yes, you are right. We corrected this mistake.

iii. Page 6 (paragraph 2): delete the word ‘group’ from ‘focus group’.

Thank you for this point. We deleted the word “group”.

iv. Page 7 (first paragraph): ‘relief’ should be ‘relieve’.

Yes, you are right. We changed the word according to your corrections.

v. Reference 55 (page 34): Randomised is spelt incorrectly.

That is right. We corrected the word “randomised”.

vi. Reference 15, 24, 55, 65, 73: the Journal names need to be converted to a Title Case.

We used the correct abbreviations for the corresponding journal title (reference 15, 24, 55 and 65). For reference 73 there is no short title available.

vii. A mixture of US English or British English has been used (e.g. page 2: stabilisation and stabilizing).

We changed stabilisation to stabilization to use AE consistently.

Discretionary Revisions

Abstract
I believe the opening sentence of the Abstract (page 2) needs to be re-worked. I’m not sure that pes planovalgus and flatfoot-associated complaints can be used interchangeably as many people with a flatfoot deformity remain asymptomatic. Furthermore, it cannot be suggested that the foot deformity ‘causes’ flatfoot complaints. I would just say that pes planovalgus is proposed to be associated with foot pain and poor foot function.

Thank you for this point. We changed the first sentences slightly according to your above mentioned suggestions.

Background
The Introduction is too long and is not free flowing or structured logically. I would suggest shorter paragraphs which address a specific idea. Furthermore, I don’t think that 35 lines (from page 7 to 9) are required to discuss issues surrounding static versus dynamic measures of foot structure/posture. This particular section draws attention away from the main objective of the RCT, which I assume is to evaluate the impact of pes planovalgus on pain and disability. I would suggest abbreviating the Introduction and adopting the following structure:

i. Prevalence of pes planovalgus;
ii. Signs/symptoms of pes planovalgus;
iii. An overview of treatments for pes planovalgus;
iv. The role of orthoses and strengthening exercises (including a proposed mechanism of action) for pes planovalgus;
v. Findings from previous research (uncontrolled studies and the Kulig et al. RCT). This would lead to a discussion of limitations associated with previous research and the lack of biomechanical and neuromuscular outcome measures. Essentially, this provides your rationale for conducting the RCT.
vi. Objectives/hypotheses.

Okay. We shortened the whole paragraph following your suggestions about the new structure.

I would also suggest that the authors be less inflammatory in their descriptions of previous research (e.g. page 7, paragraph 1: “In an even less adequate design...” and page 7, paragraph 1: “It is therefore remarkable that such weak evidence...” Just simply report the methodological issues.

Thank you for this point. We changed the sentences slightly in order not to rate the studies.
Reviewer #2:

Comments:

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.

You agree with reviewer 1. As mentioned above, we shortened the whole paragraph and chose a new structure, suggested by reviewer 1.

• 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.

Thank you for your remarks. We only removed the point “eligibility for non-surgical treatment” as it is very similar to the following point. All other inclusion and exclusion criteria have been carefully selected together with orthopaedic surgeons and foot specialists. The “too many toes sign” is removed.

• 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”?

->Since no biomechanical data of patients is available, these hypotheses might be speculative. Therefore, we analyse biomechanics and neuromuscular control in a descriptive manner. Whenever possible we refer to current evidence with referencing respective studies: e.g. change in afferent input via orthoses, changes in neuromuscular control possible. We hope that this answer satisfies your demands.

Since no data is available, we cannot postulate for example a certain change in dynamic navicular drop which might indicate a clinically meaningful treatment effect.

• 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.

A native English speaker read the submitted and the revised manuscript carefully. We corrected the manuscript versions according to his suggestions and hope that the writing in English language is now good enough for publication.

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.

Thank you for this point. Again, you agree with reviewer 1 and we changed the sentences according to his/her remarks (see above).

2. Line 39: change “missing” to “lacking”.

This was done, see corrected manuscript.

3. Line 42: what specifically are the inclusion criteria? This information should be included, at least briefly, in the abstract.

We added a few words regarding the inclusion criteria in the subheading “Methods” of the abstract.

4. Line 49-51: it is unclear what the “dosed foot load management” is.

Thank you for this point. We made an example after this sentence. The corresponding EdUReP program is described in detail further down in the main part.

5. Line 54-55: it is unclear how the kinematic data and neuromuscular activity data will be used, and during what activities.
Since no biomechanical data exists, results from kinematics and neuromuscular activity will be used descriptively. The activities are now added to the abstract.

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.
Yes, you are right. We corrected the sentence in the abstract.

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.
Thank you for this point. We added “or rigid” in the one of the first sentences of the “Background” paragraph in the main section.

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.
As we changed the order and shortened the whole paragraph, the problem mentioned should be solved now.

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

4. Line 99-106: this information on radiographic imaging doesn’t seem to be relevant to the purposes of the research.
Yes, you are right. We deleted this section.

5. Line 111-112: what types of patients are typically considered to be eligible for non-surgical treatment?
Mainly patients with PTTD stage 1 & 2 (flexible deformation) are eligible for non-surgical treatment.

6. Line 141: what is “optimization of foot loading management”?
The EdUReP program serves as background to teach the subjects how to load the feet properly without provocation of pain/increased pain level.

Methods
1. Line 247: what specific standardized biomechanical measurements?
Details regarding the mentioned biomechanical measurements can be found further down (section “Procedures”).

2. Line 259: what complains? How severe should the symptoms be? Location of the pain?
This criterion includes typical complaints of patients with symptomatic flatfoot. There is no determined level of pain or other symptoms.

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.
->This criteria is removed

4. Line 284: define “acute physical therapy”
The definition of “acute physical therapy” is having physical therapy prescribed and/or applied for this problem at the moment of inclusion or before.

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”
->The standing posture serves as a calibration situation for all following dynamic measurements. Therefore it has to be measured at the very beginning. Afterwards, walking and walking downstairs will follow.
6. Line 333: it might be helpful to have a mid-intervention assessment (at 6 weeks)
There is a mid-intervention assessment with the questionnaires PDI, FFI and the VAS (see manuscript), but
without biomechanical tests.

7. Line 333-334: details of intervention should be given in the following section to avoid repeat of information.
Thank you for this point. We removed one part of the sentence. All details regarding the interventions can be
found further below in the respective section.

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”.
->This means, that evidence shows that it might take some training adaptation to see changes in neuromuscular
control (see reference). “in the course of a longer lasting intervention” is now removed.

9. Line 370-372: this procedure of exercise should be described better.
->This is now changed to:
Heel lowering movements will be performed at a stair out of a calf raised position. For correction of rearfoot
eversion a pair of socks is squeezed between the calcanei below the medial malleoli (active correction of
rearfoot eversion and medial longitudinal arch flattening).

10. Line 367-386: how will the exercise intensity be progressed over the 12 weeks?
The intensity will be progressed according to the three mentioned references (Alfredson et al., Jonsson et al.)
and individually adapted in case of pain or other problems.

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.
->A better description is now added to the manuscript. Please see also out answers to Reviewer 1

12. Line 482-484: it is possible that some individuals may not have “preactivation” before initial touchdown”.
->Yes this is definitely right. If some individuals may not have activity before initial touchdown, than preactivity
will be zero.

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 estimate validity of retrieved quantities”.
After data entry, we will again check a random sample if the inserted values in the electronic database
correspond with the data collected at the measurements (CRF).

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.
Yes, you are right with your statement regarding the deformity, symptoms and PTTD. “Symptoms” is now added
here to clarify that the goal is to address complaints and symptoms.

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.
->Thanks for your useful comment. The difference to the Kulig RCT is, that Kulig used the best available evidence
to provide a base treatment (foot orthoses) to ALL groups. Since no RCT has tested foot orthoses against a
control condition, we designed out RCT with a sham foot orthoses group to use this as a reasonable control condition.

3. Line 569: what is the meaning of the exclamation mark?
This should be erased before submission, sorry for the confusion. We deleted the exclamation mark in the revised version of the manuscript.

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)
Yes, you are right. Due to financial reasons (funding problems) we resigned to use MRI.