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Active monitoring versus immediate abduction as treatment of stable developmental dysplasia of the hip: a systematic review of the literature

Evy M B Paulussen,[1] Frederike E C M Mulder ,[1] Nina M C Mathijssen,[2] M Adhiambo Witlox[3]

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EMBP and FECMM contributed equally.

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[1]Department of Orthopaedic Surgery, Maastricht University, Maastricht, The Netherlands
[2]Department of orthopaedic surgery, Reinier Haga Orthopedic Center, Zoetermeer, The Netherlands
[3]Department of Orthopaedic Surgery, Maastricht University Medical Centre+, Maastricht, The Netherlands

Correspondence to
Evy M B Paulussen;
evypaulussen@home.nl

ABSTRACT

Objectives This systematic review aims to compare the effects of active monitoring and abduction treatment on the Graf alpha angle, Acetabular Index (AI) and femoral head coverage in infants with stable developmental dysplasia of the hip (DDH).

Design Systematic review reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Data sources A search of the PubMed, Embase, Cochrane and Web of Science databases was performed in January 2020 and updated in January 2021.

Eligibility criteria (Non-)randomised studies comparing active monitoring with abduction treatment in infants younger than 4 months with stable DDH were included.

Data extraction and synthesis All eligible articles were methodologically assessed using the Cochrane risk of bias tools. Data were extracted by summarising the study characteristics and results.

Results Of the six included studies, two randomised studies were of low risk and two of some concerns. Two non-randomised studies were of serious risk. In total, 544 dysplastic hips (439 infants) were investigated, of which 307 were observed and 237 were treated. Two studies reported a faster improvement of the alpha angle and average acetabular coverage in treated hips at 3 months. No differences in AI between the treatment and observation group after 3 months were reported. In total, 38 infants (12%) in the observation group switched to the treatment group. At the final radiograph, 21 observed hips and 32 treated hips were dysplastic.

Conclusions There were no differences in AI between the treatment and observation group after 3 months in infants up to 4 months of age with stable DDH hips. The switch of 38 infants (12%) from the observation to the treatment group corroborates that not all infantile DDH hips will spontaneously progress into normal hips. The small study population sizes and methodological heterogeneity warrant a large randomised controlled trial to study this research question.

PROSPERO registration number CRD4202123300.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ All identified studies, independent of the quality of the studies, were included in this systematic review. Thus, providing a complete overview of current literature.
⇒ Risk of bias of the included studies was extensively reviewd.
⇒ Great heterogeneity in measurement methods and measurement moments of the included studies, made it difficult to compare study results and impossible to perform a meta-analysis.
⇒ There was great heterogeneity in the quality of the included studies, since two non-randomised studies classified as serious risk of bias.

INTRODUCTION

Developmental dysplasia of the hip (DDH) is one of the most common paediatric orthopaedic disorders in newborns and young children.[1 2] DDH comprises a spectrum of developmental hip abnormalities ranging from mild dysplasia of the acetabulum to dislocation of the femoral head.[3 4] The incidence rate of DDH differs per geographic location, ethnic background and diagnostic definition and varies between 1/1000 and 20/1000.[2 4 5] Untreated DDH can result in short-term and long-term morbidity, such as, chronic pain, gait abnormalities and early hip osteoarthritis.[4 6] To detect DDH at an early age, screening programmes have been implemented worldwide.

Controversy exists on the optimal screening method to detect DDH (universal screening vs selective screening) and timing differs considerably worldwide.[7 8] In the Netherlands, all newborns are screened for DDH within the first month after birth by the Dutch national screening programme. When newborns present with an abnormal clinical examination (knee height, passive hip abduction and the Ortolani and Barlow manoeuvres) or when risk factors (family history, breech position) are present, the newborn is referred for an ultrasound at the age of 3 months. If there is a suspicion of luxation, the infant is referred for an ultrasound within 2 weeks.[8 9]

In Europe, selective screening is also used in Belgium, France, Portugal, Sweden, Norway, Hungary, the UK and Ireland. Conversely, Austria, Germany, Switzerland, Italy, Slovenia and Slovakia use a universal ultrasound screening method.[7] The timing of ultrasound screening ranges from week 1 to week 12.[7] A third screening method is universal screening including clinical examination only.[10] Existing literature comparing screening methods is scant and shows methodological heterogeneity.[7]

Limitations of clinical examination alone are the lower sensitivity, difficulty to identify subtle signs and the majority of positive Ortolani or Barlow manoeuvres will spontaneously resolve within 2–4 weeks after birth.[10 11] Ultrasonography according to the Graf method is one of the most used methods to diagnose and classify DDH.[12 13] The Graf method classifies type two hips as stable but dysplastic hips and type three hips as unstable or luxated hips.[9] Hip ultrasonography facilitates the ability to identify smaller anomalies, thereby possibly introducing overdiagnosis.[11] A study by Roovers *et al* suggests that 85% of infantile DDH will resolve by the age of 3 months without treatment initiation.[14] The hypothesis that stable hips tend to spontaneously progress into normal hips is supported by current literature.[6 15] Currently, abduction treatment is the most opted DDH treatment in children younger than 6 months.[16] However, it is debatable whether abduction treatment alters the natural course of stable hips.[6] A study by Pollet *et al* did not find a difference in acetabular development between abduction treatment and active monitoring in infants with stable hips at the age of 3 to 4 months.[2] Therefore, the preeminent question is whether stable hips (Graf type 2) are truly pathological and warrant abduction treatment.[6] Furthermore, abduction treatment might expose the infant to complications, such as avascular necrosis (AVN) of the femoral head and transient femoral nerve palsy.[3] A systematic review of the literature is needed to summarise existing studies comparing abduction treatment and active monitoring in stable hips. The results of this systematic review might impact current screening and treatment methods and will identify knowledge gaps.

The aim of this systematic review is to compare the effects of active monitoring and abduction treatment on the Graf alpha angle, Acetabular Index (AI) and femoral head coverage (FHC) in infants with stable DDH (Graf type 2).

MATERIALS AND METHODS

Search strategy and protocol

This systematic literature review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[17] (online supplemental appendix 1). A flowchart of this process is depicted in figure 1. The databases PubMed, Embase, Cochrane and Web of Science were systematically searched in January 2020. The search was updated in January 2021. Citation software (Endnote V.X9.3.3, Clarivate Analytics, Boston, Massachusetts) facilitated the search strategy. A Boolean for the search string with the used keywords and index terms (Mesh headings) is provided (online supplemental appendix 2).

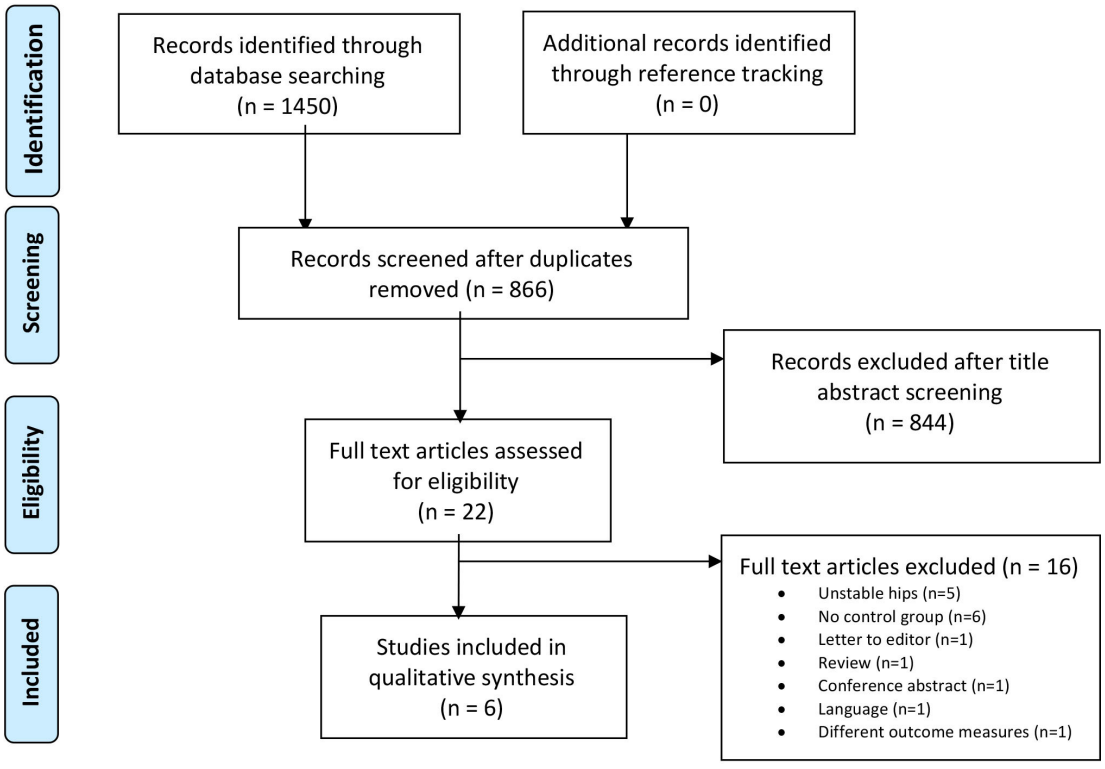

Figure 1 Flowchart of the selection process with reasons for exclusion based on full text.

Study selection

The search string was developed in consultation with a research librarian. After eliminating duplicates, the identified articles were screened by NMCM and MAW based on title and abstract. Interreviewer disagreements were solved by consensus and with assistance EMBP. Articles considered relevant by title and abstract were read in full text by EMBP, NMCM and MAW to determine final eligibility. To complete the search, reference lists of relevant articles were screened and Google Scholar was used for forward citations by EMBP.

Eligibility criteria

Studies investigating infants younger than 4 months of age presenting with stable DDH were included in this review. Studies were eligible for inclusion when presenting at least one of the following outcome values: Graf alpha angle, AI or FHC. Studies including participants with major congenital abnormalities, such as cerebral palsy or spina bifida, were excluded.

The search was restricted to the English and Dutch language. Randomised controlled trials (RCTs), pseudo-RCTs and non-randomised studies were included. For non-randomised studies, both prospective and retrospective studies with two groups (including case–control studies) were included. Studies without comparator (ie, not comparing active monitoring with abduction treatment), cross-sectional studies, case series and case reports were excluded to ensure the inclusion of high level of evidence studies.

Risk of bias

The quality of the studies was assessed by three reviewers using the revised Cochrane risk of bias tool for randomised trials (RoB 2.0) and the Cochrane tool for risk of bias in non-randomised studies (ROBINS-I). All items—that is, selection, performance, attrition, detection and reporting bias for randomised studies, complemented with confounding and recall bias for cohort studies—were rated accordingly. Since blinding of caregivers and patients was not possible due to the nature of the intervention, this aspect of performance bias was assessed less strictly for all studies. The overall risk of bias was attributed as low risk, some concerns or high risk for the randomised and low, moderate, serious or critical risk for the non-randomised studies (online supplementary appendices 3 and 4).[18 19]

Outcomes and data abstraction

To compare the included studies, one author extracted the following characteristics: inclusion and exclusion criteria (degree of dysplasia, age at time of inclusion, comorbidities, previous treatment), subject characteristics (gender, treatment allocation), used abduction device, follow-up moments, outcome measures (Graf alpha angle, AI and FHC), changes in treatment allocation and study conclusions. This process was reviewed by a second author. Effect sizes were calculated for each study based on means, SD and number of infants/hips using an online calculator.[20]

Patient and public involvement

Due to the nature of this study, patients were not involved in the development of the research question, design and conduct of this study. The outcomes of this systematic review will be reported to the Dutch patient association for developmental hip anomalies 'Vereniging Afwijkende Heupontwikkeling'.

RESULTS

Study identification

The initial search provided 1450 records of which 866 remained after removal of duplicates. No additional articles were obtained through reference tracking. All 866 articles were screened by title and abstract. Among these, 22 articles remained eligible for full text review, of which 6 were selected for quality assessment and data extraction. The reasons for exclusion by full text are outlined in the PRISMA flowchart (figure 1).

Selected articles

The six included studies consisted of four RCTs (Wood *et al*,[21] Rosendahl *et al*,[22] Brurås *et al*[23] and Pollet *et al*[2]) and two non-randomised studies, of which one was a retrospective (Sucato *et al*[24]) and one was a prospective cohort study (Kim *et al*[25]). One RCT (Brurås *et al*[23]) was a long-term follow-up of another eligible study (Rosendahl *et al*[22]).

Risk of bias assessment

Two of the four RCTs were rated as low risk of bias (Rosendahl *et al*[22] and Brurås *et al*[23]) and two of some concerns (Pollet *et al*[2] and Wood *et al*[21]). The two non-randomised studies[24 25] were rated as serious risk of bias (online supplemental appendices 3 and 4).

Cohort description

A total of 544 hips were investigated in the included studies. Of these, 307 were actively observed with ultrasound and radiograph and 237 were treated with an abduction device. These numbers do not comprise the 83 hips of Brurås *et al* since they were also included in the study of Rosendahl *et al*.[22 23] Of the 544 hips, at least 97 hips were Graf type IIb and 152 type IIc. However, not all studies reported Graf types (Wood *et al*,[21] Kim *et al*[25]) and one study included stable hips with other Graf types than IIb and IIc (Sucato *et al*[24]).

The total 544 hips belonged to 439 infants. Of these 439 infants, 357 were female and 82 were male (table 1).

Treatment strategies

All randomised studies assigned their patients to either observation (active monitoring), with ultrasound and radiograph evaluation, or abduction treatment, with Pavlik Harness or Frejka Pillow, at the time of inclusion.

Table 1 Overview of study characteristics of the included studies and the total number of included hips and infants

Reference	Study type	Inclusion and exclusion criteria	Subjects	Abduction device	Follow-up	Outcome measures
Wood *et al*[21]	RCT	Infants aged 2–6 weeks with shallow but stable hips on US (<40%–50% FHC) and clinical examination (Barlow and Ortolani and full abduction) without any previous treatment.	44 infants (29 F, 15 M) with 49 dysplastic hips (18 observed and 31 treated; type n.a.)	Pavlik harness	Baseline at 2–6 weeks, US and RTX at 3–4 months and RTX at 24 months	FHC, AI, number of hips dysplastic at final RTX
Rosendahl *et al*[22]	RCT	Infants aged 1–3 days with mild hip dysplasia (a-angle 43°–49°, Graf type IIc) and stable or instable but not dislocatable or dislocated hips, weighing>2.5 kg at birth and without major congenital abnormalities.	128 infants (97 F, 31 M) with 128 dysplastic hips (64 observed and 64 treated; 128 IIc); n=128 infants/dysplastic hips	Frejka pillow, with persistent dysplasia switch to custom fitted plastic cast	Baseline at 1–3 days, US at 6 weeks and 3 months, RTX at 6 and 12 months	a-angle, AI, number of hips dysplastic at final RTX
Bruråas *et al* [23]	RCT	Same population as Rosendahl *et al*.	83 infants (67 F, 16 M; 83 IIc) with 83 dysplastic hips (41 observed and 42 treated; 83 IIc); n=83 infants/dysplastic hips	Same as Rosendahl *et al*	Same as Rosendahl *et al*. RTX at 6 years of age	AI, number of hips dysplastic at final RTX
Pollet *et al*[2]	RCT	Infants aged 3–4 months diagnosed with clinically stable DDH (Graf type IIb and IIc) from five Dutch hospitals, without comorbidities such as congenital deformities or previous treatment.	104 infants (93 F, 11 M) with 104 dysplastic hips (49 observed and 55 treated; 97 IIb 7 IIc); n=104 infants/dysplastic hips	Pavlik harness, with persistent dysplasia switch to abduction brace or spica cast	Baseline at 3–4 months, US at 5 and 6–7 months, RTX at 9 and 24 months	a-angle, AI, number of hips dysplastic at final RTX
Sucato *et al*[24]	Retrospective cohort	Infants younger than 1 month with clinically stable hips but at least one hip Graf type IIa or worse (a-angle<60° or FHC<40%–50%).	112 infants (92 F, 20 M) with 192 dysplastic hips (149 observed and 43 treated; 0 IIb 17 IIc 175 other); n=112 infants with 192 dysplastic hips	Pavlik harness	Baseline at 1–4 weeks (mean=12.7 days), final RTX between 3 and 50 months (mean=16 months)	FHC, a-angle, number of hips dysplastic at final RTX
Kim *et al*[25]	Prospective cohort	Infants younger than 12 weeks at presentation, with at least 3 months follow-up, a normal clinical hip examination (Barlow and Ortolani) and DDH at US (a-angle 40°–55° and FHC 10%–50%) without underlying syndromes, teratological abnormalities or previous treatment.	51 infants (46 F, 5 M) with 71 dysplastic hips (27 observed and 44 treated; type n.a.); n=51 infants with 71 dysplastic hips	Pavlik harness	Baseline US at 6 weeks, RTX at 2 years	FHC, a-angle, AI, number of hips dysplastic at final RTX
Total*			n=544 dysplastic hips of which 307 were observed and 237 were treated (with at least 97 IIb and 152 IIc); n=439 infants of which 357 were female and 82 were male			

*Totals were calculated excluding Bruråas *et al*.[23]
a-angle, alpha angle; AI, Acetabular Index; DDH, developmental dysplasia of the hip; F, female; FHC, femoral head coverage; M, male; n.a, not applicable; RTC, randomised controlled trial; RTX, radiograph; US, ultrasound.

In the non-randomised studies, treatment was decided based on the discretion of the treating physician (table 1).

The age of the infant at inclusion varied from 1 day to 4 months. Follow-up was performed with ultrasound and radiograph and the maximum follow-up duration ranged from 3 months to 6 years (table 1). If sufficient progression of hip development was found, treatment was discontinued in the treated infants. Sufficient progression was defined as: the acetabular coverage to have become normal (greater than 50% cover) at 6 weeks or if the radiograph was normal (showing no signs of dysplasia and an acetabular angle of <30°) at 3 and 4 months[21]; an alpha angle>53° at 6 weeks or an alpha angle≥55° at 3 months or an AI of ≤2 SDs above the mean at 6 months[22 23]; improvement of the alpha angle at 6 or 12 weeks[2]; an alpha angle≥60°/Graf type 1/non-convex shape of the acetabulum/coverage of the femoral head of ≥50% in the non-stress view or ≥40% in the stress view or

an AI of ≤2 SDs above the mean[24]; or an alpha angle≥60° and FHC≥50% or an AI≤2 SDs above the mean.[25] In case of insufficient progression or deterioration of the dysplasia, treatment was initiated in the observed infants or continued in the treated infants (table 2). The number of infants in the observation group that switched to the treatment group are reported in the 'Treatment switch' column in table 2.

Radiological results

Two studies reported statistically significant differences in alpha angle or average acetabular coverage between observed and treated infants at 3 months.[21 22] One of these two studies also showed an increased treatment effect of abduction treatment compared with observation at 1.5 and 3 months.[22] After 3 months, none of the studies showed statistically significant differences in AI between the treatment group and observation group. Also, one study did not show an increased treatment effect of abduction treatment compared with observation at 12 months.[22]

Three of the six included studies reported that infants in the observation group had switched to the abduction treatment group. Reasons for this switch were an alpha angle<50° at 6 (n=11) or 10 weeks (n=1), an alpha angle<55° at 3 months (n=12) or an AI>2 SDs above the mean (n=5),[22] deterioration of the alpha angle at six (n=3) or 12 weeks (n=7)[2] and persistent ultrasonic dysplasia (n=2).[25] In total, 38 infants (12%) in the observation group switched to the abduction group.

At the end of the follow-up duration, 21 observed hips and 32 treated hips were still dysplastic. One study, examining the long-term effects of abduction treatment and observation in the study population of Rosendahl *et al*, reported zero observed and one treated hip to still be dysplastic at the age of 6 years (table 2). From the treatment group, two infants received an arthrogram without further surgical intervention,[21] one infant had a Salter osteotomy,[23] and two infants were treated with closed reduction and spica cast.[2] None of the infants of the observation group had a surgical intervention.

DISCUSSION

This systematic review explores one of the most pressing questions in DDH care, namely whether abduction treatment alters the natural course of stable DDH hips. This systematic review suggests that there are no differences in outcome between abduction treatment and observation in infants up to 4 months of age with stable DDH hips. Two studies reported a faster improvement of the alpha angle and average acetabular coverage in stable DDH hips that received abduction treatment at 3 months.[21 22] However, none of the six studies reported differences in AI between the treatment and observation group after 3 months.

A total of 38 infants (12%) in the observation group switched to the abduction group. This finding supports current literature that 80%–85% of stable DDH hips will spontaneously progress into normal hips.[6 14] Thereby adding evidence to the hypothesis that ultrasonography is not able to differentiate between truly pathological hips and immature hips.[6] In all studies, treatment switch was based on radiological characteristics. Although exact radiological definitions differed between studies, complicating the comparison of results. Also, two of the three studies in which infants switched groups reported that results were analysed according to the intention-to-treat principle. This might result in more optimistic results of the observation group. However, the intention of active monitoring is to actively monitor and intervene when necessary. Therefore, the intention-to-treat principle might be the best approach to represent the clinical situation. The switch of infants from the observation group to the treatment group corroborates that not all infantile DDH hips will spontaneously progress into normal hips. Possible disadvantages of active monitoring are that if treatment is warranted at a certain point, treatment is initiated at a later age and the treatment duration might be longer. However, one study reported that the median treatment duration was similar in the observation group and treatment group, namely 12 weeks.[22]

One of the included studies found no correlation between the severity of Graf classification at birth and the subsequent presence of DDH.[24] None of the other studies examined predictors of final radiographic outcome. It might be argued that early screening results in the diagnosis of more infants with hips that will spontaneously progress into normal hips and that later diagnosis will include more truly pathological hips. This hypothesis is supported by a recent prospective cohort study.[26] This study proposes screening at the age of 2 or 3 months or implementation of a wait and see policy for immature hips. Active monitoring around 2 or 3 months of age might aid in detecting late and truly pathological DDH hips while limiting overtreatment, as supported by this systematic review. However, none of the included studies analysed the relationship between initial age at diagnosis and final radiological outcome.

Limitations

The principal limitation of this systematic review is the methodological heterogeneity between the included studies. Age at diagnosis, (radiological) criteria for diagnosis and classification, follow-up schemes and criteria to initiate treatment in the observation group showed great variety. For instance, although all hips included in this review were classified as stable, only some could be attributed to Graf type IIb or IIc. Also, definitions of sufficient hip progression on ultrasonography varied between the included studies. Currently, normal values and values for truly pathological hips in infant hip ultrasonography are lacking.[2] This heterogeneity has limited the comparison of study results and a meta-analysis was not feasible. Also, the study quality varied for the included studies, with two non-randomised studies classified as serious

Table 2 Overview of the results and conclusions of the included studies

Reference	Results					Treatment switch	Conclusion
Wood *et al*[21]	Time	Outcome measure	Observed (n=18 hips)	Pavlik Harness (n=31 hips)	Treatment effect (CI)	Unclear	This study found no evidence that splintage for stable but dysplastic hips in young infants confers lasting benefit. Therefore, they do not recommend treatment in this patient group in the first 6 weeks. The known risks of splintage do not cover for the slight acceleration in hip-joint development. A follow-up with US and RTX at 3 months or later is recommended to prevent overtreatment and overdiagnosis of DDH.
	2–6 weeks (B)	FHC (%)	32.8	36.7	n.a.		
	3–4 months	FHC (%)	48.6	54.3	n.a.		
	3–4 months	AI (°)	24.3	24.8	n.a.		
	2 years	AI (°)	23.5 (n=8)	21.6 (n=26)	n.a.		
	2 years	Hips dysplastic at final RTX (n)	0	2	n.a.		
Rosendahl *et al*[22]	Time	Outcome measure	Observed (n=64 infants)	Frejka pillow (n=64 infants)	Treatment effect (CI)	30 observed hips were treated after 6 weeks or 3 months because of insufficient progression of the a-angle	Although treatment from birth may cause more rapid normalisation in infants with stable but mild dysplastic hips, surveillance until the age of 6 weeks does not result in abnormal hips at 1 year of age. A strategy of active surveillance would reduce the overall treatment rate with 0.6% which has important implications for families and healthcare costs.
	1–3 days (B)	a-angle (°) (SD)	47.0 (±1.8)	47.0 (±1.7)	n.a.		
	6 weeks	a-angle (°) (SD)	55.2 (±0.51)	58.4 (±0.48)	6.5 (5.6 to 7.3)		
	3 months	a-angle (°) (SD)	59.0 (±0.48)	61.0 (±0.49)	4.1 (3.5 to 4.7)		
	6 months	AI (°) (SD)	24.7 (±0.42)	24.2 (±0.38)	−1.2 (−1.6 to 0.9)		
	1 year	AI (°) (SD)	24.2 (±0.40)	24.2 (±0.40)	0.0 (−0.3 to 0.3)		
	1 year	Hips dysplastic at final RTX (n)	4	7	n.a.		
Brurås *et al*[23]	Time	Outcome measure	Observed (n=41 infants)	Frejka Pillow (n=42 infants)	Treatment effect (CI)	n.a.	Infants with mild dysplastic and potentially unstable hips who are randomly assigned to receive US observation or immediate treatment, have radiographically normal hips at the age of 6 years without evidence of avascular necrosis.
	1 year	AI (°) (SD)	R: 24.5 (±3.6) L: 24.9 (±3.0)	R: 24.5 (±2.8) L: 24.4 (±3.6)	R: 0.0 (−0.4 to 0.4) L: −0.2 (−0.6 to 0.3)		
	6 years	AI (°) (SD)	R: 14.9 (±3.9) L: 13.3 (±3.2)	R: 14.5 (±4.0) L: 13.6 (±3.2)	R: −0.1 (−0.5 to 0.3) L: 0.1 (−0.3 to 0.5)		
	6 years	Hips dysplastic at final RTX (n)	0	1			
Pollet *et al*[2]	Time	Outcome measure	Observed (n=49 infants)	Pavlik Harness (n=55 infants)	Treatment effect (CI)	6 hips in the observed group were treated after 6 weeks because of deterioration of the a-angle, 7 hips of the observed group were treated after 12 weeks because of persistent dysplasia	In this patient group, Pavlik harness treatment showed no difference compared with active surveillance after 12 weeks of observation. Treatment with Pavlik harness did not accelerate the improvement of the a-angle. Observation of well-centred sonographic hips up to 6 months seems sufficient to avoid overtreatment and to identify hips that do not stabilise spontaneously.
	3–4 months (B)	a-angle (°) (SD)	55.0 (±2.8)	54.2 (±3.3)	n.a.		
	5 months	a-angle (°) (SD)	58.0 (±5.2)	58.8 (±5.5)	0.1 (−0.2 to 0.5)		
	6–7 months	a-angle (°) (SD)	60.0 (±5.6)	60.5 (±3.8)	0.1 (−0.3 to 0.5)		
	9 months	AI (°) (SD)	26.2 (±5.0) (n=40)	26.4 (±4.6) (n=50)	0.0 (−0.4 to 0.5)		
	2 years	AI (°) (SD)	23.0 (±4.4) (n=31)	22.9 (±5.1) (n=40)	0.0 (−0.5 to 0.4)		
	2 years	Hips dysplastic at final RTX (n)	13	16	n.a.		

Continued

Table 2 Continued

Reference	Results					Treatment switch	Conclusion
Sucato *et al*[24]	Time	Outcome measure	Observed (n=149 hips)	Pavlik harness (n=43 hips)	Treatment effect (CI)	n.a.	Treatment of hips in infants younger than 4 weeks with a normal clinical hip examination without evidence of hip instability is not necessary at that time. Ultrasonography at that time is too sensitive and has no predictive value for the development of DDH. Ultrasonography should be used in an older age group (>1 month).
	<1 month (mean=12.7 days) (B)	a-angle (°) (SD)	56.4 (±6.6)	53.1 (±6.5)	n.a.		
	<1 month (mean=12.7 days) (B)	FHC (%) SD	42.9 (±9.0)	40.8 (±11.1)	n.a.		
	3–50 months (mean=15.9 months)	Hips dysplastic at final RTX (n)	2	0	n.a.		
Kim *et al*[25]	Time	Outcome measure	Observed (n=44 hips)	Pavlik harness (n=27 hips)	Treatment effect (CI)	2 hips in the observed group were treated after 4–8 weeks	Ninety-three percent of the observed infants had good outcome at 2-year follow-up suggesting that milder ultrasonic hip dysplasia can be observed with a good, expected outcome. An RCT is suggested to evaluate the role of abduction treatment for stable DDH.
	6 weeks (B)	a-angle (°) (SD)	48.9 (±3.9)	48.8 (±3.5)	n.a.		
	6 weeks (B)	FHC (%) SD	38.3* (±7.7)	32.2* (±9.1)	n.a.		
	2 years	AI (°) (SD)	22.1 (±3.5)	20.9 (±4.7)	−0.3 (−0.8 to 0.2)		
	2 years	Hips dysplastic at final RTX (n)	2	6	n.a.		
Total*			21 hips dysplastic at final RTX	32 hips dysplastic at final RTX		45 observed hips treated in study period	

Normal ranges: a-angle>60° beyond 3 months.[27] AI<25° beyond 1 year.[28] FHC >50%.[29]
*Totals were calculated excluding Brurås *et al*.[23]
AI, Acetabular Index; B, baseline; DDH, developmental dysplasia of the hip; FHC, femoral head coverage; L, left hip; n.a, not applicable; R, right hip; RCT, randomised controlled trials; RTX, radiograph; US, ultrasound.

risk of bias. After careful consideration, we have decided to include these two studies in this review to present a complete overview of current literature. Finally, the study of Burås *et al* is a 6-year follow-up derived from the study of Rosendahl *et al* and was included to gain insight on long-term outcomes. Since both studies included the same infants, the study of Burås *et al* was not used for calculating the total number of infants (female, male), hips (observed, treated, Graf type) and treatment switches reported in this review (tables 1 and 2).

Future directions

This systematic review suggests that abduction treatment and observation (±delayed treatment) do not result in different outcomes in infants up to 4 months of age with stable DDH hips. However, the included studies have small population sizes and show considerable methodological heterogeneity. Therefore, a RCT is warranted to study this research question in a large population. Ideally, RCTs would be embedded in current standard care follow-up routines. Since differentiating between truly pathological hips and immature hips that will naturally progress into normal hips is currently impossible, this research question remains the most pressing question in DDH care. Consequently, the development of an ultrasound classification system that will distinguish truly pathological hips from immature hips should be pursued. Also, the relation between patient demographics (e.g., age at diagnosis) and radiological criteria, as well as the relation between final radiological outcome and need to switch from observation to treatment group should be further explored. Prospective cohort studies using national registries might play an important role. Furthermore, the cost-effectiveness of observation compared with abduction treatment should be explored in a large trial.

Conclusion

Whereas two studies reported a faster improvement of the alpha angle and average acetabular coverage in stable DDH hips that received abduction treatment at 3 months, none of the six studies reported differences in AI between the treatment and observation group after 3 months in infants up to 4 months of age with stable DDH hips. The switch of 38 infants (12%) from the observation group to the treatment group corroborates that not all infantile DDH hips will spontaneously progress into normal hips.

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Patient consent for publication Not applicable.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

ORCID iD

Frederike E C M Mulder http://orcid.org/0000-0001-9307-1198

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SUPPLEMENTAL MATERIAL

Online supplementary appendix 1: PRISMA abstract checklist and PRISMA checklist

Table 3: PRISMA abstract checklist and PRISMA checklist

Section and Topic	Item #	Checklist item	Reported (Yes/No)
TITLE			
Title	1	Identify the report as a systematic review.	Yes
BACKGROUND			
Objectives	2	Provide an explicit statement of the main objective(s) or question(s) the review addresses.	Yes
METHODS			
Eligibility criteria	3	Specify the inclusion and exclusion criteria for the review.	Yes
Information sources	4	Specify the information sources (e.g. databases, registers) used to identify studies and the date when each was last searched.	Yes
Risk of bias	5	Specify the methods used to assess risk of bias in the included studies.	Yes
Synthesis of results	6	Specify the methods used to present and synthesise results.	Yes
RESULTS			
Included studies	7	Give the total number of included studies and participants and summarise relevant characteristics of studies.	Yes
Synthesis of results	8	Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (i.e. which group is favoured).	Yes
DISCUSSION			
Limitations of evidence	9	Provide a brief summary of the limitations of the evidence included in the review (e.g. study risk of bias, inconsistency and imprecision).	Yes
Interpretation	10	Provide a general interpretation of the results and important implications.	Yes
OTHER			
Funding	11	Specify the primary source of funding for the review.	Yes
Registration	12	Provide the register name and registration number.	Yes

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Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 0
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 4-5
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 5
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 6-7
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 5-6
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Appendix 2
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 6-7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 6-7
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 7
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Page 7

Section and Topic	Item #	Checklist item	Location where item is reported
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 7
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 7
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 7
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Page 7
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Table 1-2
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Not applicable
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Not applicable
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Not applicable
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Appendix 3-4
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not applicable
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 8
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 8, Figure 1
Study characteristics	17	Cite each included study and present its characteristics.	Page 8-9, Table 1-2

Section and Topic	Item #	Checklist item	Location where item is reported
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Page 8, Appendix 3-4
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Page 9-10, Table 1-2
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Table 1-2, Appendix 3-4
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Not applicable
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Not applicable
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not applicable
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Appendix 3-4
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Not applicable
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Page 11-12
	23b	Discuss any limitations of the evidence included in the review.	Page 12
	23c	Discuss any limitations of the review processes used.	Page 12
	23d	Discuss implications of the results for practice, policy, and future research.	Page 13
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 2
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Page 5-6
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Not applicable

Section and Topic	Item #	Checklist item	Location where item is reported
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Page 2
Competing interests	26	Declare any competing interests of review authors.	Page 1
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; **data extracted from included studies; data used for all analyses;** analytic code; any other materials used in the review.	Supplementary files

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Online supplementary appendix 2: Search string

a) PubMed

"Hip Dislocation, Congenital"[Mesh] OR DDH[tiab] OR CHD[tiab] OR Graf type 1[tiab] OR Graf type I[tiab] OR Graf type 2[tiab] OR Graf type II[tiab] OR Graf type 2b[tiab] OR Graf type 2c[tiab] OR Graf type IIb[tiab] OR Graf type IIc[tiab] OR ((dysplasia*[tiab] OR dyplasia*[tiab] OR dysplastic[tiab] OR dislocation*[tiab] OR displacement*[tiab]) AND ("Hip"[Mesh] OR "Hip Joint"[Mesh] OR hip[tiab] OR hips[tiab] OR coxa*[tiab])) NOT (heart disease*[tw] OR cardiolog*[tw] OR cardiovas*[tw] OR cardiac*[tw])

AND

("Equipment and Supplies"[Mesh:NoExp] OR "equipment and supplies"[tiab] OR Pavlik harness*[tiab] OR abduction device*[tiab] OR abduction brace*[tiab] OR bracing*[tiab] OR fixation*[tiab] OR splint*[tiab]) OR ("Watchful Waiting"[Mesh] OR watchful waiting[tiab] OR active surveillance[tiab] OR active monitoring[tiab] OR "wait-and-see"[tiab] OR conservative management[tiab] OR conservative treatment[tiab] OR "without treatment"[tiab] OR "no treatment"[tiab] OR "not treated"[tiab] OR observation*[tiab])

AND

"Diagnostic Imaging"[Mesh:NoExp] OR "Diagnostic imaging"[Subheading] OR (diagnostic[tiab] AND (imaging[tiab] OR image*[tiab])) OR "Ultrasonography"[Mesh] OR ultraso*[tiab] OR sonograph*[tiab] OR echograph*[tiab] OR echotomograph*[tiab] OR "Radiography"[Mesh] OR X-ray*[tiab] OR roentgen*[tiab]

AND

"Infant"[Mesh] OR child*[tiab] OR infan*[tiab] OR pediatri*[tiab] OR paediatr*[tiab] OR neonat*[tiab] OR neo-nat*[tiab] OR baby[tiab] OR babies[tiab] OR newborn*[tiab] OR new-born*[tiab] OR postneonat*[tiab] OR post-neonat*[tiab] OR postnat*[tiab] OR post-nat*[tiab] OR perinat*[tiab] OR peri-nat*[tiab]

b) Embase

Congenital hip dislocation/ OR (DDH OR CHD OR Graf type 1 OR Graf type I OR Graf type 2 OR Graf type II OR Graf type 2b OR Graf type 2c OR Graf type IIb OR Graf type IIc).ti,ab,kw. OR ((dysplasia* OR dyplasia* OR dysplastic OR dislocation* OR displacement*).ti,ab,kw. AND (hip/ OR (hip OR hips OR coxa*).ti,ab,kw.)) NOT (heart disease*.mp OR cardiolog*.mp. OR cardiovas*.mp. OR cardiac*.mp.)

AND

Devices/ OR ("equipment and supplies" OR Pavlik harness* OR abduction device* OR abduction brace* OR bracing* OR fixation* OR splint*).ti,ab,kw. OR (Watchful waiting/ OR (watchful waiting OR active surveillance OR active monitoring OR "wait-and-see" OR conservative management OR conservative treatment OR "without treatment" OR "no treatment" OR "not treated" OR observation*).ti,ab,kw.)

AND

Diagnostic imaging/ OR Diagnostic imaging equipment/ OR Diagnostic imaging.sh. OR (diagnostic.ti,ab,kw. AND (imaging OR image*).ti,ab,kw.) OR Echography/ OR radiography/ OR X-ray/ OR (echograph* OR ultraso* OR sonograph* OR echotomograph* OR X-ray* OR roentgen*).ti,ab,kw.

AND

Infant/ OR Baby/ or Newborn/ OR child/ OR (child* OR infan* OR pediatri* OR paediatr* OR neonat* OR neo-nat* OR baby OR babies OR newborn* OR new-born* OR postneonat* OR post-neonat OR postnat* OR post-nat* OR perinat* OR peri-nat*).ti,ab,kw.

c) Cochrane

((DDH OR CHD OR Graf type 1 OR Graf type I OR Graf type 2 OR Graf type II OR Graf type 2b OR Graf type 2c OR Graf type IIb OR Graf type IIc):ti,ab,kw OR ((dysplasia* OR dyplasia* OR dysplastic OR dislocation* OR displacement*):ti,ab,kw AND ((hip OR hips OR coxa*):ti,ab,kw)) NOT (heart disease* OR cardiolog* OR cardiovas* OR cardiac*):ti,ab,kw AND (("equipment and supplies" OR Pavlik harness* OR abduction device* OR abduction brace* OR bracing* OR fixation* OR splint*):ti,ab,kw OR (watchful waiting OR active surveillance OR active monitoring OR "wait-and-see" OR conservative management OR conservative treatment OR "without treatment" OR "no treatment" OR "not treated" OR observation*):ti,ab,kw) AND ((diagnostic:ti,ab,kw AND (imaging OR image*):ti,ab,kw) OR (echograph* OR ultraso* OR sonograph* OR echotomograph* OR X-ray* OR roentgen*):ti,ab,kw) AND ((child* OR infan* OR pediatri* OR paediatr* OR neonat* OR neo-nat* OR baby OR babies OR newborn* OR new-born* OR postneonat* OR post-neonat OR postnat* OR post-nat* OR perinat* OR peri-nat*):ti,ab,kw)

d) Web of Science

DDH OR CHD OR "Graf type 1" OR "Graf type I" OR "Graf type 2" OR "Graf type II" OR "Graf type 2b" OR "Graf type 2c" OR "Graf type IIb" OR "Graf type IIc" OR ((dysplasia* OR dyplasia* OR dysplastic OR dislocation* OR displacement*) AND ("Hip" OR "Hip Joint" OR hip OR hips OR coxa*)) NOT (heart disease* OR cardiolog* OR cardiovas* OR cardiac*)

AND

("equipment and supplies" OR Pavlik harness* OR abduction device* OR abduction brace* OR bracing* OR fixation* OR splint*) OR ("Watchful Waiting" OR watchful

waiting OR active surveillance OR active monitoring OR "wait-and-see" OR conservative management OR conservative treatment OR "without treatment" OR "no treatment" OR "not treated" OR observation*)

AND

(diagnostic AND (imaging OR image*)) OR "Ultrasonography" OR ultraso* OR sonograph* OR echograph* OR echotomograph* OR "Radiography" OR X-ray* OR roentgen*

AND

child* OR infan* OR pediatri* OR paediatr* OR neonat* OR neo-nat* OR baby OR babies OR newborn* OR new-born* OR postneonat* OR post-neonat* OR postnat* OR post-nat* OR perinat* OR peri-nat*

Online supplementary appendix 3: Risk of bias assessment complete

Table 4: Risk of Bias assessment with revised Cochrane risk of bias tool for randomized trials (RoB 2.0) and Cochrane tool for risk of bias in non-randomized studies (ROBINS-I)

Author/year	Study design	Risk of Bias
Wood et al., 2000	RCT	Selection bias: randomization not clearly described, baseline differences between groups, **some concerns** Performance bias: unclear if deviations from intervention occurred and if appropriate analysis was used, **some concerns** Attrition bias: some hips excluded after initial misclassification resulting in missing data, **some concerns** Detection bias: appropriate measurement methods, independent observer, **low** Reporting bias: data were analyzed according to plan, **low** Overall: **Some concerns**
Rosendahl et al., 2010	RCT	Selection bias: random allocation, no baseline differences (except for gender), **low** Performance bias: deviations from intended intervention were not balanced between groups, but were corrected for in appropriate analysis, **low** Attrition bias: data available for nearly all patients, missing data evenly distributed among both groups, **low** Detection bias: measurement methods appropriate and the same between groups, outcome assessor unaware of intervention received, **low** Reporting bias: data were analyzed according to plan, **low** Overall: **Low**
Brurås et al., 2010	RCT	Selection bias: random allocation, no baseline differences, **low** Performance bias: number deviations from intended intervention unclear, appropriate analysis used, **low** Attrition bias: data available for 65% of the patients, missing data evenly distributed among both groups, **low** Detection bias: measurement methods appropriate and the same between groups, outcome assessor unaware of intervention received, **low** Reporting bias: data were analyzed according to plan, **low** Overall: **Low**
Pollet et al., 2020	RCT	Selection bias: random allocation and comparable groups, but long inclusion duration and many patients withdrew consent, **some concerns** Performance bias: unclear if both groups received same care, appropriate analysis used, **unclear** Attrition bias: Many patients withdrew consent, but appropriate analysis used, **low** Detection bias: measuring method appropriate but at an early time, outcome assessors unaware of intervention received, **low** Reporting bias: data were analyzed according to plan, **low** Overall: **Some concerns**
Sucato et al., 1999	Retrospective cohort	Confounding bias: switches were likely to be related to outcome, but appropriate analysis used **moderate** Selection bias: in- and exclusion criteria clearly stated, start and follow-up time similar for both groups, **low** Recall bias: intervention groups clearly defined but intervention status likely to influenced by knowledge of the outcome, **serious** Performance bias: no deviations from intended interventions because of retrospective nature of the study, **low** Attrition bias: outcomes available for nearly all patients, no patients excluded because of missing data, **low** Detection bias: outcome assessors aware of intervention but methods comparable across groups and no systematic errors in measurement, **moderate** Reporting bias: reported effect not likely to be dependent on multiple measurements, analysis or subgroups, **low** Overall: **Serious**
Kim et al., 2019	Prospective cohort	Confounding bias switches were likely to be related to outcome, but appropriate analysis used, **moderate** Selection bias: in- and exclusion criteria clearly stated, start and follow-up time similar for both groups, **low** Recall bias: intervention groups clearly defined but intervention status likely to influenced by knowledge of the outcome, **serious** Performance bias: no deviations from intended intervention beyond expected in normal practice, appropriate analyses used for deviations, **low** Attrition bias: outcome data not available for all infants, but proportion was similar across groups, **low** Detection bias: outcome assessors unaware of intervention, methods comparable across groups and no systematic errors in measurement, **low** Reporting bias: reported effect not likely to be dependent on multiple measurements, analysis or subgroups, **low** Overall: **Serious**

Note: Randomized controlled trial (RCT)

Online supplementary appendix 4: Risk of bias assessment overview

Table 5: Overview of risk of bias assessment with revised Cochrane risk of bias tool for randomized trials (RoB 2.0) and Cochrane tool for risk of bias in non-randomized studies (ROBINS-I)

	Confounding bias	Selection bias	Recall bias	Performance bias	Attrition bias	Detection bias	Reporting bias	**Overall**
RCT (RoB 2.0)								
Wood, 2000	n.a.	Some concerns	n.a.	Some concerns	Some concerns	Low	Low	**Some concerns**
Rosendahl, 2010	n.a.	Low	n.a.	Low	Low	Low	Low	**Low**
Brurås, 2011	n.a.	Low	n.a.	Low	Low	Low	Low	**Low**
Pollet, 2020	n.a.	Some concerns	n.a.	Unclear	Low	Low	Low	**Some concerns**
Cohort (ROBINS-I)								
Sucato, 1999	Moderate	Low	Serious	Low	Low	Moderate	Low	**Serious**
Kim, 2019	Moderate	Low	Serious	Low	Low	Low	Low	**Serious**

Note: Randomized controlled trial (RCT), not applicable (n.a.)