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Instruments for assessing readiness to commence suck feeds in preterm infants: effects on time to establish full oral feeding and duration of hospitalisation (Review)

Crowe L, Chang A, Wallace K

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[Intervention Review]

Instruments for assessing readiness to commence suck feeds in preterm infants: effects on time to establish full oral feeding and duration of hospitalisation

Linda Crowe[1], Anne Chang[2], Karen Wallace[3]

[1]Nursing Research Centre, Mater Health Services, Brisbane, Australia. [2]School of Nursing, Queensland University of Technology, Brisbane, Australia. [3]Mater Mothers Hospital, Mater Health Services, Brisbane, Australia

Contact address: Linda Crowe, Nursing Research Centre, Mater Health Services, Brisbane, Australia. lindacrowe@hotmail.com.

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ABSTRACT

Background

One of the most challenging milestones for preterm infants is the acquisition of safe and efficient feeding skills. The majority of healthy full term infants are born with skills to coordinate their suck, swallow and respiration. However, this is not the case for preterm infants who develop these skills gradually as they transition from tube feeding to suck feeds. For preterm infants the ability to engage in oral feeding behaviour is dependent on many factors. The complexity of factors influencing feeding readiness has led some researchers to investigate the use of an individualised assessment of an infant's abilities. A limited number of instruments that aim to indicate an individual infant's readiness to commence either breast or bottle feeding have been developed.

Objectives

To determine the effects of using a feeding readiness instrument when compared to no instrument or another instrument on the outcomes of time to establish full oral feeding and duration of hospitalisations.

Search methods

We used the standard search strategy of the Cochrane Neonatal Review group to search the Cochrane Central Register of Controlled Trials (CENTRAL 2016, Issue 1), MEDLINE via PubMed (1966 to 22 February 2016), EMBASE (1980 to 22 February 2016), and CINAHL (1982 to 22 February 2016). We also searched clinical trials' databases, conference proceedings, and the reference lists of retrieved articles for randomised controlled trials and quasi-randomised trials**.**

Selection criteria

Randomised and quasi-randomised trials comparing a formal instrument to assess a preterm infant's readiness to commence suck feeds with either no instrument (usual practice) or another feeding readiness instrument.

Data collection and analysis

The standard methods of Cochrane Neonatal were used. Two authors independently screened potential studies for inclusion. No studies were found that met our inclusion criteria.

Main results

No studies met the inclusion criteria.

Authors' conclusions

There is currently no evidence to inform clinical practice, with no studies meeting the inclusion criteria for this review. Research is needed in this area to establish an evidence base for the clinical utility of implementing the use of an instrument to assess feeding readiness in the preterm infant population.

PLAIN LANGUAGE SUMMARY

Instruments for assessing readiness to commence suck feeds in preterm infants

Review question: Does using an assessment tool which has been designed to assess preterm infants' readiness to commence breast or bottle feeding improve feeding outcomes and decrease length of stay?

Background: Unlike babies born at term, who are able to breast or bottle feed soon after birth, preterm infants need time to learn to feed. This may take days or weeks after they are born. Preterm babies commence breast or bottle feeding at a time when the baby is deemed to be ready, as determined by healthcare professionals looking after the baby. The optimal timing of the introduction of suck feeds is unclear in both the literature and in practice. An individualised assessment specifically designed to assess an individual infant's readiness to commence breast or bottle feeding has been suggested as the best way to promote consistency in identifying when it is safe for an infant to commence breast or bottle feeding.

Study characteristics: No studies were found that met the inclusion criteria on this review.

Key results/Conclusion: Although a limited number of assessment tools to determine feeding readiness currently exist, no studies were found that evaluated the benefit or risk to the preterm infant. As a result, it is unclear to what extent a feeding readiness tool would assist healthcare professionals to decide when to introduce breast or bottle feeding to the preterm infant.

Quality of evidence: No evidence was found.

BACKGROUND

Description of the condition

One of the most challenging milestones for preterm infants is the acquisition of safe and efficient feeding skills (Hill 2002). The majority of healthy full-term infants are born with skills to coordinate suck, swallow and respiration that allow safe oral feeding (Lau 2003). However, this is not the case for preterm infants who develop these skills gradually as they transition from tube feeding to suck feeds (Thoyre 2003; Dodrill 2008a). This transition to full oral feeding is an important competency for the baby to attain prior to discharge home (Pickler 2003). Delays in discharge are often secondary to feeding difficulties, leading to increased financial costs (Simpson 2002). Strategies to avoid delays must be the focus of care without compromising the safety of the infant (McGrath 2004).

Introducing suck feeds as soon as the neurologic development and physical condition of the infant permits has been reported to have several advantages including shorter transition time to all suck feeds, greater maternal satisfaction and shorter hospital stay (Pridham 1993; Simpson 2002). However, feeding infants who are unable to safely commence feeding may lead to problems with respiration, growth and nutritional status, with infants being at higher risk of 1) aspiration pneumonia, 2) readmission to the neonatal intensive care unit (NICU), 3) fatigue, 4) increased energy expenditure, 5) hypoxia, 6) bradycardia and 7) deglutition apnoea (Hill 2002; Breton 2008). Therefore, careful timing is vital to ensure that the commencement of feeding is beneficial rather than detrimental to the health of the infant (McGrath 2004).

Factors influencing the preterm infant's ability to feed efficiently

include neurobehavioural maturation, physiologic stability, control of tone, behavioural state organisation and coordinated sucking, swallowing and breathing (McGrath 2004). Successful coordination of feeding is also dependent on the adequate development of the structures of the upper airway including the lips, palate, jaw, tongue, pharynx, larynx and oesophagus (Hill 2002).

Differences have been shown in the ability of infants to engage in feeding behaviour at a particular gestational age through studies of preterm infant sucking (Nyqvist 1996; Lemons 2001). Although gestational age is a guide to expected maturity, disparities are evident in the rates that infants mature (Nyqvist 1999; Simpson 2002). Furthermore, a preterm infant's feeding ability may not always be consistent at each feed while infants are transitioning from gavage feeds (McGrath 2004). Differences in the sucking patterns between breast and bottle feeding have also been found and may impact significantly on the infant's ability to commence suck feeds (Thoyre 2003).

Studies examining current practices in neonatal nurseries have found that over 50% of nurseries have no specific policy or guideline on when to commence suck feeds with nurses predominantly using behavioural cues, gestation age and weight to determine readiness (Kinneer 1994; Siddell 1994).

Description of the intervention

Several instruments to aid neonatal care providers with determining a preterm infant's readiness to commence feeding have been described. The Preterm Infant Nipple Feeding Readiness Scale (PINFRS) is a 10-item scale that scored variables such as gestational age, post-conceptual age, colour and activity, state regulation, hunger cues and tone (McGrath 2003). However, this instrument has been renamed as the Feeding Readiness and Progression in Preterms Scale (FRAPPS) (McGrath 2008). The second instrument, the Early Feeding Skill (EFS) assessment tool, not only aims to assess feeding readiness but also feeding skill and feeding recovery (Thoyre 2005). The feeding readiness section of the EFS consists of five items that assess an infant's readiness to commence oral feeds by observing its tone, energy level, state of arousal and oxygen saturation (Thoyre 2005). Lastly, Fuginaga 2007a developed and tested an 18-item preterm infant oral feeding readiness instrument consisting of items in relation to corrected gestational age, behavioural state, global posture and tone, gag reflex, tongue movement and cupping, jaw movements and maintenance of an alert state. Each item is scored from 0 to 2 with a possible maximum score of 36.

All instruments were designed so that the infant being assessed for feeding readiness could pass or fail. These assessments aim to determine whether to attempt breast or bottle feeding and may easily be repeated prior to each feed while feeding is being established.

How the intervention might work

The use of a formal screening instrument that encompasses an individual infant's behaviour and development has been suggested as a way to improve the accuracy of determining when the infant is ready to commence feeding (McGrath 2003). It is thought that many preterm babies may be ready to breast or bottle feed; however, as this readiness is often not identified they continue to be fed via a tube for longer than necessary. Alternatively, some babies who are slower at developing these skills may be introduced to breast or bottle feeding too soon. It is hypothesised that by identifying their readiness, neonatal care providers could ensure that infants have more successful feeding attempts and reduce the time taken to achieve all suck feeds and the possibility of adverse events. The use of a formalised instrument could also standardise measurement of feeding readiness and facilitate the documentation of feeding attempts.

Why it is important to do this review

The possible benefits of a screening instrument to assess feeding readiness must be weighed against the additional staff time required and other costs and possible detrimental effects such as introducing oral feeds when infants are not ready or withholding oral feeding. This review addresses the balance of benefits and risks of screening instruments for commencement of suck feeds in preterm infants in order to assist in establishing an evidence base for clinical decision-making.

OBJECTIVES

To determine the effects of using a feeding readiness instrument when compared to no instrument or another instrument on the outcomes of time to establish full oral feeding and duration of hospitalisations.

The primary objectives

1. To assess the effects of using a formal feeding readiness assessment instrument when compared to no formal instrument in preterm infants deemed ready to commence feeds based on general clinical grounds using the outcomes of time to establish full oral feedings and duration of hospitalisations.
2. To assess the effects of different formal feeding readiness assessment instruments in preterm infants deemed ready to commence feeds based on general clinical grounds using the outcomes of time to establish full oral feedings and duration of hospitalisations.

The secondary objective

To explore possible differential effects of applying a formal feeding readiness assessment instrument according to the following subgroups:

1. Gestational age (GA) at birth:
   - extremely preterm (< 28 weeks)
   - very preterm (28 to 31 weeks)
   - mildly preterm (32 to 37 weeks)

2. Chosen method of feeding:
   - breast or bottle feeding

METHODS

Criteria for considering studies for this review

Types of studies

Randomised and quasi-randomised controlled trials (including cluster trials) in which an instrument is compared with either no assessment instrument or an alternate instrument. Cross-over trials were excluded.

Types of participants

Studies which enrolled preterm infants (< 37 weeks gestation) after being deemed ready to commence either breast or bottle feeds based on general clinical grounds. Exclusion criteria included congenital malformations, syndromes or severe neurological problems.

Types of interventions

1. The experimental group involved infants who had been deemed ready on general clinical grounds and who were then assessed for readiness to commence oral feeding through the use of an instrument prior to the initiation of the first breast or bottle feed. The instrument had to include assessment of one or more of the following:
a) motor development and abilities including posture, movement, tone, reflexes;
b) behaviour state and cues including state of arousal and presence of feeding behaviour cues;
c) physiological parameters;
d) integrity of oral structures.
2. The control group involved infants who were not assessed by any formal instrument as feeding was commenced once readiness was determined on general clinical grounds.
3. A comparison group involved infants who had been deemed ready on general clinical grounds and who were then assessed for readiness to feed by an alternate feeding assessment instrument.
'General clinical grounds' was defined as a clinical impression, which may have included gestational age, medical stability or infant cues, but excluded the use of a formal assessment instrument. Instruments must have undergone psychometric evaluation including tests for criterion-related or construct validity. In groups where an instrument was used, infants had to pass prior to commencement of feeding. Physiological parameters included heart rate, respiration rate and oxygen saturation levels. Other physiological parameters used by individual trials were acceptable provided they were defined in the trial protocol.

Types of outcome measures

Primary outcomes

1. Time from randomisation to full oral feeding (days).
2. Duration of hospitalisations (days from randomisation until the end of the trial).

Secondary outcomes

1. Time from randomisation to introduction of first feed (days).
2. Age (post-conception age and days from birth) at establishment of full oral feeding.
3. Daily weight gain (g/day or g/kg/day) from time of randomisation until the end of the trial.
4. Breast feeding (partial or full) on hospital discharge (number of infants).
5. Time from randomisation to regaining birth weight (days).
6. Parental satisfaction (validated assessment tool).
7. Number of apnoea or bradycardia episodes that required intervention from the caregiver (stimulation, oronasal suction, increase in delivery of oxygen, assisted ventilation).

Search methods for identification of studies

We used the criteria and standard methods of Cochrane and Cochrane Neonatal (see the Cochrane Neonatal Group search strategy for specialized register).

Electronic searches

See Appendix 1 for previous search strategies.
For the 2016 update, we conducted a comprehensive search including: the Cochrane Central Register of Controlled Trials (CENTRAL 2016, Issue 1) in *The Cochrane Library*; MEDLINE via PubMed (1966 to 22 February 2016); EMBASE (1980 to 22

February 2016); and CINAHL (1982 to 22 February 2016). We used the following search terms: (infant, newborn OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or Newborn or infan* or neonat*) AND (commenc* OR start* OR begin* OR readiness OR Introduc*) AND (breast fe* OR breastfe* OR bottle fe* OR bottlefe* OR nipple fe* OR oral fe* OR ("Bottle Feeding") OR ("Breast Feeding") OR ("Infant Feeding") OR sucking behaviour OR sucking behavior OR (Sucking Behavior") OR feeding behavior OR feeding behavior), plus database-specific limiters for RCTs and neonates (see Appendix 2 for the full search strategies for each database). In addition we handsearched the reference lists of the full text articles that were retrieved. We did not apply language restrictions.

We searched clinical trials' registries for ongoing or recently completed trials (clinicaltrials.gov; the World Health Organization's International Trials Registry and Platform www.whoint/ictrp/search/en/; and the ISRCTN Registry).

Searching other resources

The authors also searched cited references from the retrieved articles. We contacted a number of researchers, who had either previously published an article on the topic of feeding readiness or were known to have completed preliminary psychometric testing of an instrument measuring feeding readiness, in order to identify any other studies that might meet the inclusion criteria.

Data collection and analysis

The standard methods of Cochrane Neonatal Review Group were used.

Selection of studies

Two authors (LC, KW or AC) independently screened the title and abstract of all studies identified by the above search strategy. Articles identified as potentially relevant based on the title and abstract were retrieved in a full text format and were then reassessed for selection. Those studies that did not fulfil the inclusion criteria were excluded. The authors resolved any disagreements by discussion.

Data extraction and management

If eligible studies had been found, two authors would have independently extracted and entered the data into tables using Review Manager (RevMan) 5 software. We intended to discuss any disagreements until we reached a consensus. If data from the trial reports was insufficient, we planned to contact the authors for further information.

Assessment of risk of bias in included studies

If eligible studies had been found, it was planned that these studies would be evaluated independently by two review authors (LC, KW or AC) for methodological quality in accord with the methods of Cochrane Neonatal.

We planned to evaluate the following issues in the 'Risk of bias' tables (Higgins 2011) for the following domains:

- selection bias
- performance bias
- attrition bias
- reporting bias
- any other bias

It was planned that any differences between the review authors would be resolved either by discussion or by consensus after negotiation with the third review author. See Appendix 3 for a more detailed description of risk of bias for each domain.

Measures of treatment effect

Weighted mean difference (WMD) would have been calculated for continuous data and relative risk (RR) or risk difference (RD) for dichotomous data. For each treatment effect we planned to calculate a 95% confidence interval (CI).

Unit of analysis issues

We planned that the unit of analysis would be the participating infant in individually-randomised trials and the neonatal unit (or sub-unit) for cluster-randomised trials.

Dealing with missing data

We planned to contact the authors to obtain missing data or clarify any methodological issue if necessary. We planned to assess whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we planned to reinstate missing data in the analyses.

Assessment of heterogeneity

If there had been studies to synthesise in a meta-analysis, heterogeneity would have been assessed through the visual inspection of forest plots as well as by calculating the degree of heterogeneity statistically using the I^2 statistic. If moderate or high heterogeneity had been found (I^2 statistic > 50%), the review authors would have explored potential causes (inter-study variations, intra-study variations, methodological error, publication bias and control effect) in sensitivity analysis.

Assessment of reporting biases

If there had been enough included studies, we intended to conduct a funnel plot analysis.

Data synthesis

We planned to use the standard methods of the Neonatal Review Group to synthesise the data. If there had been eligible studies to conduct a meta-analysis, we would have used weighted mean difference with a 95% CI for the continuous variables; and relative risk and risk difference with 95% CI for categorical variables. We would also have calculated number needed to treat for an additional beneficial outcome (NNTB) and number needed to treat for an additional harmful outcome (NNTH), if appropriate. To conduct the meta-analysis, we planned to use a fixed-effect model. If any cluster trials were included in the review, we would have analysed these studies separately from non-cluster trials using the inverse variance (IV) method, in consultation with the Cochrane Neonatal statistician. We would have undertaken data analysis using RevMan 5 software. If there had been studies not suitable for meta-analysis then we would have summarised the results of these studies either in narrative form or in tables. We would have analysed instruments using separate comparisons according to the type of instrument.

Quality of evidence

If there had been included studies, we planned to use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, as outlined in the GRADE Handbook (Schünemann 2013), to assess the quality of evidence for the following (clinically relevant) outcomes: time from randomisation to full oral feeding (days), duration of hospitalisations (days from randomisation until the end of the trial) and age (post-conceptual age and days from birth) at full oral feeding.

Two authors planned to independently assess the quality of the evidence for each of the outcomes above. We planned to consider evidence from randomised controlled trials as high quality but downgrade the evidence one level for serious (or two levels for very serious) limitations based upon the following: design (risk of bias); consistency across studies; directness of the evidence; precision of estimates; and presence of publication bias. We planned to use the GRADEpro 2008 Guideline Development Tool to create a 'Summary of findings' table to report the quality of the evidence. The GRADE approach results in an assessment of the quality of a body of evidence in one of four grades:

1. High: We are very confident that the true effect lies close to that of the estimate of the effect.
2. Moderate: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
3. Low: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
4. Very low: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Subgroup analysis and investigation of heterogeneity

We planned subgroup analysis for the following subgroups, if data had been available: gestational age at birth (extremely preterm < 28 weeks; very preterm 28 to 31 weeks; and mildly preterm 32 to 37 weeks); and chosen method of feeding (breast or bottle feeding).

Sensitivity analysis

Post hoc subgroup analysis would have been performed to detect the heterogeneous trials.

RESULTS

Description of studies

See: Characteristics of excluded studies.

In the 2012 review, the initial search found 955 publications; the number to be reviewed was reduced to 716 once duplicates were removed. Two review authors reviewed the titles and abstracts of all 716 publications. Only 44 articles were retrieved in the full-text format for further consideration. However, no studies were found that met the inclusion criteria for this review.

Within the 44 excluded articles, nine articles were found not to be research but a review of the literature. These nine articles were retrieved in the full-text format in order to search the reference lists to ensure no studies were missed during the electronic searching of databases. Topics of the literature review articles included initiation of, and transition to, suck feeds (Lemons 1996; Ross 2002; Thoyre 2003; McGrath 2004; Frischknecht 2005; Fernández Díaz 2007; Lau 2007; Breton 2008) as well as the diagnostic tools used to determine feeding readiness (da Costa 2008).

A number of methods were found to assist staff in determining feeding readiness in the preterm infant population including a theoretical model (Pickler 2005a); clinical guidelines (Premji 2000; Premji 2002; McCain 2003); protocols (McCain 2001; Premji 2004; Shaker 2007; Drenckpohl 2009); a clinical pathway (Kirk 2007); and scales or instruments (McGrath 2003; Thoyre 2005; Fuginaga 2007a; Ludwig 2007).

Although there were two randomised trials that evaluated the clinical utility of the implementation of a feeding protocol found in the search (McCain 2001; McCain 2002), these studies did not compare assessment of feeding readiness with no assessment but

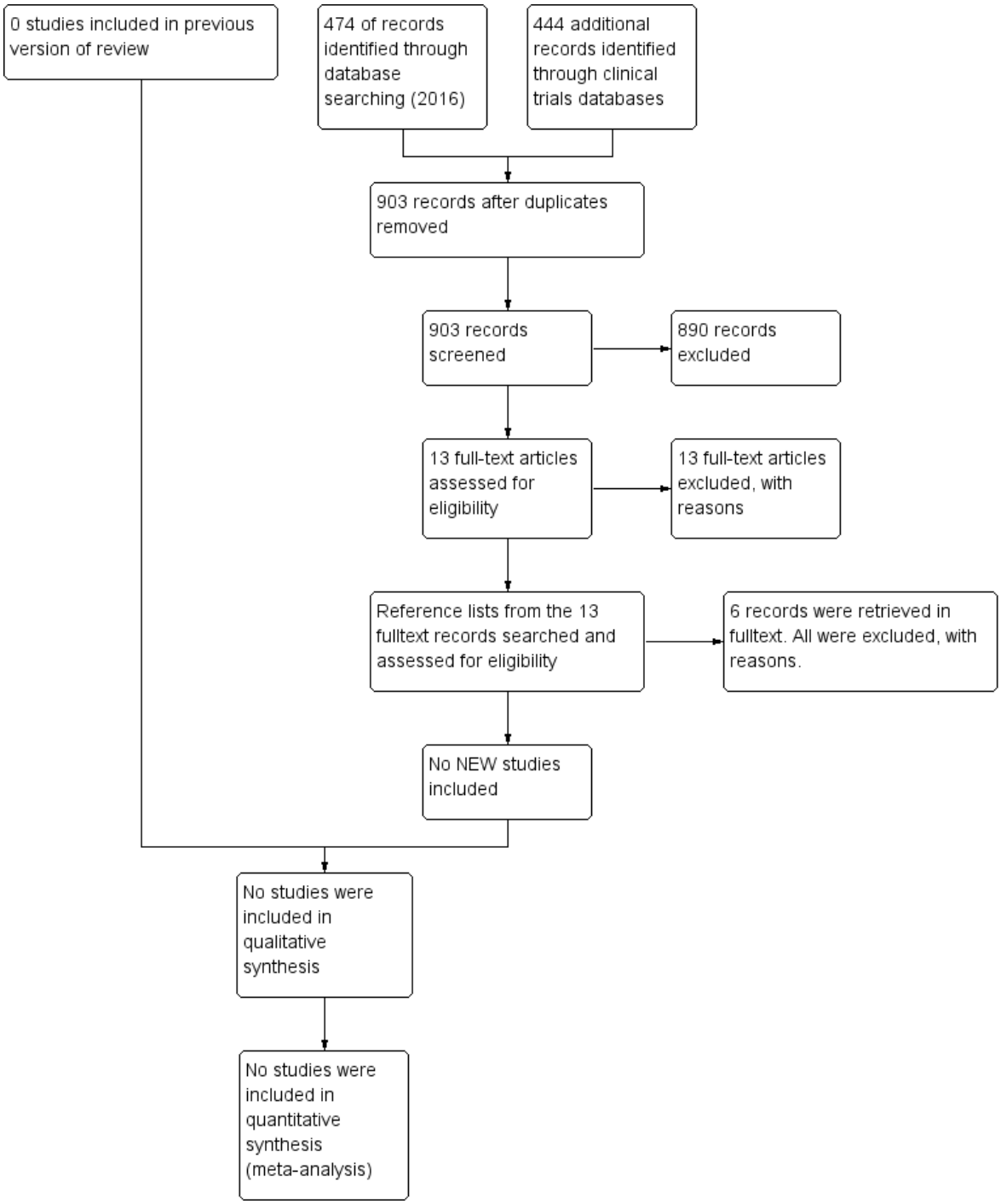
rather compared no non-nutritive sucking with the use of 10 minutes of non-nutritive sucking prior to assessing behavioural state as an indicator of feeding readiness. There were also two studies that used historical controls to evaluate their implementation into practice (Kirk 2007; Drenckpohl 2009). Other articles related to methods to determine feeding initiation or transition were either a description of the method (Premji 2002; McCain 2003; Premji 2004; Pickler 2005a; Thoyre 2005; Ludwig 2007; Shaker 2007) or psychometric testing of an instrument (McGrath 2003; Fuginaga 2007a; Fujinaga 2007b; Neiva 2008; Rossarolla 2009). Psychometric testing of the instruments did not involve an experimental design but rather other non-experimental designs such as observational studies and expert panels.

A further three observational studies were found that described the psychometric testing of instruments that either did not measure or indirectly measured the construct of feeding readiness. The Dynamic-Early Feeding Scale (D-EFS) is an observational coding scheme to continuously code videotaped oral feeding (Thoyre 2009). This instrument should not be confused with another instrument developed by the authors, the Early Feeding Skills (EFS) (Thoyre 2005), which is described in the background of this review and contains a checklist of five questions to determine feeding readiness. The other two observational studies used an existing instrument, the Neonatal Oral Motor Assessment Scale (NOMAS) that measures infants' nutritive sucking behaviours. These studies investigated the NOMAS psychometric characteristics within a healthy preterm population (Howe 2007) and as an indicator of feeding readiness (Church 2006). Non-nutritive sucking (NNS) instruments have also been utilised during the commencement and early suck feeding period to assist clinicians in determining feeding readiness in the preterm infants.

Other studies were found that contributed to the knowledge of feeding readiness and progression but did not involve assessment of feeding readiness. Staff surveys were used to document how staff decide to commence breast or bottle feeding (Kinneer 1994; Siddell 1994) as well as manage the transition period from tube feeding to all breast or bottle feeds (Dodrill 2008b). Current management of feeding initiation and progression has also been investigated using chart audits (Flint 2007; Dodrill 2008a). Observational studies were utilised to explore factors that may relate to feeding readiness (Cagan 1995; McGrath 2002; Bühler 2004; McGrath 2005; Pickler 2005b; Bauer 2008) as well as interventions that may enhance preterm infants' ability to engage in feeding behaviour (White-Traut 2002; White-Traut 2005). The effects of feeding experience, maturity and morbidity on feeding milestones (Pickler 2009) as well sucking patterns (Cunha 2009) were also studied.

In the 2016 update, a further 918 records were found (See Figure 1). Out of these 918 records , 474 records were identified from database searching while 444 records were found through searching clinical trial registries. This was reduced to 903 when duplicates were removed. A total of 13 records were retrieved in full text but all were excluded (Characteristics of excluded studies). The reference lists of each of the 13 records were searched resulting in an additional 6 records being retrieved in full text. No further studies meeting the inclusion criteria were identified (Characteristics of excluded studies).

Figure 1. Study flow diagram: review update



Of the experimental studies that were found the majority were investigating an intervention to assist the preterm infant to commence or transition to all suck feeds. These interventions were focused on: non-nutritive sucking (NNS)/oral stimulation (Somayeh 2013; Bache 2014; Harding 2014); suck and swallow exercises (Lau 2012); position of infant during bottle feeding (Dawson 2013); feeding based on oral feeding behaviours and behavioural state (McCain 2012; White-Traut 2014); as well as timing and progression of feeds (Pickler 2015). A secondary analysis of Pickler's study was also found. This analysis investigated the impact of missed feeding opportunities on time to full oral feeding (Tubbs-Cooley 2015).

A case study design was utilised in one record to illustrate the role of assessment and reflection in cue-based feeding (Thoyre 2013).

Four records were reviews which examined the literature in regards to oral feeding readiness broadly (Jones 2012; Gennattasio 2015) and more specifically oral stimulation (Greene 2013) and infant-driven feeding (Shaker 2012).

One record describes a prospective cohort study in which the researchers utilised a non-nutritive sucking instrument to determine feeding readiness (Neiva 2014). Suck feeds were commenced or withheld based upon these results and data were collected.

A limited number of studies found examined the introduction of enteral feeding in babies at risk of necrotising enterocolitis (Arnon 2013; Kempley 2013). One study examines the outcomes of an individualised feeding approach for infants who require long-term feeding management (Jadcherla 2012).

Risk of bias in included studies

No studies met the eligibility criteria.

Effects of interventions

No studies met the eligibility criteria.

DISCUSSION

The absence of randomised or quasi-randomised studies evaluating the use of a formalised instrument to assess a preterm infant's readiness has resulted in this systematic review being unable to determine the effects of using such an instrument on the time to establish full oral feeding or duration of hospitalisations.

The excluded studies of the 2012 review showed that there is an interest among researchers in how to best approach the dilemma of when to commence breast or bottle feeds. This review focused on validated instruments but there were a number of other methods found (for example care pathways, protocols, clinical guidelines) that could potentially aide clinicians in managing suck feeding initiation and progression. There were a few studies that demonstrated that the application of a feeding protocol may improve outcomes including the time taken to all suck feeds (McCain 2001; Kirk 2007; Drenckpohl 2009) and length of hospital stay (McCain 2001). The benefit of using a formalised instrument over other methods such as clinical judgement or a criterion such as gestational age is that an instrument ensures that a systematic and consistent method of assessing feeding readiness is utilised. We identified a number of instruments that specifically assessed feeding readiness; however the clinical utility of these instruments was not investigated in an experimental study. The studies were observational with their focus on establishing the validity and reliability of the tool (McGrath 2003; Fuginaga 2007a; Fujinaga 2007b; Neiva 2008; Rossarolla 2009).

Since the original search there has been continued research and development into methods to assess and support preterm infants in their transition to full suck feeds. Although no further instruments were discovered by this update, a number of the instruments or methods to assess feeding readiness cited in the 2012 review have been further developed. Both the NNS scoring system (Neiva 2014) and the Preterm Oral Feeding Readiness Scale (Fujinaga 2013) have undergone further testing by their respective authors to determine cut-off scores of when to initiate or withhold suck feeds. Furthermore, a cross-cultural validation study has been undertaken to translate the Preterm Oral Feeding Readiness Scale from English into Italian (Orsenigo 2016). Building upon their earlier work, Waitzman and Ludwig have also recently published an article describing a Delphi survey that has contributed to establishing content validity of their Infant-Driven Feeding Scales (Waitzman 2014).

Feeding readiness instruments are also starting to be utilised by other research teams in observational studies or chart audits (pre- and post-implementation) to demonstrate the clinical benefit of using a standardised assessment tool or protocol (Gelfer 2015; Wellington 2015; Bolzan 2016).

The lack of any experimental studies to establish the clinical utility of the instruments may simply be that they are too newly developed to have undergone such testing. The absence of randomised or quasi-randomised trials may also be a reflection of the practical difficulties in ensuring that the comparison group is not exposed to the intervention, particularly in the situation where the use of an instrument is compared to normal clinical practice with direct caregivers collecting data.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence to inform clinical practice with no studies meeting the inclusion criteria for this review.

Implications for research

Randomised or quasi-randomised trials are needed to evaluate the clinical utility of using an instrument to assess feeding readiness in the preterm infant population. Researchers need to also consider the use of a feeding-readiness instrument in the preterm infant breastfeeding population as the majority of observational studies investigating feeding readiness and progression are predominately focused on bottle feeding.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Arnon 2013	Does not study readiness to commence suck feeds but rather the introduction of enteral feeds within 24 hours and after 24 hours
Bache 2014	Does not study feeding readiness instruments. Studies the effects of a pre-feeding oral stimulation intervention versus no intervention
Bauer 2008	Does not compare methods to determine feeding readiness. This was an observational study involving clinical observation and assessment of feeding readiness and performance of preterm infants during the transition period from gavage to bottle feeding
Breton 2008	Literature review of introduction and transition to oral feedings
Bühler 2004	Does not compare methods of determining feeding readiness. An observational study examining factors that impact on commencement and transition to full oral feeding
Cagan 1995	Does not compare methods of determining feeding readiness. This study is an observational study examining behavioural state and feeding behaviours as indicators of feeding readiness
Church 2006	Does not compare methods of determining feeding readiness. This observational study examines the inter-rater reliability
Cunha 2009	Does not compare methods of determining feeding readiness. This study describes and compares the sucking patterns of very low birth weight preterm and full term infants
da Costa 2008	Literature review of diagnostic tools to determine feeding readiness and feeding performance
Dawson 2013	Does not study feeding readiness instruments. Studies the effects of two bottle feeding position (side lying and cradle)
Dodrill 2008a	Does not compare methods of determining feeding readiness.This study involves a retrospective chart audit examining early feeding milestones
Dodrill 2008b	Does not compare methods of determining feeding readiness. This study involves a survey of staff to investigate and document current transitional feeding practices
Drenckpohl 2009	Not a randomised or quasi-randomised study. This study uses a historical control to evaluate the implementation of a feeding protocol to initiate and advance feeds. Initiation is commenced at 30 weeks but no assessment is made
Fernández Díaz 2007	Not research but an article that discusses feeding readiness and the transition to suck feeds
Flint 2007	Does not compare methods of determining feeding readiness. This study involves an observational, retrospective cohort study design in which feeding milestones were examined

(*Continued*)

Frischknecht 2005	Not a study but an article that describes feeding readiness in preterm infants
Fuginaga 2007a	Does not compare methods of determining feeding readiness. This is a descriptive, observational study
Fujinaga 2007b	Does not compare methods of determining feeding readiness.This is an observational study to test for inter-rater reliability
Gennattasio 2015	A literature review on feeding readiness in preterm infants
Greene 2013	Not an RCT. This conference paper describes a review of oral stimulation interventions
Harding 2014	Does not study feeding readiness instruments. Studies the effects of 1) non-nutritive sucking pre-tube feed, 2) non-nutritive sucking on onset of tube feed and 3) control
Howe 2007	Does not compare methods of determining feeding readiness. This is an observational study design to assess the validity and reliability of the Neonatal Oral Motor Assessment Scale
Jadcherla 2012	Not a RCT. Does not study a feeding readiness instrument. Studies the impact of individualised feeding program on infants requiring long term feeding management
Jones 2012	Not a experimental study but a literature review.
Kempley 2013	Does not study a feeding readiness instrument. Studies the timing of initiation of milk feeds (early versus late) in growth restricted babies
Kinneer 1994	Does not compare methods of determining feeding readiness. This study involved a survey of neonatal nurseries to find out how clinicians determine feeding readiness
Kirk 2007	Not a randomised or quasi-randomised study. This study compares a historical control with a study group. No psychometric testing reported
Lau 2007	Not primary research but a discussion article on feeding initiation and progression
Lau 2012	Does not study a feeding readiness instrument. Studies the effect of a suck-swallow exercise intervention compared to usual care
Lemons 1996	Not research but an article discussing transition to breast or bottle feeds
Ludwig 2007	Not research but an article that describes a feeding readiness scale developed by authors as part of their change in feeding documentation
McCain 2001	This study does not evaluate the use of a feeding readiness indicator independently as the intervention incorporates a period of non-nutritive sucking. The effectiveness of assessing feeding readiness alone on the primary outcomes can not be established for this study

(*Continued*)

McCain 2002	This study does not evaluate the use of a feeding readiness indicator independently as the intervention incorporates a period of non-nutritive sucking. The effectiveness of assessing feeding readiness alone on the primary outcomes can not be established for this study
McCain 2003	Not a study but an article that describes an evidence-based guideline for the introduction oral feeding
McCain 2012	Does not study a feeding readiness instrument. This study investigates the use of a semi-demand protocol versus usual care with BPD infants
McGrath 2002	Does not compare methods of determining feeding readiness. This is an observational study that looks at the association between alertness and ability to engage in nutritive sucking
McGrath 2003	Does not compare methods of determining feeding readiness. This study describes the content validity as well as an observational, pilot study of a feeding readiness scale
McGrath 2004	Not research but an article discussing feeding readiness in preterm infants
McGrath 2005	Does not compare methods of determining feeding readiness. This observational study explores factors associated with feeding readiness
Neiva 2008	Does not compare methods of determining feeding readiness. This study established content validity of non-nutritive sucking scoring system as well as reporting the use of the tool within an observational study
Neiva 2014	Although investigates the use of the Non-Nutritive Sucking scoring system to assess feeding readiness not a RCT but a cohort, prospective trial
Paul 2014	Does not study a feeding readiness instrument. Studies a parenting intervention involving a mother-full term infant dyad
Pickler 2005a	Not research. This article describes a theoretical model for feeding readiness in preterm infants
Pickler 2005b	Does not compare methods of determining feeding readiness and is part of a larger study. This study investigates the relationship between feeding readiness indicators and feeding performance
Pickler 2009	Does not compare methods of determining feeding readiness. Does not measure feeding readiness. This study examines the effects of feeding experience, maturity and morbidity on clinical milestones
Pickler 2015	Does not study a feeding readiness instrument. Studies the effect of 4 different feeding regimens each differing in the timing of commencement, rate of progression of feeds and amount of experience provided
Premji 2000	Does not compare methods of assessing feeding readiness but investigates the safety and efficacy of implementing a clinical practice guideline for nutritional management compared to no guideline
Premji 2002	Not research but describes the development of a clinical practice guideline for feeding very low birth weigh infants
Premji 2004	Not research but describes the background and implementation of an oral feeding protocol

(*Continued*)

Ross 2002	Not research but an article describing the transition from gavage feeds to suck feeds in preterm infants
Rossarolla 2009	Does not compare methods of determining feeding readiness. This observational study established discriminant validity of the feeding readiness tool developed by Fujinaga
Shaker 2007	Not research but an article that describes a new feeding protocol
Shaker 2012	Not a RCT but a literature review
Siddell 1994	Does not compare methods of determining feeding readiness. This study involved a survey of neonatal nurseries to find out criteria used to determine feeding readiness
Somayeh 2013	Does not study a feeding readiness instrument. Studies the implementation of a oral stimulation intervention compared to a control group (hands placed of baby for 15 minutes)
Thoyre 2003	Not research but an article that discusses the transition from gavage to suck feeds
Thoyre 2005	Not research but an article that describes the Early Feeding Skills Assessment checklist
Thoyre 2009	Does not compare methods of determining feeding readiness. This observational study looks at the validity and reliability of the Dynamics of Early Infant Feeding instrument
Thoyre 2013	Not a RCT but case studies to illustrate cue-based feeding.
Tubbs-Cooley 2015	Not a RCT. Secondary analysis of Pickler 2015
White-Traut 2002	Not testing an assessment instrument. The study tested the effects of an auditory, tactile, visual and vestibular (ATVV) intervention on feeding readiness and performance
White-Traut 2005	Secondary analysis to examine the relationship between behavioural state and the frequency of feeding readiness behaviours
White-Traut 2014	Does not study feeding readiness instruments. Studied the effects of H-HOPE intervention versus attention control intervention

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Search Strategy 2012

CENTRAL:
There were 92 results.
Each keyword was searched for in Title, Abstract or Keywords. There were 92 results for: (preterm or premature) and (feeding or breast or bottle) and (read* or commence or introduc* or start* or establish*).
MEDLINE:
There was 367 results.
S1 preterm or pre-term or premature or low birth weight or lowbirth weight or LBW
S2 newborn* or new born* or baby or babies or neonat* or infant*
S3 S1 and S2
S4 (MH "Infant, Premature")
S5 S3 or S4
S6 commenc* or start* or begin* or readiness or Introduc*
S7 breast fe* or breastfe* or bottle fe* or bottlefe* or nipple fe* or oral fe*
S8 (MH "Bottle Feeding") or (MH "Breast Feeding") or (MH "Feeding Methods")
S9 (MH "Feeding Behavior") or (MH "Sucking Behavior") or feeding behaviour or feeding behavior or sucking behaviour or sucking behavior
S10 S7 or S8 or S9
S11 S5 and S6 and S10
EMBASE:
72 results
(neonat* OR infant * or newborn OR baby OR babies) AND (preterm OR pre-term OR premature) AND (bottle fe* OR breast fe* OR nipple fe* OR oral fe*) AND (commenc* OR readiness OR begin* OR introduc*)
CINAHL:
There was 161 results.
S1 preterm or pre-term or premature or low birth weight or lowbirth weight or LBW
S2 newborn* or new born* or baby or babies or neonat* or infant*
S3 S1 and S2
S4 (MH "Infant, Premature")
S5 S3 or S4
S6 commenc* or start* or begin* or readiness or Introduc*
S7 breast fe* or breastfe* or bottle fe* or bottlefe* or nipple fe* or oral fe*
S8 (MH "Bottle Feeding") or (MH "Breast Feeding") or (MH "Infant Feeding")
S9 sucking behaviour or sucking behavior or (MH Sucking Behavior") or feeding behavior or feeding behaviour
S10 S7 or S8 or S9
S11 S5 and S6 and S10
Health Source:
Results 66
S1 preterm or pre-term or premature
S2 newborn* or new born* or baby or babies or neonat* or infant*
S3 S1 and S2
S4 breast fe* or breastfe* or bottle fe* or bottlefe* or nipple fe* or oral fe*
S5 commenc* or start* or begin* or readiness or Introduc*

S6 S3 and S4 and S5

Web of Science:

150 results

Topic=(preterm or premature) AND Topic=(infant* or baby or babies or neonat* or newborn) AND Topic=(breastfe* or bottlefe* or nipplefe* or oral feeding) AND Topic=(commenc* or start* or readiness or introd* or establish*)Timespan=All Years. Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH.

Cochrane:

There were 22 results.

Each keyword was searched for in Title, Abstract or Keywords. There were 22 results for: (preterm or premature) and (feeding or breast or bottle) and (read* or commence or introduc* or start* or establish*).

Appendix 2. Standard search methodology - February 2016

PubMed: ((infant, newborn[MeSH] OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or infan* or neonat*) AND (randomised controlled trial [pt] OR controlled clinical trial [pt] OR Clinical Trial[ptyp] OR randomised [tiab] OR placebo [tiab] OR clinical trials as topic [mesh: noexp] OR randomly [tiab] OR trial [ti]) NOT (animals [mh] NOT humans [mh])) AND (commenc* OR start* OR begin* OR readiness or Introduc*) AND (breast fe* OR breastfe* OR bottle fe* OR bottlefe* OR nipple fe* OR oral fe* OR ("Bottle Feeding") OR ("Breast Feeding") OR ("Feeding Methods") OR ("Feeding Behavior") OR ("Sucking Behavior") OR feeding behaviour OR feeding behavior OR sucking behaviour OR sucking behavior)

EMBASE: (infant, newborn or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW or Newborn or infan* or neonat*) AND (human not animal) AND (randomised controlled trial or controlled clinical trial or randomised or placebo or clinical trials as topic or randomly or trial or clinical trial) AND (neonat* OR infant * or newborn OR baby OR babies) AND (preterm OR pre-term OR premature) AND (bottle fe* OR breast fe* OR nipple fe* OR oral fe*) AND (commenc* OR readiness OR begin* OR introduc* OR start*)

CINAHL: (infant, newborn OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or Newborn or infan* or neonat*) AND (randomised controlled trial OR controlled clinical trial OR randomised OR placebo OR clinical trials as topic OR randomly OR trial OR PT clinical trial) AND (commenc* OR start* OR begin* OR readiness OR Introduc*) AND (breast fe* OR breastfe* OR bottle fe* OR bottlefe* OR nipple fe* OR oral fe* OR ("Bottle Feeding") OR ("Breast Feeding") OR ("Infant Feeding") OR sucking behaviour OR sucking behavior OR (Sucking Behavior") OR feeding behavior OR feeding behavior)

Cochrane Library: (infant or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW) AND (feeding OR breast OR bottle) AND (read* OR commence OR introduc* OR start* OR establish*)

Appendix 3. Risk of bias tool

The following issues were to have been evaluated and entered into the 'Risk of bias' table:

1.Sequence generation (checking for possible selection bias). Was the allocation sequence adequately generated?

For each included study, we categorised the method used to generate the allocation sequence as:
a.low risk (any truly random process e.g. random number table; computer random number generator);
b.high risk (any non-random process e.g. odd or even date of birth; hospital or clinic record number);
c.unclear risk.

2.Allocation concealment (checking for possible selection bias). Was allocation adequately concealed?

For each included study, we categorised the method used to conceal the allocation sequence as:
a.low risk (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
b.high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
c.unclear risk.

3.Blinding (checking for possible performance bias). Was knowledge of the allocated intervention adequately prevented during the study? At study entry? At the time of outcome assessment?

For each included study, we categorised the methods used to blind study participants and personnel from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or classes of outcomes. We categorised the methods as:
a.low risk, high risk or unclear risk for participants;
b.low risk, high risk or unclear risk for personnel;
c.low risk, high risk or unclear risk for outcome assessors.

4.Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). Were incomplete outcome data adequately addressed?

For each included study and for each outcome, we described the completeness of data including attrition and exclusions from the analysis. We noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we re-included missing data in the analyses. We categorised the methods as:
a.low risk (< 20% missing data);
b.high risk (≥ 20% missing data);
c.unclear risk.

5.Selective reporting bias. Are reports of the study free of suggestion of selective outcome reporting?

For each included study, we described how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:
a.low risk (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
b.high risk (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified outcomes of interest or are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
c.unclear risk.

6.Other sources of bias. Was the study apparently free of other problems that could put it at a high risk of bias?

For each included study, we described any important concerns we had about other possible sources of bias (for example, whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We assessed whether each study was free of other problems that could put it at risk of bias as:
a.low risk;
b.high risk;
c.unclear risk.
If needed, we planned to explore the impact of the level of bias through undertaking sensitivity analyses.

WHAT'S NEW

Date	Event	Description
6 February 2017	Amended	Added external source of support

HISTORY

Date	Event	Description
21 July 2016	New citation required but conclusions have not changed	Conclusions are unchanged.
7 July 2016	New search has been performed	A new search was conducted in February 2016.
4 June 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Linda Crowe (LC) was the primary reviewer and author, with the help of Anne Chang (AC) and Karen Wallace (KW) who both acted as secondary reviewers and aided in the discussion and editorial process.

DECLARATIONS OF INTEREST

Linda Crowe completed preliminary testing of an instrument for commencement of breast feeds for use with preterm infants.

SOURCES OF SUPPORT

Internal sources

- Queensland Centre for Evidence Based Nursing and Midwifery Practice, Australia.
- Nursing Research Centre, Mater Health Services, South Brisbane, Queensland, Australia.
- Mater Research Support Centre, Mater Health Services, Australia.

External sources

- Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, USA.

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- National Institute for Health Research, UK.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

References were added to the background where appropriate, including the addition of a reference related to a tool developed by Fujingaga as well as a reference to the name change of the Preterm Infant Nipple Feeding Readiness tool.

The search strategy was also altered. The databases Oxford Database of Perinatal Trials and Pre-CINAHL were not searched. The original search terms in the protocol were also changed to fit with each database. See Appendices for full details of the search strategy used for each database (Appendix 1; Appendix 2).

Changes to the wording of the text were made in the methods section of the review. A more comprehensive description of the assessment of risk of bias has been provided in the review. References to RevMan 4.2 software have been replaced by RevMan 5.

We added the methodology and plan for 'Summary of findings' tables and GRADE recommendations, which were not included in the original protocol.

INDEX TERMS

Medical Subject Headings (MeSH)

*Bottle Feeding; *Breast Feeding; *Infant, Premature; *Sucking Behavior; Hospitalization; Time Factors

MeSH check words

Humans; Infant, Newborn