

Non-surgical interventions for paediatric pes planus (Protocol)

Rome K, Ashford RL, Evans A



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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The aim of this review is to evaluate the evidence from randomised controlled trials for the non-surgical intervention of paediatric pes planus.

BACKGROUND

Pes planus (flatfoot) is one of the most common conditions observed in paediatric health practice (Luhmann 2000; Sullivan 1999). The prevalence of paediatric pes planus has been reported to be between 2.7% and 12.3% (Garcia 1999). There is no universally accepted definition for pes planus. Clinically, a pes planus is one that has a low or absent longitudinal arch. A flexible flat foot will have an arch that is present in open kinetic chain (non-weight-bearing) and lost in closed kinetic chain (weight-bearing). A rigid flatfoot has loss of the longitudinal arch height in open and closed kinetic chain (Napolitano 2000). Normally developing infants have a flexible flatfoot and gradually develop a normal arch during the first decade of life (Capello 1998).

There is a wide spectrum of severity and many different aetiologies for paediatric pes planus (Capello 1998). Staheli 1987 proposed a generic classification of flatfoot deformities that differentiated between flatfeet due to physiological and pathological aetiologies. Harris 2004 reported that pes planus may exist as an isolated pathology or as part of a larger clinical pathologies such as generalised ligamentous laxity, neurological and muscular abnormalities, genetic conditions and syndromes, and collagen disorders. Luhmann 2000 states that tarsal coalitions are the most common cause of rigid flatfeet in children and adolescents. Napolitano 2000 reported that obesity, rotational deformities producing in-toeing or out-toeing, accessory navicular, ankle equinus, varus and valgus deformities of the tibia and its relationship to the weight-bearing

surface, are risk factors that may play a role in the development and function of the foot.

Notwithstanding the underlying pathology of pes planus, there are conflicting opinions on the intervention of paediatric pes planus (Garcia 1999). The primary goals of treatment of flatfeet are relief of pain or disability and the prevention of future disability (Capello 1998). While some experts consider that pes planus is normal in early childhood and that the condition usually resolves spontaneously without treatment (Brooks 1991; Volpon 1994), others experts suggest treating the flexible form of pes planus is necessary as it may lead to disability, joint damage and in later life a rigid fixed foot deformity (Aharonson 1992; Connors 1998).

The American College of Foot and Ankle Surgeons (Harris 2004) have published clinical practice guidelines for the diagnosis and treatment of paediatric pes planus. An overriding concern is that flatfoot can cause debilitating foot pain in adults and should be diagnosed early and treated appropriately. The controversy about the management of pes planus arises from the contradictory opinions expressed by different authors. Luhmann 2000 reported that a rigid pes planus is often symptomatic and requires treatment. A flexible pes planus may be either asymptomatic or symptomatic (Sullivan 1999). Luhmann 2000 suggested that the flexible type is a common diagnosis and is one which is usually not problematic and rarely needs treatment. The treatment of this condition can vary from conservative management to surgical approaches. The latter are used rarely and generally only after failure of conservative management. A plethora of conservative (non-surgical) inter-

ventions have been reported in the literature ranging from advice to foot orthoses (shoe inserts), stretching, footwear selection and modifications, activity modifications, manipulation, serial casting, appropriate weight reduction and anti-inflammatory medications. Hence, there is a need to identify and evaluate the evidence from randomised trials of non-surgical interventions used in the management paediatric pes planus.

OBJECTIVES

The aim of this review is to evaluate the evidence from randomised controlled trials for the non-surgical intervention of paediatric pes planus.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

All randomised controlled trials (RCTs) and quasi-randomised controlled clinical trials (CCTs; methods of allocating participants to a treatment which are not strictly random, e.g., date of birth, hospital record number or alternation) comparing non-surgical interventions versus placebo, sham or no intervention (control) or other non-surgical interventions for paediatric pes planus.

Types of participants

Since there is no universally accepted definition for pes planus, pes planus in this review is a term that will be used to describe a recognizable clinical deformity created by malalignment at several adjacent joints. Included will be trials with participants meeting the following criteria: children under 16 years old and pes planus pain for greater than eight weeks duration. Studies of various soft tissue diseases and pain due to tendinitis at all sites will be included provided that the pes planus pain results are presented separately or greater than 90% of participants in the study had pes planus pain. We will also include those studies whose participants have plantar heel pain, stress fractures of the metatarsals, ankle fractures, rheumatoid foot pathologies, diabetic foot, or neuromuscular conditions. Studies focusing on children with Down's, Marfans or 'Ehlers-Danlos' syndrome will also be included.

Types of intervention

These include activity modification, manipulation, serial casting, weight reduction, anti-inflammatory medication, rigid, semi-rigid or soft-foot orthoses designed to provide support or pain relief, or both at the subtalar joint; corrective footwear; anti-pronatory strapping; stretching exercises; and educational advice to children or their parents and guardians. Excluded will be studies involving surgical intervention.

Types of outcome measures

Primary outcomes:

- Pain reduction

Secondary outcomes:

- Function/disability indices of the foot
- Goniometric measurement or those that are collated in a gait laboratory that includes both kinetic and kinematic data
- Quality of life measures
- Adverse effects of treatment interventions under test
- Patient comfort

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Musculoskeletal Group methods used in reviews.

Eligible studies will be sought from electronic searches of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, INDEX TO THESIS, and DISSERTATION ABSTRACTS. In MEDLINE, subject specific search terms will be combined with the optimum search strategy for randomised trials described by Robinson 2002 (see Table 01)

The electronic search will be complemented by the following:

- checking of reference lists of relevant articles for additional studies reported in published papers, scientific meetings, and personal communications;
- downloads of Current Contents up to January 2007;
- hand searches of abstracts published in special issues of specialised journals or in conference proceedings;
- contact of content experts for additional studies and unpublished data.

METHODS OF THE REVIEW

Study identification and selection

One author (KR) will check through the titles and abstracts identified by the above searches and identify potentially eligible studies for obtaining full trial reports and study selection. The results of study selection by KR will be checked by one of the two other authors (RA and AE). Disagreement will be resolved by consensus or third party adjudication (KR).

Quality assessment of the included trials

Methodological quality for each study will be assessed independently, without masking (Jahad 1996; Schulz 1994; Verhagen 1998), by two reviewers (RA, AE) from the group using a piloted, subject-specific modification of the generic evaluation tool used by the Cochrane Musculoskeletal Group. The scoring scheme for the 11 items of internal and external validity is outlined in Table

02. There are three potential ratings: (i) meets; (ii) partially meets; and (iii) does not meet each validity criterion. The assessment of each criterion will be presented in the review, and an overall assessment of the validity of the results of individual trials will also be assessed by assigning one of three categories- low, moderate, and high risk of bias- corresponding to all criteria met, one or more criteria partially met, and one or more criteria not met. Allocation concealment will also be ranked as: A: adequate; B: unclear; C: inadequate; or D: not used. Any disagreement will be resolved by consensus or third party adjudication (KR).

Data extraction

The three authors will independently extract data and study details using a standard pre-designed form. Disagreement will be resolved by consensus or third party adjudication (KR). We will contact authors of trials if there is incomplete reporting of data.

Data analysis

For each study, we will calculate relative risks and 95% confidence limits for dichotomous outcomes, and we will compute weighted mean differences and 95% confidence limits for continuous outcomes. We will conduct meta-analyses with a fixed-effect model if studies are clinically and statistically homogenous. Where there is statistical evidence of heterogeneity (a chi-squared test with $P < 0.10$ or an I^2 test with a percentage of the variability in effect estimates $> 50\%$), we will use a random effects model.

Clinical Relevance Tables

Clinical relevance tables will be compiled under additional tables to improve the readability of the review. For dichotomous outcomes, like complications, the number needed to treat will be calculated from the control group event rate and the relative risk using the Visual Rx NNT calculator (Cates 2003). Continuous outcome tables will also be presented under additional tables. Absolute benefit will be calculated as the improvement in the intervention group minus the improvement in the control group, in the original units. Relative difference in the change from baseline will be calculated as the absolute benefit divided by the baseline mean of the control group.

Grading of the evidence

A further ranking based on the level of evidence will be performed in the manner described by Tugwell 2004 and approved by the CMSG editorial team. A simplified ranking will be used to grade the strength of scientific evidence for the trial intervention. In decreasing order:

Platinum: A published systematic review that has at least two individual controlled trials each satisfying the following:

- Sample sizes of at least 50 per group - if these do not find a statistically significant difference; they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.

- Handling of withdrawals $> 80\%$ follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) are acceptable).

- Concealment of treatment allocation.

Gold: At least one randomised clinical trial meeting all of the following criteria for the major outcome(s) as reported:

- Sample sizes of at least 50 per group - if these do not find a statistically significant difference; they are adequately powered for a 20% relative difference in the relevant outcome.
- Blinding of patients and assessors for outcomes.
- Handling of withdrawals $> 80\%$ follow up (imputations based on methods such as LOCF are acceptable).
- Concealment of treatment allocation.

Silver: A randomised trial that does not meet the above criteria. Silver ranking would also include evidence from at least one study of non-randomised cohorts that did and did not receive the therapy, or evidence from at least one high quality case-control study. A randomised trial with a 'head-to-head' comparison of agents would be considered silver level ranking unless a reference were provided to a comparison of one of the agents to placebo showing at least a 20% relative difference.

Bronze: The bronze ranking is given to evidence if at least one high quality case series without controls (including simple before/after studies in which patients act as their own control) or if the conclusion is derived from expert opinion based on clinical experience without reference to any of the foregoing (for example, argument from physiology, bench research or first principles).

POTENTIAL CONFLICT OF INTEREST

None known.

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ADDITIONAL TABLES

Table 01. MEDLINE (OVID-WEB) search strategy

MEDLINE (OVID-WEB)

1. exp flatfoot/
2. flat foot\$.mp.
3. flatfoot\$.mp.
4. flat feet.mp.
5. flatfeet.mp.
6. pes planus.mp.

Table 01. MEDLINE (OVID-WEB) search strategy (Continued)

MEDLINE (OVID-WEB)

7. painful foot.mp.
8. pes planovalgus.mp.
9. posterior tibial tendon dysfunction.mp.
10. subtalar.mp.
11. (sub\$ adj talar).mp.
12. calcane\$.mp.
13. heel bone\$.mp.
14. medical arch\$2.mp.
15. or/1-14
16. exp musculoskeletal diseases/
17. exp neuromuscular diseases/
18. exp nervous system diseases/
19. ehlers-danlos.mp.
20. down\$ syndrome.mp.
21. trisomy.mp.
22. mongolism.mp.
23. inflammatory arthritis.tw.
24. (juvenile adj3 arthritis).tw.
25. or/16-24
26. exp diabetes mellitus, type 1/
27. (diabet\$ or IDDM).tw.
28. 26 or 27
29. exp diabetes insipidus/
30. mellitus.tw.
31. 29 not (26 or 30)
32. (diabet\$ adj (insipidus not mellitus)).tw.
33. 31 or 32
34. 28 not 33
35. joint instability.sh.
36. ligament\$ laxity.mp.
37. pronat\$.mp.
38. malalignment.mp.
39. or/35-38
40. or/25,34,39
41. 15 and 40
42. randomized controlled trial.pt.
43. controlled clinical trial.pt.
44. randomized controlled trials.sh.
45. random allocation.sh.
46. double blind method.sh.
47. single-blind method.sh.
48. clinical trial.pt.
49. clinical trials.sh.
50. clinical trial.tw.
51. ((singl\$ or doubl\$ or trebl\$ or tripl\$) and (mask\$ or blind\$)).tw.
52. placebos.sh.
53. placebo\$.tw.
54. random\$.tw.
55. research design/

Table 01. MEDLINE (OVID-WEB) search strategy *(Continued)***MEDLINE (OVID-WEB)**

56. comparative study.sh.
57. evaluation studies.sh.
58. follow-up studies.sh.
59. prospective studies.sh.
60. control\$.tw.
61. prospectiv\$.tw.
62. volunteer\$.tw.
63. or/42-62
64. (animal not human).mp.
65. 63 not 64
66. 41 and 65
67. limit 66 to ("infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (6 to 12 years)" or "adolescent (13 to 18 years)")
68. child.mp.
69. children.mp.
70. childhood.mp.
71. infant\$.mp.
72. teenag\$.mp.
73. adolescen\$.mp.
74. paediatric.mp.
75. pediatric.mp.
76. or/68-75
77. 66 and 76
78. 67 or 77

Table 02. Methodological assessment tool**Quality criterion**

1. Was the assigned treatment adequately concealed prior to allocation?
2. Were the outcomes of patients who withdrew described and included in the analysis (intention to treat)?
3. Were the outcome assessors blinded to treatment status?
4. Were the treatment and control group comparable at entry?
5. . Were the subjects blind to assignment status after allocation?
6. Were the treatment providers blind to assignment status after allocation?
7. Were care programmes, other than the trial options, identical?
8. Were the inclusion and exclusion criteria clearly defined?
9. Were the outcome measures used clearly defined?
10. Was follow-up active and appropriate?
11. Was the duration of surveillance clinically appropriate?

Scores

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

Meets, Partially meets, Does not meet

COVER SHEET**Title**

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