Commissioning Brief - Background Information

Foot orthoses for children with symptomatic flat feet

This background document provides further information to support applicants for this call. It is intended to summarize what prompted the call and the existing evidence base, including relevant work from the HTA and wider NIHR research portfolio. It was researched and written on the basis of information from a search of relevant sources and databases, and in consultation with a number of experts in the field. Searches and information provided were up to date as of February 2018.

Patient group

- Flat feet – medical name pes planus – occurs when the normal arch in the foot is lost. In such cases, when the foot is on the ground, the inner side of the foot comes down to the floor rather than remaining raised, causing the foot to roll inwards.
- Flat feet in children may be classed as either ‘fixed’ or ‘flexible’. Fixed/rigid flat foot is considerably rarer and for this condition surgery may be indicated. It is for flexible flat foot (when the child can stand on tiptoe to reveal an arch) that treatment uncertainty exists.
- Flexible flat feet is normal in infants as there is a fat pad under the medial long arch to protect it during development. Nearly all children are flat footed when they start to walk and the arch usually develops between the ages of 2 and 5 years (https://patient.info/doctor/pes-planus-flat-feet).
- By the age of 3-6 years, flat feet is still common but most children develop a normal longitudinal arch by the age of 10 years (https://patient.info/doctor/pes-planus-flat-feet).
- Flexible flat feet in children is common with a prevalence of between 2.7 and 18.1% and it is thought to be the most frequent reason for attendance at paediatric orthopaedic clinics and a common reason for frequent clinical consultations for a number of other healthcare professionals.
- Why flat feet develop is debated and no single factor has been identified as the root cause. Instead, it is likely that the development of flat feet is multifactorial involving a complex relationship between bones, ligaments and muscles within the foot as well as overall limb alignment and comorbid medical conditions (including obesity).
- While most children with flat feet will not have any symptoms, flat feet can be associated with pain in the foot and ankle, foot and ankle instability, ligament strain or even leg and lower back pain.
- It remains unclear why some children develop symptoms and others do not and the exact percentage of cases that develop symptoms is also unclear, with estimates varying from 10-60%. It is also estimated that up to 63% of children have functional impairment as a result of flexible flat foot.
- Evidence also suggests that although parents may overestimate their child’s impairment from flat feet, the children themselves have significantly reduced health related quality of life compared to children with typically developing feet.

NICE and other guidance

There is no clear guidance on the non-surgical management of symptomatic flatfoot in children.

NICE support the use of sinus tarsi implants to correct and improve symptoms (Interventional procedures guidance IPG305, 2009) only in selected children with persistent mobile flatfoot due to a neuromuscular or skeletal disorder (therefore not relevant to the patient group defined in this brief) under supervision from a multidisciplinary team.
Current practice and proposed intervention

Flat foot is (or should be) assessed using the paediatric flat foot proforma but there is currently no clear and evidence-based treatment algorithm (https://patient.info/doctor/pes-planus-flat-feet).

Furthermore, the treatment of paediatric flexible flat foot is controversial. While there is clear consensus that the condition reduces with age and most children do not display symptoms, children are often unnecessarily treated (https://patient.info/doctor/pes-planus-flat-feet).

The debate between treating and monitoring asymptomatic and symptomatic pes planus is on-going with no gold standard for treating children with pes planus. This is primarily based around disagreements about whether paediatric flat foot resolves spontaneously or may lead to disability or joint damage in later life.

In addition, what this treatment should look like is also a cause for debate. The treatment of this condition can vary from conservative management to surgical approaches. While surgical treatment is very rare in children, a plethora of non-surgical approaches exist including advice, foot orthoses (shoe inserts and insoles), stretching, modified footwear, physiotherapy, serial casting or anti-inflammatory medication.

Published evidence to date on treatments for flat foot has mainly focussed on the use of foot orthoses. Foot orthoses – shoes inserts/insoles providing medial arch support – can either be standard insoles or can be especially moulded/customised to the individual child’s feet.

Thousands of insoles are prescribed for children with flat feet each year on the NHS (reviewer feedback). There is therefore a significant cost implication for the NHS both for standard insoles and also for customised ones which are significantly more expensive. Foot orthoses are widely used to treat children with flat feet and it is presumed that they prevent excessive pronation, provide neuromuscular re-education and normalise body mechanics to alleviate symptoms. However, to date there is little evidence that either form of foot orthoses is effective at relieving symptomatic flat foot in children. As providing foot orthoses is expensive to the NHS and may cause harm to the child (for example by lowering self-esteem), further evidence is required to critically assess the clinical and cost effectiveness of these interventions.

Completed research

Evidence Synthesis

Rome (2010) Non-surgical interventions for paediatric pes planus. This Cochrane review searched to June 2009 and identified just 3 trials (n=305 children) that compared different interventions (custom-made orthoses vs prefabricated orthoses vs new athletic trainers; orthopaedic shoes vs heel cups vs standard orthotics vs custom moulded orthoses; custom-made semi-rigid orthoses vs prefabricated semi-rigid vs no treatment) and measured different outcomes (pain; radiographs and clinical measures; motor proficiency) so results could not be pooled. The systematic review authors concluded that the evidence is currently too limited to draw definitive conclusions about the use of non-surgical approaches for paediatric flatfoot and that more research is needed.

A small number of reviews have been published more recently, but each highlights the lack of conclusive evidence regarding the use of orthotics, and particularly custom-made orthotics, in the management of symptomatic and asymptomatic flatfoot. No further RCT evidence is presented by any of these reviews:

Carr (2016) Pediatric Pes Planus: A State-of-the-Art Review. The authors conclude that at the moment and based on current literature, prophylactic treatment of asymptomatic flatfoot with custom orthotics is not justified, but may be indicated for those with painful symptoms to improve function. However, the literature lacks rigorous comparative studies.

Dare (2014) Pediatric flatfoot: cause, epidemiology, assessment, and treatment. This descriptive review states that “Although some authors advocate orthotics for children with asymptomatic flexible flatfeet,
there is no convincing evidence to support this practice". This review cites the same three randomised controlled trials included in the above Cochrane review and reaches similar conclusions⁶.

MacKenzie (2012) *The efficacy of nonsurgical interventions for pediatric flexible flat foot: a critical review*. This review identified 13 articles and used a structured Quality Index to evaluate the research quality of the articles. The mean Quality Index score was 35% (range: 13% to 81%), indicating poor and varying methodological quality of studies evaluating interventions for flat foot. The review authors highlight that future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up⁷.

**Primary Research**

A number of small-scale studies have been published exploring the virtues of specific foot orthoses for children with flexible flatfoot, exploring outcomes such as their impact on three dimensional movement⁸, changes in resting stance position angle⁹¹¹ and peak pressures¹². However, no new studies were identified that measured patient-relevant outcomes using validated scores such the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C) or which randomised children to different interventions.

**Research in progress**

In summary there is no ongoing research, identified during searches, that should interfere with the proposed research in this brief.

**Evidence Synthesis**


**Primary Research**

NCT02633566 *Clinical Trial of the Effect of Functional Orthoses in Children With Flat Feet*. The purpose of this study is to investigate the efficacy of functional plantar orthoses on flatfoot in children. N=61, estimated completion May 2014. Country not provided. Being conducted by a PhD student, no funder/sponsor listed.

NCT02414087 *Therapeutic Effects of Customized Insoles on Children With Flat Foot*. Using double blind, randomized controlled design to study the short-term therapeutic effects of customized arch-support shoe insoles to children with flat foot. N=52, estimated completion Dec 2015. China. (Status hasn’t been verified in over 2 years and no publication found).

**NIHR research**

No active or published research was identified during portfolio checks relating to flat feet, insoles or orthoses.
*Adults only, different condition.*

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References