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Splinting for the non-operative management of developmental dysplasia of the hip (DDH) in children under six months of age (Protocol)

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Splinting for the non-operative management of developmental dysplasia of the hip (DDH) in children under six months of age.
Cochrane Database of Systematic Reviews 2017, Issue 7. Art. No.: CD012717.
DOI: 10.1002/14651858.CD012717.

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[Intervention Protocol]

Splinting for the non-operative management of developmental dysplasia of the hip (DDH) in children under six months of age

Kerry Dwan[1], Jamie Kirkham[2], Robin W Paton[3,4,5], Emma Morley[6], Ashley William Newton[7], Daniel C Perry[8]

[1]Cochrane Central Executive, London, UK. [2]Department of Biostatistics, University of Liverpool, Liverpool, UK. [3]East Lancashire Hospitals NHS Trust, Burnley, UK. [4]School of Medicine, University of Central Lancashire, Preston, Lancashire, UK. [5]University of Manchester, Manchester, UK. [6]Steps, Warrington, UK. [7]Health Education North West (Mersey), Liverpool, UK. [8]Institute of Translational Medicine, University of Liverpool, Liverpool, UK

Contact address: Kerry Dwan, Cochrane Central Executive, St Albans House, 57-59 Haymarket, London, England, SW1Y 4QX, UK. kdwan@cochrane.org.

Editorial group: Cochrane Developmental, Psychosocial and Learning Problems Group.
Publication status and date: Edited (no change to conclusions), published in Issue 7, 2017.

Citation: Dwan K, Kirkham J, Paton RW, Morley E, Newton AW, Perry DC. Splinting for the non-operative management of developmental dysplasia of the hip (DDH) in children under six months of age. *Cochrane Database of Systematic Reviews* 2017, Issue 7. Art. No.: CD012717. DOI: 10.1002/14651858.CD012717.

ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To determine the role of splinting and the optimal treatment strategy for the non-operative management of DDH in children under six months of age. To identify if there are particular subgroups of patients for whom the optimal management strategy may differ.

BACKGROUND

Description of the condition

Developmental dysplasia of the hip (DDH) is a common paediatric condition, with a variable incidence that appears to be based on ethnicity (Loder 2011). Within the UK, USA, and Australia, the incidence is approximately 10 per 1000 live births, with 1 in 1000 hips being dislocated at birth (Storer 2006). Amongst Native Americans, however, the incidence may be more than 10 times higher, and amongst African people it is believed to be extremely rare (Loder 2011). In the UK, abnormalities of the hip are screened for as part of the Newborn and Infant Physical Examination (NIPE) programme (UK National Screening Programme 2013). A Cochrane systematic review has assessed screening for DDH (Shorter 2013). DDH encompasses a spectrum of abnormalities, which range from delayed physiological development of the hip, through to acetabular deficiency, subluxation, and dislocation of the hip. It is more common in females, babies in the breech position in the third trimester, firstborn children, oligohydramnios (not enough amniotic fluid during pregnancy), and in those with a family history of the condition (Storer 2006).

The management strategy for DDH depends on the child's age and the severity of the disease. In children under six months of age the usual strategy, once abnormalities are identified, is to apply an abduction splint, such as a Pavlik harness (Mubarak 2003), and monitor the disease progression with serial ultrasound scans (Cooper 2014). If this is successful, no further intervention is

required. If the child fails to respond to splinting, then they are managed with surgery to gently reduce (relocate) the hip, which may be achieved closed (i.e. without surgical incisions) or may necessitate a formal surgical approach to achieve reduction of the hip. There is no consensus on the length of time splinting should be pursued before reverting to surgical intervention, but reports of treatment length vary from 11 weeks to 28 weeks (Tomlinson 2016).

The paediatric hip undergoes a variety of changes in normal physiological development. Indeed, evidence has suggested that some hips that are abnormal in newborns may become normal without any intervention at all (Barlow 1962; Gardiner 1990; Shipman 2006). Therefore, there is a balance between undertreating and overtreating this condition. This is especially important because therapy with splints risks localised blood supply damage known as avascular necrosis (AVN) and femoral nerve palsy (Murnaghan 2010; Pollet 2010). The risk of AVN using a splint is in the region of 1% (Cashman 2002; Eidelman 2003), although some reports may be as high as 11% (Suzuki 2000). Furthermore, treating newborns in splints can cause considerable upset to new parents and can interfere with the bond between mothers and their new baby (Gardner 2005). Parents are also concerned about the use of splints interfering with 'tummy time' as 'tummy time' can affect both fine and gross motor skills.

Decisions regarding the treatment of DDH are typically made based on the ultrasonographic appearance of the hips. The most commonly used classification system is based on a static ultrasound image (Graf 2006; see Table 1). Other types of ultrasound assessment are also used, such as the dynamic assessment popularised by Harcke 1984; however, these techniques are typically combined with a static ultrasound assessment.

Patients with an alpha angle above 60 degrees are considered normal, and are classified as a Graf I hip (Graf 2006). Patients with an alpha angle from 50 to 59 degrees and under the age of three months are classified as Graf IIa (Karnik 2007); they are usually managed with ultrasound follow-up alone to ensure resolution. Children with a persistent alpha angle from 50 to 59 degrees and older than three months are classified as Graf IIb. In the UK, children with Graf IIb hips who are under the age of six months are frequently managed with a splint, in conjunction with ultrasound follow-up. Graf IIb hips constitute the most common reason to use a splint in the treatment of DDH; however, debate exists as to whether treating Graf IIb hips has any bearing on the outcome, with many centres ceasing to use splints for this reason. Those with more severe dysplasia (Graf III hips) or those that are dislocated (Graf IV hips) routinely receive treatment in the form of an abduction splint, but it is unclear when this should commence, which splint is best, or the extent to which splints offer additional benefit over natural history alone (Tomlinson 2016).

Therefore, it is important to establish the best practice for the non-surgical management of children with DDH under six months old, and identify the extent to which the intervention with a splint alters the prognosis of disease.

Description of the intervention

A variety of splints are used to abduct and flex the hips into the desired position.

The most commonly used splint is the Pavlik harness. This splint promotes a dynamic reduction; that is, children are free to move their legs within the range permitted by the splint. This is thought to provide a more gentle reduction than other splints that fix the legs in a predefined position, thereby potentially lowering the risk of complications. Pavlik harnesses are also readily adjustable to the size of the infant and are more convenient to store (pack flat) than fixed abduction splints.

Fixed abduction splints (e.g. Von Rosen splint) are less commonly used, with greater concerns about complications and less convenience. These splints fix the legs of the child in flexion and abduction using a hard plastic splint. One study reported excellent results with the Von Rosen splint but the quality of evidence was limited (Heikkilä 1988). Other static splints include the Denis Browne bar (which splints the hips in abduction and flexion), the Rhino brace, and the Tübingen hip flexion splint (Ottobock splint).

The Frejka pillow is a further alternative, which is described as a non-static splinting technique. This is widely used in Norway. The pillow is a further form of abduction splint; that is, a simple foam-rubber pillow that is strapped to the child to flex and abduct the legs. The legs are fixed in abduction though not rigidly fixed. The argument for the use of this splint is that it is easy to use, needing less specialist supervision than other splints (Hinderaker 1992), which is better suited to the very disperse populations (i.e. Norway). However, there are concerns about high complications and treatment failures.

All splints are applied by an individual with specialist knowledge of the use of these devices, which is typically a children's orthopaedic surgeon, an extended scope practitioner (physiotherapist or nurse with specialist training), or an orthotist. The splint is worn for a period of time defined by local policy, which will depend upon the appearance of the hip; typically this is between six and 16 weeks. Throughout the period of splinting, ultrasound scans are performed at regular intervals (typically between one and three weeks, depending upon the practitioner and type of splint used) to monitor progression. At the end of treatment, some centres immediately discontinue the use of the splint, whilst other centres 'wean' the splint and often advise treatment at night-time only for a period of time. Children are then monitored according to local policy, for a time period between three years and 16 years.

There is no national or international consensus of type of splint, duration of splinting, weaning versus complete cessation, and long-term follow-up.

How the intervention might work

The interventions seek to direct the femoral head (ball) into the acetabulum (socket), thereby promoting the development of the joint. In infants, both femoral head and acetabulum are malleable and will readily undergo plastic deformation. With both the acetabulum and femoral head appropriately aligned, plastic deformation will ensue, to enable both head and socket to form the appropriate shape. For hips that have not sufficiently developed in utero, splints position the hips in flexion and abduction to achieve the optimal position for hip development. Splints can be either dynamic splints (i.e. Pavlik splint), whereby the child is free to move his or her legs within the range permitted by the splint, or fixed (i.e. Von Rosen splint), whereby the child's legs are fixed in position to achieve the optimal position.

Why it is important to do this review

There is considerable variation in the non-operative management of DDH (Tomlinson 2016). Treatment varies by country, institution, and even surgeon. Non-operative management is not without complication. Therefore, it is important to determine an optimal strategy that achieves the greatest successes (i.e. avoids subsequent operative interventions), whilst minimising complications related to splinting (which includes AVN and femoral nerve palsy). It is also important to identify whether there are particular subgroups for whom the optimal management strategy may differ.

OBJECTIVES

To determine the role of splinting and the optimal treatment strategy for the non-operative management of DDH in children under six months of age. To identify if there are particular subgroups of patients for whom the optimal management strategy may differ.

METHODS

Criteria for considering studies for this review

Types of studies

1. Randomised controlled trials (RCTs), quasi-RCTs, and cluster-RCTs.
2. Prospective and retrospective non-randomised controlled studies and cohort studies. We will consider non-randomised trials for inclusion, as we expect that the number of randomised trials in this population will be limited.

Types of participants

Children with all severities of DDH who are under six months of age.

If studies include children over six months of age, we will contact the study authors to obtain data on children under six months of age.

We will exclude children with neurodevelopmental problems or neuromuscular syndromes.

Types of interventions

1. Dynamic splinting (i.e. Pavlik harness, Frejka pillow).
2. Static splinting (e.g. Von Rosen, Denis Browne bar, Rhino brace, Tübingen hip flexion splint (Ottobock splint)).
3. Double nappies.
4. No treatment or delayed treatment.

We will make the following comparisons.

1. Dynamic splinting versus delayed or none.
2. Static splinting versus delayed or none.
3. Double nappies versus delayed or none.
4. Dynamic versus static.

Types of outcome measures

Primary outcomes

1. Measurement of acetabular index at years 1, 2, and 5, as determined by radiographs (angle).
2. Need for operative intervention (dichotomous):
   i) to achieve reduction; and
   ii) to address dysplasia.
3. Complications (dichotomous):
   i) AVN (there are several grading systems, most commonly "total" AVN (Salter 1969), and "partial" AVN (Gage 1972));
   ii) femoral nerve palsy;
   iii) other nerve palsies; and
   iv) pressure areas on skin.

We will use the primary outcomes to populate the 'Summary of findings' table.

Secondary outcomes

1. Health economic assessment (including financial impact on the family), as reported in the included studies.
2. Bonding between parents and child (including obstacles to breastfeeding, problems with winding and bathing baby), as reported in the included studies.
3. Motor skill development, as reported in the included studies. Motor skills is an outcome that parents are concerned

about, as ' tummy time' affects both fine and gross motor skills, and the use of splints interferes with ' tummy time':

i) fine motor skill development; and
ii) gross motor skill development.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases and trials registers.

1. Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library, which includes the Cochrane Developmental, Psychosocial and Learning Problems Group's Specialised Register.
2. MEDLINE Ovid (1946 onwards).
3. MEDLINE In-Process and Other Non-Indexed Citations Ovid (current issue).
4. MEDLINE Epub Ahead of Print Ovid (current issue).
5. Embase Ovid (1974 onwards).
6. CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 onwards).
7. PEDro (Physiotherapy Evidence Database; www.pedro.org.au).
8. Science Citation Index - Expanded Web of Science (SCI-EXPANDED; 1970 onwards).
9. Conference Proceedings Citation Index - Science Web of Science (CPCI-S; 1990 onwards).
10. *Cochrane Database of Systematic Reviews* (CDSR; current issue), part of the Cochrane Library.
11. Database of Abstracts of Reviews of Effects (DARE; current issue), part of the Cochrane Library.
12. Networked Digital Library of Theses and Dissertations (NDLTD; search.ndltd.org/index.php).
13. ClinicalTrials.gov (clinicaltrials.gov).
14. World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; www.who.int/ictrp/en).

We will search MEDLINE using the search strategy in Appendix 1. This strategy will be adapted for the other databases listed above. We will not restrict the search by date, publication status, study type, or language. We will seek translations if necessary.

Searching other resources

We will search the reference lists of included studies and any relevant reviews identified by the electronic searches (see Electronic searches). We will also contact study authors to ask if they know of any other studies, including those that are ongoing and unpublished, and will handsearch *Orthopaedic Proceedings*, which is a source of abstracts from major international orthopaedic meetings (bjjprocs.boneandjoint.org.uk).

Data collection and analysis

Selection of studies

Two review authors (one clinical expert and one methodologist, e.g. KD or JK and AN or DP) will independently screen the titles and abstracts of studies identified by the search strategy for eligibility (see Criteria for considering studies for this review). They will then independently assess the full texts of potentially eligible studies. We will resolve any differences by discussion or by consulting a third review author. We will list all studies excluded after full-text assessment and their reasons for exclusion in a ' Characteristics of excluded studies' table. We will illustrate the study selection process in a PRISMA flow diagram (Moher 2009).

Data extraction and management

Two review authors (one clinical expert and one methodologist, e.g. KD or JK and AN or DP) will independently extract data onto a prepiloted data extraction form (Appendix 2), which we will manage in Microsoft Excel and refine accordingly. We will resolve any disagreements through discussion or by consulting a third review author.

Assessment of risk of bias in included studies

Two review authors (one clinical expert and one methodologist, e.g. KD or JK and AN or DP) will independently assess RCTs and quasi-RCTs for risk of bias, using Cochrane's ' Risk of bias' tool, which is described in further detail in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve disagreements through discussion or by consulting a third review author. The seven domains to be assessed are: sequence generation, allocation sequence concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential threats to validity. Review authors will assign a judgement of either unclear, low, or high risk of bias (Appendix 3), along with a justification for this decision in the ' Risk of bias' tables.

If we identify any cluster-RCTs, we will also consider (i) recruitment bias; (ii) baseline imbalance; (iii) loss of clusters; (iv) incorrect analysis; and (v) comparability with individually randomised trials.

Due to our expectation that most studies we will identify will be observational in nature, we will assess the risk of bias for non-randomised studies using the recently developed ROBINS-I (Risk Of

Bias In Non-randomised Studies - of Interventions) tool (Sterne 2016); for two outcomes of interest (need for surgical open reduction and acetabular index at one year) in each study, we will perform a separate 'Risk of bias' assessment. This tool considers seven domains of bias: two domains of bias pre-intervention (bias due to confounding and bias in selection of participants into the study), one domain of bias at intervention (bias in the classification of interventions), and four domains of bias postintervention (bias due to departures from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result). Central to implementing ROBINS-I is the consideration of confounding factors and cointerventions that have the potential to lead to bias.

Important confounders of interest in this Cochrane Review include the following.

1. Age of child at intervention (i.e. harness commencement).
2. Proportion of females.
3. Ethnicity of the participants (or if not stated, the country in which the study was conducted).
4. Clinical assessment of the hip. Dislocated hip (reducible or not reducible), clinically unstable hip (i.e. dislocatable), or clinically stable hip.
5. Ultrasound assessment of the hip. Acetabular dysplasia assessed using the alpha angle according to Graf classification of hip: I (normal), IIa or IIb (centred hip, 50 to 60 degrees of dysplasia), IIc (centred hip 43 to 50 degrees of dysplasia), III (decentred hip), and IV (dislocated hip).
6. Indication for ultrasound screening (i.e. breech presentation in third trimester, family history of DDH, lower than normal levels of amniotic fluid, ' click' on clinical screening (abnormal clinical examination producing ' click' sound on hip movements), unequal skin creases).

We will add to the above list any further confounders we identify following assessment of the included studies, if appropriate, and specify these confounders as post hoc. We do not anticipate that there will be any important cointerventions to consider. Each of the seven domains of bias contain signalling questions to facilitate judgements of risk of bias. The full signalling question and response framework for each outcome is provided in Sterne 2016. Following completion of the signalling questions, we will seek a ' Risk of bias' judgement for each domain and obtain an overall ' Risk of bias' judgement for each outcome and result being assessed. Overall risk of bias has four categories ranging from low risk of bias (the study is at low risk of bias across all domains) to critical risk of bias (the study is at critical risk of bias in at least one domain). If there is insufficient information to assess the risk of bias in one or more key domains, but there is no indication that there is any critical or serious risk of bias in any of the other domains, then we will designate the overall classification as 'no information'.

Measures of treatment effect

Dichotomous outcome data

We will summarise data from dichotomous outcomes (e.g. need for operative intervention, femoral nerve palsy, AVN) using the risk ratio (RR) and 95% confidence intervals (CIs).

AVN is measured using a grading system and therefore is categorical. If this is reported as categorical data within a trial, we will use a clinical rating of two and above to define AVN, thereby dichotomising the data. There are many different rating systems for AVN, which are difficult to amalgamate. In all rating systems type-I AVN is mild AVN that is clinically unimportant, as it completely heals without long-term consequence. We therefore plan to dichotomise the outcome to the presence or absence of clinically important AVN. If we are unable to compute an effect size, we will provide a narrative description of the results.

Continuous outcome data

For continuous outcomes (e.g. bonding between parents and child, measurement of acetabular index, fine and gross motor skills) measured on the same scale, we will compute the mean difference (MD) and 95% CIs; if different measures are reported, we will compute the standardised mean difference (SMD) and 95% CIs. If we are unable to compute an effect size, we will provide a narrative description of the results.

For measurement of acetabular index, less than 30 degrees is considered normal in children aged over six months, and less than 25 degrees for children aged 24 months. Under six months of age, an alpha angle of the hip on ultrasound scan above 60 degrees is considered normal.

Health economic assessment

We will provide a narrative description of the results of the health economic assessment.

Unit of analysis issues

Cluster-RCTs

If we include cluster-RCTs in which the trial authors have not accounted for the cluster in their analyses, we will reduce the size of each trial to its effective sample size by diving the original sample size by the design effect (by using the average cluster size and the intracluster correlation coefficient (ICC)). If the ICC value is unavailable, we will impute it from a similar study, if possible. We will then include the data in the latest version of Review Manager 5 (RevMan 5) (Review Manager 2014), using the generic inverse variance method.

Cross-over RCTs

We will exclude cross-over trials. These are not appropriate as DHH is not a chronic condition.

Multiple groups

If a study includes more than two similar intervention groups, we will combine them and compare them with the control arm, creating a single pair-wise comparison. If a study includes more than two dissimilar intervention groups, we will include these arms in the review separately, and halve the control group to ensure there is no double counting of participants.

Dealing with missing data

We will contact the authors of the included studies for missing data. For transparency, if we do not receive a reply, we will note this in the 'Characteristics of included studies' tables. If we can not obtain missing statistics (i.e. standard deviations), or calculate them from data reported in the trial report, then we will attempt to impute them for similar studies. We will not attempt imputation on missing participant data as we expect most studies to be non-randomised studies.

Assessment of heterogeneity

We will assess clinical and methodological aspects of the included studies to determine whether there is clinical or methodological heterogeneity.

We will assess statistical heterogeneity visually by looking at the forest plots. We will calculate the Chi² test and will use a P value of less than (<) 0.10 to determine statistical significance due to the low power of the test. We will also calculate the I^2 statistic and 95% CIs, which describe the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) (Higgins 2003). We will use the thresholds below for interpretation.

1. 0% to 40%: might not be important.
2. 30% to 60%: may represent moderate heterogeneity.
3. 50% to 90%: may represent substantial heterogeneity.
4. 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

If we include 10 or more studies in the review, we will construct a funnel plot to assess for publication bias. However, it should be noted that asymmetry in the funnel plot can be caused by other reasons, such as heterogeneity. We will also use Egger's test to formally assess funnel plot asymmetry (Egger 1997).

In addition, we will complete an Outcome Reporting Bias in Trials (ORBIT) matrix to help with the assessment of selective outcome reporting (Kirkham 2010).

Data synthesis

We will analyse different study designs separately (RCTs, quasi-RCTs, retrospective and prospective non-randomised studies). We will use a fixed-effect analysis unless there is substantial heterogeneity (i.e. I^2 statistic value of greater than (>) 50%); in which case, we will use a random-effects analysis as a sensitivity analysis (see Sensitivity analysis) and report both results (we will also report the Tau^2 value). We will use the inverse variance method. If there is considerable heterogeneity (i.e. I^2 statistic value > 75%), we will not conduct a meta-analysis, but will provide a narrative description of the results.

We will assess the comparisons below.

1. Splint versus no treatment or delayed treatment.
2. Double nappies versus no treatment or delayed treatment.

Subgroup analysis and investigation of heterogeneity

If sufficient studies are available, we will consider conducting the subgroup analyses listed below.

1. Age (birth to three months, three months to six months). The splint is thought to work better in younger infants.
2. Sex (boys, girls). DDH is more common in girls.
3. Type of splint (Pavlik harness or Frejka pillow; Von Rosen splint, Denis Browne bar, Rhino brace, Tübingen hip flexion splint (Ottobock splint)).
4. Clinical assessment of the hip (dislocated hip (reducible or not reducible), clinically unstable hip (i.e. dislocatable), or clinically stable hip).
5. Static ultrasound assessment of the hip. Acetabular dysplasia assessed using the alpha angle according to Graf classification of hip: I (normal), IIa or IIb (centred hip, 50 to 60 degrees of dysplasia), IIc (centred hip 43 to 50 degrees of dysplasia), III (de-centred hip), and IV (dislocated hip).
6. Dynamic ultrasound assessment of the hip (normal or abnormal (subluxed or dislocated) based on the assessment criteria used).
7. Type of dysplasia (unilateral or bilateral disease). This is important because bilateral dislocations are harder to treat and there is a higher failure rate, which is thought to be because neither of the hips form a stable base for the treatment.

Sensitivity analysis

We will conduct sensitivity analyses for our primary outcomes from RCTs and quasi-RCTs only (Primary outcomes). We will assess the impact on our results of excluding quasi-RCTs and studies at unclear or high risk of bias. We will also conduct a sensitivity analysis using a random-effects model when there is substantial heterogeneity.

GRADE

Two review authors (one clinical expert and one methodologist, e.g. KD or JK and AN or DP) will independently assess the quality of the evidence using the GRADE approach by considering the risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias. We will resolve disagreements through discussion with a third review author. We will use the GRADEpro Guideline Development Tool (GDT), GRADEpro GDT 2015, to create a 'Summary of findings' table for our primary outcomes (see Primary outcomes) for each comparison.

ACKNOWLEDGEMENTS

We thank Margaret Anderson for constructing the search strategy.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Graf classification system[1]

Graf	Sonographic hip type	Bony roof	Ossific rim	Cartilage rim	Alpha angle
Ia	Mature	Good	Sharp	Long and narrow, extends far over femoral head	> 60
Ib	Mature	Good	Usually blunt	Short and broad, but covers femoral head	> 60
IIa	Physiological delay in ossification > 3 months (physiological immature but stable hips)	Deficient	Rounded	Covers femoral head	50 to 59
IIb	Physiological delay in ossification > 3 months (inherently stable)	Deficient	Rounded	Covers femoral head	50 to 59
IIc	On point of dislocation (unstable, requires immediate treatment)	Deficient	Rounded or flat	Covers femoral head	43 to 49
IId	On point of dislocation	Severley deficient	Rounded or flat	Compressed	43 to 49
IIIa	Dislocated (subluxation)	Poor	Flat	Displaced upwards and echo poor	< 43
IIIb	Dislocated (subluxation)	Poor	Flat	Displaced upwards and more reflective than femoral head	< 43
IV	Dislocated (complete)	Poor	Flat	Interposed	< 43

1. Karnik 2007

APPENDICES

Appendix 1. MEDLINE search strategy

1 Hip Dislocation/
2 Hip Dislocation, Congenital/
3 (dislocat$ adj3 hip$).tw,kf.
4 ((dysplasia$ or dysplastic$) adj3 hip$).tw,kf.
5 ((sublux$ or sub-lux$) adj3 hip$).tw,kf.
6 Acetabul$.tw,kf.
7 (congenital$ adj3 hip$).tw,kf.
8 (developmental$ adj3 hip$).tw,kf.
9 (CDH or DDH.tw,kf.
10 or/1-9
11 exp infant/
12 (baby or babies or child$ or infant$ or newborn$ or neonat$ or p?ediatric$).tw.
13 or/11-12
14 10 and 13
15 orthopedic fixation devices/
16 splints/
17 orthosis$.tw,kf.
18 (splint$ or harness$ or brace$ or pillow$).
19 ("double napp$" or "double diaper$").tw,kf.
20 (Otto Bock$ or Ottobock$).tw,kf.
21 Pavlik$.tw,kf.
22 Denis Browne$.tw,kf.
23 Tubingen.tw,kf.
24 Frejka$.tw,kf.
25 von Rosen.tw,kf.
26 abduct$.tw,kf.
27 or/15-26
28 14 and 27

Appendix 2. Data extraction template

Study identifier (ID)	-
References (* main reference)	-
Trial registry and ID	-
Participant characteristics	
Age	-
Gender	-

(*Continued*)

Ethnicity	-
Comorbidities	-
Clinical assessment of the hip. Dislocated hip (reducible or not reducible), clinically unstable hip (i.e. dislocatable), or clinically stable hip	-
Ultrasound assessment of the hip. Acetabular dysplasia assessed using the alpha angle according to Graf classification of hip: I (normal), IIa or IIb (centred hip, 50 to 60 degrees of dysplasia), IIc (centred hip 43 to 50 degrees of dysplasia), III (de-centred hip), and IV (dislocated hip)	-
Unilateral or bilateral disease	-
Trial characteristics	
Trial design	-
Single centre or multicentre	-
Country/countries	-
How was participant eligibility defined?	-
How many people were randomised?	-

(*Continued*)

Number of participants in each intervention group	-
Number of participants who received intended treatment	-
Number of participants who were analysed	-
Splint used (include details of timing, weaning, etc.)	-
Comparator (include details of timing, weaning, etc.)	-

Risk of bias

Item	Comment	Judgement
Allocation of intervention	-	High/low/unclear
Concealment of allocation	-	High/low/unclear
Blinding of participants and personnel	-	High/low/unclear
Blinding of outcome assessment	-	High/low/unclear
Incomplete outcome data	-	High/low/unclear
Selective outcome reporting	-	High/low/unclear
Other potential threats to validity	-	High/low/unclear

Outcomes	Intervention	Control	Time point

(*Continued*)

Measurement of acetabular index, as determined by radiographs (angle)	-	-	1 year/2 years/5 years/other (specify)
Need for operative intervention to achieve reduction	-	-	-
Need for operative intervention to address dysplasia	-	-	-
Avascular necrosis (include grading system)	-	-	-
Femoral nerve palsy	-	-	-
Other nerve palsies	-	-	-
Health economic assessment (including financial impact on the family)	-	-	-
Bonding between parents and child (including obstacles to breastfeeding, problems with winding and bathing baby)	-	-	-
Fine motor skill development	-	-	-

Appendix 3. Criteria for judging risk of bias in the 'Risk of bias' assessment tool[1]

Random sequence generation **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence**	
Criteria for the judgement of low risk of bias	The study investigators describe a random component in the sequence generation process such as: 1. referring to a random number table; 2. using a computer random number generator; 3. coin tossing;

(*Continued*)

	4. shuffling cards or envelopes; 5. throwing dice; 6. drawing of lots; or 7. minimisation[1]. [1]Minimisation may be implemented without a random element, and this is considered to be equivalent to being random
Criteria for the judgement of high risk of bias	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: 1. sequence generated by odd or even date of birth; 2. sequence generated by some rule based on date (or day) of admission; or sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorisation of participants, for example: 1. allocation by judgement of the clinician; 2. allocation by preference of the participant; 3. allocation based on the results of a laboratory test or a series of tests; or 4. allocation by availability of the intervention.
Criteria for the judgement of unclear risk of bias	There is insufficient information about the sequence generation process to permit a judgement of low or high risk of bias
Allocation concealment **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment**	
Criteria for the judgement of low risk of bias	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: 1. central allocation (including telephone, web-based and pharmacy-controlled randomisation); 2. sequentially numbered drug containers of identical appearance; or 3. sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of high risk of bias	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: 1. using an open random allocation schedule (e.g. a list of random numbers); 2. using assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); 3. alternation or rotation; 4. date of birth;

(*Continued*)

	5. case record number; or 6. any other explicitly unconcealed procedure.
Criteria for the judgement of unclear risk of bias	Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example, if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque, and sealed
Blinding of participants and personnel **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study**	
Criteria for the judgement of low risk of bias	Any one of the following: 1. no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; or 2. blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of high risk of bias	Any one of the following: 1. no blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; or 2. blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of unclear risk of bias	Any one of the following: 1. insufficient information to permit judgement of low or high risk of bias; or 2. the study did not address this outcome.
Blinding of outcome assessment **Detection bias due to knowledge of the allocated interventions by outcome assessors**	
Criteria for the judgement of low risk of bias	Any one of the following: 1. no blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; or 2. blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of high risk of bias	Any one of the following: 1. no blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; or 2. blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.

(*Continued*)

Criteria for the judgement of unclear risk of bias	Any one of the following: 1. insufficient information to permit judgement of low or high risk of bias; or 2. the study did not address this outcome.
Incomplete outcome data **Attrition bias due to amount, nature, or handling of incomplete outcome data**	
Criteria for the judgement of low risk of bias	Any one of the following: 1. no missing outcome data; 2. reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); 3. missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; 4. for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; 5. for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; or 6. missing data have been imputed using appropriate methods.
Criteria for the judgement of high risk of bias	Any one of the following: 1. reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; 2. for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; 3. for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 4. 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation; or 5. potentially inappropriate application of simple imputation.
Criteria for the judgement of unclear risk of bias	Any one of the following: 1. insufficient reporting of attrition or exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided); or 2. the study did not address this outcome.

(*Continued*)

Selective reporting **Reporting bias due to selective outcome reporting**	
Criteria for the judgement of low risk of bias	Any of the following: 1. the study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way; or 2. the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).
Criteria for the judgement of high risk of bias	Any one of the following: 1. not all of the study's prespecified primary outcomes have been reported; 2. one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified; 3. one or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); 4. one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; or 5. the study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of unclear risk of bias	Insufficient information to permit judgement of low or high risk of bias. It is likely that most studies will fall into this category
Other bias **Bias due to problems not covered elsewhere in the table**	
Criteria for the judgement of low risk of bias	The study appears to be free of other sources of bias.
Criteria for the judgement of high risk of bias	There is at least one important risk of bias. For example, the study: 1. had a potential source of bias related to the specific study design used; 2. has been claimed to have been fraudulent; or 3. had some other problem.
Criteria for the judgement of unclear risk of bias	There may be a risk of bias, but there is either: 1. insufficient information to assess whether an important risk of bias exists; or 2. insufficient rationale or evidence that an identified problem will introduce bias.

1. Taken from Higgins 2011

WHAT'S NEW

Date	Event	Description
19 July 2017	Amended	Correcting spelling of author's surname.

CONTRIBUTIONS OF AUTHORS

Kerry Dwan wrote the Methods section.

Jamie Kirkham wrote the Methods section.

Robin W Patton commented on the protocol.

Emma Morley commented on the protocol.

Ashley Willam Newton wrote the Background section and commented on the protocol.

Daniel C Perry wrote the Background section, commented on the protocol, and is guarantor of the review.

DECLARATIONS OF INTEREST

Kerry Dwan is a Statistical Editor with the Cochrane Central Executive.

Jamie Kirkham - none known.

Robin W Patton - none known.

Emma Morley - none known.

Ashely William Newton - none known.

Daniel C Perry - none known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- National Institute of Health Research (NIHR), UK.

Daniel C Perry is funded as an NIHR Clinician Scientist.

- Steps, UK.

Steps fund Emma Morley.