ORTHOTIC TREATMENT FOR STAGE I AND II POSTERIOR TIBIAL TENDON DYSFUNCTION (FLAT FOOT). A SYSTEMATIC REVIEW

ABSTRACT

Objective: To investigate whether orthotic treatment is effective for the treatment of posterior tibial tendon dysfunction stages I and II (flat foot).

Data Sources: Five databases (PubMed, Scopus, PEDro, SPORTDiscus and The Cochrane Library) were searched for potential RCTs from their inception untill August 2020.

Review Methods: Only randomised controlled trials (RCT) that included subjects diagnosed with posterior tibial dysfunction in the initial stage and treated with orthotic treatments were selected. All the studies had to assess the intensity of pain after the intervention. Included RCTs were appraised using the Cochrane collaboration risk of bias tool.

Results: Four RCT articles and 186 subjects were included. 75% were at high risk of bias for blinding of participants and personnel. Three different types of conservative treatment were used in the studies: foot/ankle-foot orthoses, footwear and stretching /strengthening exercises. Foot orthoses, together with exercise programs, seemed to improve the effect of orthotic treatment. Foot orthoses with personalised internal longitudinal arch support were more effective than flat insoles or standard treatments in reducing pain.

Conclusions: The use of orthotic treatment may be effective in reducing pain in the early stages of posterior tibial tendon dysfunction although further research is needed considering individualized orthotic treatment and high-intensity monitored exercise

programs.

Keywords. Posterior tibial tendon dysfunction; Flat foot; Orthotic treatment; Foot orthoses; Pain.

INTRODUCTION

The tibialis posterior muscle is considered the main dynamic stabilizing muscle of the medial longitudinal arch (MLA) height.[1–4] When posterior tibial tendon dysfunction (PTTD) takes place pronation is prolonged until the end of the stance phase of gait resulting in pain and walking disfunction,[5,6] excessive mechanical stress and collapse of the MLA, being one of the main causes of acquired flat foot deformity in the adult.[7–9] Although further structures are involved, the PTTD is established as one of the leading causes of flat foot in the adult. [9–14]

Considering Bluman and Myerson's refined classification of PTTD,[15] in stage I patients have tenderness along the posterior tibial tendon (PTT) and in some cases a slight hindfoot valgus (5º or less). Patients in stage II have flexible hindfoot valgus, and a wide range of weaknes, lower limb functional problems and foot deformity.[16–20] This stage is subdivided into 3 categories; Stage IIA presents with forefoot varus (flexible or fixed) and possible pain along the PTT. Stage IIB involves forefoot abduction. However in stage IIC a fixed forefoot varus exists, together with medial column instability and first ray dorsiflexion.[15,21] This may be the reason why a wide typology of patients could be classified as having "flexible flat foot", and there may be variability in the treatment prescribed. Geideman and Johnson referred that conservative treatments should eliminate clinical symptoms, prevent progression foot deformity and improve hindfoot alignment.[8]

Foot orthoses are frequently recommended as non-operative treatment.[14,15,22–24] They are prescribed with the main objective of reducing pain by supporting the MLA as well as by controlling the valgus angulation of the hindfoot.[23,25–27]

Clinicians remark the importance of early diagnosis and treatment, especially of stage II while the deformity continues being moderate and is not structured.[3] The Cochrane Collaboration accepts the relevance of evaluating and synthesizing research-based evidence so that it can be incorporated into healthcare decisions.[28] To the authors' knowledge, a literature review with this aim has not been previously published. This systematic review has been carried out to know whether or not orthotic treatment has any effect when used to treat patients with stage I and II posterior tibial tendon dysfunction, or adult flexible flat foot.

METHODS

The protocol of this systematic review was registered in PROSPERO (registration number: 42020149684). PRISMA guidelines were adopted for reporting details on this systematic review.

After designing the final strategy and its adaptations to the differences of each database, five databases were searched: PubMed, Scopus, SPORTDiscus, PEDro and The Cochrane Library, being the last date of search on August 2020. Neither the year of publication nor the language of the documents was limited in any of the documents.

PubMed was used as free access tool for the search in Medline and Premedline. The search and the free search were done via Mesh terms. In Scopus the advanced search was performed, adding the predetermined options "randomised controlled trial", "randomization", "randomized controlled trial", "randomized", "randomized controlled

trial (topic)" and "randomized controlled trial as topic". Also the following childcare subjects were excluded using filters with predetermined options: "child", "child healthcare", "child preschool", "childhood disease", "children". The advanced search was done in PEDro, SPORTDiscus and in The Cochrane Library. The search strategy used can be consulted in appendix 1.

The inclusion criteria were randomized clinical trials whose participants were adults diagnosed with posterior tibial tendon dysfunction stage I or II.[15] Those randomized clinical trials which sample had no evidence about presenting posterior tibial tendon dysfunction stage I or II were excluded. There were no restrictions related to sex, race or ethnicity, kind of job position and physical or sports lifestyle.

The interventions included consisted in prescribing orthotic treatment of any characteristic. The use of another supplementary treatment and/or physical treatment was not a reason for exclusion, although this was taken into account in the analysis of the data. Any kind of comparison between interventions was valid, as long as one of them consisted in orthotic treatment. The type of results that the studies were required to report was, at least, the level of pain before and after the orthotic treatment but no studies were excluded for not presenting such results. Besides, other results were taken into account.

This review was carried out considering the method of The Cochrane Collaboration for systematic reviews.[28] Two different reviewers did the selection process independently. Both reviewers evaluated via reading the title and the abstract of each of the articles if these fulfilled the inclusion criteria previously described:

- Participants: subjects with posterior tibial tendon dysfunction stage I and II.
- Intervention: orthotic treatment.

- Comparison: whatever.
- Outcomes: whatever symptom related to posterior tibial tendón dysfunction stage I and II.
- Study design: randomized clinical trials.

After this first selection, a sole reviewer sought for the complete reports. In both evaluations, the non-fulfillment of a single criterion of eligibility was enough reason to exclude the study. This way, after the first negative item appeared, each reviewer could exclude the study without the need to continue valuing the rest of it. The risk of bias assessment in the studies was done using the software Review Manager (RevMan) recommended by The Cochrane Collaboration.[28] Reasons for exclusion were those studies that did not join the eligibility criteria previously described and/or whose level of methodological quality was doubtful. Studies in which the participants did not have pain related with their posterior tibial tendon dysfunction were excluded, as were those which did not use an orthotic treatment, or used it as a preventive or post-operative treatment without foot pain. After obtaining the manuscripts, a complete reading of the documents selected by each of the reviewers was done. In the complete reading we again valued their eligibility in accordance with the strict fulfilment of the inclusion criteria described before. This was necessary for the study to be finally selected for review.

Each reviewer had an Excel sheet to facilitate the first selection process of the studies. The selected studies were recorded in this sheet, as well as those not included and the reason for exclusion. After this process, the results of both reviewers were grouped together. Those papers which had been selected by only one of the reviewers needed of the opinion of a third evaluator to decide on the definitive inclusion or exclusion of them in the following review phase.

For the second evaluation of the reports, each reviewer used the data collection form in Word format to record each report's general information, both its identification (ID study or report) and its main characteristics (type of participants, interventions, results, etc.). The data collected were based on the eligibility criteria previously described. In this phase the complete reading and the data extraction of those studies selected in the previous process was carried out. In this case the intervention of a third reviewer was not necessary to make the final decision about whether to include some of the articles.

Finally, a sole reviewer did the complete extraction of the data of the documents eventually selected in the second evaluation. In this case a data collection form in Word format that was more extensive than the previous one was used. The Word forms were based on the translation and adaptation of the existing model designed by The Cochrane Collaboration for randomized clinical trials.[28]

RESULTS

The selection process of the articles included in the systematic review is shown in figure 1, for which a flow diagram was elaborated based on the recommendations of the PRISMA declaration.[29,30]

The four articles finally included in this systematic review are randomized clinical trials with parallel groups. Table 1 summarizes the data extracted from the studies included in the systematic review. Figures 2 and 3 show the risk of biases of the studies included in this systematic review.

Three of the four studies compared the effect of orthoses to the effect of the orthotic treatment plus exercise programs. In the Yurt et al's study,[31] three different types of orthoses were compared and every group did stretching and strenghening exercises.

The group with CAD-CAM orthoses and conventional orthoses significantly improved the pain level compared to the group of flat insole orthosis, but there were not significant differences between the CAD-CAM orthosis group and the conventional orthosis group. Both groups had a medium size effect while the flat insole orthosis group obtained a small size effect.

In case of Houck et al's study[32] all participants used the same type of foot-ankle orthosis, although this orthosis has a medial arch support with an adjustable height for each patient. One group carried out soleus, gastrocnemius and tibialis posterior stretching, while the other group did tibialis posterior and ankle plantarflexors strengthening exercises apart from the aforementioned stretching and the orthosis. Both treatments were significantly effective for pain and functional capability, but the differences between groups were minimum.

However, in the study of Kulig et al's study[16] all the participants used custom-made foot orthoses with arch support. One group carried out soleus and gastrocnemius stretching, other group did stretching and concentric exercises of progressive tibialis posterior resistance, and a third group performed stretching and eccentric exercises of tibialis posterior progressive resistance. The pain and disability measured with the Foot Function Index,[33] significantly improved in all the study groups, although the group treated with foot orthoses plus eccentric exercises showed more improvement. However, the intensity of pain after the "5-Min Walk Test" measured with Visual Analogic Scale,[34] reported significant improvements in all the groups after the intervention, but there were not significant differences between groups.

Finally, Esterman and Pilotto[35] compared the effect of foot orthoses with a placebo treatment, and no participants executed any exercise protocol. This study reported that participants who used the foot orthoses had less pain, fewer injuries and a better quality

of life, but statistically significant results did not exist due to the low treatment adherence.

DISCUSSION

The aim of this systematic review was to answer the question of whether orthotic treatment was effective when used to treat stage I and II posterior tibial tendon dysfunction, also known as adult acquired flexible flat foot. According to the qualitative analysis of the studies included, foot orthoses have shown to have positive clinical outcomes in patients with this condition, when used in conjunction with some type of excersise program.

Among 4 RCTs included in this review, only one analyzed the effect of foot orthoses without any kind of exercise program.[35] That pilot clinical trial provided some (although limited) evidence that foot orthoses could improve lower limb pain and general foot health, and decrease injury in people with flexible flat feet. However, the quantitative analysis was based on a very small sample size and the subjects' poor treatment adherence, as only 10 participants wore the orthotics provided all or most of time. Although those who used the orthoses had favorable results, half of the group did not use them for reasons related to discomfort and the negative fit between the shoe and the orthosis. This emphasizes the importance of footwear for effective orthotic treatment, although in this case, the orthosis were not personalized either, presenting exactly the same elements for all patients, according to the stage of the pathology. The remaining RTCs combined foot orthoses and home-based exercises programs to treat all participants, from only calf stretching, to calf stretching and concentric or eccentric exercices,[16] stretching or strengthening tibialis posterior muscle,[32] or these together with intrinsic muscles strengthening.[31]

Regarding the type of foot orthoses employed, Yurt et al.[31] sustained that CAD-CAM and conventional orthoses have a similar effect size to reduce pain, probably because both type of orthoses have exactly the same elements, although they were manufactured in a different way. Therefore the only difference between these two types of orthoses seemed to be that the CAD-CAM method was faster, simpler and more accurate. The positive results of flat insole orthosis, not only in their study but also in Wrobel et al's,[36] probably came from complementary treatments; but we cannot know it since these interventions were not monitored. McCormick et al.[37] sustain that the flat insoles could reduce the plantar pressures of the heel and consequently the pain, possibly due to shock absorption.

Some uncontrolled studies show the benefits of combining orthoses with exercise programs in this pathology[21,38] and also the controlled study by Kulig et al.,[16] although the appropriate intensity is not clear. To obtain a good adaptation of the tendon, the load and frequency of the exercises must be sufficient. Álvarez et al. presented positive results with a protocol of high-intensity isokinetic exercises and long sets.[21] However, Kulig et al.[38] and Bek et al.[39] used lower intensity protocols in their studies and did not replicate such good results.

In the study of Kulig et al.[16] the eccentric PT exercises group probably showed better results in terms of pain and tendon function because they performed exercises with loads three times higher than the group of concentric exercises to achieve tendon recovery. However, at pre-intervention testing, baseline Foot Function Index scores were significantly different among the 3 intervention groups. Furthermore, participants in the concentric PT exercises group had higher values of age and BMI, and lower values of arch index. Although the authors performed an ANCOVA to enable comparisons of post-intervention means after adjusting for the differences in the

baseline scores, we cannot know whether the results obtained by Kulig et al. could have been influenced by these differences. The limitation of the activity did not give rise to significant results in any group, as it happened in the study of Yurt et al.[31] This can be explained by the slight limitation that patients suffered in their daily life before treatment, despite presenting pain. Nonetheless, all groups experimented notable improvements in fuction and reductions in pain, so wearing custom orthotics and stretching the Achilles tendon seems to be a sufficient intervention.

On the other hand, in the study of Houck et al.[32] the improvements observed in the group that performed exercises as a complementary treatment to the use of orthosis, although significant, were lower compared to the study of Kulig et al,[16] being a possible cause the insufficient intensity or duration of the exercise protocol to demonstrate greater effects on pain and function. In addition, in the study by Kulig et al.[16] the orthoses were personalized, while in Houck et al's were adjustable but standardized.

The greater therapeutic adherence to the orthotic treatment in the studies by Houck et al.[32] and Kulig et al.[16] may have been linked to comfort and individualized treatment adaptation. Not all subjects had the same degree of deformity or the same stage of posterior tibial dysfunction, and therefore the degree of correction and MLA support should have not been the same. Furthermore, in the studies by Esterman and Pilotto,[35] and by Yurt et al.[31] non-personalized orthoses were used presenting metatarsal elements with a standard height and shape to all participants, while in stage II there are different deformities and degrees of severity at the forefoot.

In the authors' opinion, the studies included have certain limitations. They do not specify the process of design, manufacturing and adaptation of the orthoses to the patient or their footwear, nor whether modifications of them were made. There are other studies that report positive effects of custom-made foot orthoses pain reduction and foot

function improvement in flexible flat feet,[21,40] but there is not a consensus in their material, design or production,[41] probably due to the different characteristics of the participants of each study. In addition, some of the studies do not describe the methods followed for the diagnosis of the posterior tibial tendon dysfunction.[31,35] Also, some of the exercises programs applied to the participants were not monitored,[31] so it cannot be known their real influence on the orthoses effect.

The present study also has certain limitations, as the heterogeneous use of tools in the different studies to measure the same result. This hindered the synthesis of the results concerning the reduction of the pain, so it was carried out qualitatively. The measurement of size effect also differs between studies, so it was difficult to assess the real size effect.

To summarize, the orthotic treatment, when used in conjunction with exercise programs, seems to improve symptomatology in patients with stage I and II posterior tibial tendon dysfunction. Regarding to the manufacturing process of the orthoses, different methods have shown to be effective in the studies reviewed. Elements that support medial longitudinal arch seem to have a greater effect in reduction of pain than the orthoses that do not include them. The customization of the foot orthoses or their elements (including the arch supports) appears to have greater benefits, as well as to increase the treatment adherence. Although the positive effects of the orthotic treatment is known, there do not exist studies in which foot orthoses have eliminated pain completely. Further research is needed to find out whether or not a conservative treatment consisting only on foot orthoses is capable to completely release symptoms in adult flexible flat foot.

Clinical Messages

• Foot orthoses, together with exercise programs, may be effective in reducing pain in the early stages of posterior tibial tendon dysfunction (adult acquired flexible flat foot).

• Foot orthoses with medial longitudinal arch support seem to have a greater effect in reduction of pain.

• Custom-made orthoses seem to have greater benefits than standardized ones. Although clinicians should take into account the differents hindfoot and forefoot deformities contained in stage I and II in order to elaborate individualized orthoses.

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Ethical approval. This article does not contain any studies with human participants or animals performed by any of the authors.

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Figure 1. Stages of the selection process of the studies included in the review.

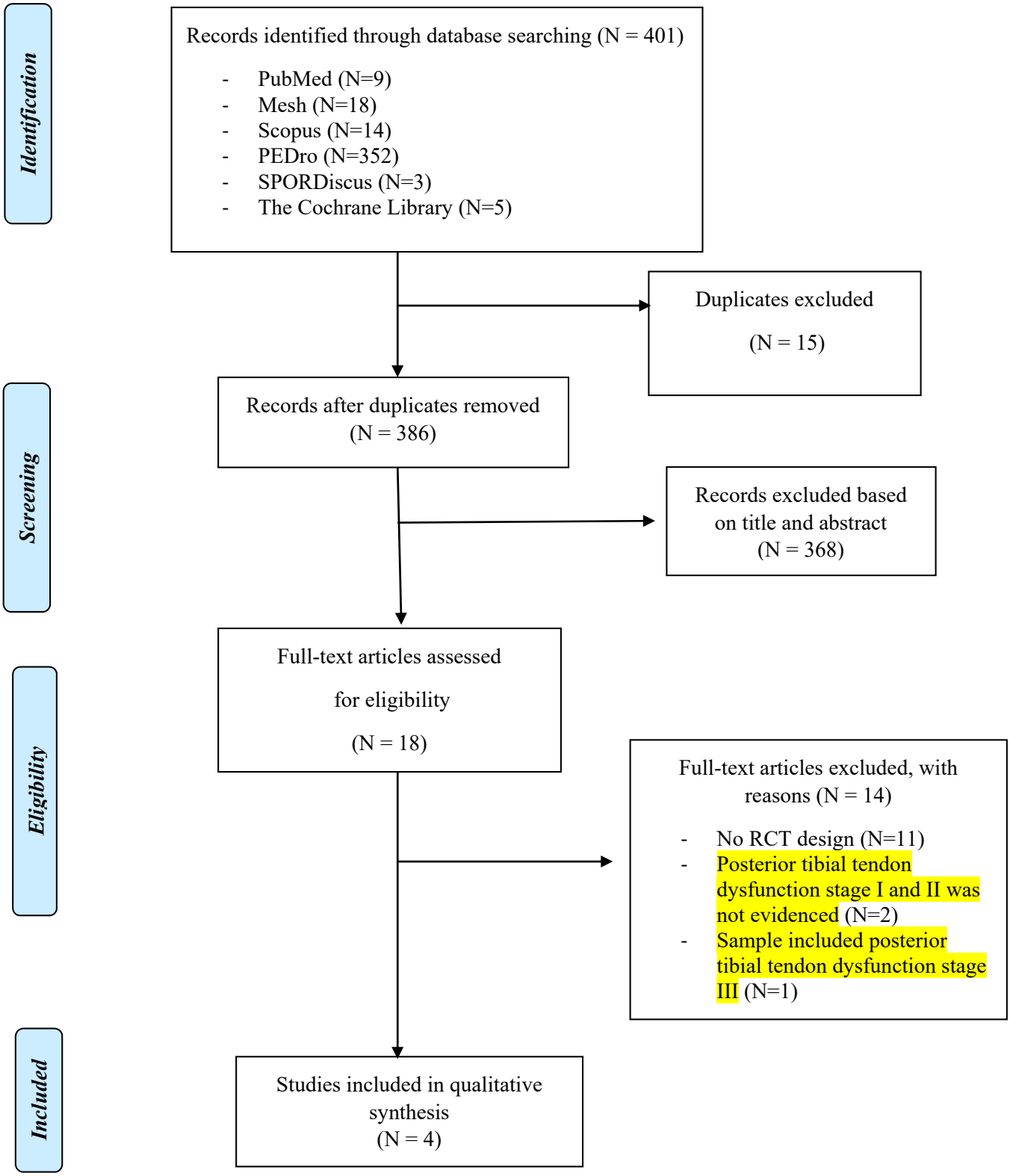


Figure 2. Risk of biases among the studies included

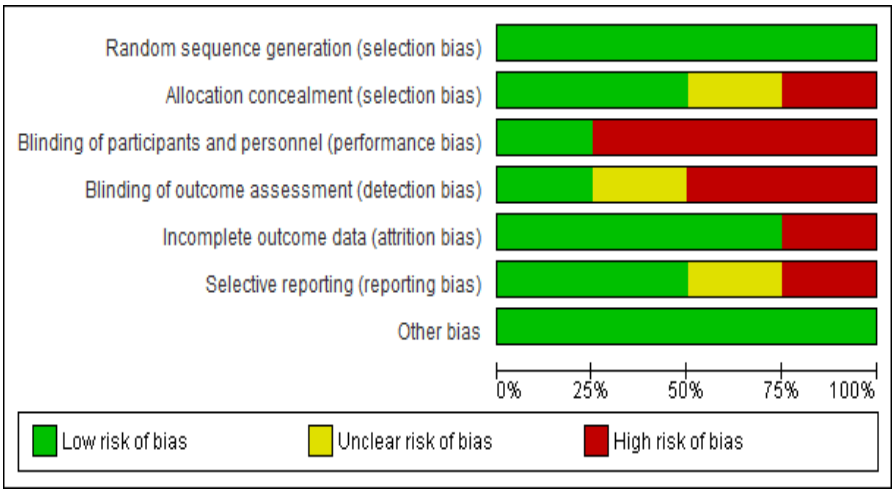
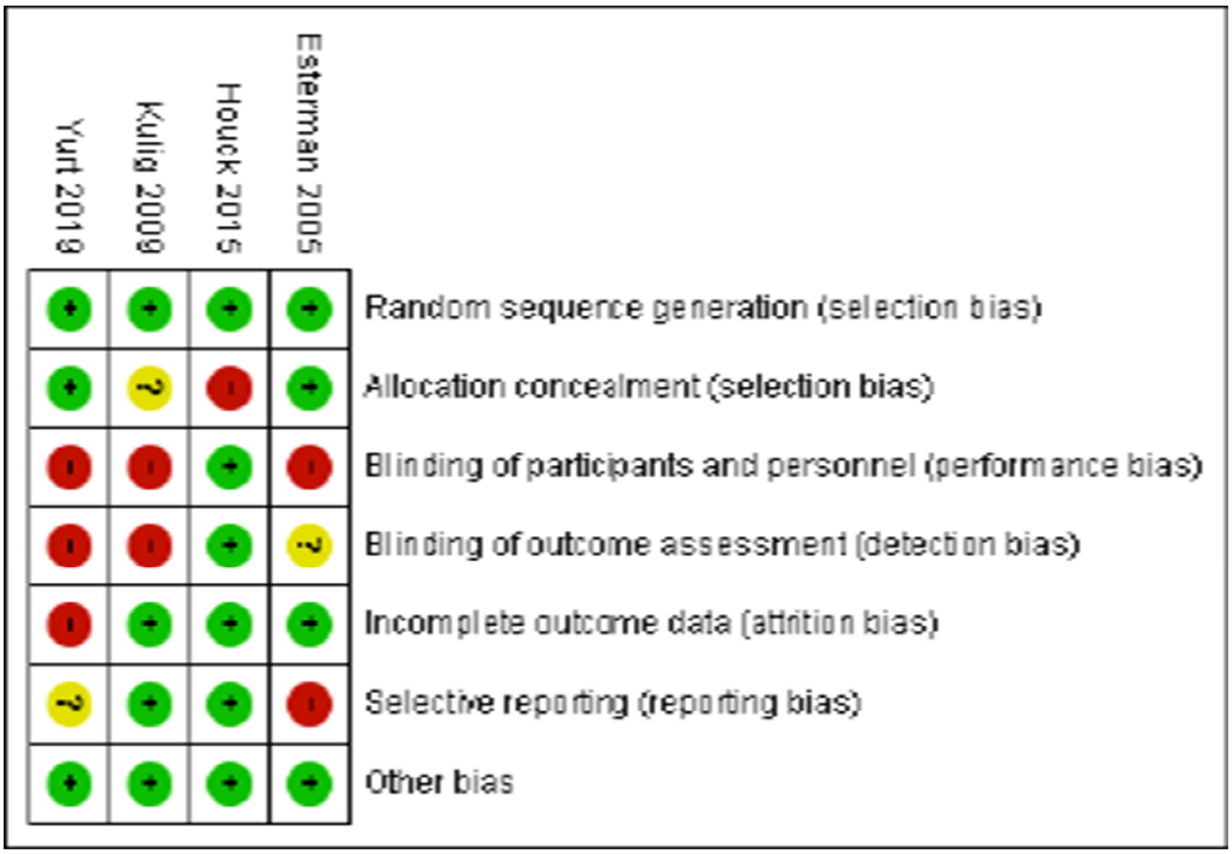


Figure 3. Risk of biases of the studies included



APPENDIX 1

Medline in PubMed

(“foot orthoses” OR “orthotic devices” OR orthos* OR orthotic* OR orthopedic* OR orthopaedic* OR insole* OR in-sole* OR innersole* OR in-shoe OR sole) AND (“pes planus” OR “posterior tibial tendon” OR flatfoot OR “adult acquired flatfoot” OR “tibialis posterior tendon dysfunction” OR “posterior tibial tendon dysfunction” OR “posterior tibial tendon insufficiency” OR “posterior tibial tenosinovitis”) AND (“stage I” OR “stage II”) AND (“randomized controlled trial” OR “controlled clinical trial” OR “randomized clinical trial as topic” OR randomly OR trial)

Mesh terms in Pubmed

("Orthotic Devices"[Mesh]) OR "Foot Orthoses"[Mesh] Filters: Randomized Controlled Trial AND ("Posterior Tibial Tendon Dysfunction"[Mesh]) OR "Flatfoot"[Mesh] Filters: Randomized Controlled Trial

Scopus

(“foot orthoses” OR “orthotic devices” OR orthos* OR orthotic* OR orthopedic* OR orthopaedic* OR insole* OR in-sole* OR innersole* OR in-shoe OR sole) AND (“pes planus” OR “posterior tibial tendon” OR flatfoot OR “adult acquired flatfoot” OR “tibialis posterior tendon dysfunction” OR “posterior tibial tendon dysfunction” OR “posterior tibial tendon insufficiency” OR “posterior tibial tenosinovitis”) AND (“stage I” OR “stage II”)

Also filters were used to limit the type of article, adding the predetermined options "randomised controlled trial", "randomization", "randomized controlled trial", "randomized", "randomized controlled trial (topic)" and "randomized controlled trial as topic".

Childcare was also excluded thanks to the filters with the predetermined options "child", "child healthcare", "child preschool", "childhood disease", "children".

PEDro

First search:

- Therapy: orthoses, taping, splinting AND
- Problem: pain AND
- Body part: foot or ankle AND
- Method: clinical trial

Second search:

- Therapy: orthoses, taping, splinting AND
- Problem: muscle weakness AND
- Body part: foot or ankle AND
- Method: clinical trial

SPORTDiscus

("foot orthoses" OR "orthotic devices" OR orthos* OR orthotic* OR orthopedic* OR orthopaedic* OR insole* OR in-sole* OR innersole* OR in-shoe OR sole) AND ("pes

planus" OR "posterior tibial tendon" OR flatfoot OR "adult acquired flatfoot" OR "tibialis posterior tendon dysfunction" OR "posterior tibial tendon dysfunction" OR "posterior tibial tendon insufficiency" OR "posterior tibial tenosinovitis") AND ("stage I" OR "stage II") AND ("randomized controlled trial" OR "controlled clinical trial" OR "randomized clinical trial as topic" OR randomly OR trial)

The Cochrane Library

("foot orthoses" OR "orthotic devices" OR orthos* OR orthotic* OR orthopedic* OR orthopaedic* OR insole* OR in-sole* OR innersole* OR in-shoe OR sole) AND ("pes planus" OR "posterior tibial tendon" OR flatfoot OR "adult acquired flatfoot" OR "tibialis posterior tendon dysfunction" OR "posterior tibial tendon dysfunction" OR "posterior tibial tendon insufficiency" OR "posterior tibial tenosinovitis") AND ("stage I" OR "stage II") AND ("randomized controlled trial" OR "controlled clinical trial" OR "randomized clinical trial as topic" OR randomly OR trial)

Table 1. Main characteristics of the studies included.

	N	Men/ Women	Average age	Followup period	Stage of PTTD*	Types of orthotics	Variables	Pre-treatment / post-treatment pain	Size effect
Yurt 2019	67	28/39	21.73 ± 2.89 [1] 23.05 ± 5.53 [2] 21.09 ± 1.95 [3]	8 weeks	I and II	CADCAM Conventional Flat insole	Pain, limitation of activity, and mental and physical health	**CADCAM***: 59.27±17.26 (51.62-66.93) / 27.84±18.41(19.67-36.01) mm (VAS*) **Conventional**: 60.32±16.82 (52.86-67.78) / 27.05±16.82 (18.29-32.21) mm (VAS) **Flat insole**: 58.48±17.51 (50.91-66.05) / 46.39±20.18(37.66-55.12) mm (VAS)	Cohen's d = 0.660 Cohen's d = 0.703 Cohen's d = 0.304
Houck 2015	39	8/28	58 ± 9 [4] 57 ± 12 [5]	12 weeks	II	Precast foot-ankle	Pain, disability, limitation of activity, perception of mobility, dysfunction and discomfort, and the PTT's* isometric strength	**Stretching group**: 35 (29-40)/18(12-25) mm (VAS) **Strengthening group**: 38 (29-46)/19 (11-27) mm (VAS)	Stretching group: P < .001 Strenghening group: P < .001
Kulig 2009	36	8/28	51.3 ± 17.2 [4] 55.3 ± 16.4 [6] 49.4 ± 12.6 [7]	12 weeks	I and II	Custom-made	Pain, disability and limitation of activity	**Orthoses**: 37.5 (25.8, 49.2) / 21.2 (10.2, 32.2) mm (VAS) **Orthoses and concentric exercise**: 34.8 (23.6, 46.0) / 13.0 (7.6, 18.4) mm (VAS) **Orthoses and excentric exercise**:	ANCOVA* identified differences among the groups (P= .048)

								46.9 (37.3, 56.5) / 10.6(5.8,15.4) mm (VAS)	
Esterman 2005	47	44/3	14 subjects are <21 years old and 11 subjects ≥21 [8] 9 subject are <21 years old and 13 subjects ≥21 [9]	8 weeks	I and II	Precast and thermo-adapted	Pain, mental and physical health, general foot health and injuries after training	**Custom-made ortheses**: Had lower limb pain = 10 / 4 No lower limb pain = 15 / 16 **No treatment:** Had lower limb pain = 5 / 4 No lower limb pain = 17 / 8	P = .606

*PTTD: Posterior tibial tendon dysfunction. *CAD-CAM: computer-aided design/computer-aided manufacturing. *VAS: visual analogue scale. *PTT: posterior tibial tendon. *ANCOVA: analysis of covariance. [1] CAD-CAM ortheses; [2] Conventional ortheses; [3] Flat insole; [4] Ortheses and stretching; [5] Ortheses, stretching and strengthening; [6] Ortheses, stretching and concentric; [7] Ortheses, stretching and eccentric; [8] Custom-made ortheses; [9] No treatment.