Ottawa Panel Evidence-Based Clinical Practice Guidelines for Foot Care in the Management of Juvenile Idiopathic Arthritis

Abstract:

Objective: To create evidence-based guidelines evaluating foot care interventions for the management of juvenile idiopathic arthritis (JIA).

Data Sources: An electronic literature search of the following databases from database inception until May 2015 was conducted: Medline (Ovid), Embase (Ovid), Cochrane CENTRAL, and clinicaltrials.gov.

Study Selection: The Ottawa Panel selection criteria targeted studies that assessed foot care or foot orthotic interventions for JIA management among those ages 0 to ≤ 18 years old. The Physiotherapy Evidence Database (PEDro) scale was used to evaluate study quality, of which only high quality studies were included (score ≥ 5). A total of 362 records were screened, resulting in three full text articles and one additional citation containing supplementary information included for analysis.

Data Extraction: Two reviewers independently extracted study data (intervention, comparator, outcome, time period, and study design) from included studies, using standardized data extraction forms. Directed by Cochrane collaboration methods, the statistical analysis produced figures and graphs representing the strength of intervention outcomes and their corresponding grades (A, B, C+, C, C-, D+, D, D-). Clinical significance was achieved when an improvement of 30% or more between intervention and control groups was present, whereas $p > 0.05$ indicated statistical significance. An expert panel Delphi consensus (≥ 80%) was required for recommendation endorsement.

Data Synthesis: All included studies were of high quality and analyzed the effects of multidisciplinary foot care, customised foot orthotics, and shoe inserts for the management of JIA. Custom-made foot orthotics and pre-fabricated shoe inserts displayed the greatest improvements in pain intensity, activity limitation, foot pain, and disability reductions (grades A, C+).

Conclusions: The use of customised foot orthotics and pre-fabricated shoe inserts seems to be a good choice for managing foot pain and function in JIA.

Key words: Foot orthotics, Juvenile Idiopathic Arthritis, Physiotherapy, Podiatry, Pediatric rheumatology

Abbreviations: JIA Content

AGREE	Appraisal of Guidelines for Research and Evaluation
CCT	Clinical Control Trial
EBCPG	Evidence-Based Clinical Practice Guidelines
JIA	Juvenile Idiopathic Arthritis
MCID	Minimal Clinical Important Difference
OMERACT	Outcome Measures for Rheumatoid Arthritis Clinical Trials
OMG	Ottawa Methods Group
PEDro	Physiotherapy Evidence Database
PRISMA	Preferred Reporting Items for Systematic and Meta-Analyses
RCT	Randomised Control Trial

Abbreviations: Intervention Outcomes/Instruments

CHAQ	Childhood Health and Assessment Questionnaire
EQ-5D VAS	EuroQol – 5 Dimensions Visual Analogue Scale
FFI	Foot Function Index
JAFIimp	Juvenile Arthritis Foot Disability Index – Impairment
JAFIal	Juvenile Arthritis Foot Disability Index – Activity Limitation
JAFIpr	Juvenile Arthritis Foot Disability Index – Participation Restriction
PedsQL	Pediatric Quality of Life Inventory
VAS	Visual analogue scale

Target Population

Patients with juvenile idiopathic arthritis (JIA) accompanied by family members (e.g. parents/guardians) as well as different types of health professionals such as registered nurses, podiatrists, pediatricians, rheumatologists, and exercise physiologists, can refer to this evidence-based clinical practice guideline (EBCPG). Arthritis based institutions and charity groups (e.g. The Arthritis Society, etc.) may also find this EBCPG to be of interest. This guideline primarily targets those between the ages of 3 and 19 years old with varying disease durations (1 month to 18 years).

Introduction

Juvenile idiopathic arthritis (JIA), is a prevalent chronic childhood autoimmune disease[1] that can cause disability in areas of the body with higher weight-bearing demands such as the foot. Foot problems (e.g. inflammation, limitation of motion) often arise among JIA patients due to affected joints, which consequently impact the feet and lead to pain, deformities[2], and malalignment[3]. Foot care and foot orthotics are often used by patients with rheumatoid arthritis[4-8], and have been shown to relieve pain by adjusting biomechanical deformities and lower limb misalignments[9]. Although deformities and foot pain are common to arthritis, foot care is infrequently considered as part of an overall management approach for JIA and represents a neglected area of study[10].

The management of JIA is frequently viewed through a multi-disciplinary lens, incorporating pharmacological and psychological interventions, along with physical and occupational therapy[11]. Unfortunately, published EBCPGs and systematic reviews investigating the use of non-pharmacological interventions, like foot care, for managing JIA lack substantial evidence and are outdated[12-15]. There is a strong need to update EBCPGs based on a quantitative and systematic methodology in order to develop rigorous recommendations on effective foot care management solutions for JIA. The proposed Ottawa Panel evidence based clinical practice guideline (EBCPG) is based on a systematic review and has consolidated all non-pharmacological foot care management options for JIA. The primary objective of this Ottawa Panel EBCPG was to develop evidence-based recommendations on foot care interventions for JIA based on a critical appraisal of comparative controlled studies. The secondary objective was to determine the strength of existing evidence-based research on foot care interventions for JIA. The third and final objective was to identify the most effective foot care interventions for JIA. In order to promote foot care for JIA management, stakeholders will require access to recent, high quality recommendations as presented within this EBCPG.

Methods

Development process of the Ottawa Panel EBCPG

The development of this Ottawa Panel EBCPG was informed by previous Ottawa Panel EBCPGs[16-19] and its methodology follows the Preferred Reporting Items for Systematic and Meta-Analyses (PRISMA) checklist[20]. The major components of the Ottawa Panel EBCPG include: 1) a systematic search of the literature as per Cochrane Collaboration methodology[21]; 2) inclusion of articles according to selection criteria, 3) study quality assessment, 4) data extraction and synthesis, 5) quantitative grading system[22]; 6) health expert review and endorsement of recommendations, and 7) planned dissemination of results.

The Ottawa Panel

The Ottawa Panel consists of the Ottawa Methods Group (OMG), which develops the EBCPG, and the Expert Panel, which reviews and approves EBCPG recommendations through a consensus process. The OMG produced evidence tables containing study data and developed recommendations for the draft EBCPG. The expert panel, which includes 15 experts: 1 physician, 6 physiotherapists, 1 occupational therapist, 2 exercise physiologists, 3 chiropodists/podiatrists and 2 consumer experts (parent and child), were sent draft EBCPG recommendations for independent review. The patient and parent consumer experts also reviewed draft EBCPG content and recommendations that had been translated into lay terms.

Endorsing the recommendations

An online Delphi questionnaire served as an EBCPG evaluation tool for members of the Expert Panel. Experts provided feedback on EBCPG layout, level of detail, clarity and relevance (part one), as well as whether they endorsed guideline recommendations for study interventions (part two). A structured Delphi questionnaire was used, contrary to an open question format, seeing as a quantitative grading scale determined guideline recommendations rather than clinical impressions[23]. Within the two parts of the Delphi questionnaire, experts were asked to evaluate the guideline using a 5-point Likert scale (1 being "not clear" or "strongly disagree" and 5 being "very clear" or "strongly agree") and respond to yes or no

questions investigating the clarity, agreement, and understanding of each recommendation. Upon receipt of all expert panel surveys, the level of group consensus was determined using statistical calculations performed in Excel (measures of central tendency and frequency). If consensus was not met, a second round was required where a revised manuscript with highlighted corrections was circulated along with a coded Excel spread sheet displaying experts' responses. These rounds continued until a consensus of at least 80% is reached or until the law of diminishing returns was observed[24] for questions within part 1 and part 2 of the survey.

Selection Criteria

The selection criteria for this EBCPG was determined *a priori* by the Ottawa Methods Group and followed the population, intervention, comparators, outcomes, period of time, and study design (PICOTS) strategy. A list of the selection criteria is presented in Appendix 1. The search strategy was conducted from database inception to May 2015 and performed in Medline (Ovid), Embase (Ovid), Cochrane CENTRAL (Ovid) and clinicaltrials.gov. Two reviewers (CS and JT) independently screened article titles and abstracts to determine if they met the inclusion criteria. Articles featuring foot care management interventions for JIA were selected for this EBCPG from a larger systematic literature search and network meta-analysis review conducted by Smith (in progress)[25]. The PRISMA diagram is shown in Appendix 2.

Methodological Quality of Included Studies

Each included study was evaluated using the PEDro scale, an appropriate tool for assessing the methodological quality of non-pharmacological studies[26 27]. This 10-point scale has been shown to be a valid and reliable assessment tool[28-32], and is frequently used to assess randomized control trials (RCTs) validity and interpretability. This EBCPG will use a 5 out of 10 cut-off score in order to only include moderate to high quality articles in the analysis[33].

Outcomes

Outcome measure data from included studies were analysed if outcome measures were validated and reliable or met the Outcome Measures for Rheumatoid Arthritis Clinical Trials (OMERACT)[34,35] criteria. Included studies must have measured a minimum of one of the inclusion criteria outcomes and used validated measures during outcome assessment. All end of treatment and follow-up (retention effect) outcome measures were presented in months in order to maintain consistency throughout the EBCPG.

Statistical Analysis

Reference Manager (version 5.3)[36], meta-analysis software, was used to analyse EBCPG data. The mean difference was calculated at end of treatment and follow-up for continuous outcome measurement data (the mean, standard deviation, and sample size). The mean difference is used to measure "the absolute difference between the mean values in two groups"[21], which can help determine if an intervention has had a significant effect on the intervention group compared to the control. Articles that were missing relevant data required for statistical analysis and whose authors were unable to be contacted were excluded.

Additionally, EBCPG figures and graphs were created using study data and statistics, as per Cochrane Collaboration methodology[37,38]. For each figure the mean difference between groups is represented by a square and the SD is represented by a horizontal line. No statistically significant difference between intervention and control groups is present if the horizontal line crosses the graph's center vertical line. This EBCPG defines the relative difference between the intervention and control group of ≥ 30% to be a clinically important improvement (minimal clinically important difference: MCID), which is supported by the American College of Rheumatology (ACR) Pediatric 30 response criteria (JIA disease activity measure)[39,40]. Calculations on the absolute benefit and the relative difference in change from baseline were used to determine clinical importance[41].

The level of evidence (e.g. level I for RCTs and level II for CCTs), clinical importance based on the MCID (MCID ≥ 30%), and statistical significance ($p < 0.05$) were used to determine recommendation grades. For a description of each grade see Table 1.

Results

Literature search

A total of 535 records along with one supplementary citation (provided by author[42]) were retrieved upon completion of the systematic search. Once duplicates were removed, 362 records were screened. According to the selection criteria, three full-text articles[43-45] and one supplementary citation[42] met the inclusion criteria and were included for final analysis. The additional citation was a book that provided supplementary raw RCT data that corresponded to one of the included studies[44]. Included studies did not share the same PICOTS therefore heterogeneity (chi-square statistic or I^2) was not calculated. Where published data was non-parametric and median and interquartile range (IQR) was calculated, raw data were required from authors[44,45]. Raw data was used to calculate mean and SD to determine graded recommendations (Cochrane Collaboration methodology).

Out of the 362 records, 321 articles were excluded because they were related to pharmacological interventions only. Therefore, 40 full-text articles were assessed for eligibility. As mentioned above, only 3 articles and 1 citation met the inclusion criteria, and 29 full-text articles were excluded. The 29 trials did not meet the inclusion criteria for the following reasons: (1) inadequate patient population[46] (2) no mention of foot orthotics[47-60] (3) inadequate study design[61-63] (4) insufficient data available[64-69] (5) inappropriate outcomes[70,71] (6) not considered as a full-text[72-74].

Study Characteristics

This EBCPG includes studies that analysed the effectiveness of foot care interventions to reduce pain, and improve function and quality of life in children with JIA. The three included RCTs included JIA

patients between the ages of 3 and 19 years old[43-45]. One study randomized participants to receive either "fitted" Foot Orthoses (FO) or 1 mm uncorrected leather boards (control)[44] and another study compared three interventions: custom-fabricated semi-rigid orthotics, pre-fabricated shoe-inserts, and new athletic shoes with soles[43]. The third study allocated participants to either a multidisciplinary foot care group or a usual care group (control)[45]. Pain relief (VAS Scale)[44], activity limitation (Foot Function Index (FFI) scales)[43] and foot-related disability (Juvenile Arthritis Foot Disability Index (JAFI))[45] were the primary outcomes of these three RCT studies, respectively. For additional information on study characteristics and population demographics refer to Appendix 3.

Delphi results

Among the 15 experts who were invited to complete the first round of the Delphi questionnaire, 100% provided answers (15/15). All part one questions (except Q.4) failed to achieve consensus. In part two, nine (out of 15) questions had strong consensus (≥ 80%), whereas six questions (7A, 10J, 10K, 10L, 11M, 11O) obtained moderate consensus (between 67% and 73%). The second Delphi round achieved strong (Q. 2 & 3) and moderate (Q. 1 & 4), and poor (Q. 5 & 6) consensus for part one, and full consensus for all questions in part two. Since the majority of the survey achieved consensus, a third round was not prepared. Rather, expert suggestions were addressed accordingly and on a case by case basis.

Excluded outcome measures

Body mass index (BMI) has been shown to have a low level of validity and was subsequently excluded from the analysis[75]. Active and limited joint count (0-77) are commonly regarded as biomedical outcome measures[39] (not specific to feet), and thus have also been excluded from our analysis.

Results of the included studies

Methodological quality (PEDro scores of included studies)

All included RCTs were assessed to be of high quality, with a PEDro score of 6 to 7 out of 10[43-45]. A summary of recommendations and their corresponding PEDro scores are provided in Appendix 4.

Effectiveness of foot care for foot pain and functional management of JIA

The findings from included RCTs exploring the effectiveness of foot care and orthotics for foot pain and functional management of JIA will be briefly outlined below. Additional information on these studies (mean difference, sample size, etc.) can be found in Appendix 3. RCTs investigated the effectiveness of fitted or custom made foot orthoses[43,44] as well as multidisciplinary foot care[45] for JIA outcomes.

Fitted foot orthoses vs Control foot orthoses (leather board; 1 mm)[44]

One level 1 RCT examined the effects of custom-fitted foot orthoses (n = 31) versus control foot orthoses (n = 29)[44] (Appendix 5). Participants were randomised into the intervention group (custom-fitted foot orthoses) or control group (Appendix 3).

At 3 months (end of intervention), the Ottawa Panel found no clinical benefit (grade C) supporting fitted foot orthoses for pain reduction (100-mm VAS) (Figure 1), quality of life (Paediatric rheumatology PedsQL), quality of life (Parent rheumatology PedsQL), quality of life (Child generic), quality of life (Parent generic)**,** CHAQ, and gait velocity (cm/sec). Neutral evidence (with no clinical benefit) favouring the control (grade D) was demonstrated for gait time (sec). Additional figures (Figures S7-S13) are available in supplemental files.

At 6 months (end of intervention), the Ottawa Panel found clinically important benefits without statistical significance (grade C+) for fitted foot orthoses in pain reduction (100-mm VAS). No clinical benefit (grade C) was observed for quality of life (Paediatric rheumatology PedsQL), quality of life (Parent rheumatology PedsQL), quality of life (Child generic), quality of life (Parent generic), CHAQ, gait time (sec), and gait velocity (cm/sec). Additional figures (Figures S14-S21) and Table (Table S3) are available in supplemental files.

This study received a PEDro score rating of 7 out of 10 (high methodological quality). The Ottawa Panel suggests the use of **custom fitted preformed foot orthotics (versus 1 mm non-customised leather board control)** for at least 6 months, in order to decrease pain (100-mm VAS) following ≥ 24 weeks[44].

Custom-made semi-rigid orthotics vs pre-fabricated off-the-shelf shoe inserts[43]

One level 1 RCT made 3 comparisons[43]. First, the effects of custom-made semi-rigid orthotics (n = 15) versus a pre-fabricated off-the-shelf shoe insert (n = 12) were explored (Appendix 3). The custom-made semi-rigid orthotics were made of metal particle-reinforced polyolefin with shock absorbing functional posts.

At 3 months (end of intervention), the Ottawa Panel suggests the use of custom-made semi-rigid orthotics which showed clinically important benefits without statistical significance (grade C+) for pain intensity (Pediatric Pain Questionnaire VAS), activity limitation (FFI), foot pain (FFI) (Figure 2) and disability. No clinical benefit (grade C) and thus no clinically important benefit was observed for timed walking (sec), physical functioning (PedsQL 4.0, child self-report), and physical functioning (PedsQL 4.0, parent proxy-report). Additional figures (Figures S30-S35) and Table (Table S4) are available in supplemental files

This study received a PEDro score rating of 7 out of 10 (high quality methodology). The Ottawa Panel suggests the use of **custom-made semi-rigid orthotics (versus pre-fabricated off-the-shelf shoe inserts)** for at least 3 months, in order to decrease pain (intensity; PPQ-VAS), activity limitation (FFI), foot pain (FFI), and reduce disability (FFI) following ≥ 12 weeks[43].

Custom-made semi-rigid orthotics vs new supportive athletic shoes[43]

In this same RCT, the effects of custom-made semi-rigid orthotics (n = 15) versus new supportive athletic shoes were explored (n = 13) (Appendix 3).

At 3 months (end of intervention), the Ottawa Panel found stronger evidence for custom-made semi-rigid orthotics which exhibited clinically important benefits with statistical significance (grade A) for pain intensity (Pediatric Pain Questionnaire VAS), activity limitation (FFI) (Figure 3), foot pain (FFI) and disability (FFI) (Figure 4). No clinical benefit (grade C) was observed for timed walking (sec), physical functioning (PedsQL 4.0, child self-report), and physical functioning (PedsQL 4.0, parent proxy-report). Additional figures (Figures S36-S40) and Table (Table S5) are available in supplemental files.

This study received a PEDro score rating of 7 out of 10 (high quality methodology). The Ottawa Panel suggests the use of **custom-made semi-rigid orthotics (versus new supportive athletic shoes)** for at least 3 months, in order to decrease pain (intensity; PPQ-VAS), activity limitation (FFI), foot pain (FFI), and reduce disability (FFI) following ≥ 12 weeks[43].

Pre-fabricated off-the-shelf shoe inserts vs new supportive athletic shoes[43]

Again, in the same study, the effects of pre-fabricated off-the-shelf shoe inserts (n = 13) versus new supportive athletic shoes were explored (n = 12) (Appendix 3).

At 3 months (end of intervention), the Ottawa Panel suggests the use of pre-fabricated off-the-shelf shoe inserts which showed clinically important benefits without statistical significance (grade C+) for pain intensity (observed; Pediatric Pain Questionnaire VAS). No clinical benefit (grade C) was found for timed walking (sec) (Figure 5), activity limitation (FFI), foot pain (FFI), disability (FFI), physical functioning (PedsQL 4.0, child self-report) and physical functioning (PedsQL 4.0, parent proxy-report). Additional figures (Figures S41-S46) and Table (Table S6) are available in supplemental files.

This study received a PEDro score rating of 7 out of 10 (high methodological quality). The Ottawa Panel suggests the use of **pre-fabricated off-the-shelf shoe inserts (versus new supportive athletic shoes)** for at least 3 months, in order to reduce pain (intensity; PPQ-VA) following ≥ 12 weeks[43].

Multidisciplinary foot care vs standard foot care[45]

One level 1 RCT explored the combined effects of multidisciplinary foot care (n = 21) versus standard foot care (n = 23)[45] (Appendix 3).

At 6 months (end of intervention), the Ottawa Panel found no clinical benefit (grade C) for multidisciplinary foot care for impairment (JAFIimp) and participation restriction (JAFIpr). Neutral evidence (with no clinical benefit) was also found favouring the control (grade D) for activity limitation (JAFIal). Additional figures (Figures S22-S24) and Table (Table S7) are available in supplemental files.

At 12 months (end of treatment), the Ottawa Panel found no clinical benefit (grade C) demonstrated for multidisciplinary foot care for activity limitation (JAFIal), participation restriction (JAFIpr) (Figure 6), pain (VAS), and health related quality of life (EQ-5D VAS self). Neutral evidence (with no clinical benefit) was found favouring the control (grade D) for impairment (JAFIimp), global functional status (CHAQ), and health related quality of life (EQ-5D VAS proxy), however clinically important benefit was not demonstrated. Additional figures (Figures S25-S29) and Table (Table S8) are available in supplemental files.

This study received a PEDro score rating of 6 out of 10 (high methodological quality). There was no clinical benefit demonstrated for any assessed outcomes therefore the Ottawa Panel cannot reasonably recommend multidisciplinary foot care (versus standard foot care) for the management of JIA.

Discussion

This Ottawa Panel EBCPG developed recommendations on three high quality studies (PEDro score ≥ 5) evaluating foot care interventions for foot pain and functional management of JIA[43-45]. Foot orthoses (custom fitted preformed FOs, custom made FOs) received positive recommendations since they achieved clinical importance with statistical significance (Grade A: pain[43], activity limitations[43], disability[43]). Positive recommendations were also shown for outcomes that obtained clinical significance without statistical significance (Grade C+: pain[43,44], activity limitation[43], disability[43]). A total of 10 positive recommendations were represented among the 3 included studies. Overall, evidence suggests that foot care interventions (foot orthotics) can improve foot pain (intensity) (2 grade A and 4 grade C+), activity limitation (1 grade A and 1 grade C+), and disability (1 grade A and 1 grade C+) in children with JIA. The remaining recommendations are listed as follows: 31 outcomes graded as C and 6 outcomes graded as D.

The Ottawa Panel methodology used in this EBCPG has been shown to be clear and rigorous, as determined through an Appraisal of Guidelines Research and Evaluation (AGREE) II assessment[76]. Previous EBCPGs that followed Ottawa Panel methodology effectively addressed 4 out of 6 domains on the AGREE II Instrument (scope and purpose, stakeholder involvement, rigour of development, and clarity of presentation), and were thus deemed to be high quality guidelines (> 60%)[77].

Studies that have evaluated foot care interventions have frequently recommended its use for OA (hip and knee) pain management. For example, both the American College of Rheumatology (ACR)[78] and the European League Against Rheumatism (EULAR)[79] recommended foot insoles (medial, lateral, or subtalar strapped lateral wedge) as a beneficial management tool for knee OA among adults[80,81]. Although systematic reviews have stated that (custom-made) shoe insoles for alternative pediatric foot problems (e.g. excess pronation of feet, flat feet, etc.) have minimal to no beneficial effect[13,82], some have shown improvement in foot pain in patients with musculoskeletal conditions, including JIA[15]. It is unclear if this is a general trend, seeing as there are currently no published systematic reviews investigating the effect of

foot orthotics specifically on JIA patients. In light of this, it is evident that more RCTs evaluating the effects of foot care interventions for people with JIA, especially with a larger sample size, are required.

For many suffering from JIA and other forms of arthritis (e.g. hip and knee), the foot can be a major source of pain and impaired physical functioning[83]. Modifiable footwear, such as foot orthotics and insoles, have be shown to reduce lower extremity stress through the realignment and adjustment of gait pattern and foot muscle activation[84,85]. This leads to a reduction of biomechanical stress loading on the joint and increases favourable muscle activity which may provide therapeutic relief for those affected by RA, OA, or JIA[86,87]. Currently, few studies have confirmed a strong association between arthritis development and foot form and function, particularly among the JIA population.

Although foot orthoses have been shown to be effective, the literature has indicated poor patient compliance among those wearing orthotic devices for therapeutic benefit. One systematic review investigating the compliance of (OA, RA, etc.) patients with orthotic devises for the lower extremities confirmed a high percentage of patients choosing to not use prescribed orthotic devices, due to varying reasons including pain and discomfort[88]. One study had a low attrition rate[43], whereas another study displayed difficulties achieving an appropriate number of patients[45]. The third study was overpowered in anticipation of potential dropouts[44]. Interestingly, those who left the study (if required) declared reasons other than pain or discomfort as their primary motivation[43-45]. Although most included studies evaluated the effect of foot care interventions in the short term, one study noted that compliance was associated with comfort[43].

Limitations

Limitations of the Ottawa Panel EBCPG

Clinical discretion is advised upon reading EBCPG foot care recommendations due to wide confidence intervals and the limited number of included RCTs analysed in this guideline. Therefore, it is possible for primary RCTs[43-45] to have found significant findings within their study that may not be statistically significant within this EBCPG and may not have received a positive recommendation (e.g. grade C+). In

addition, non-parametric raw data was requested from authors in order to calculate the mean and SD (parametric statistics required for determining recommendations). This unavoidable conflict may have produced skewed results for some outcomes measures, potentially rendering significant outcomes (in primary studies) as insignificant within the EBCPG. As a result, the Ottawa Panel recommendations are conservative. In addition, it is possible to consider various MCIDs according to the outcome assessed within included RCTs. For instance, the MCID for the visual analogue scale (VAS) for pediatric rheumatology is 8 mm[90], while the Pediatric Quality of Life Inventory (PedsQL) is 5 mm[91]. To overcome this problem a standard MCID score of 30% for each outcome was used to determine if a clinically important benefit was detected[39,40]. It is possible, however, for outcome clinical improvement (at end of treatment and follow up) to remain undetected while applying a standardised MCID of 30%.

Limitations of the primary included studies

One RCT[45] conducted an ANOVA statistical analysis to analyse raw data, therefore in order to determine which intervention was statistically significant, interventions were analysed in pairs (mean and relative difference). Additionally, the study[45] intervention group received more intra-articular cortico-steroid injections (ICIs) than the control group (13 ICIs vs 7 ICIs) although it is unclear if this difference is statistically significant or if the quantity of ICIs administered had a biased influence on this group. It is important to note that inconsistencies were present between our EBCPG recommendations and the conclusions from included RCTs for the following outcomes: pain relief (VAS)[44], quality of life (PedsQL – paediatric rheumatology)[44], quality of life (parent rheumatology)[44], quality of life (PedsQL – child generic)[44], and quality of life (PedsQL – parent generic)[44]. Thus, the Ottawa Panel recommendations remain conservative (i.e. grade C+) regardless of statistically significant results for certain outcomes in the primary RCTs.

Appendices 6,7,8 provides additional details on conflicting outcome measures and corresponding gradings which may assist clinicians in interpreting these results. Self-reported outcome measures, such as pain and quality of life, may introduce information bias which should be taken into consideration when

applying these recommendations in practice. Furthermore, parent proxy-reports (e.g. physical function), where parents may be subjectively influenced, can present the same issue. Although all included studies were considered high quality[31], their small sample size should also be considered when interpreting findings.

Conclusion

The Ottawa Panel found moderate evidence to support the use of foot care in foot pain and functional management of patients with JIA between the ages of 3 and 19 years with varying disease durations. According to three high quality RCTs, foot orthotics (preformed, custom fitted or custom made) can produce beneficial effects among patients with JIA, particularly for reducing foot pain and activity limitation. It would be interesting to explore the impact of JIA disease duration on the effect of foot care for foot pain and functional management in JIA and how foot care management options can be improved to increase therapeutic effect. Given the lack of research in this field, more RCTs with larger sample sizes are warranted to more accurately determine the effect of foot care on JIA patients and to confirm any beneficial long term effects.

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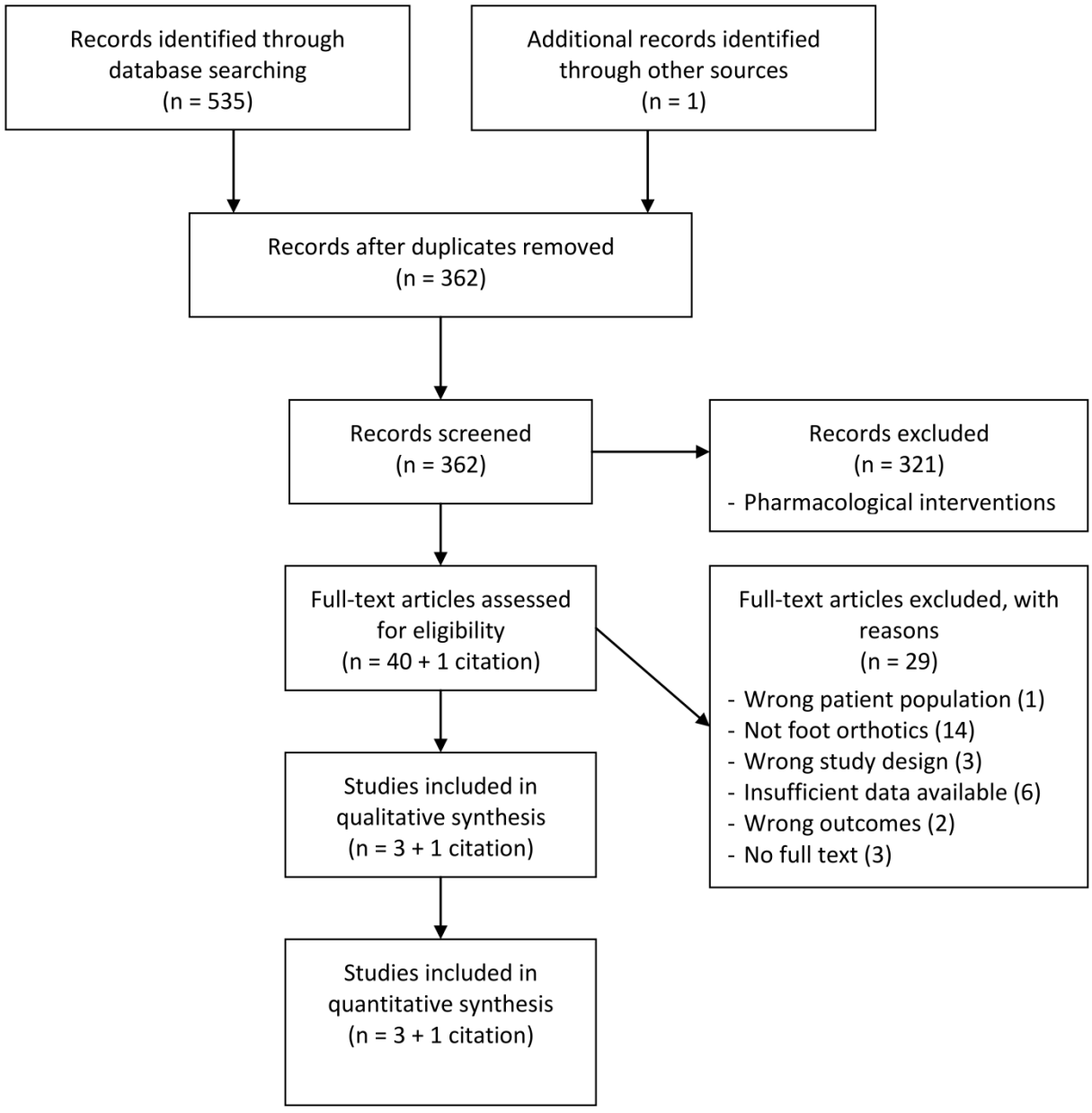
Appendix 1. Study flow diagram (PRISMA)



Appendix 2. Characteristics of Included Studies

Author/ Year	Sample size	Population Details	Symptom duration or date of diagnosis	Age (Mean, SD for control)	Treatment	Comparison group	Concurrent therapy	Session/ week No. of weeks	Follow-up months	PEDro Score
Coda et al. 2014	60 recruited Gr 1: 31 Gr 2: 29	Inclusion criteria: diagnosed with JIA according to International League of Associations for Rheumatology criteria, disease onset from 5-18yr in lower extremity joint, previous failure in orthotic management (patient must not have worn any FO's for a period of 3 months minimum, able to walk at least 15 m without assistive devices, minimum of 6 months after start of disease modifying antirheumatic drug therapy Exclusion criteria: Unable to walk		Gr 1: 10.64 (3.84) Gr 2: 11.17 (3.51)	Gr 1: Slimflex-Plus FOs were used for the 'fitted FOs'. Participants were instructed to use the FOs gradually for the first few days and then to use them at all times.	Gr 2: The control FOs was made with leather board and did not have corrections. Participants were instructed to use the FOs gradually for the first few days and then to use them at all times.		Use: All the time for 6 months	End of treatment: 3 and 6 months	7

Author/ Year	Sample size	Population Details	Symptom duration or date of diagnosis	Age (Mean, SD for control)	Treatment	Comparison group	Concurrent therapy	Session/ week No. of weeks	Follow-up months	PEDro Score
		barefoot or shod, associated musculoskeletal disease, central or peripheral nerve disease and endocrine disorders, previous foot surgery, current FOs use, where supply of FOs is contraindicated								
Powell et al. 2005	48 screened; 40 completed Gr 1: 15/40 completed Gr 2: 12/40 completed Gr 3: 13/40 completed	Inclusion criteria: diagnosed with JIA, a minimum of 5 years of age, active disease determined by tender and swollen foot joint count of the ankle, subtalar, hindfoot, and/or metatarsal joints, at least 1 month but less than 2 years persistent foot/ankle pain, stable medication the month before entry and during		Gr 1: 12.14 (3.32) Gr 2: 12.17 (3.04) Gr 3: 13.77 (4.55)	Gr 1: Custom-made orthotics made of metal particle-reinforced polyolefin with shock absorbing functional post.	Gr 2: Prefabricated off-the-shelf shoes inserts made of 1/8" flat neoprene. Gr 3: New supportive athletic shoes with a medial longitudinal arch support and shock absorbing soles worn alone.		Use: All the time for 3 months	End of treatment: 3 months	7

Author/ Year	Sample size	Population Details	Symptom duration or date of diagnosis	Age (Mean, SD for control)	Treatment	Comparison group	Concurrent therapy	Session/ week No. of weeks	Follow-up months	PEDro Score
		the study and ability to walk at least 50 feet without assistance. Exclusion criteria: foot osseous anomaly, previous foot/ankle surgery, joint injections during and 6 months before study, and previous use of shoe inserts or foot orthotics.								
Hendry et al. 2013	Total: 44 Gr 1: 21 Gr 2: 23	Inclusion criteria: diagnosis of JIA according to International League of Associations for Rheumatology (ILAR), being treated at the Royal Hospital for Sick Children, arthritis in at least one of the foot joints (small or large joints) or	Disease duration, years, mean (SD) Gr 1: 3.74 (2.65) Gr 2: 4.06 (3.33)	Gr 1: 10.1 (4.22) Gr 2: 10.0 (3.39)	Gr 1: Consultations with a paediatric rheumatologist, podiatrist (orthotic therapy), physiotherapist and sonographer. Participants were advised on basic foot care, footwear,	Gr 2: out of the 23 participants, 5 had a referral to the standard care arm podiatrist (3 of them received FOS), 7 received ICIs, and participants received	The children received standard medical care during the study.	N/A	End of treatment at 6 and 12 months	6

Author/ Year	Sample size	Population Details	Symptom duration or date of diagnosis	Age (Mean, SD for control)	Treatment	Comparison group	Concurrent therapy	Session/ week No. of weeks	Follow-up months	PEDro Score
		polyarthritis of both the large and small joints in the foot. Children and adolescents receiving podiatric care. Exclusion criteria: unconfirmed JIA and arthritis in the upper limb, jaw or neck.			exercises and simple joint protection. Out of the 21 participants, 17 were prescribed FOs, 4 received splints, 13 received MSUS-guided ICIs in the joint and/or around the soft tissue of the foot and ankle and participants received stable, new or higher dosed medications.	stable, new or higher dosed medications.				

Appendix 3. Summary of Recommendations

Fitted FOs vs Control FOs (leather board (1mm) without corrections), level I RCT (N = 60, high quality [PEDro score 7/10]) (Coda 2014)[44]:

- **Grade C+ (clinically important benefit demonstrated without statistical significance)** for: pain (VAS) at **end of treatment 6 months.**

- **Grade C (no benefit demonstrated)** for: pain (VAS), quality of life (PedsQL – pediatric rheumatology), quality of life (PedsQL – parent rheumatology), quality of life (PedsQL – child generic), quality of life (PedsQL – parent generic), quality of life (CHAQ), and gait velocity (cm/sec) at **end of treatment 3 months**; for quality of life (PedsQL – pediatric rheumatology), quality of life (PedsQL – parent rheumatology), quality of life (PedsQL – child generic), quality of life (PedsQL - parent generic), quality of life (CHAQ), gait time [s], and gait velocity [cm/sec] at **end of treatment 6 months**.

- **Grade D (no benefit demonstrated but favouring control)** for: gait time [s] at **end of treatment 3 months**.

Foot orthotics vs Shoe inserts, level 1 RCT (N = 27, high quality [PEDro score 7/10]) (Powell 2005)[43]:

- **Grade C+ (clinically important benefit demonstrated without statistical significance)** for: pain intensity [Pediatric Pain Questionnaire (PPQ) – VAS], activity limitation [Foot Function Index (FFI)], foot pain (FFI), and disability (FFI) at **end of treatment 3 months**.

- **Grade C (no benefit demonstrated)** for: timed walking [s], physical functioning (PedsQL 4.0 Generic Core Scales, child self-report), and physical functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report) at **end of treatment 3 months.**

Foot orthotics vs Shoes only, level I RCT (N = 28, high quality [PEDro score 7/10]) (Powell 2005)[43]:

- **Grade A (clinically important benefit demonstrated with statistical significance)** for: pain intensity [Pediatric Pain Questionnaire (PPQ) - VAS], activity limitation [Foot Function Index (FFI)], foot pain (FFI), and disability (FFI) **at end of treatment 3 months**.

- **Grade C (no benefit demonstrated)** for: timed walking [s], physical functioning (PedsQL 4.0 Generic Core Scales, child self- report), and physical functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report) at **end of treatment 3 months**.

Shoe inserts vs Shoes only, level I RCT (N = 25, high quality [PEDro score 7/10]) (Powell 2005):

- **Grade C+ (clinically important benefit demonstrated without statistical significance)** for: pain intensity [Pediatric Pain Questionnaire (PPQ) – VAS] at **end of treatment 3 months.**

- **Grade C (no benefit demonstrated)** for: timed walking [s], activity limitation [Foot Function Index (FFI), foot pain (FFI), disability (FFI), physical functioning (PedsQL 4.0 Generic Core Scales, child self-report), and physical functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report) at **end of treatment 3 months.**

Multidisciplinary foot care vs Standard care, level I RCT (N = 44, high quality [PEDro score 6/10]) (Hendry 2013):

- **Grade C (no benefit demonstrated)** for: activity limitation [Juvenile Arthritis Foot Disability Index (JAFIal)] at **end of treatment 6 months;** for: activity limitation (JAFIal), participation restriction (JAFIpr), pain (VAS), and health related quality of life (EQ-5D VAS self) at **end of treatment 12 months.**

- **Grade D (no benefit demonstrated but favouring control)** for: impairment (JAFIimp), and participation restriction (JAFIpr) at **end of treatment 6 months**; for: impairment (JAFIimp), global functional status (CHAQ), and health related quality of life (EQ-5D VAS proxy) at **end of treatment 12 months.**

Appendix 4. Fitted Foot Orthoses (FO) vs Control Foot Orthoses (FO) (End of Treatment: 3 months)

Study	Study Groups: Intervention (I) and Control (C)	Outcome	No. of Patients	Baseline Mean	End of Study Mean	Absolute Benefit	Relative Difference in Change From Baseline	Mean Difference (MD) 95% Confidence Interval (CI)	Grade
Coda et al., 2014	I: Fitted FOs	Pain (VAS) Primary Outcome	31	22.51	16.45	-4.41	-20%	MD: -2.88 CI Low: -15.7 CI High: 9.94	C
	C: Control FOs		29	20.98	19.33				
Coda et al., 2014	I: Fitted FOs	Quality of life (PedsQL - paediatric rheumatology) Secondary Outcome	31	68.28	80.58	13.26	18%	MD: 5.92 CI Low: -3.58 CI High: 15.42	C
	C: Control FOs		29	75.62	74.66				
Coda et al., 2014	I: Fitted FOs	Quality of life (PedsQL - parent rheumatology) Secondary Outcome	31	67.29	76.37	4.49	6%	MD: 0.6 CI Low: -9.66 CI High: 10.86	C

Study	Study Groups: Intervention (I) and Control (C)	Outcome	No. of Patients	Baseline Mean	End of Study Mean	Absolute Benefit	Relative Difference in Change From Baseline	Mean Difference (MD) 95% Confidence Interval (CI)	Grade
	C: Control FOs		29	71.18	75.77				
Coda et al., 2014	I: Fitted FOs	Quality of life (PedsQL – child generic) Secondary Outcome	31	72.31	81.69	9.13	12%	MD: 2.9 CI Low: -6 CI High: 11.8	C
	C: Control FOs		29	78.54	78.79				
Coda et al., 2014	I: Fitted FOs	Quality of life (PedsQL – parent generic) Secondary Outcome	31	68.81	78.11	1.59	2%	MD:-0.8 CI Low: -10.58 CI High: 8.98	C
	C: Control FOs		29	71.2	78.91				
Coda et al., 2014	I: Fitted FOs	Quality of life (CHAQ) Secondary Outcome	31	0.6	0.46	0.11	17%	MD: 0.02 CI Low: -0.29 CI High: 0.33	C
	C: Control FOs		29	0.69	0.44				
Coda et al., 2014	I: Fitted FOs	Gait time (sec) Secondary Outcome	31	1.26	1.32	0.05	4%	MD: 0.12 CI Low: -0.12 CI High: 0.36	D

Study	Study Groups: Intervention (I) and Control (C)	Outcome	No. of Patients	Baseline Mean	End of Study Mean	Absolute Benefit	Relative Difference in Change From Baseline	Mean Difference (MD) 95% Confidence Interval (CI)	Grade
	C: Control FOs		29	1.19	1.2				
Coda et al., 2014	I: Fitted FOs	Gait velocity (cm/sec) Secondary Outcome	31	109.7	108.63	1.27	1%	MD: -4.27 CI Low: -13.72 CI High: 5.18	C
	C: Control FOs		29	115.24	112.9				

Appendix 5.
Outcome Measure Characteristics*

Conflicting Outcome Measures: Same measured outcome with different recommendations		
Study	Outcome Measure	Characteristics
Powell et al., 2005[43]	Foot pain	- Instrument: Foot Function Index (FFI) - Measured by: Self-administered - Reliability and Validity: SooHoo, Samimi, Vyas, Botzler, et al., 2006[43,63]†
	Pain intensity	- Instrument: Pediatric Pain Questionnaire–Visual Analog Scale (VAS: 0-10) - Measured by: Self-administered - Validity: Rapoff, 2003[64]

* Additional information within Discussion section of manuscript
† Not specifically validated for children

Appendix 6. Positive EBCPG Recommendations with Study Details

Details of the study			Improved Outcome Measures
Study	**Population**	**Intervention Details**	**Grade possibilities:** **[A, B, C+, C, D, D+, D-]**
Powell et al., 2005[43]	• Diagnosed with JIA • At least 5 years of age • Active disease in the foot and ankle	**Foot orthotics** • Custom made shock absorbing orthotics with metal particle-reinforced polyolefin **Shoe inserts** • Off-the-shelf shoes inserts pre-fabricated from flat neoprene **Shoes only** • Supportive athletic shoes with arch support and shock absorbing soles	**END OF TREATMENT (3 months):** **Foot orthotics vs Shoe inserts** - **[C+]** Pain intensity (PPQ: VAS) - **[C+]** Activity limitation (FFI) - **[C+]** Foot pain (FFI) - **[C+]** Disability (FFI) **Foot orthotics vs Shoes only** - **[A]** Pain intensity (PPQ: VAS) - **[A]** Activity limitation (FFI) - **[A]** Foot pain (FFI) - **[A]** Disability (FFI) **Foot orthotics vs Shoes only** - **[C+]** Pain intensity (PPQ: VAS)
Coda et al., 2014[44]	• Onset of disease between the ages of 5-18 • Diagnosis of any JIA subtype • Disease involvement in the joints of the lower limbs	**Fitted Foot Orthoses** • Custom fitted preformed foot orthoses • Patients gradually wore foot orthoses all the time after having tried them on	**END OF TREATMENT (6 months):** - **[C+]** Pain (VAS)

Hendry et al., 2013[45]	• Children or adolescents with JIA • Documented arthritis in the foot	**Multidisciplinary foot care** • Education on foot care, footwear, exercises and joint protection • Possibility of foot orthoses, splints and/or ICIs • Stable, new, or higher dosed medication	**No positive recommendations**

ICI: Intra-articular corticosteroid injections; PPQ: Pediatric Pain Questionnaire; FFI: Foot Function Index; VAS : Visual Analogue Scale

Appendix 7. Comparison of Primary & Secondary Outcome Measures with Recommendations

Study	Primary Outcome		Secondary Outcome	
Coda et al., 2014[44]	**End of Treatment (3 months)**		**End of Treatment (3 months)**	
	Fitted FOs vs Control FOs			
	• Pain (VAS)	C	• Quality of life (PedsQL – paediatric rheumatology)	C
			• Quality of life (PedsQL – parent rheumatology)	C
			• Quality of life (PedsQL – child generic)	C
			• Quality of life (PedsQL – parent generic)	C
			• Quality of life (CHAQ)	C
			• Gait velocity [cm/sec]	C
			• Gait time [s]	D
	End of treatment (6 months)		**End of treatment (6 months)**	
	Fitted FOs vs Control FOs			
	• Pain (VAS)	C+	• Quality of life (PedsQL – paediatric rheumatology)	C
			• Quality of life (PedsQL – parent rheumatology)	C
			• Quality of life (PedsQL – child generic)	C
			• Quality of life (PedsQL - parent generic)	C
			• Quality of life (CHAQ)	C
			• Gait time [s]	C
			• Gait velocity [cm/sec]	C
Powell et al., 2005[43]	**End of Treatment (3 months)**		**End of Treatment (3 months)**	
	Foot orthotics vs Shoe inserts			
	• Activity limitation (FFI)	C+	• Pain intensity [Pediatric Pain Questionnaire (PPQ) - VAS]	C+
	• Foot pain (FFI)	C+	• Timed walking [s]	C
	• Disability (FFI)	C+	• Physical Functioning (PedsQL 4.0 Generic Core Scales, child self-report)	C
			• Physical Functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report)	C
	Foot orthotics vs Shoes only			
	• Activity limitation (FFI)	A	• Pain intensity [(PPQ) - VAS]	A
			• Timed walking [s]	C
			• Physical functioning (PedsQL 4.0 Generic Core Scales, child self-	C
	• Foot pain (FFI)	A		

	• Disability (FFI)	A	report) • Physical Functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report)	C
	Shoe inserts vs Shoes only			
	• Activity limitation (FFI) • Foot pain (FFI) • Disability (FFI)	C C C	• Pain intensity [(PPQ) - VAS] • Physical functioning (PedsQL 4.0 Generic Core Scales, child self-report) • Physical Functioning (PedsQL 4.0 Generic Core Scales, parent proxy-report)	C+ C C
Hendry et al., 2013[45]	**End of Treatment (6 months)**		**End of Treatment (6 months)**	
	• Activity limitation (JAFIal) • Impairment (JAFIimp) • Participation restriction (JAFIpr)	C D D	No secondary outcomes were measured	
	End of Treatment (12 months)		**End of Treatment (12 months)**	
	• Activity limitation (JAFIal) • Impairment (JAFIimp) • Participation restriction (JAFIpr)	C D D	• Pain (VAS) • Health related quality of life (EQ-5D VAS self)	C C

* Conflicting recommendations between instruments measuring similar outcomes are explained within the discussion

† Long term effects were noted for these outcome measures

FFI: Foot Function Index; VAS: Visual Analogue Scale; JAFI: Juvenile Arthritis Foot Disability Index; PedsQL: Pediatric Quality of Life Inventory; PPQ: Pediatric Pain Questionnaire; CHAQ: Childhood Health and Assessment Questionnaire