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[Intervention Review]

Interventions for congenital talipes equinovarus (clubfoot)

Kelly Gray¹, Verity Pacey¹, Paul Gibbons², David Little², Joshua Burns³

¹Department of Physiotherapy, The Children's Hospital at Westmead, Westmead, Australia. ²Department of Orthopaedic Surgery, The Children's Hospital at Westmead, Westmead, Australia. ³Faculty of Health Sciences, The University of Sydney, and Institute for Neuroscience and Muscle Research, The Children's Hospital at Westmead, Westmead, Australia

Contact address: Kelly Gray, Department of Physiotherapy, The Children's Hospital at Westmead, Locked Bag 4001, Westmead, New South Wales, 2145, Australia. kellye@chw.edu.au.

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ABSTRACT

Background

Congenital talipes equinovarus (CTEV), which is also known as clubfoot, is a common congenital orthopaedic condition characterised by an excessively turned in foot (equinovarus) and high medial longitudinal arch (cavus). If left untreated it can result in long-term disability, deformity and pain. Interventions can be conservative (such as splinting or stretching) or surgical. The review was first published in 2012 and we reviewed new searches in 2013 (update published 2014).

Objectives

To evaluate the effectiveness of interventions for CTEV.

Search methods

On 29 April 2013, we searched CENTRAL (2013, Issue 3 in *The Cochrane Library*), MEDLINE (January 1966 to April 2013), EMBASE (January 1980 to April 2013), CINAHL Plus (January 1937 to April 2013), AMED (1985 to April 2013), and the Physiotherapy Evidence Database (PEDro to April 2013). We also searched for ongoing trials in the WHO International Clinical Trials Registry Platform (2006 to July 2013) and ClinicalTrials.gov (to November 2013). We checked the references of included studies. We searched NHSEED, DARE and HTA for information for inclusion in the Discussion.

Selection criteria

Randomised controlled trials (RCTs) and quasi-RCTs evaluating interventions for CTEV. Participants were people of all ages with CTEV of either one or both feet.

Data collection and analysis

Two authors independently assessed risk of bias in included trials and extracted the data. We contacted authors of included trials for missing information. We collected adverse event information from trials when it was available.

Main results

We identified 14 trials in which there were 607 participants; one of the trials was newly included at this 2014 update. The use of different outcome measures prevented pooling of data for meta-analysis even when interventions and participants were comparable. All trials displayed bias in four or more areas. One trial reported on the primary outcome of function, though raw data were not available to be analysed. We were able to analyse data on foot alignment (Pirani score), a secondary outcome, from three trials. Two of the trials involved participants at initial presentation. One reported that the Ponseti technique significantly improved foot alignment compared to the Kite technique. After 10 weeks of serial casting, the average total Pirani score of the Ponseti group was 1.15 (95% confidence interval (CI) 0.98 to

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1.32) lower than that of the Kite group. The second trial found the Ponseti technique to be superior to a traditional technique, with average total Pirani scores of the Ponseti participants 1.50 lower (95% CI 0.72 to 2.28) after serial casting and Achilles tenotomy. A trial in which the type of presentation was not reported found no difference between an accelerated Ponseti or standard Ponseti treatment. At the end of serial casting, the average total Pirani scores in the standard group were 0.31 lower (95% CI -0.40 to 1.02) than the accelerated group. Two trials in initial cases found relapse following Ponseti treatment was more likely to be corrected with further serial casting compared to the Kite groups which more often required major surgery (risk difference 25% and 50%). There is a lack of evidence for different plaster casting products, the addition of botulinum toxin A during the Ponseti technique, different types of major foot surgery, continuous passive motion treatment following major foot surgery, or treatment of relapsed or neglected cases of CTEV. Most trials did not report on adverse events. In trials evaluating serial casting techniques, adverse events included cast slippage (needing replacement), plaster sores (pressure areas) and skin irritation. Adverse events following surgical procedures included infection and the need for skin grafting.

Authors' conclusions

From the limited evidence available, the Ponseti technique produced significantly better short-term foot alignment compared to the Kite technique and compared to a traditional technique. The quality of this evidence was low to very low. An accelerated Ponseti technique may be as effective as a standard technique, according to moderate quality evidence. Relapse following the Kite technique more often led to major surgery compared to relapse following the Ponseti technique. We could draw no conclusions from other included trials because of the limited use of validated outcome measures and lack of available raw data. Future randomised controlled trials should address these issues.

PLAIN LANGUAGE SUMMARY

Interventions for congenital talipes equinovarus (clubfoot)

Review question

The purpose of this review was to assess treatments for congenital talipes equinovarus (clubfoot).

Background

Clubfoot is a condition, present at birth, in which the foot is in an inturned position. There is no known cause. Different treatments might be effective at different stages: at birth (initial presentation); when initial treatment does not work (resistant presentation); when the initial treatment works but the clubfoot returns (relapse/recurrent presentation); and when there has been no early treatment (neglected presentation). Treatment aims to put the foot back into a normal position and be pain-free throughout life.

Treatment can be non-surgical, surgical or both. Non-surgical treatment (for example plaster casting or stretches) gently stretch the foot into a normal position. Surgery may involve the muscles, tendons, ligaments or joints.

Study characteristics

From our searches we found 14 trials with 607 participants. All trials had problems of design or conduct that might have affected the results. Treatments were studied at birth (eight trials, 326 participants), during relapse (four trials, 181 participants) or at an unknown time (two trials, 100 participants).

Results and quality of the evidence

Our main measure of the success of treatment was function (how well the foot worked in everyday life). Only one trial reported on function; however, data were not available to re-analyse. We analysed data from three trials. When treated at birth, foot position was better after Ponseti plaster casting than after Kite plaster casting. The quality of this evidence was low. When treated at birth, foot position was better after Ponseti plaster casting than after a traditional technique (another type of plaster casting). The quality of this evidence was very low. One trial found Ponseti plaster casting three times per week to be as good as weekly Ponseti casting. This trial did not state at which stage the treatment was done. The quality of this evidence was moderate. Relapse following Kite technique more often required major surgery than relapse following the Ponseti technique. Data were not available to assess the results for adding botulinum toxin A to the Ponseti treatment, using different types of plaster casts in the Ponseti treatment, different foot surgeries or the treatment of relapsed or neglected clubfoot. Most trials did not report on harmful effects. When reported, harmful effects during plaster casting included casts slipping, plaster sores and skin irritation. Harmful effects of infection and skin grafting were reported after surgery.

Further well-designed trials are needed to confirm these findings and to decide which is the best treatment for each presentation.

The searches for the review are up to date to April 2013.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Kite versus Ponseti technique for treatment of initial congenital talipes equinovarus (clubfoot)

Kite versus Ponseti technique for treatment of initial congenital talipes equinovarus (CTEV, clubfoot)

Patient or population: patients with CTEV at initial presentation

Settings: single outpatient clinic

Intervention: Kite versus Ponseti technique

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Kite technique	Ponseti technique				
Function - not measured	See comment	See comment	Not estimable	-	-	Function was an outcome in 6 trials but validated scales not used except in one study for which raw data were not available.
Foot alignment Pirani score ¹ . Scale from: 0 to 6. Follow-up: 10 weeks	The mean foot alignment score in the control groups was 2.12 points ²	The mean foot alignment score in the intervention groups was 1.15 lower (1.32 to 0.98 lower)	-	60 (1 study)	⊕⊕⊕⊖ low ³	-
Gait assessment - not reported	See comment	See comment	Not estimable	-	-	No trial assessed gait using a validated measure
Health-related quality of life - not reported	See comment	See comment	Not estimable	-	-	Assessed in one study but raw data not available for analysis.
Adverse events	See comment	See comment	Not estimable	-	-	One trial reported plaster sores and skin ulceration with casting without specifying the treatment group

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **CTEV:** congenital talipes equinovarus

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ A lower score indicates better alignment.

² Final mean Ponseti score of pooled results from three strata.

³ There was an overall unclear risk of bias.

Summary of findings 2. Ponseti versus traditional treatment (plaster casting and surgery) for treatment of initial congenital talipes equinovarus (clubfoot)

Ponseti versus traditional treatment (plaster casting and surgery) for treatment of initial congenital talipes equinovarus (CTEV, clubfoot)

Patient or population: patients with CTEV at initial presentation

Settings: single centre

Intervention: Ponseti versus traditional treatment (plaster casting and surgery)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Traditional treatment (plaster casting and surgery)	Ponseti technique				
Function PODCI	See comment	See comment	Not estimable	-	See comment	Data not suitable for analysis
Foot alignment Pirani score ¹ . Scale from: 0 to 6.	The mean foot alignment score in the control groups was 1.8 points ²	The mean foot alignment score in the intervention groups was 1.5 lower (2.28 to 0.72 lower)	-	28 (1 study)	⊕⊕⊕⊕ very low ^{3,4,5}	-
Gait assessment - not measured	-	-	Not estimable	-	-	-
Health-related quality of life PODCI	See comment	See comment	Not estimable	-	See comment	Data not suitable for analysis

Adverse events	See comment	See comment	Not estimable	-	See comment	There were no adverse events
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*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **CTEV:** congenital talipes equinovarus; **PODCI:** Pediatric Outcomes Data Collection Instrument; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ A lower score indicates better alignment.

² Final mean Pirani score in control group.

³ Overall unclear risk of bias.

⁴ Early stopping rule was instigated.

⁵ Small number of participants.

Summary of findings 3. Standard Ponseti technique versus an accelerated Ponseti technique for congenital talipes equinovarus (clubfoot)

Standard Ponseti technique versus an accelerated Ponseti technique for congenital talipes equinovarus (CTEV, clubfoot)

Patient or population: patients with CTEV (type of case (e.g. initial presentation or relapsed) not specified)

Settings: single centre

Intervention: standard Ponseti technique versus an accelerated Ponseti technique

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Standard Ponseti technique	Accelerated Ponseti technique				
Function - not measured	-	-	Not estimable	-	-	-
Foot alignment Pirani score ¹ . Scale from: 0 to 6.	The median foot alignment score in the control groups was 0.5 points ²	The mean foot alignment score in the intervention groups was 0.31 higher (0.4 lower to 1.02 higher)	-	40 (1 study)	⊕⊕⊕⊖ moderate ³	-

Gait assessment - not measured	-	-	Not estimable	-	-	-
Health-related quality of life - not measured	-	-	Not estimable	-	-	-
Adverse events - not reported	-	-	Not estimable	-	-	-

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ A lower score indicates better alignment.

² Final mean Pirani score for control group (standard Ponseti).

³ Unclear overall bias.

BACKGROUND

Description of the condition

Congenital talipes equinovarus (CTEV), also known as clubfoot, is a common congenital paediatric condition, occurring in 1 to 2 per 1000 newborns (Dobbs 2006). It is characterised by an excessively turned in foot (equinovarus) and high medial longitudinal arch (cavus), which if left untreated leads to long-term functional disability, deformity and pain (Ponseti 2005). CTEV is thought to begin as the limb buds form and can be diagnosed on ultrasound from 12 weeks gestation (Keret 2002). There are two types of CTEV: idiopathic (isolated) and syndromic (those associated with other syndromes or conditions). In both the cause is unknown, although hypotheses include associated transient gene activity, as seen in developmental dysplasia of the hips (Ponseti 2005); neuromuscular disease (Handelsman 1982; Lovell 2007); and lack of foetal movement (Hester 2009). Emerging literature suggests a polygenic cause (Dobbs 2009). Syndromic CTEV is often severe and more resistant to treatment (Janicki 2009).

Description of the intervention

The treatment of CTEV varies but is usually conservative in initial cases, with surgical options reserved for correction of any resistant (remaining) deformity. Conservative treatment includes: stretching, for example the French Functional method (Richards 2008); varied serial casting (plaster casts) and bracing, including Ponseti and Kite techniques (Sud 2007); minor surgical intervention, for example Achilles tenotomy (release of the heel cord), tibialis anterior tendon transfer (moving a muscle in the foot) and Achilles lengthening (lengthening of the calf muscle); the use of external fixator devices (surgical application of a metal brace) (Ponseti 2005); and botulinum toxin injections (Alvarez 2005).

The Ponseti technique is currently the most practised treatment with excellent long-term outcomes (30 years) (Cooper 1995). This technique involves six to eight weeks of long leg plaster casts (toe to groin) with gentle manipulation around the talar head (a part of the ankle joint). Casts are changed once per week. Up to 90% of cases require an Achilles tenotomy to correct remaining equinus (heel cord tightness) deformity (Haft 2007). This is considered part of routine treatment. Patients are then required to wear a boots and bar brace for 23 hours per day for three months and then during sleep until four years of age (Ponseti 2005). The Ponseti technique has been shown to significantly reduce the need for major foot surgery (Morcuende 2004; Zions 2010).

The Kite technique was widely practised until the emergence of the Ponseti technique. The Kite technique involves long leg plaster casts (toe to groin) with manipulation occurring around the calcaneo-cuboid joint (a joint in the foot) (Kite 1972). Casting may continue for up to two years (Dobbs 2009) with 50% to 75% of cases requiring major surgical intervention (Lovell 1979).

Unfortunately, with all treatments, relapses are common and may occur in up to 37% of children within two years (Richards 2008) and in up to 47% before four years of age (Laaveg 1980). Causes of relapse include non-compliance with bracing regimes (such as the Ponseti method) (Morcuende 2004), relative overactivity of the tibialis anterior tendon (Ponseti 2005) and progressive neuromuscular disease (Lovell 2007; Masrouha 2012). When left untreated, the foot gradually returns to its original position. In mild

cases the child may overload the lateral border of their foot during walking and in extreme cases walk on the outside border of the foot (cuboid and fifth metatarsal) with resulting callosities and pain.

In children with relapsed CTEV, intervention is required to prevent further progressive deformity. Historically, relapses were treated with major surgical intervention including muscle, ligament and joint releases (for example posteromedial soft tissue release) or bony operations (for example wedge osteotomies) (Dobbs 2000). Long-term observational studies have found poorer outcomes in patients treated with major foot surgery (Dobbs 2006; Graf 2010; Ippolito 2003). Clinicians are therefore beginning to employ the same conservative techniques used in initial CTEV to treat relapses (Nogueira 2009).

How the intervention might work

Frequent stretching and active assisted movement (for example the French functional method) has been shown to be effective in achieving good joint alignment in patients less than two years old with CTEV (Richards 2007).

Serial plaster casting (for example the Ponseti and Kite techniques), involving sustained stretching for an extended period, is thought to improve the extensibility of surrounding tissue and joint capsules. Magnetic resonance imaging studies of babies with CTEV show that musculature, ligament and bony changes are possible with weekly Ponseti casting (Pirani 2001). Studies have demonstrated increases in both the length and numbers of sarcomeres when a muscle is immobilised in a lengthened position for an extended period of time (Cusick 1990).

Minor surgical procedures, those which are joint sparing (do not involve the ankle or foot joints), are thought to result in good long-term outcomes, with pain-free feet (Dietz 2006). Examples include Achilles tenotomies (surgically releasing the Achilles tendon), which have been shown in very young children to result in direct elongation of the tendon (De Gheldere 2008; Radler 2007) and tibialis anterior tendon transfer, which aims to restore the balance of musculature around the foot by making the tibialis anterior muscle pull the foot directly up rather than up and twisting in (with the big toe up) (Kuo 2001; Laaveg 1980). In severe cases, relapsed CTEV may require a combination of these procedures or major bone or joint surgery to correct the position of the foot and ankle.

Botulinum toxin, a potent neuromuscular agent, causes partial temporary muscular paralysis allowing for lengthening through sustained stretching (for example serial casting). When used in the triceps surae (calf muscle), it may prevent the need for Achilles tenotomy or other major surgery (Alvarez 2005).

Why it is important to do this review

The treatment of CTEV remained varied and inconsistent until the Ponseti technique became widely practised. This technique has shown favourable long-term outcomes (Cooper 1995), but relapses are common. A systematic review of all interventions for initial and relapsed CTEV will assist the clinician in providing the most effective treatment and allow for ongoing evaluation of these interventions in the future. This review was first published in 2012 and updated in 2013.

OBJECTIVES

To evaluate the effectiveness of interventions for CTEV.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) or quasi-RCTs of interventions for the treatment of CTEV. Quasi-RCTs are those where systematic methods of allocation are used, for example date of birth, hospital number or date.

Types of participants

People of all ages with CTEV of either one or both feet.

Types of interventions

We included any intervention aimed at reducing or eliminating the deformity associated with CTEV (for example cavus, adductus, varus and equinus), including but not limited to the following:

- stretching, for example passive and active stretching using taping or plaster casts (serial casting);
- surgery, for example muscle lengthening, tendon transfers, osteotomies (operations on bone) and external fixators (surgically applied brackets which can stretch joints); and
- other, for example botulinum toxin.

Types of outcome measures

The outcomes listed here are not eligibility criteria for this review, but are outcomes of interest within whichever studies are included.

Primary outcomes

- Function: self reported or parent- or proxy-reported day-to-day function at a minimum of one year post-treatment, as measured by any validated assessment tool, for example Clubfoot Disease Specific Index (DSI) (Dietz 2009); physical component of the Child Health Questionnaire (CHQ) (Landgraf 1999) and physical subscale of the Short Form 36 Health Survey (SF-36) (Ware 1992).

Studies with different follow-up periods were to be combined with appropriate adjustments if the assumption of steady rates of change were justified. This was not possible with the data available.

Secondary outcomes

- Foot alignment (measured by any validated assessment tool, for example, radiographic, Foot Posture Index (Redmond 2006), Dimeglio scale (Diméglio 1995), Pirani score (Pirani 2008)).
- Gait assessment (for example, pedobarography, 3D kinematics).
- Parent- or patient-reported health-related quality of life (measured by any validated assessment tool, for example, CHQ).
- Adverse events (classified as 'any adverse event', 'adverse event leading to withdrawal of treatment', and 'life-threatening (severe) adverse event' (requiring admission to hospital or adverse outcome leading to permanent disability or death)).

Measures were to be assessed at a minimum of one year; however, some outcomes (for example foot alignment) measured at the end of treatment determined whether further alternative

treatment (such as surgery) was required. We have therefore included significant findings (clinically or statistically) at the end of treatment where indicated.

We planned to combine studies with different follow-up periods with appropriate adjustments if the assumption of steady rates of change were justified; however, this was not possible with the data available. We presented the following outcomes in 'Summary of findings' tables as far as data allowed:

- function (self reported or parent- or proxy-reported);
- foot alignment;
- gait assessment;
- health related quality of life; and
- adverse events.

Search methods for identification of studies

Electronic searches

On 29 April 2013, we searched CENTRAL (2013, Issue 3, in *The Cochrane Library*), MEDLINE (January 1966 to April 2013), EMBASE (January 1980 to April 2013), AMED (January 1985 to April 2013), CINAHL Plus (January 1937 to April 2013), PEDro (January 1929 to April 2013). We searched the WHO International Clinical Trials Registry Platform (ICTRP) (2006 to July 2013) (www.who.int/ictip/en/) and ClinicalTrials.gov (www.clinicaltrials.gov) for ongoing trials. There were no language or publication restrictions. We searched NHS Economic Evaluation Database (NHSEED), Database of Abstracts of Reviews of Effectiveness (DARE) and Health Technology Assessment Database (HTA) (2013, Issue 1 in *The Cochrane Library*), for information to include in the [Discussion](#),

The detailed search strategies are shown in the Appendices: CENTRAL and NHSEED, [Appendix 1](#); MEDLINE, [Appendix 2](#); EMBASE, [Appendix 3](#); AMED, [Appendix 4](#); CINAHL Plus, [Appendix 5](#); PEDro [Appendix 6](#); WHO ICTRP, [Appendix 7](#) and ClinicalTrials.gov, [Appendix 8](#).

Searching other resources

We reviewed the bibliographies of the trials identified and, if appropriate, contacted the authors as well as known experts in the field to identify additional studies. We handsearched the reference sections of retrieved articles, relevant thesis publications and the reports or conference proceedings of relevant symposia, for example the International Clubfoot Symposium. We contacted registered expert clinicians in the field to identify additional published or unpublished data. We specified no limitations on language or year published.

Data collection and analysis

Selection of studies

Two review authors (KG and VP) independently assessed the titles and abstracts of trials identified by the search. The same two authors reviewed full text copies of potentially relevant trials to determine eligibility based on inclusion criteria.

We did not mask study authorship and results during the study selection process as the effect of assessor masking has not been established by empirical evidence (Higgins 2008c). The review authors resolved disagreements by discussion and, if necessary, arbitration by a third review author (JB). Arbitration by the third

reviewer resolved all disputes so we did not contact study authors for additional information.

Data extraction and management

Two review authors (KG and VP) independently extracted data using separate, standardised, prepared forms. We contacted trial authors to provide any missing information. One review author (KG) entered data into the Cochrane statistical software, Review Manager (RevMan 2008), and a second (VP) checked the data entry. The review authors resolved disagreements by discussion and, if necessary, arbitration by a third author (JB).

Assessment of risk of bias in included studies

Two review authors (KG and VP) independently rated the risk of bias in the reviewed studies using a standardised grading system described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008, updated Higgins 2011). There were no disagreements between the authors for assessment of risk of bias. Any disagreements would have been resolved by discussion and, if necessary, arbitration by a third author (JB). The grading system considered the following domains:

- sequence generation;
- allocation concealment;
- blinding of participants, personnel and outcome assessors;
- other potential threats to validity (such as financial conflicts of interest, single author or single centre trials);
- incomplete outcome data; and
- selective outcome reporting.

We created a 'Risk of bias' table for each included study showing our judgement for each domain. We used judgements of 'High risk of bias', 'Low risk of bias' or 'Unclear risk of bias', where 'Unclear risk of bias' indicates an unknown risk of bias or that an entry is not relevant to the study. We included a comment to support each of our assessments. We generated a 'Risk of bias summary' using RevMan to present all of the judgements in a cross-tabulation of study by risk of bias domain.

Measures of treatment effect

If there was more than one trial with a specific intervention we planned to perform a meta-analysis using RevMan. Where the same outcome measures were used, we planned to calculate mean differences (MD) and 95% confidence intervals (CIs) for continuous variables. Where outcome measures differed but measured the same construct, we planned to calculate standardised mean differences (SMD) and 95% CIs. For dichotomous outcomes, we planned to determine risk ratios (RRs) and 95% CIs using a fixed-effect model, where heterogeneity permitted (see [Assessment of heterogeneity](#)).

Unit of analysis issues

Although we planned to include cross-over trials, there were none. If we had identified cross-over trials we planned to use the generic inverse variance (GIV) facility in RevMan to combine the estimated difference in effects from each study with its standard error (SE).

A number of trials included data from bilateral (including both right and left feet) and unilateral cases. In bilateral cases, right and left feet from the same subject are likely to be correlated

(not independent). An analysis that ignores this correlation will provide CIs and P values that are invalid, and may detect spurious significance. However, there are statistical techniques available to overcome this. Where raw data was available (Harnett 2011), we used a linear mixed model with random subject effects. As well as providing a valid analysis of this study, the linear mixed model gave an estimate of the correlation between measurements taken from left and right feet in participants who received the same intervention. Making the assumption that this correlation was consistent in other trials with the same outcome variable, we were able to adjust results and re-analyse published data. We have provided details of each analysis in the description of each study.

Dealing with missing data

If the study authors had not performed an intention-to-treat analysis, we would have done so before entry of data into RevMan, provided sufficient data were available.

Assessment of heterogeneity

We assessed clinical heterogeneity across trials; however, none were sufficiently clinically homogenous in terms of participants, intervention, and outcomes to include them in a meta-analysis.

Assessment of reporting biases

We took the following measures to reduce reporting biases.

- We performed comprehensive searches to identify randomised, quasi randomised and cross-over trials.
- We sought to include unpublished relevant studies, including those registered at inception.
- If it had been possible, we planned to detect reporting biases using funnel plots to assess for small study effects (Higgins 2008b).

Data synthesis

We used RevMan for data analysis. One author (KG) entered statistical data and a second review author (VP) checked the data entry. We resolved all disagreements by discussion with a third review author (JB).

Subgroup analysis and investigation of heterogeneity

The following predefined subgroup analyses would have been performed if sufficient data had been available.

1. Age: birth to two years, two to four years, four to 10 years, 10 to 20 years, and over 20 years of age (relapses are most common in the birth to two year range and decrease with age). The literature has previously reported subgroup analysis (Laaveg 1980; Richards 2008).
2. Unilateral versus bilateral CTEV.
3. Idiopathic versus syndromic CTEV (associated with other conditions).
4. Initial versus relapsed CTEV.

We would have followed the same methodological principles for meta-analysis of subgroups as for the primary analysis.

Sensitivity analysis

If clinical heterogeneity had been present, we planned to carry out a sensitivity analysis by omitting from the meta-analysis trials

at high risk of bias, or which were unpublished, or funded by industry. We would have made omissions in order, for example we would have removed studies with unclear or inadequate allocation concealment, re-run the analysis, then removed studies with unclear blinding and re-run the analysis, and so on.

If data had been available, we planned to include cost-benefit analysis of interventions for the treatment of CTEV in the [Discussion](#), making use of the non-randomised data where necessary.

Risk of bias in the review process

The review has a published protocol ([Gray 2010](#)). We have documented any deviations from the protocol in [Differences between protocol and review](#).

RESULTS

Description of studies

Results of the search

Electronic searches retrieved 460 citations (CENTRAL 48, MEDLINE 254, EMBASE 107, CINAHL Plus 12, AMED 21, and PeDRO 5). Forty-three studies were identified as potentially relevant. Searching reference lists of included trials did not identify any additional potentially relevant trials. Our search of WHO ICTRP revealed 21 studies and ClinicalTrials.gov revealed 28 studies. None were included in the review as Ongoing studies.

There were 2 papers in NHSEED and none in DARE or HTA databases.

Included studies

Fourteen trials met the criteria for inclusion in the review ([Cummings 2009](#); [El-Deeb 2007](#); [Harnett 2011](#); [Kaewpornasawan 2007](#); [Lahoti 2008](#); [Manzone 1999](#); [Pittner 2008](#); [Rijal 2010](#); [Sanghvi 2009](#); [Selmani 2012](#); [Siddiqui 2007](#); [Sud 2008](#); [Zeifang 2005](#); [Zwick 2009](#)). Electronic searching identified all these trials. Details of individual trials are presented in the tables [Characteristics of included studies](#) and 'Characteristics of included trials' ([Table 1](#)).

Seven trials were parallel-designed RCTs ([Cummings 2009](#); [Harnett 2011](#); [Kaewpornasawan 2007](#); [Rijal 2010](#); [Selmani 2012](#); [Zeifang 2005](#); [Zwick 2009](#)), three were quasi-RCTs ([El-Deeb 2007](#); [Pittner 2008](#); [Sud 2008](#)) and the remaining four were randomised but the method was not described ([Lahoti 2008](#); [Manzone 1999](#); [Sanghvi 2009](#); [Siddiqui 2007](#)). The duration of follow-up averaged 25 months and ranged from end of treatment ([Harnett 2011](#); [Pittner 2008](#); [Rijal 2010](#); [Siddiqui 2007](#)) to 48 months ([Lahoti 2008](#); [Zeifang 2005](#)). All trials were published in the English language in peer reviewed journals between 1999 and 2013.

Eight trials assessed treatment in participants without any prior intervention (initial presentation) ([Cummings 2009](#); [Manzone 1999](#); [Pittner 2008](#); [Rijal 2010](#); [Sanghvi 2009](#); [Selmani 2012](#); [Sud 2008](#); [Zwick 2009](#)), four assessed treatment in resistant cases (those who had undergone prior intervention without full correction of the deformity) ([El-Deeb 2007](#); [Kaewpornasawan 2007](#); [Lahoti 2008](#); [Zeifang 2005](#)) and two did not state if there had been a prior intervention ([Harnett 2011](#); [Siddiqui 2007](#)).

Excluded studies

We excluded 29 potentially relevant studies after reading full-text versions. Twenty-eight were not RCTs ([Andriess 2008](#); [Atar 1993](#); [Aurell 2005](#); [Chang 1991](#); [DePuy 1989](#); [DeRosa 1986](#); [Dimeglio 1996](#); [Doğan 2002](#); [Farsetti 2009](#); [Faulks 2009](#); [Halanski 2010](#); [Ippolito 2003](#); [Janicki 2011](#); [Kesemenli 2003](#); [Kuo 2001](#); [Li 2007](#); [Miura 2005](#); [Napiontek 2000](#); [Narang 2011](#); [Nilgün 2011](#); [O'Brien 2004](#); [Ponseti 2006](#); [Richards 2008](#); [Simons 1985](#); [Steinman 2009](#); [Tschopp 2002](#); [Uglow 2000](#); [Xu 2011](#)) and one study did not state whether randomisation was undertaken ([Thompson 1982](#)).

Risk of bias in included studies

All studies displayed potential risk of bias in at least four areas. One trial had an overall high risk of bias ([Sud 2008](#)). The remaining 13 trials ([Cummings 2009](#); [El-Deeb 2007](#); [Harnett 2011](#); [Kaewpornasawan 2007](#); [Lahoti 2008](#); [Manzone 1999](#); [Pittner 2008](#); [Rijal 2010](#); [Sanghvi 2009](#); [Selmani 2012](#); [Siddiqui 2007](#); [Zeifang 2005](#); [Zwick 2009](#)) had unclear risks of bias. Review authors' judgements about each risk of bias item for each included study are summarised in [Figure 1](#).

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study. Green = low risk of bias; yellow = unclear risk of bias; red = high risk of bias.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Cummings 2009	?	?	+	+	?	?
El-Deeb 2007	-	-	-	?	?	?
Harnett 2011	+	-	?	?	?	?
Kaewpornsawan 2007	?	?	-	+	?	?
Lahoti 2008	?	?	-	+	?	?
Manzone 1999	?	?	-	+	?	?
Pittner 2008	?	-	-	-	?	?
Rijal 2010	+	?	-	+	-	?
Sanghvi 2009	?	?	-	+	-	?
Selmani 2012	+	?	-	-	?	?
Siddiqui 2007	?	?	-	+	?	-
Sud 2008	-	-	-	-	-	?
Zeifang 2005	+	?	-	-	-	?
Zwick 2009	+	?	-	-	?	-

Allocation

Participants in eight trials were randomly allocated to treatment groups using computer number generation (Harnett 2011; Rijal 2010; Selmani 2012; Zeifang 2005), medical record numbers (Pittner 2008), random number table (Zwick 2009), random selection of unmarked vials (Cummings 2009) and unmarked envelopes (Kaewpornsawan 2007). Quasi-randomisation occurred in two trials that used sequencing based on arrival (El-Deeb 2007; Sud 2008). Four trials did not state the method of randomisation. (Manzone 1999, Lahoti 2008; Sanghvi 2009; Siddiqui 2007). Concealment of allocation was not adequate in any trial. Three trials had inadequate concealment (El-Deeb 2007; Pittner 2008; Sud 2008) and the remaining eleven trials (Cummings 2009; Harnett 2011; Kaewpornsawan 2007; Lahoti 2008; Manzone 1999; Rijal 2010;

Sanghvi 2009; Selmani 2012; Siddiqui 2007; Zeifang 2005; Zwick 2009) were unclear, owing to insufficient information.

Blinding

It was not possible to blind the intervention provider in any included trial. Participants were blinded to the intervention in one trial (Cummings 2009), in which participants received either botulinum toxin or a placebo. The remaining trials provided insufficient information on blinding of participants. Outcome assessors were blinded to the intervention in six trials (Cummings 2009; Lahoti 2008; Rijal 2010; Selmani 2012; Sud 2008; Zeifang 2005) and were not blinded in three (Pittner 2008; Sanghvi 2009; Zwick 2009). The remaining five trials (El-Deeb 2007; Harnett

2011; Kaewpornasawan 2007; Manzone 1999; Selmani 2012; Siddiqui 2007) provided insufficient information to permit judgement.

Incomplete outcome data

Seven trials had no missing data (Cummings 2009; Kaewpornasawan 2007; Lahoti 2008; Manzone 1999; Rijal 2010; Sanghvi 2009; Siddiqui 2007). Four had missing data which were not addressed (Pittner 2008; Selmani 2012; Sud 2008; Zeifang 2005). Missing data in two trials (Harnett 2011; Zwick 2009) were addressed by an intention-to-treat analysis but several participants broke protocol by changing treatment arms. El-Deeb 2007 provided insufficient information to determine the risk of bias from incomplete outcome measures.

Selective reporting

Two studies had incomplete reporting: in one of them outcomes could not be reported because of missing data (Sanghvi 2009) and the other (Sud 2008) did not report on outcomes defined in the materials and methods. Five trials had identifiable selective reporting (Rijal 2010; Sanghvi 2009; Selmani 2012; Sud 2008; Zeifang 2005). The remaining nine trials (Cummings 2009; El-Deeb 2007; Harnett 2011; Kaewpornasawan 2007; Lahoti 2008; Pittner 2008; Rijal 2010; Siddiqui 2007; Zwick 2009) were assessed as unclear, as there was insufficient information to make a judgement.

Other potential sources of bias

Two trials had other identifiable sources of bias. Zwick 2009 had a formal stopping rule as one treatment arm was leading to much greater rates of major surgical intervention. Siddiqui 2007 reported on a procedure the authors had developed. All remaining trials were considered to have an 'Unclear risk of bias' for this domain, owing to insufficient information on baseline characteristics (Cummings 2009; El-Deeb 2007; Kaewpornasawan 2007; Lahoti 2008; Manzone 1999; Sanghvi 2009) or insufficient information to permit judgement (Harnett 2011; Pittner 2008; Rijal 2010; Selmani 2012; Sud 2008; Zeifang 2005).

Effects of interventions

See: [Summary of findings for the main comparison Kite versus Ponseti technique for treatment of initial congenital talipes equinovarus \(clubfoot\)](#); [Summary of findings 2 Ponseti versus traditional treatment \(plaster casting and surgery\) for treatment of initial congenital talipes equinovarus \(clubfoot\)](#); [Summary of findings 3 Standard Ponseti technique versus an accelerated Ponseti technique for congenital talipes equinovarus \(clubfoot\)](#)

Eleven comparisons were reported. Five trials compared the Ponseti technique with other treatments: the Kite technique (Rijal 2010; Sanghvi 2009; Selmani 2012; Sud 2008) and traditional casting with surgery (Zwick 2009). Three trials examined modification of the Ponseti technique, one by different casting materials (Pittner 2008), one by the addition of botulinum toxin A (Cummings 2009) and one by use of an accelerated Ponseti treatment schedule (Harnett 2011). Five trials compared different major surgical interventions (El-Deeb 2007; Kaewpornasawan 2007; Lahoti 2008; Manzone 1999; Siddiqui 2007) and one compared two postoperative regimes (Zeifang 2005). Details of interventions are provided in the tables [Characteristics of included studies](#) and [Table 1](#), 'Characteristics of included trials'. Comparisons are ordered in groups: treatment for initial presentations (comparisons 1 to 6), treatment for resistant cases (comparisons 7 to 10) and other presentations (comparison 11).

Participants

A total of 607 participants with CTEV were included. In trials assessing initial treatment there were 326 participants (487 feet) and in trials assessing resistant deformity there were 181 participants (256 feet). Two reports were unclear: Harnett 2011 treated 40 participants (61 feet), but did not state the timing of the intervention and Siddiqui 2007 included 60 participants but did not state the number of included feet. The number of participants ranged from 13 (26 feet) to 100 (150 feet). Of the ten trials for which adequate details were reported, 298 (64%) participants were male and 168 (36%) were female. Lahoti 2008 did not report on gender. Pittner 2008, Zeifang 2005 and Sud 2008 reported drop-outs prior to data analysis.

Of the eight trials assessing initial treatment, two reported an average age of participants: 16.3 months (Rijal 2010) and 7.7 months (Manzone 1999). Two specified age ranges: less than two weeks (Zwick 2009), and 0 to 30 days (Cummings 2009). Sanghvi 2009 included a range of age groups from birth to greater than 36 weeks. Following removal of drop-out data, participants in Pittner 2008 had an average age of 10 days, Selmani 2012 an average of 33 days, and in Sud 2008, an average age of 29 days.

In the four trials that assessed treatment for resistant CTEV, participants had an average age of 8.3 months.

In the two unclear trials, Harnett 2011 included participants less than 90 days old and participants in Siddiqui 2007 had an average age of 9.6 months.

Inclusion of idiopathic cases was specified in three of the seven trials assessing initial treatment (Manzone 1999; Rijal 2010; Selmani 2012). A further three trials stated exclusion of CTEV cases associated with syndromes or with other deformities (Sanghvi 2009; Sud 2008; Zwick 2009). Cummings 2009 and Pittner 2008 did not report inclusion or exclusion criteria. Of the four trials assessing treatment of resistant CTEV, two specified idiopathic CTEV as an inclusion criterion (El-Deeb 2007; Zeifang 2005) and one specifically excluded syndromic CTEV or similar cases (Kaewpornasawan 2007). Lahoti 2008 included two feet (1 participant) with syndromic CTEV. Of the unclear trials, Harnett 2011 included idiopathic cases and Siddiqui 2007 did not report on inclusion or exclusion criteria.

Statistical considerations

Several studies were comparable, with similar treatment and participant cohorts; however they employed different outcome measures, which precluded pooling for meta-analysis. Nine authors responded to requests for additional information. One author was able to provide raw data in order to perform re-analysis (Harnett 2011).

A linear mixed model was used in the analysis of raw data for Harnett 2011. This assumed that outcomes were normally distributed; however, Pirani scores are not normally distributed, so we used a computed bootstrap CI as a check on the robustness of the results from this study. Exact details are given in the description of the results from this study.

Outcomes

Primary outcome

Function was an outcome in six trials ([El-Deeb 2007](#); [Kaewpornawan 2007](#); [Manzone 1999](#); [Sanghvi 2009](#); [Sud 2008](#); [Zwick 2009](#)). Only one used a validated functional scale, the Pediatric Outcomes Data Collection Instrument (PODCI) ([Zwick 2009](#)) but raw data were not available for analysis.

Secondary outcomes

Radiography was an outcome in four trials ([El-Deeb 2007](#); [Manzone 1999](#); [Sanghvi 2009](#); [Zwick 2009](#)) but raw data were not available for analysis.

Foot alignment was assessed in all trials. Foot alignment is a key outcome used at the end of initial treatment to determine the next course of treatment (for example bracing or major foot surgery).

Seven trials used validated scales specific to CTEV: the Dimeglio scale ([Pittner 2008](#); [Zeifang 2005](#)) and the Pirani score ([Harnett 2011](#); [Lahoti 2008](#); [Rijal 2010](#); [Selmani 2012](#); [Zwick 2009](#)). Both scores assess several components of foot alignment. The sums of these scores form a final severity score; in both scales a higher score correlates with greater severity. Further detail on the Pirani score can be found in [Table 2 \(Pirani 2008\)](#). No raw data from the Dimeglio scale were available for analysis. [Harnett 2011](#) provided raw Pirani score data, and statistical analysis of this raw data allowed for analysis of all published Pirani data.

No trial investigated gait using a validated method.

Parent- or patient-reported health-related quality of life was assessed in one trial ([Zwick 2009](#)), using the PODCI.

Adverse events were documented in six trials ([Kaewpornawan 2007](#); [Manzone 1999](#); [Pittner 2008](#); [Sanghvi 2009](#); [Siddiqui 2007](#); [Zwick 2009](#)). In two trials involving plaster casting treatment, [Sanghvi 2009](#) reported plaster sores and skin ulceration (five participants, 8%) and [Pittner 2008](#) reported minor skin irritation

and plaster casts slipping (11 participants, 35%). The groups in which these events occurred was not stated. In trials that assessed surgical interventions, the incidence of adverse events was reported in four ([Kaewpornawan 2007](#); [Manzone 1999](#); [Siddiqui 2007](#); [Zwick 2009](#)). [Manzone 1999](#) reported superficial infections (two feet) requiring antibiotics and skin breakdown. One foot required skin grafting. [Kaewpornawan 2007](#) reported skin infections in both groups: posteromedial soft tissue release (four feet, 8.5%) and complete circumferential subtalar release (two feet, 5.1%). [Siddiqui 2007](#) reported wound infections in both groups: window procedure (one foot, 3%) and the Turco procedure (six feet, 20%). The Turco procedure also produced skin breakdown and wound dehiscence (opening) (two feet, 7%). [Zwick 2009](#) reported no complications in either treatment group. Adverse events were not addressed in the remaining trials.

Relapse was documented in 13 trials. In initial cases, in up to three years of follow-up, three trials reported relapse with Ponseti and Kite techniques ([Sanghvi 2009](#); [Selmani 2012](#); [Sud 2008](#)). [Selmani 2012](#) did not report what treatment was required to correct the 11 feet in the Kite group. In the two feet of the Ponseti group which required surgery, the type of surgery was not stated. [Sanghvi 2009](#) and [Sud 2008](#) found the risk difference for major surgery following relapse was 25% and 50% higher in the Kite group respectively. Meta-analysis was not performed due to small numbers. In resistant CTEV all cases of relapse required major foot surgery to correct.

Initial Cases

Eight trials investigated treatment for initial presentation of CTEV.

Comparison 1: Ponseti versus Kite technique

Four studies compared Ponseti versus Kite techniques ([Rijal 2010](#); [Sanghvi 2009](#); [Selmani 2012](#); [Sud 2008](#)). All trials included cases of idiopathic CTEV only. We could analyse foot alignment data (Pirani scores) from one trial ([Rijal 2010](#)). The Pirani score is scored from zero to six and a higher score indicates worse alignment. Results were analysed at the end of 10 weeks of serial casting and published in three strata. All strata found the Ponseti technique to be superior to the Kite technique ([Analysis 1.1, Figure 2](#)).

Figure 2. Forest plot of comparison: 1 Kite versus Ponseti technique for treatment of initial CTEV. Pirani score after 10 weeks of serial casting.

Strata 1 (12 participants, 24 feet) consisted of the randomised participants with bilateral CTEV, where one foot was treated with the Ponseti technique and the other with the Kite technique. At the end of serial casting, the mean (SDs) of the total Pirani scores were 1.20 (0.57) in the Ponseti group versus 2.36 (0.67) in the Kite group. To calculate a valid SE for the difference between these means the matching needs to be taken into account, since there may be within (intrinsic) patient differences (for example ligament laxity). This requires knowledge of the correlation between measurements on left and right feet. Since this is unknown in this study, we used the estimate from the [Harnett 2011](#) study.

The estimated MD is 1.16 (2.36 minus 1.20). Assuming that the correlation between means is 0.8704 (calculated from raw [Harnett 2011](#) data), the SD of within subject differences is 0.330 ($0.330^2 = 0.57^2 + 0.67^2 - 2 \times 0.874 \times 0.67 \times 0.57$) and hence the SE of the MD is 0.095 ($0.330 / \sqrt{12}$), giving a 95% CI for the difference of 0.97 to 1.35.

Strata 2 (10 participants, 20 feet) consisted of the randomised participants with bilateral CTEV, where both feet received the same treatment (four participants the Ponseti technique and six the Kite technique). Denoting the mean of the left and right scores as the combined score, analysis can compare the group-specific means of these combined scores. At the end of serial casting, the mean (SDs) of the total Pirani scores in the Ponseti group for left feet were 0.62 (0.48) versus 1.00 (0.41) in right feet. Assuming that the correlation between right and left feet from the same subject is 0.8704, the mean of the combined scores ((left + right) / 2) is 0.81 and the SD is 0.430 ($0.430^2 = (0.48^2 + 0.41^2 + 2 \times 0.8704 \times 0.48 \times 0.41) / 4$). At the end of serial casting, the total Pirani scores in the Kite group were 2.1 (0.68) for left feet and 2.00 (0.32) for right feet. Therefore, the average combined score was 2.05 and the SD was 0.486 ($0.486^2 = 0.68^2 + 0.32^2 + 2 \times 0.8704 \times 0.68 \times 0.32) / 4$). Accordingly, the estimated difference of means between groups was 1.24 (2.05 minus 0.81) and the SE was 0.293 ($0.293^2 = (0.430^2 / 4) + (0.486^2 / 6)$), giving a 95% CI for the difference of 0.67 to 1.81.

Strata 3 (16 participants, 16 feet) consisted of the randomised participants with unilateral CTEV. Ten participants were treated with the Ponseti technique and six with the Kite technique. At follow-up, the mean (SDs) of the total Pirani scores were 1.05 (0.49) in the Ponseti group versus 1.91 (0.73) in the Kite group. The estimated difference of the means between groups was 0.86 (1.91 minus 1.05) and the SE was 0.336 ($0.336^2 = (0.49^2 / 10) + (0.73^2 / 6)$), giving a CI for the difference of 0.20 to 1.52.

Pooling the results from the three strata gave an MD of 1.15 (95% CI 0.98 to 1.32) in favour of the Ponseti technique ([Analysis 1.1, Figure 2](#)).

Significant outcomes should be viewed with caution as all groups contained small numbers. Relapses were seen in both groups. [Sanghvi 2009](#) and [Sud 2008](#) found the risk difference for major surgery following relapse was 25% and 50% higher in the Kite group respectively. Meta-analysis was not performed due to small numbers. Details of relapse are provided in [Table 3](#) 'Details of relapse. Ponseti versus Kite'.

Comparison 2: Ponseti technique versus traditional treatment (serial casting followed by posteromedial soft tissue release)

One trial compared Ponseti to a traditional treatment in idiopathic CTEV ([Zwick 2009](#)). We were able to analyse foot alignment data (Pirani scores).

Participants were randomised to either Ponseti (nine participants, 12 feet) or traditional technique (10 participants, 16 feet). Published mean (SD) total Pirani scores were 0.3 (0.3) in the Ponseti group (at the completion of serial casting and tenotomy) and 1.8 (1.2) in the traditional group (at the completion of a different type of serial casting). Assuming that the correlation between right and left foot scores from the same subject is r , the standard error of the mean of N observations from n subjects with SD σ , is given by $\sigma (N + 2r(N - n))^{0.5} / N$. Therefore the estimated SE of the mean is 0.104 in the Ponseti group and 0.386 in the traditional group. The estimated SE

for the difference in means is 0.400 ($0.400^2 = 0.104^2 + 0.386^2$), giving

a difference in the means of 1.50 (95% CI 0.72 to 2.28) in favour of the Ponseti technique (Analysis 2.1, Figure 3).

Figure 3. Forest plot of comparison: 2 Ponseti versus traditional treatment (plaster casting and surgery) for treatment of initial CTEV. Pirani score at end of initial Ponseti (serial plaster casting and tenotomy) and traditional treatment (serial plaster casting only).

Relapse was seen in two of nine participants in the Ponseti group within two months of completion of serial casting. Both changed to the traditional group and underwent major surgery.

Comparison 3: Ponseti technique, plaster of Paris versus semi-rigid casting

One trial compared plaster of Paris to semi-rigid casting (Pittner 2008). It was not stated if cases were idiopathic. We were unable to estimate a treatment effect because data from a validated assessment method to collect primary or secondary outcomes were not available.

Comparison 4: Ponseti technique, addition of botulinum toxin versus placebo

One study assessed the addition of botulinum toxin to the Ponseti technique (Cummings 2009). It was not stated if cases were idiopathic. We were unable to estimate a treatment effect as data from validated outcome measures were not available. Relapses were reported in both groups but data was not available to analyse.

Comparison 5: posteromedial soft tissue release versus circumferential subtalar release

One study assessed posteromedial soft tissue release versus circumferential subtalar release in idiopathic CTEV (Manzone 1999). We were unable to draw a conclusion for this comparison as data from validated measures did not state when postoperative assessment was completed, and we were unable to obtain raw data. Relapse was noted in one patient (two feet) as a result of skin necrosis by the end of follow-up (27 months).

Resistant Cases

Four trials investigated treatment for resistant CTEV.

Comparison 6: posteromedial soft tissue release versus subtalar release

One trial compared posteromedial soft tissue release and subtalar release in children at an average age 5.9 months who had failed to respond to prior conservative treatment (Kaewpornawan 2007). Children were excluded if associated syndromes were present. Prior treatment was not defined. We were unable to estimate a treatment effect as data from validated outcome measures were not available. Relapse was noted in both groups but data were not available to analyse.

Comparison 7: talocalcaneal interosseous ligament lengthening versus control during posteromedial soft tissue release surgery

One trial evaluated lengthening of the talocalcaneal interosseous ligament (TCIL) (El-Deeb 2007) in idiopathic severe or very severe (grade III or IV on Dimeglio scale) CTEV, which had failed repeated manipulation. We were unable to estimate a treatment effect as raw data were unavailable to re-analyse. Relapse was seen in both groups but data were not available to re-analyse. All relapses required surgical intervention.

Comparison 8: flexor hallucis longus and flexor digitorum longus lengthening versus simple decompression during surgery for toe flexion deformity in CTEV

One trial evaluated decompression versus lengthening of flexor hallucis longus and flexor digitorum longus in children (average age of 9.5 months) with CTEV with an average Pirani score of 5.5 (Lahoti 2008). Two syndromic feet were included (one in each group). Prior treatment was not defined. We were unable to estimate a treatment effect as data from validated outcome measures were not available. Three participants presented with hindfoot relapse by the end of follow-up (average four years); however, it was not stated if further treatment was required.

Comparison 9: continuous passive motion (CPM) versus immobilisation in a cast post CTEV surgery

One trial compared CPM versus immobilisation in a cast post CTEV surgery in children (average age of 8.2 months) after six months of failed manipulation and casting (Zeifang 2005). All children were classified as having severe CTEV (Dimeglio grade III). We were unable to estimate a treatment effect as data from validated outcome measures were not available. Relapse of one patient (cast group) with bilateral deformity occurred shortly after surgery and the participant was excluded; residual deformity in each group was noted at 48 months of follow-up. Further treatment was not documented.

Relapsed cases

No RCTs examined treatments for recurrent or relapsing CTEV.

Neglected cases

No RCTs examined treatments for neglected CTEV.

Other

Comparison 10: standard Ponseti technique versus an accelerated Ponseti technique

One trial compared an accelerated Ponseti technique (cast changes three times per week) compared to the standard technique (weekly cast changes) in idiopathic CTEV (Harnett 2011). Published data included combined unilateral and bilateral cases. The author provided raw data on foot alignment (Pirani score), which could be re-analysed.

Figure 4. Forest plot of comparison: 3 Standard Ponseti technique versus an accelerated Ponseti technique, outcome: 3.1 Pirani score at the end of serial plaster casting.

As the Pirani scores were highly skewed (not normally distributed), a bootstrap CI was also constructed as a check on the robustness of these results. A non-parametric bootstrap (stratified by group, bilateral or unilateral status and clustered by subject) constructed from 100000 bootstrap samples gave a 95% CI extending from -0.201 to 0.863). Although this CI is narrower than that reported above, the difference is still not statistically significant (Analysis 3.1, Figure 4).

In addition, it was reported that fewer plaster casts were required in the accelerated Ponseti group (Harnett 2011). No relapses occurred within six months.

Comparison 11: Window versus Turco surgery

One trial compared Window versus Turco surgery for idiopathic CTEV in children (mean age 9.6 months) with mild to moderate CTEV (Dimeglio grade I and II) (Siddiqui 2007). Pre-treatment was not defined. We were unable to estimate a treatment effect as data from validated outcome measures were not available. Relapse was reported in both groups but raw data were not available to re-analyse.

DISCUSSION

Current research identified

The treatment of CTEV continues to evolve. There are four distinct areas of therapeutic research: initial presentation, resistant deformity (after unsuccessful treatment), relapsed deformity (recurrence of deformity some time after initial satisfactory treatment) and neglected deformity (no early initial treatment). Within these categories two subgroups are recognised: idiopathic CTEV and syndromic CTEV. Since different presentations of CTEV were analysed separately using a variety of validated and non-validated outcome measures with diverse statistical approaches, we are unable to draw a single, overall conclusion regarding treatment for this condition.

Participants were randomised into either standard Ponseti (21 participants, 32 feet) or accelerated Ponseti (19 participants, 29 feet). Analysis using a linear mixed model with random subject effects gave an estimated difference in mean total mean Pirani scores at follow-up of 0.311 (SE = 0.363, 95% CI -0.399 to 1.022, Analysis 3.1, Figure 4). Using this model, the estimated correlation coefficient for left and right foot measurements in a group which received the same treatment was 0.8704).

Study design

Inclusion and exclusion criteria

Trials in which study design and inclusion criteria were not adequately described were not included. Rigid inclusion and exclusion criteria regarding prior treatment is essential to allow the reader to judge homogeneity of the participant population. Syndromic CTEV is known to be more resistant to treatment (Janicki 2009; Ponseti 2006) and may influence outcomes when combined with idiopathic cases. In relapsed cases, the treatment required may be influenced by the initial treatment prescribed (Halanski 2010a).

Blinding

No trials blinded participants. For trials where two surgical interventions were compared and postoperative care was identical in both groups, it is unlikely that participant (or carer) blinding would have affected the outcome because the care and compliance is virtually identical. Pittner 2008 compared semi-rigid (fibreglass) casting and plaster of Paris and Rijal 2010, Selmani 2012, Sud 2008 and Sanghvi 2009 compared Kite to Ponseti techniques of casting. It is unlikely that participant (or carer) blinding would have affected outcome in these cases because the care and compliance required by the participant is virtually identical. Siddiqui 2007 did not provide postoperative care details, therefore it is unknown if blinding may have affected bias.

Dealing with bilateral and unilateral cases

Inclusion criteria of one or both limbs per participant is a contentious issue in many fields, including foot and ankle orthopaedics (Bryant 2006; Perera 2007). Randomisation can occur at the participant or the limb level. When randomisation occurs at the participant level but feet in bilateral and unilateral cases are pooled, a unit of analysis error occurs. In bilateral cases each limb does not respond independently of the other and therefore violates the underlying independence assumption of statistical analysis. In cases where bilateral and unilateral cases are included, disproportionate weighting is given to the bilateral cases. For example, many treatments of CTEV involve participant compliance with bracing, such that if a participant with bilateral CTEV is non-

compliant, two feet are affected by the one person. Including both feet from one participant may narrow CIs and overstate findings. Therefore, findings involving pooling of bilateral and unilateral cases should be interpreted with caution. Ten trials randomised participants (Cummings 2009; Harnett 2011; Kaewpornasawan 2007; Pittner 2008; Sanghvi 2009; Selmani 2012; Siddiqui 2007; Sud 2008; Zeifang 2005; Zwick 2009) and four trials randomised feet (El-Deeb 2007; Lahoti 2008; Manzone 1999; Rijal 2010). In bilateral cases all trials except one (Zeifang 2005) included all feet. Zeifang 2005 tossed a coin and only included one foot from each participant in their analysis.

Several options exist to overcome this issue. With raw data, post hoc statistical re-analysis of one limb per person can be performed (Lesaffre 2010; Perera 2007). During study design, randomisation by exclusion of the second limb or joint, randomly selecting one limb in bilateral cases, analysing bilateral cases as a distinct subgroup or stratifying bilateral and unilateral cases can be undertaken (Bryant 2006). Alternatively, statistical techniques, such as linear mixed models can be used.

Lahoti 2008 randomly allocated each foot to a different intervention. In bilateral cases where each foot is randomly assigned to a different treatment, there is less variation between individuals, allowing a more precise estimation of the treatment effect. However, the analysis of bilateral cases where each foot receives a different intervention still requires an appropriate statistical analysis to account for any potential within-participant correlation.

Outcomes

Function and quality of life

Function was an outcome in six trials (El-Deeb 2007; Kaewpornasawan 2007; Manzone 1999; Sanghvi 2009; Sud 2008; Zwick 2009) with one using a validated scale (Zwick 2009). However, this trial combined bilateral and unilateral cases and raw data were not available to appropriately re-analyse. Valid assessment of function is required as part of CTEV assessment as routine objective measures for CTEV (for example, x-ray) do not reliably correlate with function (Farsetti 2006; Fridman 2007; Kuo 2001; Vitale 2005).

Generic health-related quality of life was also assessed by Zwick 2009 using the validated PODCI. Currently no condition-specific quality of life instrument has been validated for CTEV. In the future, quality of life assessment might provide further information, particularly in cases where treatment requires long-term compliance with bracing or rehabilitation after surgery.

Foot alignment

Foot alignment was assessed in all trials. Ten trials used validated outcome measures (El-Deeb 2007; Harnett 2011; Lahoti 2008; Manzone 1999; Pittner 2008; Sanghvi 2009; Selmani 2012; Rijal 2010; Zeifang 2005; Zwick 2009). As CTEV deformity occurs in several planes of movement (Ponseti 2005), assessment of foot alignment using valid scales is essential to report on all aspects of the deformity. Poor foot alignment correlates with the requirement for further intervention.

Reporting on compliance

Compliance was not formally assessed in any of the included trials. In five trials, different regimes of bracing and postoperative

care requiring parent or carer compliance were required (Sanghvi 2009; Selmani 2012; Sud 2008; Zeifang 2005; Zwick 2009). Four trials recorded compliance through communication with parents (Cummings 2009; Sud 2008; Zeifang 2005; Zwick 2009). Accurate assessment of compliance was noted as a limitation in two trials (Selmani 2012; Zeifang 2005). Cummings 2009 was unable to demonstrate an association between compliance and rate of relapse. Compliance with bracing has been shown to influence the rate of relapse (Haft 2007; Morcuende 2004). However, compliance with bracing is very difficult to assess objectively and no reliable and valid method has been reported.

Reporting on relapse

Thirteen trials reported on relapse (Cummings 2009; El-Deeb 2007; Harnett 2011; Kaewpornasawan 2007; Lahoti 2008; Manzone 1999; Rijal 2010; Sanghvi 2009; Selmani 2012; Siddiqui 2007; Sud 2008; Zeifang 2005; Zwick 2009); however, no trial defined relapse in their initial protocol. Many factors define relapse, making it difficult to report on. There is emerging literature attempting to discriminate relapse from mild resistant deformity (Halanski 2010b). In CTEV, a relapse can include multiple deformities, for example, equinus (tightness of the heel), adductus (in-turning of the foot) or cavus (high arch). Therefore, the treatment to correct relapse can be an indication of the severity of the deformity. A summary of reported relapse is provided in Table 4.

Two main types of relapse are recognised: passive and dynamic (or residual). Passive relapse refers to a loss in range of movement, whereas dynamic refers to a positional relapse where passive range is still present. Dynamic relapse, if left untreated, can lead to a passive relapse (Ponseti 2005). Treatment options depend on the type of relapse (Farsetti 2006; Haft 2007; Nogueira 2009; Ponseti 2005). A well defined outcome measure of relapsed cases will allow the reader to determine the long-term outcome of the initial treatment.

Cost-benefit analysis

One trial has examined the cost-effectiveness of Ponseti versus primary surgical management for initial treatment of idiopathic CTEV in 55 participants (86 feet) in the New Zealand socialised healthcare system (Halanski 2009). Initially designed as an RCT, only nine participants agreed to randomisation, with the remainder choosing their treatment path. Cost analysis was divided into four groups: unilateral CTEV total cost, bilateral CTEV total cost, unilateral CTEV with recurrence total cost and bilateral CTEV with recurrence total cost. Secondary outcome measures of number of clinic visits, days in hospital, number of visits to operating theatres, operating room time, antibiotic doses and pain medication doses were also examined.

During the average follow-up period of 3.5 years, total cost of treatment per foot was significantly less in the Ponseti group for unilateral CTEV, bilateral CTEV and bilateral CTEV with recurrence. Total cost was not significantly different between groups for unilateral CTEV with recurrence. Furthermore, the surgical group required a greater average number of days in hospital and doses of pain medication.

This trial also calculated the equivalent cost of the above treatment in the United States healthcare system, reporting significantly higher costs in the surgical arm for unilateral CTEV, bilateral CTEV and unilateral CTEV with recurrence.

Summary of main results

Initial cases

Eight trials evaluated initial presentations of CTEV. One trial found the Ponseti technique to produce significantly better foot alignment at the end of serial casting compared to the Kite technique. Adverse events were not reported. Correction of relapse following Ponseti treatment required major foot surgery less often than relapse after Kite treatment. Another trial found the Ponseti technique to be superior to a traditional technique (plaster casting followed by major foot surgery). This trial had small numbers as a formal stopping rule was activated after the Kite technique was observed to lead to higher rates of major surgery than the Ponseti technique. No conclusions could be drawn for other interventions: surgery; modification of the Ponseti technique through the use of different plaster casting products (plaster of Paris versus semi-rigid casting); or the addition of botulinum toxin A to the Ponseti technique. The reporting of adverse events was limited in all trials. In those involving serial casting (plaster casting) adverse events included pressure areas, cast slippage and skin irritations.

Resistant cases

All trials evaluating resistant cases involved major surgical procedures or postoperative care (for example CPM). No conclusions could be drawn with the data available. All relapses required major surgical intervention to correct any recurrent deformity.

Other cases

One trial concluded that the accelerated Ponseti technique (cast changes three times per week) was as effective as the standard Ponseti technique (weekly cast changes). No conclusions could be drawn for two surgical procedures (Window versus Turco procedures) due to limited available data, but wound infections were reported to be higher in the Turco group (20% versus 3%) as were wound dehiscence (opening), skin necrosis (7%) and scarring and fibrosis (10%).

Relapsed cases

No conclusions could be drawn for recurrent cases.

Neglected cases

No conclusions could be drawn for neglected cases.

Overall completeness and applicability of evidence

There are limitations to this review. This review includes RCTs and quasi-RCTs. Due to ethical considerations, most trials investigating treatment of CTEV are not RCTs but comparisons of treatments which have been selected by the parent, carer or clinician. Inclusion of these additional trials may have allowed further analysis, however the lack of randomisation would have introduced significant bias.

Quality of the evidence

Limitations of available evidence

It is clear that well powered long-term RCTs are needed. While there is limited evidence of the Ponseti technique providing superior short-term results to other techniques, long-term observational studies (30 to 45 years) suggest that the Ponseti technique

reduces the need for major foot surgery (surgery involving joints) (Morcuende 2004; Zions 2010) and is more likely to lead to a pain-free foot in adulthood (Cooper 1995; Ippolito 2003). Many studies did not comment on adverse events. Therefore analysis of adverse events could not be undertaken due to lack of data.

The evidence base for treatment of CTEV remains incomplete. Many clinically important aspects of care have not been evaluated in RCTs. The following list identifies some of the evidence gaps in the current body of literature.

- Comparison of different conservative techniques for the treatment of resistant CTEV.
- Treatment of participants with relapsed (recurrent) CTEV (those who have undergone prior treatment with satisfactory results and present with recurrence of the deformity).
- Treatment of non-idiopathic CTEV (for example atypical or complex CTEV, or CTEV associated with syndromes).
- Treatment of neglected CTEV.

Potential biases in the review process

Locating relevant trials

We identified all the trials in this review through electronic searching. All were published in English-language journals. Although we made efforts to identify trials reported in languages other than English and considered some papers for possible inclusion, they did not meet our criteria. We are reasonably confident that we identified all relevant trials because RCTs in CTEV are rare and therefore typically published.

Agreements and disagreements with other studies or reviews

To date there have been no other systematic reviews of RCTs of interventions for CTEV.

AUTHORS' CONCLUSIONS

Implications for practice

Few randomised controlled trials exist evaluating the various presentations of congenital talipes equinovarus and they provide limited evidence on which to base clinical decisions. Evidence is accumulating, but small sample sizes and the limited use of validated outcome measures limit clear conclusions.

In initial cases, the main findings from this review based on the evidence from randomised controlled trials are as follows.

- The Ponseti technique produced significantly better foot alignment in the short term compared to the Kite technique, based on low quality evidence. While relapse rates were similar between groups, the participants in the Ponseti group less often required major surgery to correct relapse.
- The Ponseti technique produced significantly better foot alignment in the short term compared to a traditional technique. The quality of this evidence was very low.

There was a further finding in other cases (it was not stated if a prior intervention had taken place).

- One trial showed no statistically significant difference in the effectiveness of an standard Ponseti technique compared with an accelerated technique. This evidence was of moderate quality.

Implications for research

To develop a strong evidence base for the treatment of various presentations of congenital talipes equinovarus, there needs to be further evaluation in well designed randomised controlled trials. However, observational studies ([Cooper 1995](#); [Ippolito 2003](#)) have shown the Ponseti technique to produce superior long-term (30- to 45-year) results compared to major foot surgery. Randomisation may be considered unethical in certain circumstances and well designed controlled trials may provide more opportunities to analyse different treatments. The following measures would improve the quality of future trials assessing interventions for congenital talipes equinovarus: ensuring baseline comparability by detailed inclusion and exclusion criteria; employing the use of valid and reliable outcome measures for function and quality of life; investigating robust methods to measure compliance; evaluation of treatment for relapsed and neglected cases and those with non-idopathic congenital talipes equinovarus. Consideration must also

be given to statistical analysis, particularly when pooling unilateral and bilateral cases.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cummings 2009

Methods	RCT. Two-arm parallel-group design
Participants	20 participants with 32 CTEV feet who presented to a single centre
	Inclusion criteria: full-term infants aged 0 to 30 days, with CTEV Dimeglio grade III
	Exclusion criteria: none stated
	PARTICIPANT CHARACTERISTICS
	Age: birth to 30 days
	Sex male (%): 60%
	<u>Botulinium toxin A group</u>
	Characteristics of feet: 17 feet. 3 right, 2 left, 6 bilateral
	<u>Placebo group</u>
	Characteristics of feet: 15 feet. 2 right, 1 left, 6 bilateral

Interventions for congenital talipes equinovarus (clubfoot) (Review)

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Cummings 2009 (Continued)

Interventions	<p>Botulinum toxin A versus placebo</p> <p>Randomisation of participants (not feet)</p> <p>Both botulinum toxin A and placebo solutions manufactured and placed in identical vials by the manufacturer. Vials were coded by the manufacturer. A pharmacist at the centre randomly chose a vial and delivered it to the neurology clinic</p> <p>Gastrocnemius and tibialis posterior muscles were injected under EMG (electromyography, a technique which records activity in muscles) guidance by a paediatric neurologist prior to initiation of serial casting using the Ponseti technique</p> <p>After the foot deformity was corrected (heel varus $\geq$ neutral; forefoot adduction $\geq$ neutral; dorsiflexion $\geq$ 15°) feet were braced in reverse last shoes attached to an abduction orthosis set at 70°</p> <p>Feet that were not corrected with casting alone underwent a percutaneous Achilles tenotomy under local anaesthetic followed by further serial casting, until corrected</p> <p>Follow-up average: 27 months (15 months to 4 years)</p>
Outcomes	<p>Time in cast for correction</p> <p>Need for Achilles tenotomy</p> <p>Relapse rate</p> <p>Treatment required for correction of relapse</p>
Notes	This study did not state if children with syndromal CTEV were included or excluded

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Placebo or botulinum toxin A was randomly selected by the pharmacist
Allocation concealment (selection bias)	Unclear risk	Vials were randomly selected by the pharmacist
Blinding (performance bias and detection bias) All outcomes	Low risk	Treater, assessor and participants blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Unclear risk	The definition of relapse was not provided
Other bias	Unclear risk	Did not state if syndromal CTEV type feet were excluded

El-Deeb 2007

Methods	Quasi-RCT. Two-arm parallel-group design
Participants	46 participants with 66 feet with resistant idiopathic CTEV, referred to a single centre

Interventions for congenital talipes equinovarus (clubfoot) (Review)

El-Deeb 2007 (Continued)

Inclusion criteria: idiopathic CTEV which failed conservative treatment (techniques unknown), requiring posteromedial soft tissue release

Exclusion criteria: none stated

PARTICIPANT CHARACTERISTICS

Age mean (range) in months: 9 (3 to 24)

Sex male (%): 89%

Characteristics of feet: 11 left, 15 right, 20 bilateral

Baseline severity: 51 feet Dimeglio grade IV (very severe), 15 feet Dimeglio grade III (severe)

Talocalcaneal interosseous ligament released

Characteristics of feet: not stated

Talocalcaneal interosseous ligament not released

Characteristics of feet: not stated

Interventions	<p>Talocalcaal interosseous ligament release versus control in posteromedial soft tissue release for resistant CTEV</p> <p>Randomisation of feet (not participants)</p> <p>Feet were allocated equally on an alternate basis</p> <p>Postoperative care was the same in both groups. Long leg plaster in corrected position which was then changed every 3 weeks into an overcorrected position. Total time immobilised in cast was 12 weeks. Antivarus boots or splints then worn for one year</p> <p>Follow-up average in months: 28 (24 to 36)</p>
Outcomes	<p>Radiological: x-ray</p> <p>Radiological: MRI scans at 5 months postoperatively in 40 participants (20 from each group)</p> <p>Scoring system based on combination of clinical and radiographic outcomes at an average of 28 months (range, 24 to 36 months)</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Alternate sequence generation
Allocation concealment (selection bias)	High risk	Alternate sequence generation
Blinding (performance bias and detection bias) All outcomes	High risk	Unable to blind intervention provider. Unsure if assessors were blinded. Unsure if families were aware which surgery was done
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some participants had MRI scans. Unable to provide to all participants due to logistics and cost, unsure how the limited numbers were selected

El-Deeb 2007 (Continued)

Selective reporting (reporting bias)	Unclear risk	The Simons system of reporting was modified. Mentioned cosmetic appearance, clinical range and strength, but did not report on these
Other bias	Unclear risk	Unsure if groups were comparable at baseline

Harnett 2011

Methods	RCT. Two-arm parallel-group design
Participants	<p>40 participants with 60 feet who presented to a single centre</p> <p>Inclusion criteria: idiopathic CTEV, less than 90 days of age, local residency, informed consent</p> <p>Exclusion criteria: none stated</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>Age mean (range): 31 days (7 to 55)</p> <p><u>Ponseti standard group</u></p> <p>Sex male (%): 48%</p> <p>Characteristics of feet: 21 participants (32 feet). 11 bilateral cases</p> <p>Baseline severity: median Pirani score 5 (range 4 to 6)</p> <p><u>Ponseti accelerated group</u></p> <p>Sex male (%): 53%</p> <p>Characteristics of feet: 19 participants (29 feet), 9 bilateral cases</p> <p>Baseline severity: median Pirani score 5.5 (range 4.5 to 6)</p>
Interventions	<p>Ponseti standard protocol versus Ponseti accelerated protocol for treatment of initial CTEV</p> <p>Participants were randomised (not feet)</p> <p>The Ponseti standard group underwent treatment with long leg plaster casts (toe to groin) which were changed weekly. An Achilles tenotomy was performed if dorsiflexion was <10°. They then wore abduction bracing for 23 hours per day for 3 months followed by night-time wear only, until 3 years of age.</p> <p>The Ponseti accelerated group underwent the same treatment with the exception that long leg plaster casts were changed 3 times per week. If the deformity did not correct within 21 days the participant reverted to the standard protocol of weekly changes</p> <p>Follow-up: minimum 6 months (average 251 days)</p>
Outcomes	<p>Pirani score</p> <p>Number of days to correction (prior to an Achilles tenotomy)</p>
Notes	There were no relapses at follow-up
Risk of bias	
Bias	Authors' judgement Support for judgement

Harnett 2011 (Continued)

Random sequence generation (selection bias)	Low risk	Computer number generation
Allocation concealment (selection bias)	High risk	It was not possible for the intervention providers or participants to be blinded
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Unable to blind participants. Not stated if assessor was blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	One child died during treatment. Intention-to-treat analysis used
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement
Other bias	Unclear risk	Transport costs were covered to minimise loss to follow-up

Kaewpornsawan 2007

Methods	RCT. Two-arm parallel-group design
Participants	<p>86 participants with 128 CTEV feet</p> <p>Inclusion criteria: idiopathic CTEV which failed conservative treatment (treatment unknown), requiring surgery</p> <p>Exclusion criteria: children with arthrogryposis multiplex congenita, myelomeningocele, cerebral palsy, syndromic clubfoot. Failed previous CTEV surgery</p> <p>PARTICIPANT CHARACTERISTICS</p> <p><u>Modified posteromedial release</u></p> <p>Age mean (range) in months: 5.8 (3 to 12)</p> <p>Sex male (%): 55.3%</p> <p>Characteristics of feet: 25 unilateral, 22 bilateral</p> <p>Baseline severity: Dimeglio grade 1, 1 foot; Dimeglio grade 2, 26 feet; Dimeglio grade 3, 35 feet; Dimeglio grade 4, 7 feet</p> <p><u>Modified complete subtalar release</u></p> <p>Age mean (range) in months: 6 (3 to 12)</p> <p>Sex male (%): 56.4%</p> <p>Characteristics of feet: 19 unilateral, 20 bilateral</p> <p>Baseline severity: Dimeglio grade 1, 2 feet; Dimeglio grade 2, 28 feet; Dimeglio grade 3, 29 feet; Dimeglio grade 4, 0 feet</p>
Interventions	<p>Modified posteromedial release versus modified complete subtalar release for clubfoot after failed conservative treatment</p> <p>Randomisation of participants (not feet)</p>

Kaewpornawan 2007 (Continued)

Modified posteromedial release: standard posteromedial approach. Lengthening of tendo Achilles and tibialis posterior. Release of the origin of abductor hallucis, capsulotomy of the talonavicular, posterior tibiotalar, the talocalcaneal and medial calcaneocuboid joints. Division of plantar, calcaneofibular, superficial deltoid, spring ligament and master knot of Henry. In cases with residual toe flexion, FHL and FDL were lengthened. Kirschener wires were inserted through the talonavicular and talocalcaneal joint

Modified subtalar release: a Cincinnati incision was used. The talocalcaneal and deep deltoid ligament were preserved. The talonavicular and calcaneocuboid joint were opened medially and laterally. Kirschener wires were inserted through the talonavicular and talocalcaneal joint

Both groups had the same postoperative care. Kirschner wires were removed at 6 weeks postoperatively. Long leg casts remained in situ for 12 weeks postoperatively

After cast removal, orthopaedic shoes or Denis-Brown boots were prescribed (length of time not stated)

Follow-up average: 19.4 months

Outcomes	Ponseti score Turco evaluation Dimeglio scale
Notes	Baseline assessment of groups P = 0.06

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Simple randomisation by envelope
Allocation concealment (selection bias)	Unclear risk	"The surgeon blindly opened the envelope that indicated the type of surgery." Unsure if sequentially numbered or opaque
Blinding (performance bias and detection bias) All outcomes	High risk	Assessor blinding not stated. Intervention provider unable to be blinded. Participant blinding unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	Unclear risk	Insufficient information to permit judgement
Other bias	Unclear risk	Prior treatment was not outlined

Lahoti 2008

Methods	RCT. Matched pair design
Participants	13 participants with bilateral CTEV requiring soft tissue release Inclusion criteria: bilateral resistant CTEV undergoing soft tissue release Exclusion criteria: none stated

Lahoti 2008 (Continued)

PARTICIPANT CHARACTERISTICS

Age mean (range) in months: 10 (9 to 12)

Baseline severity: 11 idiopathic cases, 2 syndromal cases. Pirani score 5.5 in 6 children and 6 in 7 children

FHL and FDL lengthening

Age mean: 10 months

Sex male (%): 77%

Characteristics of feet: 13 feet. 5 right, 8 left

Baseline severity: 5.5 average Pirani score

FHL and FDL decompression

Age mean: 10 months

Sex male (%): 77%

Characteristics of feet: 13 feet. 8 left, 5 right

Baseline severity: 5.5 average Pirani score

Interventions	<p>Lengthening of FHL and FDL versus simple decompression of the same muscles during soft tissue release for resistant CTEV</p> <p>Randomisation of feet (not participants)</p> <p>All participants had bilateral CTEV requiring surgery</p> <p>All feet underwent a complete soft tissue release through the Cinicinnati incision. One side was randomly selected to undergo FHL and FDL lengthening, the other side simple decompression</p> <p>Postoperative management the same in all feet</p> <p>Follow-up average: 48 months</p>
Outcomes	<p>Harrold and Walker scale</p> <p>Pirani score</p>
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Surgeon not blinded to intervention. Assessors were blinded. Blinding of participants unlikely to affect outcome
Incomplete outcome data (attrition bias)	Low risk	No missing data

Lahoti 2008 (Continued)

All outcomes

Selective reporting (reporting bias)	Unclear risk	Insufficient information on outcome measures
Other bias	Unclear risk	2 syndromic feet were included

Manzone 1999

Methods	RCT. Two-arm parallel-group design
Participants	<p>20 participants with 30 CTEV feet</p> <p>Inclusion criteria: resistant CTEV which had not undergone prior conservative treatment</p> <p>Exclusion criteria: none stated</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>Age mean (range) in months: 7.7 (3.5 to 19)</p> <p>Sex male (%): 75%</p> <p>Characteristics of feet: 13 right, 17 left; 20 of these were bilateral, 10 were unilateral</p> <p>Baseline severity: unknown.</p> <p>Groups were matched for birthweight, age of treatment (between 3 months and walking age), weight at surgery, neurologic skills development at surgery, geographic origin, socioeconomic status and associated pathologies</p> <p><u>PMR</u></p> <p>Characteristics of feet: 15 feet in total (12 participants), 6 bilateral, 5 unilateral. The remaining 4 feet (2 participants) were bilateral cases where one foot was randomised to each group</p> <p>Baseline severity: not stated</p> <p><u>CCSR</u></p> <p>Characteristics of feet: 15 feet in total (12 participants), 6 bilateral, 5 unilateral. The remaining 4 feet (2 participants) were bilateral cases where one foot was randomised to each group</p> <p>Baseline severity: not stated</p>
Interventions	<p>PMR versus CCSR</p> <p>Randomisation of feet</p> <p>The PMR was completed as described by Turco with some modifications. A long leg cast is worn for 6 weeks postoperatively. Kirschner wires are then removed and a short leg plaster is worn for a further 4 weeks. Following this an AFO is worn at night</p> <p>The CCSR was completed according to McKay and Simmons using a Cincinnati approach with modifications. The Achilles tendon underwent Z-lengthening, all posteromedial tendons underwent z-plasty. The posterior tibiofibular ligament and plantar fascia were only occasionally cut. The interosseous talocalcaneal ligament was never incised. A long leg plaster with the foot in equinus was in situ for 7 to 10 days postoperatively. This was then changed to a long leg cast with the foot in dorsiflexion for a further 5 weeks. The Kirschner wires were then withdrawn and a short leg cast was worn for a further 4 weeks</p>

Manzone 1999 (Continued)

All participants underwent the same long-term postoperative care; however, it was not stated if AFO worn in CCSR group

Follow-up in months (range): 27 (18 to 40)

Outcomes	Radiographic	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not described
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Intervention provider unable to be blinded. Participant blinding unlikely to affect outcome. Insufficient information regarding assessor blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	Unclear risk	Unsure of time of postoperative x-ray, unsure which groups had adverse outcomes
Other bias	Unclear risk	Unsure of baseline severity

Pittner 2008

Methods	RCT. Two-arm parallel-group design
Participants	<p>34 participants with 42 CTEV feet who attended authors outpatient clinics</p> <p>Inclusion criteria: initial presentation of CTEV</p> <p>Exclusion criteria: none stated</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>3 participants excluded prior to data analysis. 1 lost to follow-up, 1 had medical complications and 1 switched groups during treatment</p> <p><u>Fibreglass</u></p> <p>Age mean (SD) weeks: 1.07 (0.57)</p> <p>Sex male (%): 69%</p> <p>Characteristics of feet: 13 participants. 16 feet: 8 left, 8 right</p> <p>Baseline severity: Dimeglio scale score average: 13.1</p> <p><u>Plaster</u></p>

Pittner 2008 (Continued)

Age mean (SD) weeks: 1.89 (1.88)

Sex male (%): 100%

Characteristics of feet: 18 participants. 23 feet: 9 left, 14 right

Baseline severity: Dimeglio scale average: 12.3

Interventions	<p>Semi-rigid (fibreglass) casts versus plaster of Paris casts for Ponseti treatment of initial presentation of CTEV</p> <p>Randomisation was done according to medical record number. Feet were enrolled separately, but participants were randomised, i.e. if a participant had bilateral CTEV, both feet were randomised to the same group</p> <p>In the semi-rigid (fibreglass) group, casting was done using Scotchcast Softcast (3M). In the control group, plaster of Paris was used</p> <p>Follow-up: end of treatment</p>
Outcomes	<p>Dimeglio scale</p> <p>Parent satisfaction questionnaire</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Sequence generated by medical record number. Not stated how this was done
Allocation concealment (selection bias)	High risk	Sequence generated by medical record number
Blinding (performance bias and detection bias) All outcomes	High risk	Unable to blind intervention providers. Assessors not blinded. Participant blinding unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	High risk	Several participants were excluded after randomisation or lost to follow-up. Their data were removed from the study
Selective reporting (reporting bias)	Unclear risk	Outcomes not stated at outset but reported in results
Other bias	Unclear risk	Insufficient information

Rijal 2010

Methods	RCT. Two-arm parallel-group design
Participants	<p>38 participants with 60 CTEV feet who presented to one outpatient clinic</p> <p>Inclusion criteria: CTEV</p> <p>Exclusion criteria: prior intervention for CTEV, over 2 years old</p>

Rijal 2010 (Continued)

PARTICIPANT CHARACTERISTICS

Age mean (SD, range) days: 195.7 (202.81 3 to 720 days)

Sex male (%): 76.2%

Baseline severity: unclear (report states the groups were equal at baseline for age, sex and Pirani scores)

Ponseti

Characteristics of feet: 30 feet. 10 unilateral, 8 (4 participants) bilateral. The remaining 12 feet (12 participants) were bilateral cases where one foot was randomised to each group

Kite

Characteristics of feet: 30 feet. 6 feet unilateral, 12 feet (6 participants) bilateral. The remaining 12 feet (12 participants) were bilateral cases where one foot was randomised to each group

Interventions	<p>Ponseti versus Kite technique in initial treatment of CTEV</p> <p>Randomisation of feet (not participants)</p> <p>Casts were changed in both groups at weekly intervals for 10 weeks. Tendo Achilles tenotomy was undertaken in both groups for those with residual equinus deformity. Feet which were not corrected at the end of 10 weeks were subject to surgical correction</p> <p>Follow-up: end of treatment</p>
Outcomes	Pirani score
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Unable to blind intervention providers. Observers were blinded. Participant blinding unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	High risk	Insufficient information on adverse events
Other bias	Unclear risk	Unsure of operative intervention required after each intervention

Sanghvi 2009

Methods	RCT. Two-arm parallel-group design
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Interventions for congenital talipes equinovarus (clubfoot) (Review)

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Sanghvi 2009 (Continued)

Participants	<p>42 participants with 64 CTEV feet</p> <p>Inclusion criteria: idiopathic CTEV, initial presentation</p> <p>Exclusion criteria: myelocoele, meningomyelocoele, arthrogryposis multiplex congenital, other neuro-muscular disorders</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>Baseline severity: not stated</p> <p><u>Ponseti</u></p> <p>21 participants</p> <p>Age mean (SD): 13.2 (11.9) weeks</p> <p>Sex male (%): 62%</p> <p>Characteristics of feet: 30 feet. 18 bilateral (9 participants): 6 right, 6 left</p> <p>Baseline severity: not stated</p> <p><u>Kite</u></p> <p>21 participants</p> <p>Age mean (SD): 12.2 (10) weeks</p> <p>Sex male (%): 67%</p> <p>Characteristics of feet: 34 feet. 26 bilateral (13 participants): 5 right, 3 left</p> <p>Baseline severity: not stated</p>
Interventions	<p>Ponseti versus Kite technique for treatment of initial CTEV</p> <p>Randomisation of participants to each group (not feet)</p> <p>In the Ponseti group, casts were changed every 7 to 10 days. Achilles tenotomy was performed in those with residual equinus. Bracing in abduction orthosis using Denis-Brown splints was done with the affected foot at 70° of external rotation and the unaffected foot at 40° to 45° of external rotation. Splints were worn full time until walking age, and then at night only. During the day, shoes with an open toe box, straight medial border. Lateral flaring of the sole and reverse Thomas heels were used until the age of 4 to 5 years</p> <p>In the Kite group, toe to groin casts were changed every 7 to 10 days until full correction. The final position was maintained in full time bracing in a neutral position with a heel lock and straight medial bar. Once the participant began walking, the brace was used at night only. During the day, shoes with an open toe box, straight medial border, lateral flaring of the sole and reverse Thomas heels were used until the age of 4 to 5 years</p> <p>Follow-up average: 36 months</p>
Outcomes	<p>Radiographic</p> <p>Range of movement</p>
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement

Sanghvi 2009 (Continued)

Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Unable to blind intervention provider. Assessor not blinded. Blinding of participant unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	High risk	Incomplete outcome reporting, e.g. radiographic. Cannot be entered into the meta-analysis
Other bias	Unclear risk	Insufficient information on baseline assessment for both groups

Selmani 2012

Methods	RCT. Two-arm parallel-group design
Participants	<p>100 participants with 150 CTEV feet</p> <p>Inclusion criteria: idiopathic CTEV, less than 3 months of age, initial presentation (no prior treatment)</p> <p>Exclusion criteria: myelocoele, meningomyelocoele, arthrogryposis multiplex congenital, other neuromuscular causes</p> <p>PARTICIPANT CHARACTERISTICS</p> <p><u>Ponseti</u></p> <p>50 participants</p> <p>Age mean (SD): 35.3 (25.4) days</p> <p>Sex male (%): 60%</p> <p>Characteristics of feet: 76 feet.</p> <p>Baseline severity: Pirani Score mean (SD): 5.2 (0.8)</p> <p><u>Kite</u></p> <p>50 participants</p> <p>Age mean (SD): 32.45 (26.3) days</p> <p>Sex male (%): 56%</p> <p>Characteristics of feet: 74 feet.</p> <p>Baseline severity: Pirani Score mean (SD): 5.1 (0.7)</p>
Interventions	<p>Ponseti versus Kite technique for treatment of initial CTEV</p> <p>Randomisation of participants to each group (not feet)</p>

Selmani 2012 (Continued)

In the Ponseti group, casts were changed every 7 to 10 days until the foot was corrected or the participant was one year of age. Achilles tenotomy was performed in those with residual equinus. Bracing in abduction orthosis using Denis-Brown splints was done with the affected foot at 70° of external rotation and the unaffected foot at 40° to 45° of external rotation. Splints were worn full time until walking age, and then at night only. During the day, shoes with an open toe box, straight medial border. Lateral flaring of the sole and reverse Thomas heels were used until the age of 4 years

Follow-up average (SD): 36.2 (3.2) months

In the Kite group, toe to groin casts were changed every 7 to 10 days until full correction or the participant was one year of age. The final position was maintained in full time bracing in a neutral position with a heel lock and straight medial bar. Once the participant began walking, the brace was used at night only. During the day, shoes with an open toe box, straight medial border, lateral flaring of the sole and reverse Thomas heels were used until the age of 4 years

Follow-up average (SD): 35.1 (2.5) months

Outcomes	Pirani score, range of movement	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random computer number generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Intervention provider could not be blinded. Assessors were blinded. Participant and carer blinding not possible, which could affect outcome
Incomplete outcome data (attrition bias) All outcomes	High risk	Several participants were excluded after randomisation or lost to follow-up. Their data were excluded from final analysis
Selective reporting (reporting bias)	Unclear risk	Described functional outcome of corrected feet only. Adverse events not documented
Other bias	Unclear risk	Unknown if relapsed patients were part of original failure group. Treatment for relapsed cases in the Kite group not stated

Siddiqui 2007

Methods	RCT. Two-arm parallel-group design
Participants	60 patients who presented to a single centre (number of CTEV feet unknown) Inclusion criteria: CTEV with Dimeglio grade I and II undergoing surgical correction Exclusion criteria: CTEV with Dimeglio grade III and IV PARTICIPANT CHARACTERISTICS Age range in months: 6 to 18

Siddiqui 2007 (Continued)

Sex male (%): 61.7%

Baseline severity: Dimeglio grade I, 20 participants; Dimeglio grade II, 40 participants

Window procedure

Age mean: 9.5 months

Characteristics of feet: 30 participants (bilateral and unilateral numbers not reported)

Baseline severity: not stated

Turco procedure

Age mean: 9.6 months

Characteristics of feet: 30 participants (bilateral and unilateral numbers not reported)

Baseline severity: not stated

Interventions	<p>Window procedure versus Turco procedure for treatment of CTEV</p> <p>Participants were randomised equally into both groups</p> <p>The Window procedure was not described in detail in the article. It utilises five or six small incisions rather than a long posteromedial incision. Postoperatively the foot is placed in a plaster in the corrected position. Details of the plaster were not provided</p> <p>In the Turco group, postoperatively a cast was not applied for 15 days because of oedema</p> <p>Follow-up: not stated</p>
Outcomes	<p>Dimeglio scale</p> <p>Postoperative assessment criteria according to Beatson 6 months after surgery</p> <p>Time in theatre</p> <p>Adverse events</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Unable to blind intervention provider. Assessor blinding not reported. Participant blinding unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	Unclear risk	Follow-up time not reported

Interventions for congenital talipes equinovarus (clubfoot) (Review)

Siddiqui 2007 (Continued)

Other bias	High risk	Procedure was developed, used and assessed by the same team within the same population. Bilateral and unilateral numbers not reported. Follow-up times not reported
------------	-----------	---

Sud 2008

Methods	Quasi RCT. Two-arm parallel-group design
Participants	<p>53 participants with 81 CTEV feet who presented to a single centre</p> <p>Inclusion criteria: < 3 months of age, idiopathic CTEV</p> <p>Exclusion criteria: non-idiopathic CTEV, > 3 months of age</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>8 participants lost to follow-up and excluded prior to data analysis</p> <p><u>Ponseti</u></p> <p>Age mean (SD) days: 31.75 (27.4)</p> <p>Sex male (%): 60.8%</p> <p>Characteristics of feet: 23 participants, 36 feet. 26 bilateral (13 participants), 4 right, 6 left</p> <p>Baseline severity (Dimeglio scale score mean (SD)): 14.39 (3.2)</p> <p><u>Kite</u></p> <p>Age mean (SD) days: 26.06 (21.4)</p> <p>Sex male (%): 77.2%</p> <p>Characteristics of feet: 22 participants, 31 feet. 18 bilateral (9 participants), 5 right, 8 left</p> <p>Baseline severity (Dimeglio scale score mean (SD)): 16.19 (2.8)</p>
Interventions	<p>Ponseti versus Kite</p> <p>Randomisation of participants (not feet)</p> <p>In the Ponseti group, weekly manipulation and casting was done until correction or 1 year (whichever came first). Correction was defined as 50° to 60° external rotation and 15° dorsiflexion with or without an Achilles tenotomy. Following correction, feet were placed in abduction bracing at 50° to 60° of external rotation, worn full time for 2 to 3 months then at night until 2 to 4 years of age</p> <p>In the Kite group, manipulation and casting was done till the foot was corrected. Correction was maintained in a night brace in dorsiflexion and slight valgus</p> <p>Follow-up average: 26 months</p>
Outcomes	<p>Dimeglio scale</p> <p>Range of movement</p>
Notes	
Risk of bias	

Sud 2008 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Alternate allocation
Allocation concealment (selection bias)	High risk	Alternate allocation
Blinding (performance bias and detection bias) All outcomes	High risk	Intervention provider unable to be blinded. Assessor was blinded. Participant blinding unlikely to affect outcome
Incomplete outcome data (attrition bias) All outcomes	High risk	8 participants were excluded or lost to follow-up and excluded from analysis
Selective reporting (reporting bias)	High risk	Prespecified outcomes were unclear in methods
Other bias	Unclear risk	Insufficient information to permit judgment

Zeifang 2005

Methods	RCT, two-arm parallel group design
Participants	<p>36 participants with 36 CTEV feet who presented to a single centre</p> <p>Inclusion criteria: idiopathic CTEV. Failed conservative treatment for 6 months. Dimeglio grade III. Underwent posteromedial lateral release</p> <p>Exclusion criteria: none stated</p> <p>PARTICIPANT CHARACTERISTICS</p> <p>In bilateral cases, one foot was randomly selected by tossing a coin</p> <p>1 bilateral case with early relapse was excluded prior to data analysis (leaving 37 participants with 37 feet for analysis)</p> <p>Age mean (range) in months: 8.2 (5 to 12)</p> <p>Sex male (%): 71%</p> <p><u>CPM</u></p> <p>Characteristics of feet: 18 feet</p> <p><u>Immobilisation in a cast</u></p> <p>Characteristics of feet: 19 feet</p>
Interventions	<p>CPM versus immobilisation in a cast, after surgery for resistant CTEV</p> <p>Randomisation of participants. However, bilateral feet received the same postoperative management.</p> <p>In both groups a cast was applied postoperatively for the first 10 days. Kirschner wires were removed from all feet 2 weeks postoperatively</p> <p>In the casting group, casting for another 4.5 weeks was undertaken</p>

Zeifang 2005 (Continued)

In the CPM group, computer-assisted 3-dimensional therapy using a Kinetic 5090 Ankle CPM machine was used with a standardised protocol. CPM was applied for 4 hours per day. During rest periods, removable splints were applied

6 weeks after surgery, all feet were treated with a brace at night. Physiotherapy was provided to both groups for a further 6 months. When the participants began to walk, they were provided with heel cups to place in conventional shoes

Follow-up: 48 months

Outcomes	Dimeglio scale	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer number generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Intervention provider could not be blinded. Assessors were blinded. Participant and carer blinding not possible, which could affect outcome
Incomplete outcome data (attrition bias) All outcomes	High risk	Two feet were lost to follow-up. One participant was excluded after randomisation and removed from data analysis
Selective reporting (reporting bias)	High risk	Compliance with CPM unclear. No measurement of pain postoperatively
Other bias	Unclear risk	Insufficient information to permit judgement

Zwicky 2009

Methods	RCT. Two-arm parallel-group design
Participants	<p>19 participants with 28 CTEV feet who presented to a single centre</p> <p>Inclusion criteria: idiopathic CTEV, less than 2 weeks of age</p> <p>Exclusion criteria: none stated</p> <p>PARTICIPANT CHARACTERISTICS</p> <p><u>Ponseti</u></p> <p>Age mean (SD) weeks: 0.7 (0.8)</p> <p>Sex male (%): 33%</p> <p>Characteristics of feet: 9 participants (12 feet)</p> <p>2 participants (2 feet) opted out. Intention-to treat-analysis was done.</p>

Zwrick 2009 (Continued)

Baseline severity: Pirani score 4.6 (1.5)

Posteromedial soft tissue release

Age mean (SD) weeks: 0.4 (0.4)

Sex male (%): 70%

Characteristics of feet: 10 participants (16 feet)

Baseline severity: Pirani score 4.5 (1.1)

Interventions	<p>Ponseti versus surgical intervention</p> <p>Randomisation was done on participants</p> <p>Treatment using the Ponseti technique was done with long leg casts changed weekly. All participants required an Achilles tenotomy which were done under general anaesthesia and then placed back into a long leg cast for a further 3 weeks. Correction was maintained in a brace with external rotation of 70° for affected feet and 45° for unaffected feet. The brace was worn full time until 6 months of age, then for 18 hours per day until the child started standing. Once standing, the brace was worn at night until 2 years of age. Following this participants were placed into custom moulded shoes with an insole with a heel counter, moderate flange at the medial aspect of the cuboid and medial aspect of the first metatarsal head</p> <p>Participants in the surgical group underwent similar weekly manipulative casting as those in the Ponseti group until 6 to 8 months of age. All residual deformities were then treated with a posteromedial release via a Cincinnati incision and fixated with Kirschner wires and long leg casts. Kirschner wires were removed at 4 weeks and casts removed at 6 weeks postoperatively. Correction was maintained with rigid knee ankle foot orthoses, worn at night until 3 years of age. Moulded orthoses were prescribed once the participant was able to stand and walk</p> <p>Follow-up average: 42 months</p>
Outcomes	<p>Pirani score</p> <p>PODCI</p> <p>Functional Rating System (FRS) Laaveg and Ponseti</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding of intervention provider not possible. Assessor not blinded. Unable to blind participants or families
Incomplete outcome data (attrition bias) All outcomes	High risk	'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation

Zwack 2009 (Continued)

Selective reporting (reporting bias)	Unclear risk	Insufficient information
Other bias	High risk	Stopped early secondary to ethical implications. The traditional technique was leading to greater rates of major surgical intervention compared to the Ponseti technique. Different assessors for different outcome measures

AFO: ankle foot orthosis

CPM: continuous passive motion

CTEV: congenital talipes equinovarus

FDL: flexor digitorum longus

FHL: flexor hallucis longus

MRI: magnetic resonance imaging

PODCI: Pediatric Outcomes Data Collection Instrument

RCT: randomised controlled trial

SD: standard deviation

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Andriesse 2008	Not an RCT. Allocation was consecutive
Atar 1993	Not an RCT
Aurell 2005	Not an RCT. Treatment was allocated according to which hospital the participant attended
Chang 1991	Not an RCT
DePuy 1989	Not an RCT. A retrospective review of treatment method
DeRosa 1986	Not an RCT
Dimeglio 1996	Not an RCT
Doğan 2002	Not an RCT
Farsetti 2009	Not an RCT
Faulks 2009	Not an RCT. A controlled clinical trial
Halanski 2010	Not an RCT. A controlled clinical trial
Ippolito 2003	Not an RCT
Janicki 2011	Not an RCT
Kesemenli 2003	Not an RCT
Kuo 2001	Not an RCT
Li 2007	Not an RCT
Miura 2005	No mention of randomisation

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Study	Reason for exclusion
Napiontek 2000	Not an RCT
Narang 2011	Not an RCT
Nilgün 2011	Not an RCT
O'Brien 2004	Not an RCT. A retrospective review
Ponseti 2006	Not an RCT. A case series
Richards 2008	Not an RCT. A controlled clinical trial
Simons 1985	Not an RCT
Steinman 2009	Not an RCT. A controlled clinical trial
Thompson 1982	No mention of randomisation
Tschopp 2002	Not an RCT
Uglow 2000	Not an RCT
Xu 2011	Not an RCT

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

NCT01067651

Trial name or title	Comparison of casting materials for the treatment of clubfoot using the Ponseti method
Methods	Randomised, parallel assignment, open label
Participants	Infants up to 12 weeks of age with congenital idiopathic clubfoot
Interventions	Plaster of Paris (POP) or semi-rigid fibreglass softcast (SRF, 3M Scotchcast), using the Ponseti method
Outcomes	Primary: number of casts required for correction Secondary: need for tenotomy, ease of cast removal, time of cast removal, methods of cast removal, other concerns about the casting material
Starting date	Not given
Contact information	Jason Howard, MD
Notes	Alberta Children's Hospital, Calgary, Canada

DATA AND ANALYSES

Comparison 1. Kite versus Ponseti technique for treatment of initial CTEV

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pirani score at 10 weeks	1	60	Mean Difference (Fixed, 95% CI)	-1.15 [-1.32, -0.98]
1.1 Bilateral cases, one foot assigned to Ponseti, one to Kite	1	24	Mean Difference (Fixed, 95% CI)	-1.16 [-1.35, -0.97]
1.2 Bilateral cases, both feet assigned to the same treatment (Ponseti or Kite)	1	20	Mean Difference (Fixed, 95% CI)	-1.24 [-1.81, -0.67]
1.3 Unilateral cases, assigned to either Ponseti or Kite	1	16	Mean Difference (Fixed, 95% CI)	-0.86 [-1.52, -0.20]

Analysis 1.1. Comparison 1 Kite versus Ponseti technique for treatment of initial CTEV, Outcome 1 Pirani score at 10 weeks.

Comparison 2. Ponseti versus traditional treatment (plaster casting and surgery) for treatment of initial CTEV

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pirani score at end of serial plaster casting	1	28	Mean Difference (Fixed, 95% CI)	-1.5 [-2.28, -0.72]

Analysis 2.1. Comparison 2 Ponseti versus traditional treatment (plaster casting and surgery) for treatment of initial CTEV, Outcome 1 Pirani score at end of serial plaster casting.

Comparison 3. Standard Ponseti technique versus an accelerated Ponseti technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pirani score at the end of serial plaster casting	1	40	Mean Difference (Fixed, 95% CI)	0.31 [-0.40, 1.02]

Analysis 3.1. Comparison 3 Standard Ponseti technique versus an accelerated Ponseti technique, Outcome 1 Pirani score at the end of serial plaster casting.

ADDITIONAL TABLES

Table 1. Characteristics of included trials

Study ID	No.No. of of randomisation (feet / participants)	Combining of all feet in bilateral and unilateral cases?	CTEV case	CTEV diagnosis	Average start age (SD)	Treatment	Outcome measure	Average Follow-up time (months)
Cummings 2009	20 32 Participants	Y	Initial	Not stated	0 to 30 days	Botulinum toxin versus placebo with Ponseti technique	Dimeglio scale	27
El-Deeb 2007	46 66 Feet	Y	Resistant	Idiopathic	9 months	TCIL release versus placebo during surgery for CTEV	Radiography, Dimeglio scale	28
Harnett 2011	40 51 Participants	Y	Not stated	Idiopathic	< 90 days	Ponseti standard versus Ponseti accelerated protocol	Pirani score	0
Kaewporn-sawan 2007	86 128 Participants	Y	Resistant	Idiopathic	5.9 months	PMR versus complete subtalar release surgery	Nil	19.4
Lahoti 2008	13 26 Feet	Bilateral cases only	Resistant	Included 2 syndromic feet (1 in each arm)	10 months	FHL and FDL lengthening versus simple decompression in CTEV surgery	Pirani score	48
Manzone 1999	20 30 Feet	Y	Initial	Idiopathic	7.7 months	PMR versus complete subtalar release surgery	nil	27
Pittner 2008	34 42 Participants	Y	Initial	Not stated	10 days	Sem-rigid cast versus plaster of Paris cast with Ponseti technique	Dimeglio scale	0
Rijal 2010	38 60 Feet	N	Initial	Idiopathic	16.3 months	Ponseti versus Kite technique	Pirani score	0
Sanghvi 2009	42 64 Participants	Y	Initial	Idiopathic	≤ 9 months	Ponseti versus Kite technique	Radiography	36
Selmani 2012	100150 Participants	Y	Initial	Idiopathic	33 days	Ponseti versus Kite technique	Pirani score	36

Table 1. Characteristics of included trials (Continued)

Siddiqui 2007	60	≥60	Participant	Unsure	Not stated	Not stated	9.6 months	Window versus Turco surgery for CTEV	Nil	0
Sud 2008	53	81	Participants	Y	Initial	Idiopathic	29 days	Ponseti versus Kite technique	Nil	26
Zeifang 2005	36	36	Participants	Note. In bilateral cases one foot was randomly selected for inclusion	Resistant	Idiopathic	8.2 months	CPM versus immobilisation in plaster cast after surgery for CTEV	Nil	48
Zwick 2009	19	28	Participants	Y	Initial	Idiopathic	< 2 weeks	Ponseti versus traditional technique (serial casting and PMR)	Pirani score, PODCI, radiography	42

CPM: continuous passive motion

CTEV: congenital talipes equinovarus

FDL: flexor digitorum longus

FHL: flexor hallucis longus

PMR: posteromedial soft tissue release

PODCI: Pediatric Outcomes Data Collection Instrument

SD: standard deviation

TCIL: talocalcaneal interosseus ligament

Table 2. Pirani score

A score is given to each of the following six components	
Midfoot	Hindfoot
Curved lateral border	Posterior crease
Medial crease	Rigidity of equinus
Talar head coverage	Empty heel
Score	
0	Normal (completely correctable)
0.5	Moderately normal (partially correctable)
1	Severely abnormal (not correctable)
The total score is between 0 (best) and 6 (worst)	

The Pirani score ([Pirani 2008](#)).

Table 3. Details of relapse: Ponseti versus Kite

Trial/ treatment group	No of participant relapse (feet)	No of bilateral cases (feet)	No of unilateral cases (feet)	Treatment for bilateral relapse (feet)			Treatment for unilateral relapse (feet)	
				Casting +/- minor surgery	Mix	Major surgery	Casting +/- minor surgery	Major surgery
Sanghvi 2009								
Ponseti	2(3)	1(2)	1(1)	-	1(2)	-	1(1)	-
Kite	4(5)	1(2)	3(3)	-	-	-	1(1)	2(2)
Sud 2008								
Ponseti	5(7)	2(4)	3(3)	2(4)	-	-	3(3)	-
Kite	8(8)	-	8(8)	-	-	-	4(4)	4(4)

Table 4. Reported details of relapses

Study ID	Treatment	Reported on relapses	Description of deformity with valid scales	Group relapses occurred in	Timing of relapse reported	Treatment required to correct described?
Cummings 2009	Botulinum toxin A versus placebo in Ponseti treatment	Y	N	Y	Y	Y
El-Deeb 2007	TCIL release versus control in CTEV surgery	Y	N	Y	N	Y
Harnett 2011	Ponseti standard versus Ponseti accelerated protocol	Y	N	N/A	N/A	N/A
Kaewpornawan 2007	Modified PMR versus CCSR	Y	N	Y	N	Y
Lahoti 2008	FHL and FDL lengthen versus simple decompression	Y	N	N	N	N
Manzone 1999	PMR versus CCSR	Y	N	N	N	N
Pittner 2008	Semi-rigid versus POP for Ponseti treatment	No: follow-up to end of treatment only				
Rijal 2010	Ponseti versus Kite	No: follow-up to end of treatment only				
Sanghvi 2009	Ponseti versus Kite	Y	N	Y	N	Y
Selmani 2012	Ponseti versus Kite	Y	N	Y	Y	Partial
Siddiqui 2007	Window versus Turco surgery	Y	N	Y	N	N
Sud 2008	Ponseti versus Kite	Y	Y	Y	Y	Y
Zeifang 2005	CPM versus immobilisation in a cast after CTEV surgery	Y	N	Y	Y	N
Zwick 2009	Ponseti versus traditional treatment	Y	N	Y	Y	Y

CCSR: complete circumferential subtalar release

CPM: continuous passive motion

CTEV: congenital talipes equinovarus

FDL: flexor digitorum longus

FHL: flexor hallucis longus

PMR: posteromedial release

POP: plaster of Paris

TCIL: talocalcaneal interosseus ligament

APPENDICES

Appendix 1. CENTRAL and NHSEED search strategy

#1(clubfoot or clubfeet or CTEV or talipes)

Appendix 2. MEDLINE OvidSP search strategy

Database: Ovid MEDLINE(R) <1946 to April Week 3 2013>

Search Strategy:

-
- 1 randomized controlled trial.pt. (346797)
 - 2 controlled clinical trial.pt. (85759)
 - 3 randomized.ab. (249438)
 - 4 placebo.ab. (137469)
 - 5 drug therapy.fs. (1603091)
 - 6 randomly.ab. (178468)
 - 7 trial.ab. (257183)
 - 8 groups.ab. (1160728)
 - 9 or/1-8 (2992626)
 - 10 exp animals/ not humans.sh. (3804093)
 - 11 9 not 10 (2543370)
 - 12 Clubfoot/ (3099)
 - 13 (clubfoot or clubfeet or talipes or ctev).tw. (2326)
 - 14 12 or 13 (3773)
 - 15 11 and 14 (256)
 - 16 remove duplicates from 15 (254)

Appendix 3. EMBASE OvidSP search strategy

Database: Embase <1980 to 2013 Week 17>

Search Strategy:

-
- 1 crossover-procedure.sh. (36732)
 - 2 double-blind procedure.sh. (114243)
 - 3 single-blind procedure.sh. (17288)
 - 4 randomized controlled trial.sh. (341042)
 - 5 (random\$ or crossover\$ or cross over\$ or placebo\$ or (doubl\$ adj blind\$) or allocat\$).tw,ot. (948490)
 - 6 trial.ti. (143998)
 - 7 clinical trial/ (877056)
 - 8 or/1-7 (1554924)
 - 9 (animal/ or nonhuman/ or animal experiment/) and human/ (1255221)
 - 10 animal/ or nonanimal/ or animal experiment/ (3379111)
 - 11 10 not 9 (2795799)
 - 12 8 not 11 (1462587)
 - 13 limit 12 to embase (1139689)
 - 14 clubfoot/ (3621)
 - 15 (clubfoot or clubfeet or talipes or ctev).mp. (4636)
 - 16 14 or 15 (4636)
 - 17 13 and 16 (107)
 - 18 remove duplicates from 17 (107)

Appendix 4. AMED OvidSP search strategy

Database: AMED (Allied and Complementary Medicine) <1985 to April 2013>

Search Strategy:

-
- 1 Randomized controlled trials/ (1591)
 - 2 Random allocation/ (309)
 - 3 Double blind method/ (473)
 - 4 Single-Blind Method/ (36)
 - 5 exp Clinical Trials/ (3263)
 - 6 (clin\$ adj25 trial\$).tw. (5620)
 - 7 ((singl\$ or doubl\$ or treb\$ or trip\$) adj25 (blind\$ or mask\$ or dummy)).tw. (2314)

8 placebos/ (527)
9 placebo\$.tw. (2563)
10 random\$.tw. (13355)
11 research design/ (1711)
12 Prospective Studies/ (583)
13 meta analysis/ (115)
14 (meta?analys\$ or systematic review\$).tw. (2012)
15 control\$.tw. (28603)
16 (multicenter or multicentre).tw. (762)
17 ((study or studies or design\$) adj25 (factorial or prospective or intervention or crossover or cross-over or quasi-experiment\$)).tw. (10145)
18 or/1-17 (44082)
19 Clubfoot/ (165)
20 (clubfoot or clubfeet or talipes or ctev).tw. (200)
21 (clubfoot or clubfeet or talipes or ctev).mp. (200)
22 19 or 20 (200)
23 18 and 22 (21)

Appendix 5. CINAHL EBSCOhost search strategy

Monday, April 29, 2013 10:37:50 AM

S25 S23 AND S24 4
S24 EM 20110315- 295,623
S23 S22 12 [exclude Medline records]
S22 S18 and S21 142
S21 S19 or S20 579
S20 clubfoot or clubfeet or talipes or ctev 579
S19 (MH "Clubfoot") 519
S18 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 602,631
S17 ABAB design* 79
S16 TI random* or AB random* 121,947
S15 (TI (cross?over or placebo* or control* or factorial or sham? or dummy)) or (AB (cross?over or placebo* or control* or factorial or sham? or dummy)) 249,438
S14 (TI (clin* or intervention* or compar* or experiment* or preventive or therapeutic) or AB (clin* or intervention* or compar* or experiment* or preventive or therapeutic)) and (TI (trial*) or AB (trial*)) 85,182
S13 (TI (meta?analys* or systematic review*)) or (AB (meta?analys* or systematic review*)) 26,453
S12 (TI (single* or doubl* or tripl* or trebl*) or AB (single* or doubl* or tripl* or trebl*)) and (TI (blind* or mask*) or AB (blind* or mask*)) 19,578
S11 PT ("clinical trial" or "systematic review") 108,077
S10 (MH "Factorial Design") 866
S9 (MH "Concurrent Prospective Studies") or (MH "Prospective Studies") 203,222
S8 (MH "Meta Analysis") 16,149
S7 (MH "Solomon Four-Group Design") or (MH "Static Group Comparison") 33
S6 (MH "Quasi-Experimental Studies") 5,944
S5 (MH "Placebos") 8,132
S4 (MH "Double-Blind Studies") or (MH "Triple-Blind Studies") 26,479
S3 (MH "Clinical Trials+") 158,969
S2 (MH "Crossover Design") 10,356
S1 (MH "Random Assignment") or (MH "Random Sample") or (MH "Simple Random Sample") or (MH "Stratified Random Sample") or (MH "Systematic Random Sample") 60,710

Appendix 6. PEDro search strategy

Monday, July 22, 2013

We used a simple search strategy using the following terms:

clubfoot, clubfeet, talipes, ctev (5)

Appendix 7. WHO International Clinical Trials Registry Platform (ICTRP)

Thursday, July 25, 2013

We used a simple search strategy using the following terms:

clubfoot, clubfeet, talipes, ctév (21)

Appendix 8. Clinicaltrials.gov search strategy

Wednesday, November 27, 2013

We used a simple search strategy using the following terms:

clubfoot, clubfeet, ctév (28)

WHAT'S NEW

Date	Event	Description
21 November 2013	New citation required but conclusions have not changed	Updated search incorporated
28 September 2013	New search has been performed	One new randomised controlled trial comparing Ponseti and Kite techniques added. Conclusions are unchanged Discussion on cost benefit analysis between major surgery and the Ponseti technique added based on a new identified trial

CONTRIBUTIONS OF AUTHORS

KG wrote the first draft with the assistance of JB, PG, DL and VP.

DECLARATIONS OF INTEREST

JB: research activities are funded by grants and donations from the NHMRC (National Health and Medical Research Council of Australia, Fellowship #1007569 and Centre of Research Excellence #1031893), NIH (National Institutes of Neurological Disorders and Stroke and Office of Rare Diseases, #U54NS065712), Muscular Dystrophy Association, CMT Association of Australia, Foot Power International, Australian Podiatry Education and Research Fund and CMT Association (USA).

PG: No known conflicts of interest.

KG has received funding through the Sydney Medical School, University of Sydney to attend the International Clubfoot Congress in 2011.

DL has received research grants from Novartis, Amgen, Celgene and acted on advisory boards for Lilly and Amgen.

VP: none known.

SOURCES OF SUPPORT

Internal sources

- The Children's Hospital at Westmead, NSW, Australia.
- The University of Sydney, NSW, Australia.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol discussed treatments for initial and relapsed CTEV, but a cohort of resistant cases (initial treatment which did not successfully correct the deformity) were identified during this review. Therefore we had to define this additional area in order to differentiate these participants from relapsed cases (i.e. those which had undergone prior treatment with successful outcomes and present with recurrence of deformity).

The protocol defined outcome measures at a minimum of one year. This was essential as relapse is considered a common occurrence in the treatment of CTEV and defining end of treatment would not have encompassed this outcome. However, once the literature was identified it became apparent that end of treatment foot alignment often significantly affected further treatment. This is highlighted in particular with the identification of resistant cases, which often required significant surgical intervention. Therefore where relevant (for example, at the end of initial treatment), we included results prior to one year.

Treatment for relapse was not a prespecified outcome; however, we noted that it significantly affected further treatment in certain cohorts. Therefore, where data were available, we described the treatment to correct relapse.

A number of trials included data from bilateral (including both right and left feet) and unilateral cases. In bilateral cases, right and left feet from the same subject are unlikely to respond independently. When pooled with unilateral cases, results should be viewed with caution. As this problem became apparent only when we analysed the data, we used statistical methods not defined in the protocol to overcome this bias.

Dr Chris Frost was an additional author in the first published version of the review.

We searched NHSEED, DARE and HTA databases for additional information to use in the Discussion and clinical trials registries for ongoing trials.

INDEX TERMS

Medical Subject Headings (MeSH)

Botulinum Toxins, Type A [therapeutic use]; Casts, Surgical; Clubfoot [*therapy]; Decompression, Surgical [methods]; Ligaments, Articular [surgery]; Motion Therapy, Continuous Passive [methods]; Neuromuscular Agents [therapeutic use]; Orthopedic Procedures [methods]; Randomized Controlled Trials as Topic; Recurrence; Treatment Outcome

MeSH check words

Female; Humans; Infant; Infant, Newborn; Male