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[Intervention Review]

Oral stimulation for promoting oral feeding in preterm infants

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ABSTRACT

Background

Preterm infants (< 37 weeks' postmenstrual age) are often delayed in attaining oral feeding. Normal oral feeding is suggested as an important outcome for the timing of discharge from the hospital and can be an early indicator of neuromotor integrity and developmental outcomes. A range of oral stimulation interventions may help infants to develop sucking and oromotor co-ordination, promoting earlier oral feeding and earlier hospital discharge.

Objectives

To determine the effectiveness of oral stimulation interventions for attainment of oral feeding in preterm infants born before 37 weeks' postmenstrual age (PMA).

To conduct subgroup analyses for the following prespecified subgroups.

• Extremely preterm infants born at < 28 weeks' PMA.

• Very preterm infants born from 28 to < 32 weeks' PMA.

• Infants breast-fed exclusively.

• Infants bottle-fed exclusively.

• Infants who were both breast-fed and bottle-fed.

Search methods

We used the standard search strategy of the Cochrane Neonatal Review Group to search the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE via PubMed (1966 to 25 February 2016), Embase (1980 to 25 February 2016) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to 25 February 2016). We searched clinical trials databases, conference proceedings and the reference lists of retrieved articles.

Selection criteria

Randomised and quasi-randomised controlled trials comparing a defined oral stimulation intervention with no intervention, standard care, sham treatment or non-oral intervention in preterm infants and reporting at least one of the specified outcomes.

Data collection and analysis

One review author searched the databases and identified studies for screening. Two review authors screened the abstracts of these studies and full-text copies when needed to identify trials for inclusion in the review. All review authors independently extracted the data and analysed each study for risk of bias across the five domains of bias. All review authors discussed and analysed the data and used the GRADE system to rate the quality of the evidence. Review authors divided studies into two groups for comparison: intervention versus standard care and intervention versus other non-oral or sham intervention. We performed meta-analysis using a fixed-effect model.

Main results

This review included 19 randomised trials with a total of 823 participants. Almost all included trials had several methodological weaknesses. Meta-analysis showed that oral stimulation reduced the time to transition to oral feeding compared with standard care (mean difference (MD) -4.81, 95% confidence interval (CI) -5.56 to -4.06 days) and compared with another non-oral intervention (MD -9.01, 95% CI -10.30 to -7.71 days), as well as the duration of initial hospitalisation compared with standard care (MD -5.26, 95% CI -7.34 to -3.19 days) and compared with another non-oral intervention (MD -9.01, 95% CI -10.30 to -7.71 days).

Investigators reported shorter duration of parenteral nutrition for infants compared with standard care (MD -5.30, 95% CI -9.73 to -0.87 days) and compared with another non-oral intervention (MD -8.70, 95% CI -15.46 to -1.94 days). They could identify no effect on breast-feeding outcomes nor on weight gain.

Authors' conclusions

Although the included studies suggest that oral stimulation shortens hospital stay, days to exclusive oral feeding and duration of parenteral nutrition, one must interpret results of these studies with caution, as risk of bias and poor methodological quality are high overall. Well-designed trials of oral stimulation interventions for preterm infants are warranted. Such trials should use reliable methods of randomisation while concealing treatment allocation, blinding caregivers to treatment when possible and paying particular attention to blinding of outcome assessors.

PLAIN LANGUAGE SUMMARY

Effects of oral stimulation for oral feeding in preterm infants

Review questions

Do oral stimulation interventions that involve finger stimulation protocols in preterm infants born before 37 weeks' gestation:

• reduce time taken to achieve exclusive oral feeding and time spent in hospital?

• result in exclusive oral feeding, exclusive breast feeding or any direct breast feeding?

• increase sucking strength?

• increase rate of growth and improve development?

Background

Many preterm infants have delayed establishment of oral (suck) feeding and are fed at first with feeding tubes or with intravenous (parenteral) nutrition. Development of oral feeding skills needs careful co-ordination of sucking, swallowing and breathing. In preterm infants, the development of oral feeding can be challenging because of long hospitalisations, breathing difficulties and other medical conditions associated with preterm birth. Unpleasant procedures such as ventilation or frequent suctioning of secretions from the mouth or nose can negatively impact feeding skills. International guidelines for the transition from tube feeding to oral feeding vary widely. Healthcare providers use a range of interventions to improve sucking and feeding skills in preterm infants, and studies report faster transition time from tube feeds to oral feeds, reduced length of stay in hospital and improvement in infants' sucking skills. No Cochrane review has assessed the intervention involving finger stimulation of the mouth before and during feeds.

Study characteristics

This review included randomised controlled trials (RCTs) that explored oral stimulation by finger stimulation only in preterm infants. Review authors identified studies to be included by searching electronic databases, clinical trials registers, peer-reviewed journals and published conference proceedings.

Key results

We included 19 studies of poor quality with small numbers of participants. Study findings suggest that oral stimulation interventions can shorten the transition to oral feeding, reduce length of hospital stay and decrease time spent on parenteral nutrition. No studies looked at longer-term outcomes of the interventions (i.e. beyond six months). Studies have reported no effect on breast feeding outcomes nor on weight gain.

Quality of evidence

These studies were small and most were of low or very low methodological quality. Review authors identified no high-quality studies that could support the efficacy, effectiveness and safety of oral stimulation interventions. Larger, well-designed RCTs are needed to help inform parents and caregivers about the possible benefits and harms of this intervention.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Comparison group 1

Patient or population: preterm infants
Setting: NICU
Intervention: oral stimulation
Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with standard care	Risk with oral stimulation				
Days to full oral feeding	Mean days to full oral feeding: 0	Mean days to full oral feeding in the intervention group: 5.22, undefined lower (6.86 lower to 3.59 lower)	-	376 (8 RCTs)	⊕⊕◯◯ Low [a,b,c,d,e,f,g,h]	Heterogeneity (I^2 = 68%) between these studies was substantial, with high risk of bias overall between them
Weight gain	Mean weight gain: 0	Mean weight gain in the intervention group: 0.05, undefined lower (1.19 lower to 1.09 higher)	-	81 (2 RCTs)	⊕⊕◯◯ Low [a,b,e,f,g]	
Total hospital stay (days)	Mean total hospital stay (days): 0	Mean total hospital stay (days) in the intervention group: 5.26, undefined lower (7.34 lower to 3.19 lower)	-	301 (7 RCTs)	⊕◯◯◯ Very low [a,b,c,d,e,f]	
Duration (days) of parenteral nutrition	Mean duration (days) of parenteral nutrition: 0	Mean duration (days) of parenteral nutrition in the intervention group: 5.3, undefined lower (9.73 lower to 0.87 lower)	-	19 (1 RCT)	⊕◯◯◯ Very low [a,b,c,f]	

Exclusive direct breast feeding at discharge	350 per 1000	641 per 1000 (366 to 847)	RR 1.83 (0.96 to 3.48)	59 (1 RCT)	⊕◯◯◯ Very low[a,b,c,e]
Any direct breast feeding at discharge	348 per 1000	431 per 1000 (202 to 925)	RR 1.24 (0.58 to 2.66)	110 (2 RCTs)	⊕◯◯◯ Very low[a,b,c,d]

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; OR: odds ratio; RR: risk ratio.

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a] High risk of selection bias.
[b] High risk of performance bias.
[c] High risk of detection bias.
[d] Substantial heterogeneity (50% to 90%).
[e] High risk of attrition bias.
[f] High risk of reporting bias.
[g] Moderate heterogeneity (30% to 60%).
[h] Considerable heterogeneity (75% to 100%).

BACKGROUND

Preterm infants, particularly very preterm (< 32 weeks') infants, often have substantial delays in attaining independent oral feeding (American Academy of Pediatrics 2008; Eichenwald 2001; Engle 2007; Jadcherla 2010). Acquiring the skills needed for safe oral feeding is a complex process, and very preterm infants frequently have lengthy initial hospital stays until they can demonstrate the ability to show feeding and satiation cues; sustain suck, swallow and breathing throughout oral feeding; and maintain nutritional intake to support growth and development (Lau 2000a; Lau 2011; MacMullen 2000; Premji 2004). Several factors help to promote maturation, including practice, co-ordination, increased strength and decreased fatigue (Amaizu 2008; Cunha 2009; Joung 2006; Lau 2000a). Although maturation of oral feeding functions will enhance their performance, it is co-ordination of these activities in conjunction with swallowing and respiratory control that will ultimately lead to 'readiness to oral feed' in a safe and efficient manner (Lau 2011).

Development can be significantly disrupted by comorbidities present in preterm infants, such as respiratory disease (Lau 2015; Mandich 1996; Miller 2007), brain injury (Medoff-Cooper 1996) and necrotising enterocolitis (NIH 2008), which limit opportunities for sucking and deprive the infant of essential sensory and motor experiences during a critical period of brain development when the central patterning of suck and feeding skill is refined (da Costa 2010b; da Costa 2010c; Howe 2007; Mizuno 2007; Stumm 2008; Thoyre 2003a; Thoyre 2003b). Medical interventions used with preterm infants, such as prolonged endotracheal intubation (Bier 1993), continuous positive airway pressure (CPAP), nasal cannulation and regular oropharyngeal, nasal or tracheal suction (White-Traut 2005) may result in negative responses to oral feeding (Bingham 2009; Jadcherla 2010; Rocha 2007) and long-term oral sensitivity (Dodrill 2004). Other factors, such as prefeeding behaviour state, feeding readiness and feeding experience, also influence feeding performance in preterm infants (Burklow 2002; Dodrill 2008a; Howe 2007; Joung 2006; Kinneer 1994; Pickler 2006).

Few preterm infants are adequate oral feeders from birth, and many receive enteral feeds by tube, necessitating longer hospital stays as they transition from tube (gavage) feeds to oral feeds. Occasionally, preterm infants do not have adequate oral intake at term corrected age, and they remain partially or exclusively tube fed for months or years. Pathways for facilitating the transition from tube to oral feeding in this population can vary between centres and are dependent on a variety of factors, such as age, weight, oral motor skills, feeding techniques and feeding experience (Cowen 2006; Dougherty 2008; Howe 2007). Initiation of oral feeding is often based on infant weight and postmenstrual age (PMA), but empirically derived guidelines for starting or progressing oral feeds are not available (Crowe 2006; Dodrill 2008c; Pickler 2006).

Should feeding commence earlier in this population, estimated economic data identify potential cost savings in the USA ranging from $3500 (Field 1982) to $280 million in hospitalisation charges per infant for board alone (Daley 2000). More recent figures estimate that a three-day decrease in hospital stay for this population could result in savings of more than two billion dollars annually (Lessen 2011).

Description of the condition

Oral feeding is a complex skill that requires the integration of breathing, sucking and swallowing in the context of overall motor stability and incoming sensory stimuli (Arvedson 2010; da Costa 2010a; Fadavi 1997; Kelly 2007; Lau 2000a; Lefton-Greif 2007; Ross 2002). This skill depends upon brainstem central pattern generators, whose activity is influenced by chemosensory and oral tactile input (Amaizu 2008; Bingham 2009; Lau 2011; Lau 2015; Wolf 1992). The ability to progress to successful feeding depends on the infant's ability to co-ordinate the muscles of the jaw, lips, tongue, palate and pharynx, upper trunk and respiratory systems to support a safe swallow. It is also dependent on normal sensory functioning seen in primitive reflexes such as rooting, gag and an intact swallow reflex and intraoral and pharyngeal sensation.
Researchers have described the developmental stages of sucking in preterm infants during oral feeding (Amaizu 2008; Cunha 2009; Dodrill 2008b; Lau 2000a; Medoff-Cooper 1993; Neiva 2007 (an additional reporting of Neiva 2006)). Varying components of sucking physiology, such as sucking amplitude, rate and pressure intensity; timing of sucking cycles; and proficiency and efficiency (Bingham 2009; Lau 2011; Medoff-Cooper 2000; Neiva 2007 (an additional reporting of Neiva 2006); Poore 2008a; Stumm 2008), appear to mature over time at varying rates, depending on the factors outlined above (Amaizu 2008; Lau 1997; Pickler 2006). Experience with oral feeding appears to have a positive effect on the characteristics of sucking (Cunha 2009; Pickler 2006; Simpson 2002). One analysis of nutritive sucking function in very low and extremely low birth weight infants outlines how weakness of oral muscular function and minimal sucking skill can bring about weakness of intensity of sucking pressure, decreased time of the sucking stage in a sucking cycle and unstable intensity of sucking pressure and time, causing low efficiency of milk intake and smaller amounts of milk swallowed during each sucking period (Matsubara 2005). These problems lasted longer in an extremely low birth weight group than in a small group of full-term infants. The presence of a persistently disorganised sucking pattern after 37 weeks can be predictive of neurodevelopmental outcomes at six months and 12 months (Tsai 2010). Although enteral milk feeding is critical for their optimal growth and development, few preterm infants feed adequately orally from birth. Consequently, these infants remain tube fed in hospital for protracted periods as they learn to feed orally, contributing to increased healthcare costs and heightened family stress (Swift 2010).

Description of the intervention

The intervention programmes referred to earlier in this review are designed to facilitate the development of oral motor and sensory skills required for sucking and swallowing. Such direct programmes often involve stroking perioral and intraoral structures in a specific way with a gloved finger for a specified time before feeding (Fucile 2002; Fucile 2002a; Fucile 2011; Lessen 2009; Pimenta 2008). Techniques such as stroking the cheeks are reported to enhance the sucking rate, and providing cheek and chin/jaw support may facilitate sucking efficiency during feeding (Boiron 2007). Positive effects on the rhythm of pharyngeal swallowing in response to oral sensorimotor programmes have been described (Boiron 2009, an additional reporting of Boiron 2007). Many of the interventions described involve some level of training and require skilled delivery by a nurse, an occupational therapist, a speech and language therapist, a parent or other developmental specialists.

How the intervention might work

These interventions are designed to reduce oral hypersensitivity, improve range of motion and strength of muscles for sucking (Fucile 2002), increase oral motor organisation (Case-Smith 1989) and activate reflex behaviours that facilitate nutritive sucking (Leonard 1980; Neiva 2007 (an additional reporting of Neiva 2006)). In general, these techniques aim to normalise sensation by restoring reflexes and in turn elicit normal oral movements of lips, tongue, jaw and pharynx for development of sucking and swallowing. As well as facilitating the development of oral skills for eventual feeding, these interventions provide such beneficial effects as accelerated transition from tube feeding to independent oral feeding (McCain 2001; Pinelli 2005), enhanced sucking maturation (Boiron 2007; Harding 2006; Leonard 1980; Poore 2008b), earlier achievement of oral feeding (Boiron 2007; Harding 2006), reduction in bottle feeding stress (Pickler 1992), increased volume intake (Boiron 2007; Einarsson-Brackes 1994), greater weight gain (Bernbaum 1983; Gaebler 1996) and fewer days of hospitalisation (Gaebler 1996; Harding 2006; Johnston 1999; Pinelli 2005).

Although no adverse effects of these interventions have been reported to date, effects that may be observed as indicators of feeding stress in this group include heart rate variability (McCain 1995; McCain 2010) and apnoeic episodes associated with feeding-induced apnoea (Eichenwald 2001; Howe 2007; Thoyre 2003a; Thoyre 2003b). Other possible adverse effects include oral trauma to the mouth, oral infection or both. Silent aspiration of oral feeds is an ongoing concern that needs careful monitoring in this group (Miller 2007). The introduction of any implement or device into the oral cavity can cause an increase in salivary flow rate. For preterm infants who display weakness and inco-ordination in the oropharyngeal system, and are unable to consistently control and swallow their own saliva, the sudden increase in saliva associated with the introduction of a soother or a gloved finger, for example, may be overwhelming and may increase stress and risk of aspiration of oral secretions (Wolf 1992).

Why it is important to do this review

Several other systematic reviews and meta-analyses (Arvedson 2010; Crowe 2006 Daley 2000; Pinelli 2005) have studied general approaches to feeding, including use of pacifiers, but none has yet evaluated the evidence for specific oral stimulation interventions based on finger stimulation protocols. Previous reviews have had a broad scope, resulting in wide heterogeneity and variability among participants, interventions and outcome measures (Arvedson 2010; Daley 2000), or review authors have looked only at non-nutritive sucking activities (Cowen 2006; Pinelli 2005). Therefore, this review will compare only finger stimulation protocols as oral stimulation interventions and will determine their effects on outcomes such as neonatal intensive care unit (NICU)/hospital discharge, time to attainment of oral feeding, duration of parenteral feeding, suck/swallow maturation and anthropometrical measures such as weight gain, length and head circumference. For the purposes of this review, we have revised the definition of oral stimulation from that proposed in the protocol (Greene 2012) (see Differences between protocol and review). Oral stimulation is currently defined as direct delivery of sensory stimulation by a finger stroking protocol to the perioral and/or oral area, designed to elicit movement responses in the lips, jaw, soft palate, pharynx, larynx and respiratory muscles to influence oropharyngeal and respiratory sensorimotor mechanisms, to improve function for sucking and feeding in preterm infants. Oral stimulation should occur before or during nutritive sucking (NS) and non-nutritive sucking (NNS) events with tube feeds.

It is unclear whether oral stimulation interventions, specifically those using finger stimulation protocols, result in earlier exclusive oral feeding in preterm infants. It is important to determine whether exclusive oral feeding as a result of this intervention contributes to earlier NICU discharge and subsequent hospital discharge. This review is important because it will (1) assist healthcare providers in clarifying policy related to implementing treatment for preterm infants in appropriate clinical settings and (2) assist in promoting evidence-based practice internationally in the treatment of preterm infants.

If these interventions are found to be effective, they could become a routine and standard part of delivery of care to preterm infants in NICU settings, facilitating earlier discharge and reducing costs of care associated with long hospital stay.

OBJECTIVES

Primary objectives

To examine the effectiveness of oral stimulation interventions for attainment of oral feeding in preterm infants born before 37 weeks' postmenstrual age (PMA).

To conduct subgroup analyses for the following prespecified subgroups.

- Extremely preterm infants born at < 28 weeks' PMA.
- Very preterm infants born from 28 to < 32 weeks' PMA.
- Infants breast fed exclusively.
- Infants bottle fed exclusively.
- Infants who were both breast fed and bottle fed.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published and unpublished randomised controlled trials (RCTs) and quasi-randomised controlled trials reported in any language. We classified as RCTs all trials that involved at least one test treatment aimed at improving oral motor function and one control treatment, with concurrent enrolment and follow-up of both test-treated and control-treated groups. We classified as quasi-RCTs all trials that involved at least one test treatment aimed at improving oral motor function and one control treatment, with concurrent enrolment and follow-up of test-treated and control-treated groups, when the method of allocation was known but was not considered strictly random, for example, alternate allocation by day or date of birth or medical record number. We excluded cross-over trials.

Types of participants

We included all trials of preterm infants of mixed ages in which the data allowed for extraction of participants up to 37 weeks' PMA. The intervention could occur at any time from date of birth. We did not exclude trials that included infants with comorbid impairments, such as neurological or structural impairments. Participants had to be deemed medically stable for the intervention. We excluded participants who presented with defined respiratory disease, as this particular subgroup is at increased risk of feeding disorders, and comparison between these infants and healthy preterm infants is difficult. We excluded trials of infants presenting with significant comorbid conditions that preclude the introduction of oral feeding.

Types of interventions

We included all trials involving oral stimulation interventions that occurred in any clinical setting with delivery by a trained person or team, including nurse, occupational therapist, speech and language therapist, other developmental specialist or parent. We considered any dosage, intensity, frequency, duration and timing of delivery of interventions. We made the following comparisons.

- Oral stimulation intervention versus no intervention or standard care or sham treatment.
- Oral stimulation intervention versus non-oral intervention.
- Oral stimulation intervention versus other oral stimulation delivered by a different method (e.g. dosage/intensity, frequency, duration and/or timing of delivery, mode of delivery, personnel delivering the intervention).

Types of outcome measures

We considered the following outcome measures as potential measures of success: outcome measures that signified improvement in feeding ability and oromotor function of the preterm infant and that reduced NICU and/or overall hospital stay.

Primary outcomes

- Time (days) taken to achieve exclusive oral feeding, defined as ingestion of all nutrient volumes in a 24-hour period without gavage (McCain 2001)
- Time (days) spent in NICU
- Total hospital stay (days)
- Duration (days) of parenteral nutrition

Secondary outcomes

- Exclusive oral feeding at 40 weeks' PMA
- Exclusive direct breast feeding at 40 weeks' PMA
- Any direct breast feeding at 40 weeks' PMA
- Weight gain (g/kg/d)
- Length (cm/d)
- Head circumference (cm/d)
- Maturation in sucking strength (measured by rate of milk intake (mL/min); suction amplitude (mmHg)/sucks/min)
- Developmental outcomes ascertained by a validated instrument at 12 to 18 months
- Adverse outcomes, such as sepsis, oral infection, oral trauma, apnoea or bradycardia episodes requiring intervention from the caregiver (stimulation, oronasal suction, increased delivery of oxygen, assisted ventilation), increased salivary flow (as measured by the presence of saliva beyond the level of the lips), oxygen dependence at 36 weeks' PMA, death during initial hospital stay
- Necrotising enterocolitis (≥ Bell's stage 2)
- Retinopathy of prematurity (any stage and ≥ stage 3)
- Family satisfaction with intervention

- Non-compliance with intervention

We considered three time frames for follow-up.

- Immediate change.
- Medium-term change (three to six months).
- Long-term change (beyond six months).

Search methods for identification of studies

We included in the review published and unpublished studies of trials on humans reported in any language.

Electronic searches

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

We conducted a comprehensive search that included the Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 1), in *The Cochrane Library*; MEDLINE via PubMed (1996 to current); Embase (1980 to current); and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to current), using the following search terms: ((non-nutritive suck*) OR pacifier OR dummy OR (myofunctional therapy) OR oromotor OR (oral motor) OR sensorimotor OR ((suck OR oral OR orocutaneous OR physical OR mechanical OR sensory OR somatosensory OR pre-feeding) AND (stimulation OR training OR support)) AND (feed* OR growth)), (Note: Growth was included as a term only in *The Cochrane Library*), plus database-specific limiters for RCTs and neonates (see Appendix 2 for the full search strategy for each database). We applied no language restrictions.

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

Searching other resources

We checked published abstracts from the following organisations.

- American Speech-Language-Hearing Association: Perspectives Special Interest Group 13 (2001 to 2016).
- Royal College of Speech and Language Therapists (1999 to 2016).
- Neonatal Society via www.neonatalsociety.ac.uk (2001 to 2016).
- British Association of Perinatal Medicine (guidelines/reports/newsletters only) (2003 to 2016).
- Conference on Feeding and Eating in Infancy and Early Childhood, Institute of Child Health Great Ormond Street (2010 to 2016).

Abstracts for the following organisations were available via standard databases through our online searches.

- American Dysphagia Research Society (DRS) and European Society for Swallowing Disorders (ESSD): *Dysphagia Journal,* from 1992 to 2016.
- American Academy of Pediatrics: *Paediatrics, Hospital Paediatrics*.
- American Society for Parenteral and Enteral Nutrition (ASPEN): *Journal of Parenteral and Enteral Nutrition*, *Nutrition in Clinical Practice*.
- European Society for Swallowing Disorders (ESSD): *Dysphagia Journal,* DRS above.
- Canadian Pediatric Society.
- European Academy of Paediatrics: *European Journal of Paediatrics,* online archive from 2011 to 2016.
- European Society for Paediatric Research: *Pediatric Research,* online archive from 1967 to 2016.

Personal communication with other relevant groups was not considered necessary.

Data collection and analysis

Selection of studies

We merged search results using reference management software (RefWorks) and removed duplicate records. Two review authors (ZG, MW) used a screening form to individually examine the titles and abstracts of identified studies. We classified studies for this review as 'include', 'unsure' or 'exclude'. We excluded reports that clearly did not meet the inclusion criteria and were not relevant. We resolved disagreements on inclusion of studies through discussion. All review authors independently reviewed full texts of reports identified as 'include' or 'unsure'. We resolved disagreements on compliance with eligibility criteria through discussion. We determined that it was not necessary to contact any study authors.

Data extraction and management

We used a specifically devised data extraction form to extract data from study reports (Greene 2012). All review authors independently extracted data from each report to minimise errors and reduce potential risk of bias. We resolved disagreements through discussion.

Assessment of risk of bias in included studies

We analysed each study individually for bias across the five domains of bias and added this information to the Characteristics of included studies table. We evaluated the following issues and entered this information into the risk of bias table (Higgins 2008).

Sequence generation (checking for possible selection bias)

Was the allocation sequence adequately generated?
For each included study, we considered the method used to generate the allocation sequence as:

- adequate (any truly random process, e.g. random number table, computer random number generator);
- inadequate (any non-random process, e.g. odd or even date of birth, hospital or clinic record number); or
- unclear.

Allocation concealment (checking for possible selection bias)

Was allocation adequately concealed?
For each included study, we considered the method used to conceal the allocation sequence as:

- adequate (e.g. telephone or central randomisation, consecutively numbered sealed opaque envelopes);
- inadequate (e.g. open random allocation, unsealed or non-opaque envelopes, alternation, date of birth); or
- unclear.

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 considered the methods used to blind study participants and personnel from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or different classes of outcomes. We categorised methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel; or
- adequate, inadequate or unclear for outcome assessors.

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 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 number of randomised participants), reasons for attrition or exclusion when reported and whether missing data were balanced across groups or were related to outcomes.

When sufficient information was reported or supplied by the trial authors, we included this missing data in the analyses and categorised the method as:

- adequate (< 20% missing data);
- inadequate (≥ 20% missing data); or
- unclear.

Selective reporting bias

Are reports of the study free of the 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 methods as:

- adequate (when it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (when not all the study's prespecified outcomes have been reported; when one or more reported primary outcomes that were not prespecified outcomes of interest are reported incompletely and so cannot be used; when the study fails to include results of a key outcome that would have been expected to have been reported); or
- unclear.

We also considered other issues that may affect reporting bias, such as publication, time lag, language, duplicate publication and citation.

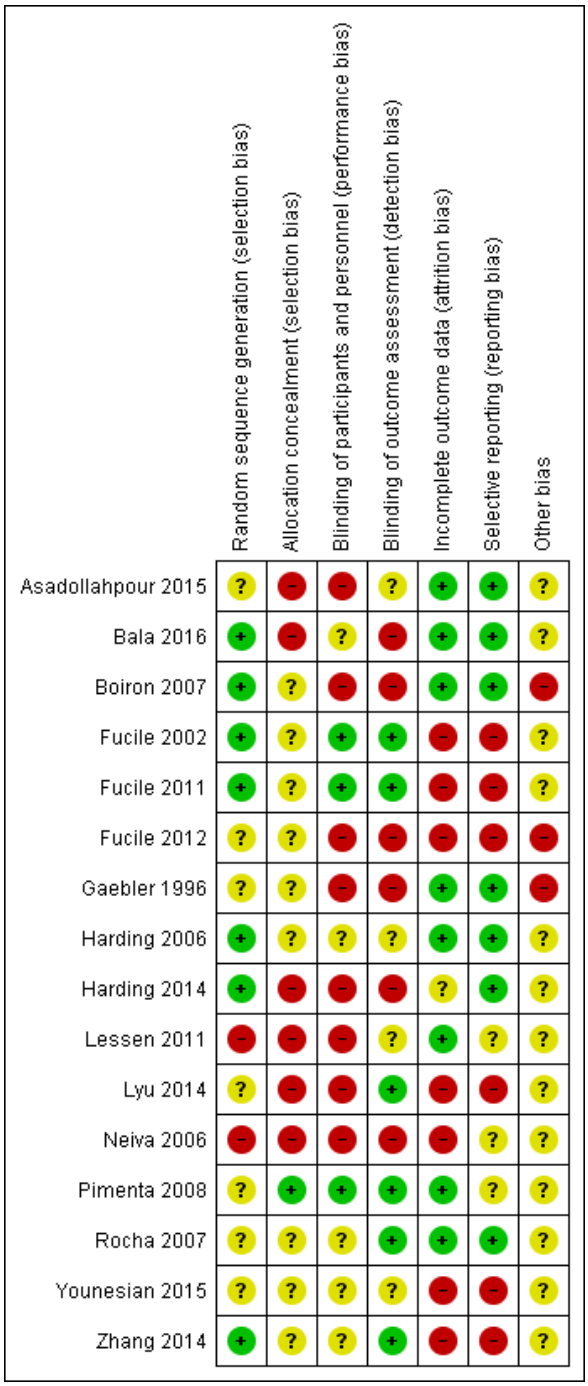
Other sources of bias

Was the study apparently free of other problems that could put it at high risk of bias?
For each included study, we described important concerns that we had about other possible sources of bias (e.g. whether we noted a potential source of bias related to the specific study design, whether the trial was stopped early because of some data-dependent process). We assessed whether each study was free of other problems that could put it at risk of bias as:

- yes;
- no; or
- unclear.

If needed, we planned to explore the impact of the level of bias by undertaking sensitivity analyses.
We created a 'Risk of bias' table for each study in Review Manager 5.3 (RevMan 2015) (Figure 1).

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Measures of treatment effect

We calculated risk ratio (RR) and risk difference (RD) for dichotomous data, and mean difference (MD) for continuous data, with respective 95% confidence intervals (CIs), in Review Manager 5.3 (RevMan 2015).

Unit of analysis issues

The unit of analysis was the individual preterm infant.

Dealing with missing data

We planned to contact study authors to seek missing data if we judged that these data would be useful for the review.

Assessment of heterogeneity

If more than one trial was included in a meta-analysis, we examined the treatment effects of individual trials and heterogeneity between trial results by inspecting the forest plots. We calculated the I^2 statistic for each analysis to quantify inconsistency across studies and to describe the percentage of variability in effect estimates that may be due to heterogeneity rather than to sampling error.

Data synthesis

We performed meta-analyses when data were presented with sufficient information. We used mean difference (MD) for continuous outcomes when analysing interventions and outcomes of sufficient homogeneity. For dichotomous outcomes, we used risk ratio (RR) and risk difference (RD) and the fixed-effect model for meta-analysis.

Quality of evidence

We used 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: days to full oral feeding, weight gain, days of parenteral nutrition, total hospital stay (days), exclusive direct breast feeding at discharge and any direct breast feeding at discharge.

Two authors independently assessed the quality of the evidence for each of the outcomes above. We considered evidence from randomized controlled trials as high quality but downgraded 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 used the GRADEpro 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

If sufficient data were available, we planned to undertake subgroup analyses of:

- infants born at < 28 weeks' PMA;
- infants born from 28 to < 32 weeks' PMA;
- infants breast fed exclusively;
- infants bottle fed exclusively; and
- infants who were both breast fed and bottle fed.

Sensitivity analysis

We planned to perform sensitivity analyses based on methodological quality.

RESULTS

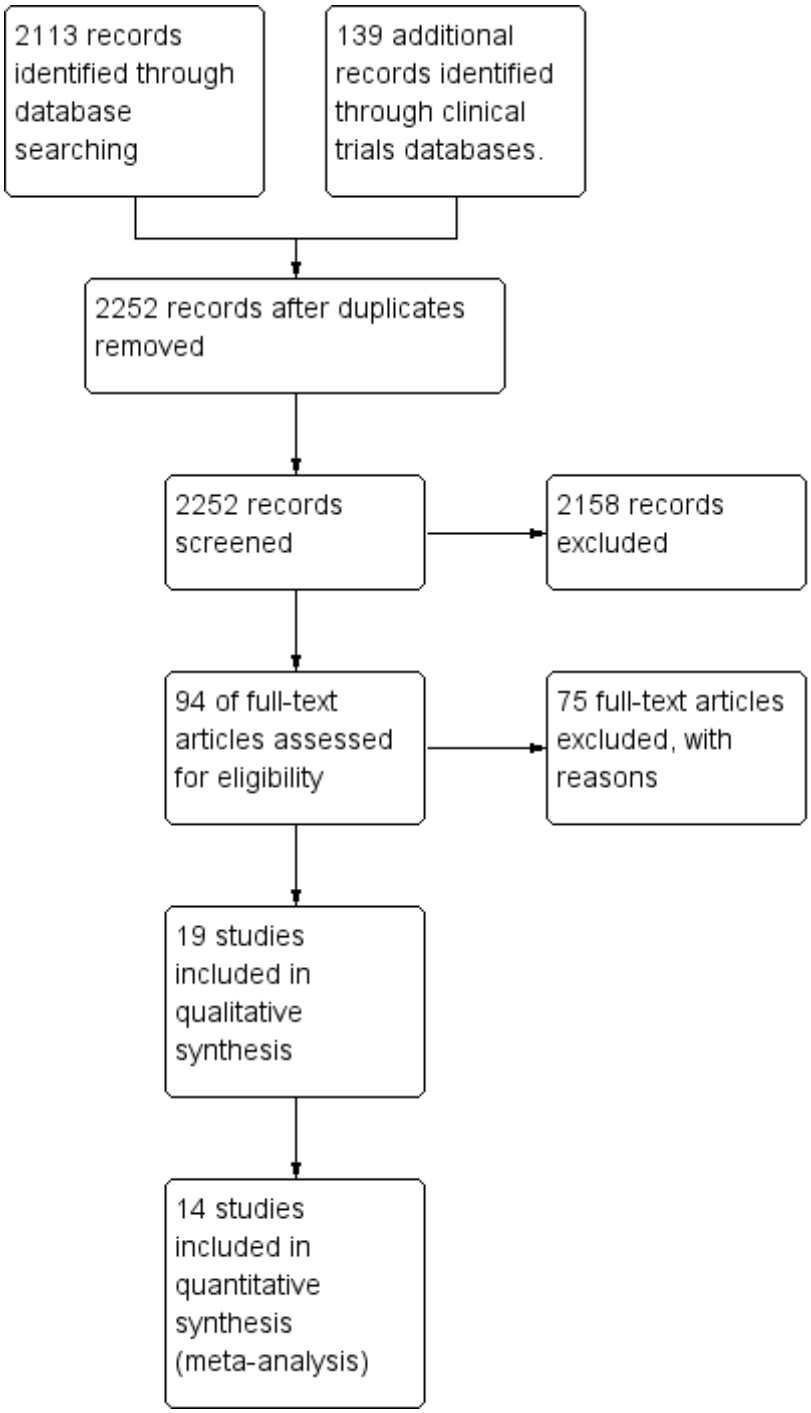
Description of studies

Results of the search

The search yielded 2252 studies after duplicates were excluded (Figure 2). Screening of titles resulted in 94 trials for further scrutiny. Review authors determined that 17 studies were potentially eligible for inclusion in the review. On further inspection at data extraction, we had to exclude the stage 1 study, as data could not be extracted in relation to infants under 37 weeks' PMA (Howard 2003). Therefore, a total of 16 studies were eligible for full data extraction. All studies were published in English. Searching of conference proceedings revealed no abstracts apart from

the ASHA (American Speech-Language-Hearing Association) Perspectives Special Interest Group 13 (2001 to 2016), for which a separate online search revealed 73 abstracts; we identified six as relevant to this topic, but all were reviews or summaries of the literature, and we excluded them on this basis (Gosa 2006; Faherty 2006; Lau 2014; Ross 2008b; Shaker 2010; Sheppard 2005).

Figure 2. Study flow diagram.



Included studies

See Characteristics of included studies.

We included 16 RCTs (no quasi-RCTs) that enrolled between 14 and 108 participants, for a total of 825 participants.

All trials reported finger stimulation protocols before feeds (gavage or oral) with or without other supports. Broadly, these fell into two comparison types (Table 1).

- Oral stimulation versus no intervention or standard care (Bala 2016; Boiron 2007; Gaebler 1996; Harding 2006; Harding 2014; Lyu 2014; Neiva 2006; Younesian 2015; Zhang 2014).
- Oral stimulation versus another non-oral stimulation intervention (Asadollahpour 2015; Fucile 2002; Fucile 2011; Fucile 2012; Lessen 2011; Pimenta 2008; Rocha 2007).

No studies assessed an oral stimulation intervention versus another oral stimulation intervention that differed in method (e.g. dosage/intensity, frequency, duration and/or timing of delivery, mode of delivery, personnel delivering the intervention).

Interventions

'Fucile protocol'

Nine trials replicated the 15-minute finger stimulation protocol described by Fucile 2002 as their primary oral stimulation intervention (Asadollahpour 2015; Fucile 2011; Fucile 2012; Harding 2014; Lyu 2014; Pimenta 2008; Rocha 2007; Younesian 2015; Zhang 2014). This 'Fucile protocol' is a clearly described prefeeding finger stimulation protocol that involves 12 minutes of structured finger stroking and three minutes of pacifier sucking (i.e. 15 minutes once a day for one consecutive day one to 30 minutes before a tube feeding). Researchers clearly describe a sham stimulation for the control group.

Interventions in other trials

The other studies reported a range of interventions that differed in dose, frequency and method of delivery. Bala 2016 used an intervention described by Hwang 2010 - a five-minute prefeeding oral stimulation programme delivered before feeds five times a day, involving three minutes of manual perioral and intraoral stimulation, followed by two minutes on a pacifier. Gaebler 1996 described a different five-minute oral stroking protocol that was completed three times daily, five days a week, before feeds. Harding 2006 described another finger stimulation protocol delivered by parents by which a finger or a pacifier could be used to elicit non-nutritive sucking, then the finger or pacifier remained in the infant's mouth for the first 10 minutes of tube feeding from when feeding readiness was demonstrated until all feeds were given orally. This was done three times daily. The stimulation protocols reported by Neiva 2006 were vague and were not replicable; investigators simply stated that groups received no stimulation, received non-nutritive sucking with a pacifier or received stimulation of non-nutritive sucking with a gloved finger. Stimulation was done daily for 10 minutes, except on weekends. The finger stimulation protocol described by Boiron 2007 differs again from those described above, involving a 12-minute finger stimulation programme with or without oral support during feeding. The protocol was delivered once a day 30 minutes before gavage feeds for the last 14 consecutive days of gavage feeds. Lessen 2011 described a five-minute oral motor programme delivered from 29 weeks' PMA once a day for seven consecutive days.

Outcomes

Most trials reported outcome observations only for the short term (i.e. on discharge from NICU), with the exception of Pimenta 2008, which followed groups up to six months of age. Several primary and secondary outcome measures were not reported by any studies (i.e. time (days) spent in NICU (one of our primary outcomes)), and secondary outcomes included direct breast feeding at term corrected age, developmental outcomes at 12 to 18 months of age, retinopathy of prematurity, family satisfaction and non-compliance with the intervention. Harding 2014 reported follow-up at six months. Researchers noted numerous hospital readmissions, problems with oral feeding within that time frame and receptive and expressive language ratings on the Preschool Language Scales - a standardised and validated assessment tool - but these did not fall within the remit of our outcome measures.

Excluded studies

See Characteristics of excluded studies.

Risk of bias in included studies

Review authors noted variable risk of bias across all studies across all domains, with generally poorly described randomisation methods and poor allocation concealment and blinding of participants and outcome assessors (Figure 1). Only three studies performed reasonably well across the seven domains in terms of adequate sequence generation; adequate blinding of participants, personnel and outcome assessors; reports of complete data; and apparent low risk of selective reporting (Harding 2006; Pimenta 2008; Rocha 2007). The risk of bias graph (Figure 1) shows high risk of bias across the 16 studies for allocation concealment, blinding of participants and personnel, blinding of outcome assessment and incomplete outcome data.

Allocation

Seven studies adequately described their random sequence generation methods (Bala 2016; Boiron 2007; Fucile 2002; Fucile 2011; Harding 2006; Harding 2014; Zhang 2014). We could not determine the method used in the other 12 studies. Only one study described adequate allocation concealment (Pimenta 2008). We could not determine allocation concealment in 15 studies. Eight studies had unclear methods of allocation (Fucile 2002; Fucile 2011; Fucile 2012; Gaebler 1996; Harding 2006; Rocha 2007; Younesian 2015; Zhang 2014), and seven provided a poor or no description of allocation (Asadollahpour 2015; Bala 2016; Boiron 2007; Harding 2014; Lessen 2011; Lyu 2014; Neiva 2006).

Blinding

Only five studies described blinding of participants and personnel (Fucile 2002; Fucile 2011; Pimenta 2008; Rocha 2007; Zhang 2014). Only six studies described blinding of outcome assessors (Fucile 2002; Fucile 2011; Lyu 2014; Pimenta 2008; Rocha 2007; Zhang 2014).

Incomplete outcome data

Review authors noted missing data in several studies, particularly in relation to behavioural data taken at every intervention and adverse effects.Eight trials provided complete data (Asadollahpour 2015; Bala 2016; Boiron 2007; Gaebler 1996; Harding 2006; Lessen 2011; Pimenta 2008; Rocha 2007).

Selective reporting

Seven trials had low risk of reporting bias (Asadollahpour 2015; Bala 2016; Boiron 2007; Gaebler 1996; Harding 2006; Harding 2014; Rocha 2007); remaining studies had unclear or high risk of reporting bias.

Other potential sources of bias

Four trials had other biases (Boiron 2007; Fucile 2012; Gaebler 1996; Neiva 2006). It was unclear whether other sources of bias were present in the remainder.

Effects of interventions

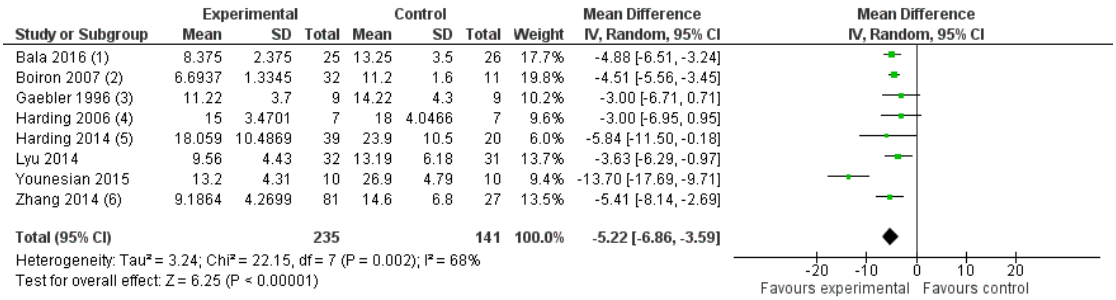
See: **Summary of findings for the main comparison** Summary of findings table 1. Oral stimulation intervention versus standard care; **Summary of findings 2** Summary of findings table 2. Oral stimulation intervention versus other non-oral intervention

Comparison group 1

Days to full oral feeding

(Analysis 1.1; Figure 3)

Figure 3. Comparison group 1. Analysis 1.1. Days to full oral feeding.



Footnotes
(1) Median and range only provided. We calculated estimated mean and standard deviation from figures provided
(2) Data for 3 intervention groups combined
(3) Number of days in the study reported
(4) Median and range only provided. We calculated estimated mean and standard deviation from figures provided
(5) Data combined for 2 intervention groups/SD was calculated by authors from information provided
(6) Data combined for 3 intervention groups

Meta-analysis showed statistically significantly fewer days taken to attain full oral feeding in the intervention groups (MD -4.81, 95% CI -5.56 to -4.06, I^2 = 68%, eight trials, 376 infants). Four of these studies (Harding 2014; Lyu 2014; Younesian 2015; Zhang 2014) followed the 'Fucile protocol', and the remaining studies (Bala 2016; Boiron 2007; Gaebler 1996; Harding 2006) used a range of different interventions. The GRADE rating for methodological quality was low (Summary of findings for the main comparison).

Weight gain

(Analysis 1.2)

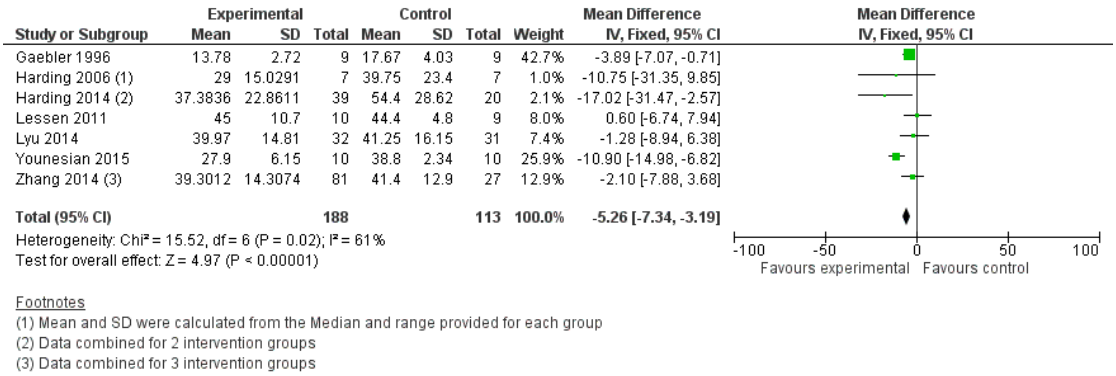
Only two studies used 'weight gain' as an outcome measure (Gaebler 1996; Lyu 2014). Other studies used varying terminology to describe weight: Younesian 2015 described weight change from four oral feeds a day/four to eight oral feeds a day/eight oral feeds a day until discharge (grams), and Zhang 2014 described % weight gain. Therefore, we included only two studies in the meta-analysis, which showed no significant effect of the intervention on weight gain (MD 0.73 grams, 95% CI -1.05 to 2.51 grams, I^2 = 41%, two trials, 81 infants).

The GRADE rating for methodological quality was low (Summary of findings for the main comparison).

Days in hospital

(Analysis 1.3; Figure 4)

Figure 4. Comparison group 1. Analysis 1.3. Total hospital stay (days).



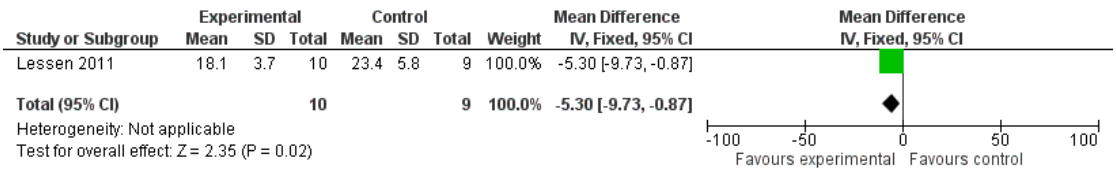
Footnotes
(1) Mean and SD were calculated from the Median and range provided for each group
(2) Data combined for 2 intervention groups
(3) Data combined for 3 intervention groups

Meta-analysis showed that the intervention group had a statistically significantly shorter hospital stay (MD -5.26 days, 95% CI -7.34 to -3.19 days, I^2 = 61%, seven trials, 301 infants). The GRADE rating for methodological quality was very low (Summary of findings for the main comparison).

Duration of parenteral nutrition (days)

(Analysis 1.4; Figure 5)

Figure 5. Comparison group 1. Analysis 1.4. Duration (days) of parenteral nutrition.



Lessen 2011 reported a statistically significant reduction in the number of days of parenteral nutrition in the intervention group (MD -5.30, 95% CI -9.73 to -0.87). The GRADE rating for methodological quality was very low (Summary of findings for the main comparison).

Exclusive direct breast feeding on discharge

(Analysis 1.5)

Harding 2014 did not show a statistically significant difference in exclusive direct breast feeding on discharge with the intervention (RR 1.83, 95% CI 0.96 to 3.48). The GRADE rating for methodological quality was very low (Summary of findings for the main comparison).

Any/Partial direct breast feeding on discharge

(Analysis 1.6)

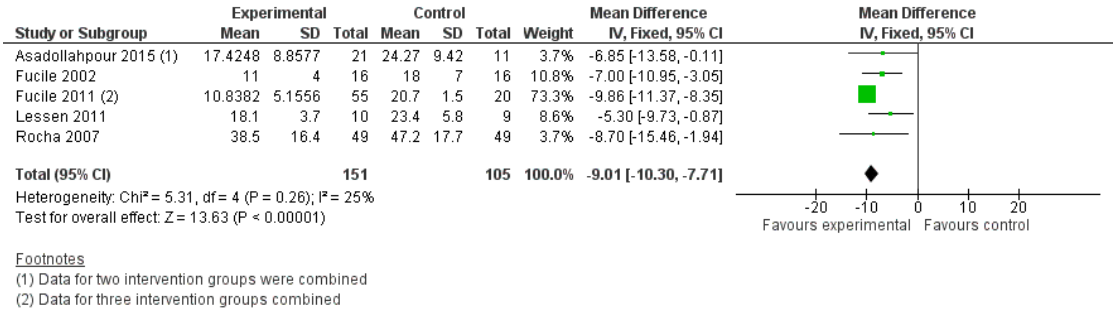
Meta-analysis did not show a statistically significant effect on any or partial direct breast feeding on discharge with the intervention (RR 1.24, 95% CI 0.58 to 2.66, I^2 = 60%, two trials, 100 infants). The GRADE rating for methodological quality was very low (Summary of findings for the main comparison).

Comparison group 2

Time (days) to achieve exclusive oral feeding

(Analysis 2.1; Figure 6)

Figure 6. Comparison group 2. Analysis 2.1. Time (days) to achieve exclusive oral feeding.

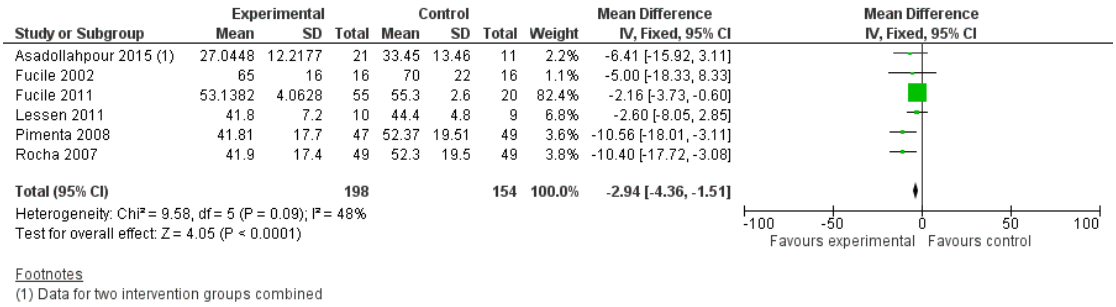


Meta-analysis showed a statistically significant reduction in days to achieve exclusive oral feeding with the intervention (MD -9.01 days, 95% CI -10.30 to -7.71, I^2 = 25%, five trials, 256 infants). The GRADE rating for methodological quality was low (Summary of findings 2).

Days in hospital

(Analysis 2.2; Figure 7)

Figure 7. Comparison group 2. Analysis 2.2. Total hospital stay (days).

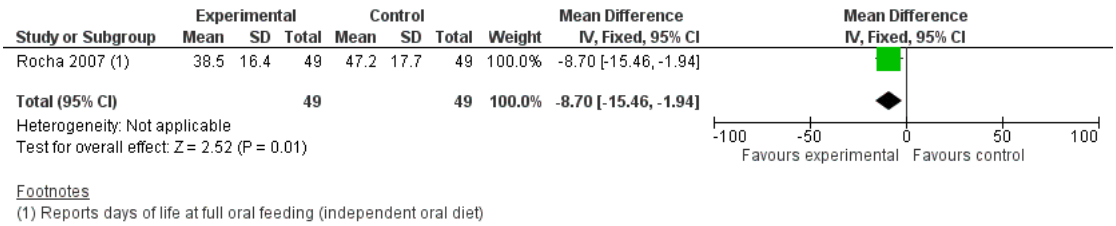


Meta-analysis showed a statistically significant reduction in total hospital stay (days) for the intervention group (MD -2.94, 95% CI -4.36 to -1.51, I^2 = 48%, six trials, 352 infants). The GRADE rating for methodological quality was low (Summary of findings 2).

Duration (days) parenteral nutrition

(Analysis 2.3; Figure 8)

Figure 8. Comparison group 2. Analysis 2.3. Duration (days) of parenteral nutrition.



Rocha 2007 showed a statistically significantly shorter duration of parenteral nutrition in the intervention group (MD -8.70, 95% CI -15.46 to -1.94). The GRADE rating was low.

Weight gain

No studies described 'weight gain' as an outcome measure. Asadollahpour 2015 reported 'weight changes', Fucile 2011 reported 'weight at end of intervention' and Rocha 2007 described 'weight at discharge (g)'; however, these researchers did provide data for weight gain in the first and second weeks of the study for each group (g/kg/d). Therefore, meta-analysis was not possible.

Length gain

This outcome was not reported by any trials.

Head circumference growth

This outcome was not reported by any trials.

Exclusive direct breast feeding at discharge

(Analysis 2.4)

Pimenta 2008 showed no statistically significant difference in exclusive direct breast feeding at discharge with the intervention (RR 0.96, 95% CI 0.72, 1.28). The GRADE rating was moderate.

Maturation in sucking strength

Twelve trials reported a wide variety of different and thereby incomparable suck, swallow and feeding measures, including sucking pressure (mmHg), number of bolus feeds per day, percentage milk ingested daily, number of swallows per minute, number of swallow bursts per minute, number of isolated swallows per minute, rate of milk transfer (mL/min), sucking pattern maturation, sucking frequency and amplitude, proficiency (% milk in first five minutes of feed), volume transfer (% volume consumed/total), volume loss, stage of sucking at different time frames, suction and expression amplitude; suck, swallow and respiratory co-ordination; % nipple feeds engaged in, Revised Neonatal Oral Motor Assessment Scale (R-NOMAS) scores at days 1, 3 and 5; proficiency (Gaebler 1996); NOMAS scores (Harding 2006; Harding 2014); oral feeding progression, oral feeding performance and efficiency (Lyu 2014); easy beginning of sucking, labial sealing, sucking rhythm, labial/tongue/jaw co-ordination (Neiva 2006); numbers of bursts and pauses per minute, mean duration of bursts and pauses, number of sucks per second (Neiva 2007, an additional reporting of Neiva 2006); and rate of milk transfer (mL/min), proficiency and volume transfer at days 1 and 4, and at end of trial (Zhang 2014).

Length (cm/d)

No data are available for this outcome.

Head circumference (cm/d)

No data are available for this outcome.

Developmental outcomes ascertained by a validated instrument at 12 to 18 months

No data are available for this outcome.

Necrotising enterocolitis (≥ Bell's stage 2)

No data are available for this outcome.

Retinopathy of prematurity (any stage and ≥ stage 3)

No data are available for this outcome.

Family satisfaction with intervention

No data are available for this outcome.

Non-compliance with intervention

No data are available for this outcome.

Adverse effects

No adverse effects such as sepsis, oral infection, oral trauma, apnoea or bradycardia episodes that require intervention from the caregiver (stimulation, oronasal suction, increase in delivery of oxygen, assisted ventilation), increase in salivary flow (as measured by the presence of saliva beyond the level of the lips), oxygen dependence at 36 weeks PMA or death during initial hospital stay were reported. Many studies did report adverse effects of apnoea and bradycardia that were self-resolving and did not require intervention other than cessation of the oral stimulation intervention.

ADDITIONAL SUMMARY OF FINDINGS [*Explanation*]

Comparison group 2

Patient or population: preterm infants
Setting: NICU
Intervention: oral stimulation
Comparison: non-oral intervention

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with non-oral intervention	Risk with oral stimulation				
Time (days) to achieve exclusive oral feeding	Mean time (days) to achieve exclusive oral feeding: 0	Mean time (days) to achieve exclusive oral feeding in the intervention group: 9.01, undefined lower (10.3 lower to 7.71 lower)	-	256 (5 RCTs)	⊕⊕◯◯ Low[1,4,5,6,7,8]	Heterogeneity (I^2 = 25%) between studies was low, and issues with selection, performance and attrition bias were noted
Total hospital stay (days)	Mean total hospital stay (days): 0	Mean total hospital stay (days) in the intervention group: 2.94, undefined lower (4.36 lower to 1.51 lower)	-	352 (6 RCTs)	⊕⊕◯◯ Low[1,2,5,6]	
Duration (days) of parenteral nutrition	Mean duration (days) of parenteral nutrition: 0	Mean duration (days) of parenteral nutrition in the intervention group: 8.7, undefined lower (15.46 lower to 1.94 lower)	-	98 (1 RCT)	⊕⊕⊕◯ Low	Only 1 study included Wide confidence interval Not fully blinded
Exclusive direct breast feeding at discharge	500 per 1000	479 per 1000 (346 to 617)	RR 0.96 (0.72 to 1.28)	196 (1 RCT)	⊕⊕⊕◯ Moderate	Only 1 study included

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; OR: odds ratio; RR: risk ratio.

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]High risk of reporting bias.
[2]Moderate heterogeneity (30% to 60%).
[3]Substantial heterogeneity (50% to 90%).
[4]Considerable heterogeneity (75% to 100%).
[5]High risk of selection bias.
[6]High risk of performance bias.
[7]High risk of attrition bias.
[8]Low heterogeneity (0 to 40%).

DISCUSSION

Preterm infants who received oral stimulation rather than usual care took fewer days to attain full oral feeding (mean difference (MD) -4.81, 95% confidence interval (CI) -5.56 to -4.06), had a statistically significantly shorter hospital stay (MD -5.62, 95% CI -7.34 to -3.19) and had a statistically significant reduction in the number of days of parenteral nutrition (MD -5.30, 95% CI -9.73 to -0.87). Oral stimulation intervention in this group appeared to have no influence on breast feeding outcomes nor on weight gain compared with usual care.

Infants who received oral stimulation had a statistically significant reduction in the number of days it took to achieve exclusive oral feeding (MD -8.81, 95% CI -10.05 to -7.58), a statistically significant reduction in total hospital stay (days) (MD -2.94, 95% CI -4.36 to -1.51) and a statistically significantly shorter duration of parenteral nutrition (MD -8.70, 95% CI -15.46 to -1.94) compared with these outcomes following usual care. Oral stimulation intervention in this group did not appear to have an impact on breast feeding outcomes.

Summary of main results

We identified 19 randomised controlled trials (RCTs) that were eligible for inclusion in this review. All were of low methodological quality overall.

Investigators reported a range of oral stimulation interventions that appear beneficial for preterm infants in terms of reduced length of hospital stay and earlier transition to oral feeding, with reduced length of time on parenteral nutrition.

Overall completeness and applicability of evidence

The included studies reported positive outcomes involving length of hospital stay, transition times from tube (gavage) to oral feeding and duration of parenteral nutrition. These studies ranged in size but most were small, and they were often poorly designed. Study results should be interpreted with caution and methodological limitations should be assessed when potential use of an intervention is considered.

Quality of the evidence

Trends in the data appear to indicate that providing an oral stimulation intervention by a finger stimulation protocol reduces length of hospital stay, time taken to achieve oral feeding and time spent on parenteral nutrition, but all of the analyses are based on studies of limited methodological quality. Results of the data analysis are encouraging but must be interpreted with caution, given the high risk of bias encountered across virtually all of the included studies.

For comparison group 1, the quality of the evidence ranged from low (days to oral feeding, weight gain) to very low (total hospital stay, parenteral nutrition, breast feeding).

For comparison group 2, the quality of the evidence ranged from moderate (duration of parenteral nutrition, exclusive direct breast feeding at discharge) to low (time to exclusive oral feeding, total hospital stay, days of parenteral nutrition).

Potential biases in the review process

We strove to decrease biases in the review process. Two review authors (ZG, MW) individually examined the titles and abstracts of identified studies while using a screening form. All review authors were involved in the data extraction process. The Cochrane Neonatal Review Group was actively supportive at all stages from designing the database search strategy and conducting the database search to providing advice on methods and making revisions to same.

Our deviations from the protocol consisted of redefinition of oral stimulation interventions, re-scoping of the review focus and application of the GRADE method in assessing the quality of evidence. Our deviations from the protocol were unlikely to introduce bias into the review process.

Agreements and disagreements with other studies or reviews

Not applicable.

AUTHORS' CONCLUSIONS

Implications for practice

Small studies with variable risk of bias and poor methodological quality suggest that oral stimulation interventions shorten the time taken for preterm infants to achieve exclusive oral feeding, reduce length of hospital stay and reduce days on parenteral nutrition. The quality of these studies varied from moderate to very low; therefore, findings should be interpreted with caution. It is apparent however that using an oral stimulation intervention does have a statistically significant positive influence on the outcomes reported, despite varying levels of evidence, and should be considered for all infants in the neonatal intensive care unit (NICU).

Implications for research

Well-designed studies of oral stimulation interventions for preterm infants are warranted. Such studies should:

- clearly define the intervention;

- measure clinically important outcomes that are not limited to those determined before hospital discharge;

- enrol adequate numbers of infants to reliably determine a difference in the primary outcome between groups;

- use a reliable of method of randomisation;
- conceal the treatment allocation;
- blind caregivers to treatment when possible;
- pay particular attention to blinding of outcome assessors; and
- report all outcomes.

Methods used to assess sucking and feeding have not been standardised. This has led to lack of standardised reporting of clinically relevant outcomes for suck and swallow maturation. The terminology used to describe sucking and feeding skills should be made more uniform, so studies can be more comparable and outcomes more clinically relevant.

ACKNOWLEDGEMENTS

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Dr William Maguire, Hull York Medical School & Centre for Reviews and Dissemination, University of York, UK, provided advice on methods.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Asadollahpour 2015

Methods	Country: Iran RCT Three study groups. Randomisation method not fully described No evidence of allocation concealment Blinding of personnel delivering the intervention unclear Blinding of outcome assessor unclear
Participants	Preterm infants from 26 to 32 weeks of gestational age fed through a tube with birth weight 1000 to 2000 grams **NNS intervention group:** N = 11 (6 male/5 female), GA 30.18 ± 1.77 weeks, birth weight 1406.36 grams **Prefeeding oral stimulation group:** N = 10 (5 male/5 female), GA 30.01 ± 1.76, birth weight 1343.01 grams **Control group:** N = 11 (5 male/6 female), GA 30.29±1.95, birth weight 1393.63 grams
Interventions	• **NNS intervention:** thrice-daily stroking of the palate for 5 minutes to elicit a suck. This intervention was delivered by a speech and language therapist (SLT) who was 'blinding to research' and was performed through insertion of the SLT's little finger into infant's oral cavity to gently stroke the hard palate to elicit a suck. NNS stimuli were started during initial 5 minutes of tube feeding and were administered for 10 consecutive days. Protocol same as that described by Harding 2009 • **Prefeeding oral stimulation intervention:** performed by the same SLT. Oral stimulation programme consisted of once-daily stroking of cheeks, gums and tongue, followed by 3 minutes of non-nutritive sucking for 15 minutes. Protocol same as that described by Fucile 2002 • **Control:** Group received sham intervention. For this group, the same SLT placed her hands in the incubator without touching the infant for 15 minutes. This was administered for 10 consecutive days
Outcomes	**Primary outcome:** time to attain independent oral feeding **Secondary outcomes:** • Length of hospital stay • Weight gain
Notes	For birth weight, median values provided. Mean or standard deviation had to be calculated. Adverse events not recorded or reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random assignment was performed by 'a simple randomisation method', whereby

Asadollahpour 2015 (*Continued*)

		infants were randomly assigned to NNS (n = 11), prefeeding oral stimulation (n = 10) and control (n = 11) groups. This was not clearly described
Allocation concealment (selection bias)	High risk	Despite study authors reporting, "This intervention delivered by one speech therapist who was blinding to research", this SLT delivered all interventions and therefore was aware of allocation in all groups
Blinding of participants and personnel (performance bias) All outcomes	High risk	Same SLT delivered all interventions and sham interventions and was not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Weight was measured by 'a nurse'. It is unclear whether the same nurse measured all infants, or whether the nurse on duty at the time of weigh in performed the measurements
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes are reported. No data were missing.
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review were reported
Other bias	Unclear risk	Information was insufficient to permit judgement. Adverse events were not recorded or reported

Bala 2016

Methods	Country: India RCT Two study groups. Randomisation method described No evidence of allocation concealment Blinding of personnel delivering the intervention unclear Blinding of outcome assessor unclear
Participants	51 healthy stable neonates who had reached full gavage feeding, were in transition from gavage to spoon feeding and were receiving NNS and kangaroo mother care (KMC) as routine care **Treatment group:** 25 infants (10 male/15 female), gestational age 30.9 (1.7) weeks, birth weight 1285 (283) grams **Control group:** 26 infants (16 male/10 female), gestational age 30.3 (1.5) weeks, birth weight 1212 (323) grams

Interventions	Intervention is not directly described, but Hwang 2010 is cited as a reference for the protocol. Hwang 2010 describes a 5-minute programme modified from existing literature, which involves 3 minutes of manual perioral and intraoral stimulation, followed by 2 minutes on a pacifier Mothers were trained in oromotor stimulation (OMS) by principal investigator **Intervention group:** OMS finger stimulation protocol plus standard care (NNS & KMC) delivered by mothers trained on approach by PI **Control group:** standard care described only as NNS and KMC
Outcomes	**Primary outcome:** comparison of transition time from full gavage feed to partial and full spoon feed • Partial spoon feed was defined as accepting nearly 50% of the total volume of milk by spoon and 50% by orogastric tube during each feed, and 1 to 2 full spoon feeds in a day. • Feeding efficacy was assessed by volume of total spoon feed intake (mL/kg/feed) and by spoon feed intake rate per minute (mL/min). **Secondary outcome:** assessment of total volume of milk by spoon at each feed and time required to complete full spoon feed and partial direct breast feed at discharge • Partial breast feed was defined as when baby was accepting full breast feed 5 to 6 times a day and the rest of feeds by spoon.
Notes	Study authors report, "No harms or unintended effects like desaturation, aspiration, apnoea, hypothermia, bradycardia, or infection were observed"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment was performed with computer-generated random numbers Sequentially numbered sealed opaque envelopes were opened by the principal investigator to assign infants to intervention groups
Allocation concealment (selection bias)	High risk	Principal investigator was not blinded to allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	OMS was performed by mothers in the intervention group. It is unclear whether they were blinded to group allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Study authors state, "intervention and assessment could not be blinded due to its nature"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes are reported for all infants who achieved partial spoon feed, full spoon feed

Bala 2016 (*Continued*)

		and partial breast feed at discharge
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	Information was insufficient to permit judgement.

Boiron 2007

Methods	Country: France RCT Four study groups. Randomisation method described Allocation concealment unclear Blinding of personnel delivering the intervention unclear Blinding of outcome assessor unclear
Participants	43 participants were recruited and participated in the study (23 males/20 females); all were born between 29 and less than 34 weeks and entered the protocol at between 32 and less than 34 weeks GA; no older than 4 days of age **Treatment group 1 (stimulation and support):** 9 participants (5 males/4 females), age range 32 to 34 weeks, mean GA 31.3 weeks, mean birth weight 1718 grams **Treatment group 2 (stimulation):** 11 participants (4 males/7 females), age range 32 to 24 weeks, mean GA 31.1 weeks, mean birth weight 1446 grams **Treatment group 3 (support):** 11 participants (7 male/4 female), age range 32 to 34 weeks, mean GA 31.6 weeks, mean birth weight 1714 grams **Control group:** 11 participants (7 male/4 female), age range 32 to 34 weeks, mean GA 31.1 weeks, mean birth weight 1442 grams
Interventions	**Treatment group 1:** received oral stimulation and support **Treatment group 2:** received oral stimulation only **Treatment group 3:** received support only **Control group:** no intervention described; assumed standard care Infants in treatment group 1 received 12 minutes of a clearly described oral stimulation protocol 30 minutes before gavage feed for last 14 consecutive days of period of gavage, and oral support for 2 oral feeds a day for a maximum of 10 minutes per bottle during the transition period. Treatment groups 2 and 3 each received only 1 component of this programme
Outcomes	All participants had a baseline sucking assessment with a pacifier and a transducer recording system. Five-minute recordings were taken at 3, 7 and 14 days **Outcome measures:** • Sucking pressure • Time (days) taken to attain exclusive oral feeding • Number of bottle feeds per day and quantity of milk (percentage) ingested per day
Notes	Adverse events were not reported.

Boiron 2007 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A blocked randomisation process is described: "randomisation lists were computer generated with blocks of varying size"
Allocation concealment (selection bias)	Unclear risk	This is not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Investigators were not blinded to intervention groups.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Measures of sucking were made by investigators; it is unclear who decided to increase volume of oral feeding
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes are reported. No data were missing.
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	High risk	Adverse events were not reported. It is unclear who decided to increase volume of oral feeding as intervention progressed

Fucile 2002

Methods	Country: USA RCT **Random sequence generation:** stratified random sampling technique used to ensure that groups were similar in mean gestational age and birth weight Allocation concealment unclear No blinding of personnel delivering the intervention. Researchers carried out both treatment and sham treatments. Caregivers and family blinded to intervention Blinding of outcome assessors unclear **Treatment duration:** 10 consecutive days
Participants	32 participants in total: 19 females, 13 males 16 participants in each group **Treatment group:** N = 16, age range 28 ± 1.3 weeks, GA 26.4 to 29.9 weeks, birth weight 1044 ± 260 (740 to 1500) grams **Control group:** N = 16, age range 28.1 ± 1.1 weeks, GA 26.0 to 29.7 weeks, birth weight 959 ± 244 (560 to 1300) grams

Interventions	Nursing and medical staff were reported to be blinded to the intervention, as a screen was placed around the isolette during any intervention. Both groups were monitored from time of entry into the study until discharge from the hospital. Initiation and advancement of oral feeding were left to the discretion of the attending physician and nurses who were responsible for standard feeding care. Measures were taken at the introduction of oral feeds, at 1 oral feed per day, at 4 oral feeds per day and at 8 oral feeds per day. Interventions were started 48 hours after discontinuation of nasal CPAP. Intervention was not administered if infants were disturbed 30 minutes before the intervention, and it was stopped if infants were medically unstable and/or had any episodes of oxygen desaturation and/or apnoea/bradycardia during the intervention. Treatment group received a prefeeding oral stimulation programme consisting of a 12-minute finger stroking protocol, followed by 3 minutes of sucking on a pacifier. Intervention lasted 15 minutes and was performed once a day for 10 consecutive days, 15 to 30 minutes before a tube feeding Control group received sham stimulation identical to the prefeeding stimulation programme, except that they did not receive the 15-minute finger stroking and pacifier portion of the protocol
Outcomes	• Days to transition from complete tube feeding to independent oral feeds • Days to 1 oral feed a day • Days to 4 oral feeds a day • % volume intake • Rate of milk transfer (mL/min) • Length of stay • PMA and weight at both 1 to 2 oral feeds per day and 6 to 8 oral feeds per day • Sucking pattern maturation • Sucking frequency and amplitude • Behavioural state before and after feeds, number of episodes of apnoea, bradycardia or oxygen desaturation
Notes	Both gestational age (GA) and postmenstrual age (PMA) are used in the report. GA is used to describe age at birth and age range of groups, PMA to describe age at feeding Some adverse effects were reported in 1 case, in which bradycardia was observed but resolved spontaneously

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Infants were randomised into control or experimental groups in blocks of 4, stratified by gestational age (26 to 27 vs 28 to 29 weeks)
Allocation concealment (selection bias)	Unclear risk	This was not described.
Blinding of participants and personnel (performance bias)	Low risk	Researchers carried out both treatments and sham treatments. Caregivers and fam-

Fucile 2002 (*Continued*)

All outcomes		ily were blinded to intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Advancement of oral feeding was done at the discretion of physicians, who were blinded to treatment allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	It is reported that groups were similar in baseline characteristics, such as number of infants who received breast feedings throughout the study, gastric residuals, oxygen requirement, episodes of oxygen desaturation and/or apnoea/bradycardia at the 3 monitored feeding sessions and behavioural state, although data are not provided to confirm
Selective reporting (reporting bias)	High risk	Not all outcomes are fully reported as above.
Other bias	Unclear risk	Information provided was insufficient to permit judgement.

Fucile 2011

Methods	Country: USA RCT **Random sequence generation:** infants randomised through stratified blocked randomisation **Follow-up:** participants monitored from study start to hospital discharge **Treatment duration:** 14 days
Participants	75 infants were enrolled: **Group 1:** N = 19 (12 male/7 female), 10 age 26 to 29 weeks GA, 9 age 30 to 32 weeks GA, birth weight not provided but weight at introduction of oral feeding was 2001.3 (63.3) grams **Group 2:** N = 18 (11 male/7 female), 8 were 26 to 29 weeks GA, 10 were 30 to 32 weeks GA, birth weight not provided but weight at introduction of oral feeding was 2065.6 (108.7) grams **Group 3:** N = 18 (10 male/8 female), 11 were 26 to 29 weeks GA, 7 were 30 to 32 weeks GA, birth weight not provided but weight at introduction of oral feeding was 1952.1 (48.7) grams **Control group:** N = 20 (16 male/4 female), 9 were 26 to 29 weeks GA, 11 were 30 to 32 weeks GA, birth weight not given but weight at introduction of oral feeding was 1885.2 (61.5) grams
Interventions	**Group 1, oral (O):** twice-daily finger stroking protocol of the cheeks, lips, gums and tongue for 12 minutes and NNS for 3 minutes as per previously described protocol **Group 2, T/K:** twice-daily stroking of the head, neck, back, arms and legs for 10 minutes and passive range of motion to the limbs for 5 minutes

	Group 3, O + T/K: 15 minutes of O or T/K, each once a day, in random order **Control intervention:** Researcher placed her hands in the incubator but did not touch the infant for 15 minutes twice daily Assigned interventions were started 48 hours after discontinuation of nasal CPAP and were administered in two 15-minute sessions/d for 10 days over a 14-day period. Sessions were provided 30 minutes before tube feedings, with a minimum 3-hour interval between sessions, to clinically stable infants. Interventions were stopped if adverse effects were observed. All interventions were administered by the same researcher. A screen was placed around the incubator for all interventions Data on the primary outcome were gathered from the charts of 10 additional infants to assess for any potential Hawthorne effect (Hawthorne group)
Outcomes	• Time to attainment of oral feeding • Proficiency (% milk in first 5 minutes) • Volume transfer (% volume consumed/total) • Rate of transfer (mL/min) • Volume loss, length of hospital stay • Neurobiological risk score • Apnoea • Bradycardia • Oxygen desaturation • Fussing • Crying • Spitting up • Number of infants receiving co-interventions (occupational, physical and/or speech therapy) • Number of parental visits
Notes	Both GA and PMA were used to describe participant age. **Adverse events:** Of 1100 administered interventions, 13 (1.1%) were stopped because of apnoea, bradycardia or oxygen desaturation episodes, all of which resolved spontaneously

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised in blocks (size not stated) stratified by gestational age (26 to 29 vs 30 to 32 weeks) and time ("every 3 months")
Allocation concealment (selection bias)	Unclear risk	This was not described.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Blinding of caregivers was attempted by sham procedure (therapist placed hands in incubator for 15 minutes) with screen placed around the incubator Investigator was not blinded to the intervention but was not involved in outcome

Fucile 2011 (*Continued*)

		measurement
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Primary outcome was time to independent oral feeding; feeding advancement was done at the discretion of blinded physicians
Incomplete outcome data (attrition bias) All outcomes	High risk	Information was provided regarding number of infants receiving co-interventions (occupational, physical and/or speech therapy) Number of parental visits was not reported.
Selective reporting (reporting bias)	High risk	As above. Information was provided regarding number of infants receiving co-interventions (occupational, physical and/or speech therapy) Number of parental visits was not reported.
Other bias	Unclear risk	Parental visit and therapy intervention information is required to inform interpretation of outcomes

Fucile 2012

Methods	Country: USA RCT **Random sequence generation:** infants randomised by stratified blocked randomisation **Allocation concealment:** no **Blinding of personnel delivering the intervention:** unclear **Blinding of outcome assessors:** unclear **Treatment duration:** 14 days
Participants	75 infants were enrolled: **Group 1, O:** N = 19 (12 male/7 female), age range 29.6 weeks GA (SEM 0.4), 10 were 26 to 29 weeks GA, 9 were 30 to 32 weeks GA, birth weight 1359.7 (78.2) grams **Group 2, T/K:** N = 18 (11 male/7 female), 8 were 26 to 29 weeks GA, 10 were 30 to 32 weeks GA, birth weight 1325.4 (53.3) grams **Group 3, O + T/K:** N = 18 (10 male/8 female), 11 were 26 to 29 weeks GA, 7 were 30 to 32 weeks GA, birth weight 1329.6 (39.1) grams **Control group:** N = 20 (16 male/4 female), 9 were 26 to 29 weeks GA, 11 were 30 to 32 weeks GA, birth weight 1346.6 (39.3) grams
Interventions	**Group 1, oral (O):** twice-daily finger stroking protocol of the cheeks, lips, gums and tongue for 12 minutes and NNS for 3 minutes as per previously described protocol **Group 2, T/K:** twice-daily stroking of the head, neck, back, arms and legs for 10 minutes and passive range of motion to the limbs for 5 minutes **Group 3, O + T/K:** 15 minutes of O or T/K, each once a day, in random order **Control intervention:** Researcher placed her hands in the incubator but did not touch the infant for 15 minutes twice daily

	Assigned interventions were started 48 hours after discontinuation of nasal CPAP and were administered in two 15-minute sessions/d for 10 days over a 14-day period. Sessions were provided 30 minutes before tube feedings, with a minimum 3-hour interval between sessions, to clinically stable infants. Interventions were stopped if adverse effects were observed Participants were monitored from study start to hospital discharge. Nutritive sucking skills were assessed on a 5-point stage of sucking scale, suck/swallow co-ordination was assessed by a suck-to-swallow ratio and respiratory patterns were assessed with nipple-bottle apparatus that simultaneously recorded suck, swallow and respiration. These measurements were monitored once during 3 oral feeding sessions, when infants were taking 1 to 2, 3 to 5 and 6 to 8 oral feedings per day. Management of feeding was left to the discretion of attending neonatologists. Nurses were responsible for standard feeding care
Outcomes	• Stage of sucking • Stage of sucking at 1 to 2 oral feeds/d • 3 to 5 oral feeds/d • 6 to 8 oral feeds/d • Suction amplitude • Expression amplitude • Suck/swallow co-ordination • Swallow/respiratory co-ordination • Pause-swallow-pause (P-SW-P) patterns • Expire-swallow-expire (E-SW-E) patterns Also recorded were severity of illness, number of infants receiving all or partial breast feeding, number of co-interventions (occupational/physical and/or speech therapy), number of parental visits, PMA, days of life, behavioural state during feeding measured on a 3-point scale and episodes of apnoea, bradycardia and/or oxygen desaturation at the 3 monitored oral feeding sessions
Notes	Adverse events were not reported although they were recorded as part of the protocol Although not stated in the study, the profile of these study participants is the same as in Fucile 2011.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Although it was not explicitly stated, this paper appears to report secondary outcomes for infants described in Fucile 2011, as identical numbers of infants are reported in each of the 4 groups. If so, infants in Fucile 2011 were randomised in blocks (size not stated) stratified by gestational age (26 to 29 and 30 to 32 weeks GA) and time (3-month intervals)

Fucile 2012 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	This was not described, although a screen was placed around the incubator for all interventions
Blinding of participants and personnel (performance bias) All outcomes	High risk	Caregivers were blinded. All interventions were administered by the same researcher, who therefore must have been aware of allocation
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded researcher assessed outcomes.
Incomplete outcome data (attrition bias) All outcomes	High risk	Some outcomes were reported for all 75 infants; some data were missing
Selective reporting (reporting bias)	High risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have not been reported. The protocol specifies that the following co-variates were considered and recorded: severity of illness, number of infants receiving all or partial breast feeding, number of co-interventions (occupational/physical and/or speech therapy), number of parental visits, PMA, days of life, behavioural state during feeding measured on a 3-point scale and episodes of apnoea, bradycardia and/or oxygen desaturation at the 3 monitored oral feeding sessions. No outcomes were reported for these co-variates
Other bias	High risk	Although it was not stated in the study, the profile of these study participants is the same as in Fucile 2011.

Gaebler 1996

Methods	Country: USA RCT **Random sequence generation:** no information **Allocation concealment:** no information **Blinding of personnel delivering the intervention:** no **Blinding of outcome assessors:** no
Participants	18 participants **Experimental group:** N = 9 (6 male/3 female/9 Caucasian), mean birth age (range) 32.3 weeks GA (30 to 34), age (range) at start of study 34.3 weeks PCA (32 to 36), mean

	(range) birth weight 1836 (1605 to 2282) grams **Control group:** N = 9 (6 male/3 female/8 Caucasian/1 Black-Caucasion), mean birth age (range) 32.4 weeks GA (31-34), age (range) at start of study 34.1 weeks PCA (33 to 36), mean (range) birth weight 1729 (1410 to 1975) grams
Interventions	NPIA was administered within 24 hours of entry to study, between 30 and 90 minutes before a scheduled feeding by 1 of 4 occupational or physical therapists. Recommendations were made to nursing staff. Then all parents and nurses were provided with information regarding a 5-minute stroking protocol Parents of the experimental group were given further separate instruction about a 2-minute oral motor protocol. They were instructed to carry it out 3 times a day, 5 days a week, before feedings, only until infants were nipple feeding all of their feedings for 24 hours. Parents were instructed to feed infants after they had administered the prefeeding protocol (stroking protocol or stroking, perioral and intraoral protocol). If parents were not able to administer the protocol, nursing staff did so. R-NOMAS was administered within 48 hours of first nipple feed, then again on the following third and fifth days. They were discharged from the study once the infant managed all feeds orally for 24 hours All protocols were to be carried out 5 minutes before feeding, 3 times a day for 5 days Control group carried out a stroking protocol only, involving stroking baby in the isolette on back of head, across neck and shoulders, down head, down legs and down arms, 5 minutes before scheduled feeding. Experimental group was instructed to do the stroking protocol, then a 2-minute oral motor stimulation protocol. Oral stimulation protocol was to take place outside the isolette if the infant was to be held for the feeding, otherwise inside the isolette
Outcomes	• % nipple feeds engaged in • R-NOMAS scores at assessment 1, day 3 and day 5 • Discharge from hospital (days) • Days in study • Intake for first 5 minutes of nutritive sucking on third and fifth days of R-NOMAS testing • Between-group maturation/age • Number of prefeeding protocols
Notes	Adverse effects and unwanted symptoms were not reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details were provided about how infants were assigned to either group
Allocation concealment (selection bias)	Unclear risk	No information was provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Protocols were posted on the isolettes, so therapists and nursing staff were aware of group assignments

Gaebler 1996 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were 1 of the 4 researchers; all were aware of group assignments, as above
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcome data were provided for all infants.
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported. No data were missing
Other bias	High risk	Parents were instructed to feed infants after they had administered the prefeeding protocol and to hold infants in a supported, flexed position for all feedings - nipple or gavage - to facilitate active sucking. This could have had an influence on ability to suck and feed, thereby introducing bias. Additionally, both parents and nursing staff/researchers carried out the interventions, which may have added variability in delivery of interventions

Harding 2006

Methods	Country: UK RCT Random sequence generation using stratified random sampling technique Allocation concealment reported Blinding of personnel delivering the intervention unclear Blinding of outcome assessors: unclear
Participants	14 participants (3 male/11 female) - paired groups **Pair 1:** GA 27 weeks, birth weight 1325 grams (intervention infant)/1085 grams (control infant) **Pair 2:** GA 29 weeks, birth weight 1325 grams (intervention infant)/1420 grams (control infant) **Pair 3:** GA 30 weeks, birth weight 1500 grams (intervention infant)/1650 grams (control infant) **Pair 4:** GA 32 weeks, birth weight 1920 grams (intervention infant)/1925 grams (control infant) **Pair 5:** GA 34 weeks, birth weight 1900 grams (intervention infant)/1925 grams (control infant) **Pair 6:** GA 34 weeks, birth weight 1875 grams (intervention infant)/1930 grams (control infant) **Pair 7:** GA 35 weeks, birth weight 2050 grams (intervention infant)/2205 grams (control infant)

Interventions	Intervention was delivered by parents. **Experimental group:** Parents provided 10 minutes of oral stimulation by gently stroking the bottom lip with a finger or a pacifier, then moving intraorally to stimulate the tongue with a gentle front-to-back movement until the finger/pacifier was prompting an NNS pattern. This was carried out during the first 10 minutes of a tube feed from the time infants demonstrated readiness to attempt oral feeding with no supplements until they received all feeds orally **Control group:** No oral stimulation protocol was followed, but infants received usual developmental care approach from the unit, with an SLT providing verbal support and discussion of oral feeding
Outcomes	• Days taken to achieve oral feeding • Days spent in hospital • NOMAS scores
Notes	No adverse effects were recorded or reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A 'matched pairs design' was used. Infants were matched for gestational age and as closely as possible for birth weight. A member of each pair was randomly allocated to treatment or control through a stratified random sampling technique. Allocation was completed by computer-generated random number system
Allocation concealment (selection bias)	Unclear risk	This was not described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Parents performed the intervention. It is unclear whether parents or medical/nursing staff were aware of group allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"The assessment was conducted by the researcher and a speech & language therapist. .. who was unaware of the group allocation' It is unclear whether the researcher and the speech and language therapist were aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were reported for all enrolled infants.
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the re-

Harding 2006 (*Continued*)

		view have been reported
Other bias	Unclear risk	No adverse effects were recorded or reported.

Harding 2014

Methods	Country: UK RCT Random allocation by computer-generated distribution
Participants	59 premature infants born between 26 and 35 weeks
Interventions	Parents, nursing and therapy staff completed the interventions Parents were encouraged to implement the programme a minimum of 3 times a day Nursing/therapy staff completed interventions if parents were unable to be present **Group 1:** NNS (i.e. perioral stimulation programme, as per Fuclie et al, 2002) before start of tube feeding **Group 2:** NNS at start of tube feeding **Group 3:** standard care
Outcomes	• Days to full oral feeding • Days in hospital • Number of infants discharged home while breast feeding • NOMAS scores • Expressive and Receptive Language scores on Preschool Language Scales (PLS)
Notes	Adverse events were not reported. Investigators did not record how many intervention sessions were completed by parents/nurse/therapist per participant

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Participants were randomised to 1 of 3 groups by computer-generated distribution
Allocation concealment (selection bias)	High risk	This was a non-blinded study.
Blinding of participants and personnel (performance bias) All outcomes	High risk	This was a non-blinded study. Parents and therapy staff and nursing staff could all complete the interventions when necessary
Blinding of outcome assessment (detection bias) All outcomes	High risk	This was a non-blinded study.

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 60 enrolled infants, 4 did not complete the study: 2 deteriorated with changes in health and did not progress with the intervention, 2 moved away from the area No intention-to-treat analysis was completed. Acceptable reasons were provided for missing data, and all groups were equally balanced
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	Information was insufficient to permit judgement.

Lessen 2011

Methods	Country: USA RCT **Random sequence generation:** yes **Allocation concealment:** unclear **Blinding of personnel delivering the intervention:** unclear **Blinding of outcome assessors:** unclear
Participants	A total of 19 participants were included: **PIOMI (intervention) group:** N = 10 (4 male/6 female), age range 28.1 ± 0.6 weeks PMA, birth weight 1017.3 ± 127.1 grams, weight at entry to study 1.0 ± 124.6 kg **Control group:** N = 9 (3 male/6 female), age range 28.0 ± 0.9 weeks PMA, birth weight 913 ± 87.8 grams, weight at entry to study 915 ± 145.2 grams Infants were enrolled if they were born between 26 and 29 weeks PMA and were appropriate for gestational age, were clinically stable but could be receiving oxygen via high-flow nasal cannula and had no comorbidities
Interventions	**Experimental group:** received PIOMI (premature infant oral motor intervention), which is a 5-minute oral motor programme that provides assisted movement to activate muscle contraction and provides movement against resistance to build strength. Each intervention was separated by a minimum of 9 hours and a maximum of 36 hours, with 24 hours being ideal **Control group:** did not receive the 5-minute oral stimulation intervention. PI or RA stood at the bedside during that time with both hands inside the isolette for 5 minutes, not touching the infant. Intervention took place over 7 consecutive days and outcomes were measured until discharge. Data collection began on the day the infant reached 29 weeks PMA (before oral feed commencement) and continued once a day for 7 consecutive days, ending at 30 weeks PMA. Oral feeding trial could then commence. Intervention was carried out before a feeding once a day for 7 consecutive days. A card on each participant's bed identified him/her as a participant in the study, but group assignments were blinded to nursing and medical staff and to parents by a curtain pulled around the

	infant's bed for both control (sham) and intervention groups. Feeding progression was tracked through a 6-phase feeding progression protocol. The intervention was provided by the PI or by 1 of 3 research assistants (RAs)
Outcomes	• Mean days gavage feeds to total oral feeds • Transition time through feeding phases • Length of stay • Mean birth weight • Apnoea • Bradycardia
Notes	Nine of 16 infants who received the PIOMI intervention experienced 1 to 3 mild apnoea/bradycardia episodes across the 7 days that were self-corrected after pausing the intervention, and the intervention was continued with no further signs of intolerance

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	"All infants were randomly assigned in blocks of 2". Possible selection bias cannot be ruled out
Allocation concealment (selection bias)	High risk	Infants allocated in "blocks of 2"; therefore next allocation of next infant was known. Also, "if subjects in either group were dropped, they were replaced by assigning the next enrolled subject to that group to maintain equal numbers in groups"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Allocation was concealed from medical and nursing staff and parents by screening researcher who performed intervention or sham. Blinding of some key study personnel was attempted, but researcher was not blinded to the groups; this is likely to introduce performance bias. It is unclear whether outcome assessor was blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Progression of oral feeding was determined from bedside charts, but it is unclear who decided on progression of oral feeds
Incomplete outcome data (attrition bias) All outcomes	Low risk	Eleven (of 30) enrolled infants were excluded post randomisation, and reasons were provided

Lessen 2011 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	Information was insufficient to permit judgement.

Lyu 2014

Methods	Country: China RCT
Participants	Healthy preterm infants born between 29 and 34 weeks GA **Intervention group:** N = 32 (male 16/female16), GA 30.87 ± 1.47 weeks, weight 1597.38 ± 264.263 grams **Control group:** N = 31 (16 male/15 female), GA 30.92 ± 1.48 weeks, weight 1652.50 ± 327.468 grams
Interventions	Oral stimulation programme was developed by Fucile (2002) and consisted of 12 minutes of oral stimulation and 3 minutes of non-nutritive sucking Control group received routine feeding care.
Outcomes	• Oral feeding progression • Oral feeding performance/efficiency • Transition time to full oral feeding • Weight gain • Length of hospital stay • Episodes of apnoea, bradycardia and/or oxygen desaturation during the oral feeding session and behavioural state at the start of the feeding session based on the Anderson Behavioural State Scale were recorded.
Notes	Study authors also provided data on duration of parenteral feeding, although this is not listed as an outcome measure. Ten incidents in experimental groups due to delay or stopping halfway were recorded during the intervention process. Eight incidents were caused by delay because infants were disturbed by a medical or nursing intervention, and 2 sessions were halted after infants suffered an episode of bradycardia, which resolved spontaneously

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Infants were randomly assigned to experimental and control groups by computer-generated random number assignment. Sample size ranged from 1 to 72 as a result of the random number generator feature in Microsoft Excel. Infants receiving numbers 1 to 36 were assigned to the experimental group, and those receiving numbers 37 to 72 were assigned to the control

Lyu 2014 (*Continued*)

		group. Selection bias may be present
Allocation concealment (selection bias)	High risk	The order of the allocation sequence was saved and sealed in an envelope; researchers opened the envelope and recorded groups when infants met the inclusion criteria and after parental informed consent was obtained. Researchers were most likely aware of group allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	This was not reported.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The nurse on duty, who was blind to group assignments, recorded the duration and volume of feeds in every observed oral feeding session
Incomplete outcome data (attrition bias) All outcomes	High risk	Behavioural state feeding data, which were recorded at the start of the feeding session, were not reported
Selective reporting (reporting bias)	High risk	Behavioural outcome data were omitted.
Other bias	Unclear risk	Information was insufficient to permit judgement.

Neiva 2006

Methods	Country: Brazil RCT
Participants	95 preterm infants Participants were divided into 3 groups. Weekly sucking evaluations (NNS and NS) were filmed in a standardised manner (not described) as performed by the researcher. First evaluation co-incided with first oral feeding **Control group:** N = 35 (15 male/20 female), birth age 30.2 (SD 1.82) weeks GA, age at start of study 31.4 (SD 1.5) weeks GA, birth weight 1389.1 (404.7) grams, weight at study entry 1283 (SD 372.2) grams **Group 2 (NNS with pacifier):** N = 30 (17 male/13 female), birth age 30.6 (SD 1.45) weeks GA, age at start of study 31.7 (SD 1.2) weeks GA, birth weight 1357 (SD 324.2) grams, weight at study entry 1294 (SD 338.5) grams **Group 3 (NNS with gloved finger):** N = 30 (15 male/15 female), birth age 30.6 (SD 1.4) weeks GA, age at start of study 31.7 (SD 1.3) weeks GA, birth weight 1425 (SD 298.4) grams, weight at study entry 1330 (SD 305.4) grams
Interventions	**Control:** assumed to be standard care **Stimulation with pacifier:** orthodontic NUK pacifier used for premature infants daily, except on weekends, for 10 minutes at the same time as gavage feeds **Stimulation with gloved finger:** not described but delivered daily, except on weekends, for 10 minutes at the same time as orogastric feeds

Outcomes	• Easy beginning of sucking • Labial sealing • Sucking rhythm • Labial, tongue and jaw co-ordination • Stress signs • Numbers of bursts and pauses per minute • Mean duration of bursts and pauses • Number of sucks per second
Notes	It was difficult to interpret the data and present meaningful results Language is a problem; study was published in English, but most likely this is not the first language of study authors Data were difficult to interpret. Abbreviations were unclear

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Infants were "distributed in a random manner", to ensure a balanced distribution of GA at birth and corrected GA in the 3 study groups. No other details were available
Allocation concealment (selection bias)	High risk	All interventions and assessments were carried out by the researcher. No apparent attempts were made to conceal group allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	No reference is made to blinding of medical and nursing staff, family or primary caregivers
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessor (i.e. researcher) was aware of group assignment
Incomplete outcome data (attrition bias) All outcomes	High risk	Summary statistics were provided, but it is unclear how many infants they describe
Selective reporting (reporting bias)	Unclear risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported, but individual data are not available. Results were difficult to interpret because several abbreviations used in the tables were not explained in the text nor in the Results section
Other bias	Unclear risk	Report was difficult to interpret.

Pimenta 2008

Methods	Country: Brazil RCT
Participants	2 groups of healthy, stable, low birth weight, preterm infants were enrolled 98 were enrolled; 96 remained in the study until they reached corrected age of 6 months **Group 1 (Experimental):** N = 47, GA at birth 30.5 ± 1.2 weeks, GA (range) on reaching clinical stability 32 (28.6 to 35.5) weeks GA, birth weight 1204 ± 222 grams **Group 2 (Control):** N = 49, GA at birth 30.2 ± 1.8 weeks, GA (range) on reaching clinical stability 32.4 (27.5 to 34.4) weeks, birth weight 1125 ± 221 grams
Interventions	Experimental group received a standardised sensory-motor-oral stimulation programme and non-nutritive sucking, delivered by 3 trained SLTs. Groups were followed until 6 months corrected age **Group 1 (Experimental):** finger stimulation programme and NNS with a pacifier, as per Fucile 2002, performed once a day for 15 minutes during gavage feed for 10 days until oral diet commenced **Group 2 (Control):** sham stimulation during which the researcher stood around the incubator for the same length of time as group 1, while infants were positioned and gavage fed. No stimulation or pacifier was offered
Outcomes	• Breast feeding rates on discharge (%) • Breast feeding rates at 3 months • Breast feeding rates at 6 months • Length of stay
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Infants were randomly assigned"; sequence generation was not described
Allocation concealment (selection bias)	Low risk	Sequentially numbered, sealed, opaque, non-translucent envelopes were used
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blinding of medical staff at the neonatal intensive care unit and at the outpatient ward, of nursing staff who provided care to the infants, of the speech therapist who assessed infant capacity to begin sucking and of mothers was reported. Three speech therapists who delivered intervention or sham procedure to enrolled infants were not blinded to group allocation. Therefore, some key study personnel were not blinded, but as outcome assessors and all other personnel were blinded, non-blinding of researchers is unlikely to introduce bias
Blinding of outcome assessment (detection bias)	Low risk	A single external SLT who was double-blinded performed clinical assessment of ability to initiate oral feeding

Pimenta 2008 (*Continued*)

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Two infants in experimental group were lost to follow-up at 6 months Intention-to-treat analysis was reported. Reasons for loss to follow-up were not given.
Selective reporting (reporting bias)	Unclear risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	It is unclear whether other biases were present.

Rocha 2007

Methods	Country: Brazil RCT
Participants	Very low birth weight, healthy, stable preterm infants **Experimental group:** N = 49, GA 30.5 ± 1.7 weeks, birth weight 1195 ± 221 grams **Control group:** N = 49, GA 30.2 ± 1.8 weeks, birth weight 1125 ± 221 grams
Interventions	**Experimental group:** received a stimulation protocol, as per Fucile 2002, plus non-nutritive sucking that appears to last 15 minutes. Not clear when it took place and under what conditions. It appears that this was continued until the newborn began an exclusively oral diet - for at least 10 days **Control group:** received gavage tube diet with a sham procedure for 15 minutes, but this is not described
Outcomes	• Length of stay • Beginning of sucking • Age at discharge • Discharge from hospital (days) Other outcomes reported but not addressed by study authors are days of life at introduction to oral feeds, days of life at full oral feeds, days of life at discharge, GA at introduction to initial oral feeds, GA at introduction of full oral feeds and GA at discharge
Notes	No adverse events were recorded or reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	A double-blind randomised clinical trial was performed. Randomisation was stratified on the basis of gestation age ranges (26 to 28, 28.1 to 30, 30.1 to 32) Newborns were randomised when they reached a full enteral diet (i.e. 100 kcal/kg/d)

Rocha 2007 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Information was insufficient to permit judgement of 'yes' or 'no'
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Procedures were performed by 3 SLTs, who used a previously standardised method; this is not directly described, but the Fucile 2002 protocol is cited. Therefore, staff could not have been blinded to group allocation. Staff members who measured the weight of newborns were unaware of newborn group status. Researchers had no influence on newborn hospital discharge date. Therefore, some key study personnel were not blinded, but as outcome assessors and some other personnel were blinded, non-blinding of researchers is unlikely to introduce bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The newborn's capacity to begin an oral diet was clinically evaluated 3 times a day by an external experienced SLT blinded to which group the child belonged
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data are reported for all participants.
Selective reporting (reporting bias)	Low risk	All of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	This is unclear.

Younesian 2015

Methods	RCT Country: Iran
Participants	20 healthy preterm neonates Intervention group N = 10 (5 boys and 5 girls) GA 31.20 ± 0.78 weeks Control group N = 10 (5 boys and 5 girls) GA 30.90 ± 0.73 weeks All fed by tube
Interventions	Oral sensory motor stimulation programme (15-minute stimulation programme, whose first 12 minutes included stroking the cheeks, lips, gums and tongue, and whose last 3 minutes included the newborn sucking on an index finger of the speech therapist, who was trained by the researchers) was given to the experimental group. This stimulation programme replicated that described in Fucile 2002. Interventions were started before the start of oral feeding and were applied once per day for 10 sequential days, 20 to 40 minutes before initiation of tube feeding. Control group received no stimulation except routine nursery care
Outcomes	• Time (days) to full oral feeding • Length of hospital stay • Weight gain

Notes	Other co-variates were taken into account, including infant's behavioural state at the beginning and at the end of feeding time via the preterm infant's behavioural scale, as well as bradycardia, apnoea and oxygen desaturation throughout oral feeding Two sessions were implemented owing to medical instability. Two sessions were cancelled because infants had an episode of bradycardia

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Convenience sampling was performed; participants were randomly assigned by a simple randomisation method Method was not described; therefore, information was insufficient to permit a judgement of 'adequate' or 'inadequate'
Allocation concealment (selection bias)	Unclear risk	Information was insufficient to permit judgement.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Both nurses and physicians involved in infant management were blinded to group assignment, but breaking of blinding was possible if SLT was noted to be delivering intervention to other infants in the unit not involved in the study. The intervention SLT was aware of intervention group assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Infants were weighed by the same nurse every day at 7 a.m. without clothes and diapers and before feeding. Practitioners who measured the weight of newborns were blinded to assigned group and hospital discharge time. It was not stated who recorded time to oral feeding and length of stay, and it is unclear whether they were blinded to group allocation. Commencement and advancement of oral feeding were assigned to the attending physician, who was reported to be blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Information on infants' behavioural state at the beginning and at the end of feeding time obtained via the Preterm Infants Scale is not reported
Selective reporting (reporting bias)	High risk	Not all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported
Other bias	Unclear risk	Adverse events were not reported.

Zhang 2014

Methods	RCT Country: China Randomised groups
Participants	108 preterm infants
Interventions	**Group 1, NNS:** sucked on pacifier for 5 minutes 7 to 8 times a day **Group 2, oral stimulation (OS):** 12-minute peristimulation programme, as per Fucile 2002 **Group 3:** combined both of the above interventions
Outcomes	• Transition time to full oral feeding • Rate of transfer (mL/min) at D1, D4, D4, DA (autonomous feeding) • Proficiency (i.e. volume of milk taken during first 5 minutes at D1, D4, D4, DA (autonomous feeding)) • Volume transfer (i.e. volume consumed as % of the total at D1, D4, D4, DA (autonomous feeding)) • Length of stay • Average weight gain (%) • Degree of illness recorded on Neonatal Medical Index at admission to NICU
Notes	Behavioural state was measured at the start of the feeding session by the Anderson Behavioural State Scale Episodes of apnoea, bradycardia and/or oxygen desaturation during the feeding session were also measured

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised by stratified blocked randomisation
Allocation concealment (selection bias)	Unclear risk	Information was insufficient to permit judgement.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Two experienced researchers were responsible for administration of all interventions. Initiation and advancement of oral feeding were left to the discretion of the physician; it is unclear whether the physician was blinded. It is unclear whether other personnel (nurses, parents) were blinded to allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Initiation and advancement of oral feeding were left to the discretion of the physician. Feeding variables (rate of transfer/proficiency/volume transfer at days 1, 4

		and 7) and DA (day autonomous feeding achieved) were monitored by a second researcher, who was blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Study authors report, 'there was no difference in terms of behavioural state and numbers of episodes of apnoea, bradycardia or oxygen desaturations'; however, apart from severity of illness scores (Neonatal Medicine Index) provided in the table of baseline characteristics, no other data are provided to confirm this Behavioural state data before and after feeds also are not reported
Selective reporting (reporting bias)	High risk	This is the same as above.
Other bias	Unclear risk	Information was insufficient to permit judgement.

CPAP: continuous positive airway pressure.
DA: day autonomous feeding achieved.
GA: gestational age.
KMC: kangaroo mother care.
NICU: neonatal intensive care unit.
NNS: non-nutritive sucking.
NPIA: Neurobehavioral Preterm Infant Assessment.
NS: nutritive sucking.
OMS: oromotor stimulation.
PCA: postconceptional age.
PI: principal investigator.
PIOMI: premature infant oral motor intervention.
PLS: Preschool Language Scales.
PMA: postmenstrual age.
RA: research assistant.
RCT: randomised controlled trial.
R-NOMAS: Revised Neonatal Oral Motor Assessment Scale.
SEM: standard error of the mean.
SLT: speech and language therapist.

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

Study	Reason for exclusion
Anderson 1986	This is a descriptive literature review of interventions only
Bache 2014	Populations described were preterm infants with respiratory distress syndrome and chronic lung disease, making comparison with healthy preterm infants difficult.
Barlow 2008	Researchers described an adapted pulsating pacifie r for patterned orocutaneous stimulation, not a finger stimulation protocol
Barlow 2014a	Outcomes were specific to non-nutritive sucking parameters only, not to feeding. The population under investigation consists of preterm infants with respiratory distress syndrome and preterm infants of diabetic mothers. It is difficult to compare these infants with healthy preterm infants
Barlow 2014b	Populations described are preterm infants with respiratory distress syndrome and chronic lung disease, making comparison with healthy preterm infants difficult
Bingham 2010	This was not a randomised controlled trial. It was a prospective observational study of 51 infants in various NICUs
Bragelien 2007	Method of sucking stimulation described as the intervention was based on 'Vojta's' technique (i.e. initiating reflex activity of striate and smooth muscle by stroking the chest and underneath the jaw). This was not a finger stimulation protocol by our definition
Breton 2008	This is a review of literature and current research.
Brown 2013	This case study design did not involve oral stimulation.
Case-Smith 1988	This trial used a single-study design.
Chang 2007	Intervention described was not an oral stimulation intervention
Chorna 2014	A percentage of both intervention and control groups had ' whit e matter injury , all types ' and ' white matter injury, severe ', as reported, and these participants cannot be extracted from the rest of the group . Therefore, not all infants in both groups were 'healthy preterm infants', and this study cannot be compared with the other included studies, from which such infants were excluded
Christensen 1976	This study did not include premature infants and was not a randomised controlled trial
Coker-Bolt 2013	This was not a randomised controlled trial. Two groups were compared, including 1 treatment group and 1 historical group, which did not receive treatment
Collins 2004	Intervention described is not an oral stimulation intervention
Dawson 2013	No oral stimulation intervention was reported.
De Curtis 1986	This study used an inadequate design and inappropriate outcome measures

(*Continued*)

Dieter 1997	This study is a literature review.
Einarsson-Brackes 1994	This is not a randomised controlled trial.
Engebretson 1997	Appropriate outcome measures were not included.
Ernst 1989	Intervention involves use of pa cifiers during tube feeds and did not involve a finger stimulation protocol
Faherty 2006	This is a review and discussion of the literature.
Fan 2013	This trial did not report on any of our primary or secondary outcomes
Fewtrell 2012	This trial assessed bottle design - not oral stimulation.
Field 1982	Infants were given pacifiers during all tube feeds. Study did not involve a finger stimulation programme
Finan 1996	This study described development of a piece of equipment for assessing the sucking ability of preterm infants
Fucile 2009	A controlled flow vacuum free bottle system is not an oral stimulation intervention
Gill 1988	No relevant outcomes were measured. Behavioural state observations were reported
Gill 1992	No relevant outcomes were measured. Behavioural state observations were reported
Glass 1994	This is a review article.
Gosa 2006	This is a review and discussion of current literature.
Hill 2000	This was a cross-over trial.
Howard 2003	This study did not include preterm infants < 37 weeks.
Hwang 2010	This was not a randomised controlled trial.
Kao 2010	This study used a cross-over design.
Kumar 2010	Spoon feeding is not an oral stimulation intervention.
Lau 2000b	This was not a randomised controlled trial.
Lau 2012	Intervention options involve pacifier sucking and swallowing or placing a milk bolus on the tongue, where the bolus rests before entering the pharynx. Neither is a finger stimulation protocol by our definition
Lau 2014	This is a review and discussion of current literature.
Loewy 2013	Music therapy described involves presentation of audio only to premature infants and does not involve an oral stimulation intervention

(*Continued*)

Luo 2012	The study population consisted of mechanically ventilated preterm infants, making comparison with healthy preterm infants difficult. Additionally, outcomes did not include oral feeding, but rather time to reach full enteral feeding, birth weight recovery time, body weight growth rate, hospitalisation time, feeding tolerance and mechanical ventilation-related complications
Malhotra 1999	This was not a randomised controlled trial.
Mattes 1996	Intervention involved s weet tastes presented on a m odified pacifier - not a finger stimulation protocol
McCain 1995	This was not a randomised controlled trial. Infants served as their own controls
McCain 2001	Intervention involved semi-demand gavage feeding with pacifier for NNS; this was already explored in a previous Cochrane review (Watson 2015)
McCain 2002	Intervention involved semi-demand gavage feeding with pacifier for NNS; this was already explored in a previous Cochrane review (Watson 2015)
McCain 2012	Study looked at transition from gavage to nipple feeding for preterm infants with bronchopulmonary dysplasia, making comparison with healthy preterm infants difficult. Additionally, use of a pacifier was not consistent for all infants and appears to have been done only to bring the baby to an alert state for feeding trials, only if necessary; this was not an integral component of the intervention
Moyses 2013	This is a systematic review - not an RCT.
Philbin 2011	This study describes an assessment technique/process only.
Pickler 1996	This was not a randomised controlled trial.
Pickler 2004	This study used an inadequate randomised cross-over design, by which participants were their own controls over 2 bottle feeds
Poore 2008b	Intervention was the NTrainer device, which delivers digitally patterned orocutaneo us stimulation via an adapted pacifier - not a finger stimulation protocol
Poore 2009	This was not a randomised controlled trial. It was a descriptive review
Puckett 2008	This study did not test an oral stimulation intervention.
Rocha 2002	This was not a randomised controlled trial.
Ross 2008a	This is a review and discussion of current literature.
Ross 2008b	This is a descriptive review article.
Ross 2011	This study describes the development of an assessment protocol
Ross 2013	This is a systematic review.

(*Continued*)

Scheel 2005	This was not a randomised controlled trial.
Shaker 2010	This is a review and discussion of current literature.
Shaker 2013	This is a descriptive review of current literature and practice
Sheppard 2005	This is a review of current literature.
Sheppard 2007	This is a descriptive review of the literature.
Simpson 2002	Intervention described is not an oral stimulation intervention
Stade 2002	Intervention described is not an oral stimulation intervention
Standley 2000	This was not a randomised controlled trial.
Standley 2003	This was not a randomised controlled trial.
Standley 2010	Investigators used the P a cifier Activated Lullaby intervention (music activated in cot on commence ment of pacifier sucking), which does not involve a finger stimula tion protocol
Standley 2012	This discussion paper reviews previously published data (Standley 2010a).
Thoyre 2012	This study did not include oral stimulation and was not a randomised controlled trial
Thukral 2012	Researchers used skin-to-skin contact - not oral stimulation
Vianna 2011	Investigators did not provide an oral stimulation intervention
White 2013	This is a review of current practice and does not involve oral stimulation
White-Traut 2002a	Intervention described (ATVV) was not an oral stimulation intervention
White-Traut 2002b	Intervention described (ATVV) was not an oral stimulation intervention
White-Traut 2013a	This was a case study.
White-Traut 2013b	This was not an RCT; it is descriptive only.
Yildiz 2011b	Intervention groups included infants who were provided with pacifiers during gavage feeds , lullabies during gavage feeds or s tandard gavage feed care . No finger stimulation protocols were used
Yildiz 2011a	This study looks at olfaction - not an oral stimulation intervention
Zimmerman 2009	This is a general review of the literature.

ATVV: auditory, tactile, visual and vestibular intervention.
NICU: neonatal intensive care unit.
NNS: non-nutritive sucking.
RCT: randomised controlled trial.

DATA AND ANALYSES

Comparison 1. Comparison 1. Oral stimulation versus no intervention/standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Days to full oral feeding	8	376	Mean Difference (IV, Random, 95% CI)	-5.22 [-6.86, -3.59]
2 Weight gain	2	81	Mean Difference (IV, Fixed, 95% CI)	0.73 [-1.05, 2.51]
3 Total hospital stay (days)	7	301	Mean Difference (IV, Fixed, 95% CI)	-5.26 [-7.34, -3.19]
4 Duration (days) of parenteral nutrition	1	19	Mean Difference (IV, Fixed, 95% CI)	-5.30 [-9.73, -0.87]
5 Exclusive direct breast feeding at discharge	1	59	Risk Ratio (M-H, Fixed, 95% CI)	1.83 [0.96, 3.48]
6 Any direct breast feeding at discharge	2	110	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.58, 2.66]

Comparison 2. Comparison 2. Oral stimulation versus non-oral intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Time (days) to achieve exclusive oral feeding	5	256	Mean Difference (IV, Fixed, 95% CI)	-9.01 [-10.30, -7.71]
2 Total hospital stay (days)	6	352	Mean Difference (IV, Fixed, 95% CI)	-2.94 [-4.36, -1.51]
3 Duration (days) of parenteral nutrition	1	98	Mean Difference (IV, Fixed, 95% CI)	-8.70 [-15.46, -1.94]
4 Exclusive direct breast feeding at discharge	1	196	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.72, 1.28]

Analysis 1.1. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 1 Days to full oral feeding.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

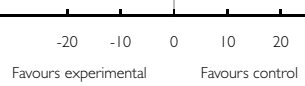
Outcome: 1 Days to full oral feeding

Study or subgroup	Experimental		Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Random,95% CI		IV,Random,95% CI
Bala 2016 (1)	25	8.375 (2.375)	26	13.25 (3.5)		17.7 %	-4.88 [-6.51, -3.24]
Boiron 2007 (2)	32	6.6937 (1.3345)	11	11.2 (1.6)		19.8 %	-4.51 [-5.56, -3.45]
Gaebler 1996 (3)	9	11.22 (3.7)	9	14.22 (4.3)		10.2 %	-3.00 [-6.71, 0.71]
Harding 2006 (4)	7	15 (3.4701)	7	18 (4.0466)		9.6 %	-3.00 [-6.95, 0.95]
Harding 2014 (5)	39	18.059 (10.4869)	20	23.9 (10.5)		6.0 %	-5.84 [-11.50, -0.18]
Lyu 2014	32	9.56 (4.43)	31	13.19 (6.18)		13.7 %	-3.63 [-6.29, -0.97]
Younesian 2015	10	13.2 (4.31)	10	26.9 (4.79)		9.4 %	-13.70 [-17.69, -9.71]
Zhang 2014 (6)	81	9.1864 (4.2699)	27	14.6 (6.8)		13.5 %	-5.41 [-8.14, -2.69]
Total (95% CI)	**235**		**141**			**100.0 %**	**-5.22 [-6.86, -3.59]**

Heterogeneity: $Tau^2 = 3.24$; $Chi^2 = 22.15$, df = 7 (P = 0.002); $I^2 = 68\%$

Test for overall effect: Z = 6.25 (P < 0.00001)

Test for subgroup differences: Not applicable



(1) Median and range only provided. We calculated estimated mean and standard deviation from figures provided

(2) Data for 3 intervention groups combined

(3) Number of days in the study reported

(4) Median and range only provided. We calculated estimated mean and standard deviation from figures provided

(5) Data combined for 2 intervention groups/SD was calculated by authors from information provided

(6) Data combined for 3 intervention groups

Analysis 1.2. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 2 Weight gain .

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

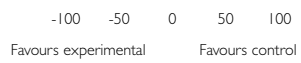
Outcome: 2 Weight gain

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Gaebler 1996	9	31.56 (6.6)	9	27.23 (5.7)		9.8 %	4.33 [-1.37, 10.03]
Lyu 2014	32	11.39 (3.86)	31	11.05 (3.73)		90.2 %	0.34 [-1.53, 2.21]
Total (95% CI)	**41**		**40**			**100.0 %**	**0.73 [-1.05, 2.51]**

Heterogeneity: Chi^2 = 1.70, df = 1 (P = 0.19); I^2 =41%

Test for overall effect: Z = 0.80 (P = 0.42)

Test for subgroup differences: Not applicable



Analysis 1.3. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 3 Total hospital stay (days).

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

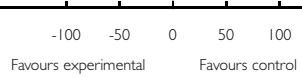
Outcome: 3 Total hospital stay (days)

Study or subgroup	Experimental		Control		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
Gaebler 1996	9	13.78 (2.72)	9	17.67 (4.03)		42.7 %	-3.89 [-7.07, -0.71]
Harding 2006 (1)	7	29 (15.0291)	7	39.75 (23.4)		1.0 %	-10.75 [-31.35, 9.85]
Harding 2014 (2)	39	37.3836 (22.8611)	20	54.4 (28.62)		2.1 %	-17.02 [-31.47, -2.57]
Lessen 2011	10	45 (10.7)	9	44.4 (4.8)		8.0 %	0.60 [-6.74, 7.94]
Lyu 2014	32	39.97 (14.81)	31	41.25 (16.15)		7.4 %	-1.28 [-8.94, 6.38]
Younesian 2015	10	27.9 (6.15)	10	38.8 (2.34)		25.9 %	-10.90 [-14.98, -6.82]
Zhang 2014 (3)	81	39.3012 (14.3074)	27	41.4 (12.9)		12.9 %	-2.10 [-7.88, 3.68]
Total (95% CI)	**188**		**113**			**100.0 %**	**-5.26 [-7.34, -3.19]**

Heterogeneity: Chi^2 = 15.52, df = 6 (P = 0.02); I^2 =61%

Test for overall effect: Z = 4.97 (P < 0.00001)

Test for subgroup differences: Not applicable



(1) Mean and SD were calculated from the Median and range provided for each group

(2) Data combined for 2 intervention groups

(3) Data combined for 3 intervention groups

Analysis 1.4. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 4 Duration (days) of parenteral nutrition.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

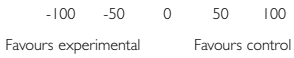
Outcome: 4 Duration (days) of parenteral nutrition

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Lessen 2011	10	18.1 (3.7)	9	23.4 (5.8)		100.0 %	-5.30 [-9.73, -0.87]
Total (95% CI)	**10**		**9**			**100.0 %**	**-5.30 [-9.73, -0.87]**

Heterogeneity: not applicable

Test for overall effect: Z = 2.35 (P = 0.019)

Test for subgroup differences: Not applicable



Analysis 1.5. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 5 Exclusive direct breast feeding at discharge.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

Outcome: 5 Exclusive direct breast feeding at discharge

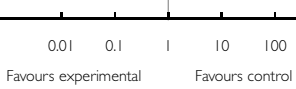
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Harding 2014	25/39	7/20		100.0 %	1.83 [0.96, 3.48]
Total (95% CI)	**39**	**20**		**100.0 %**	**1.83 [0.96, 3.48]**

Total events: 25 (Experimental), 7 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 1.85 (P = 0.065)

Test for subgroup differences: Not applicable

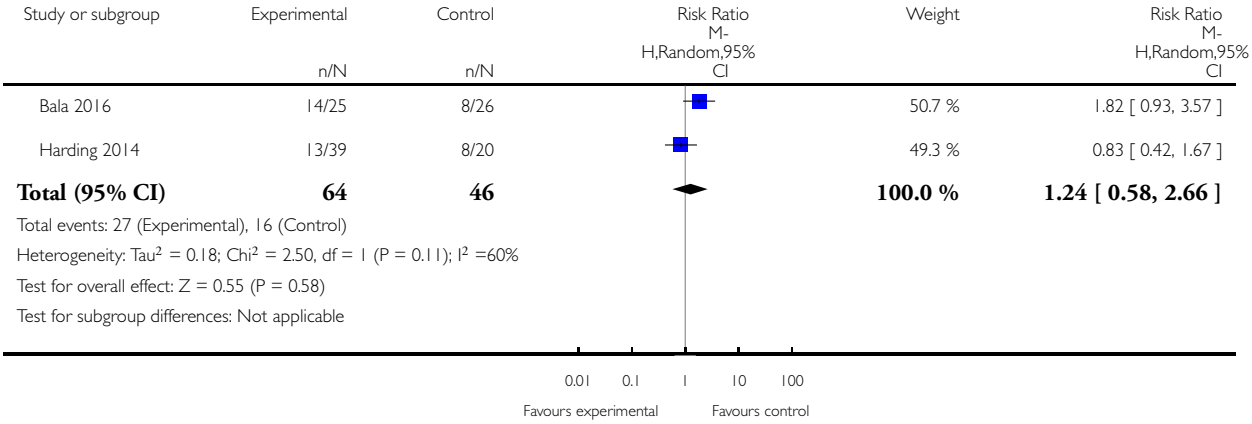


Analysis 1.6. Comparison 1 Comparison 1. Oral stimulation versus no intervention/standard care, Outcome 6 Any direct breast feeding at discharge.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 1 Comparison 1. Oral stimulation versus no intervention/standard care

Outcome: 6 Any direct breast feeding at discharge



Analysis 2.1. Comparison 2 Comparison 2. Oral stimulation versus non-oral intervention, Outcome 1 Time (days) to achieve exclusive oral feeding.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 2 Comparison 2. Oral stimulation versus non-oral intervention

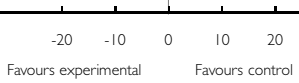
Outcome: 1 Time (days) to achieve exclusive oral feeding

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Asadollahpour 2015 (1)	21	17.4248 (8.8577)	11	24.27 (9.42)		3.7 %	-6.85 [-13.58, -0.11]
Fucile 2002	16	11 (4)	16	18 (7)		10.8 %	-7.00 [-10.95, -3.05]
Fucile 2011 (2)	55	10.8382 (5.1556)	20	20.7 (1.5)		73.3 %	-9.86 [-11.37, -8.35]
Lessen 2011	10	18.1 (3.7)	9	23.4 (5.8)		8.6 %	-5.30 [-9.73, -0.87]
Rocha 2007	49	38.5 (16.4)	49	47.2 (17.7)		3.7 %	-8.70 [-15.46, -1.94]
Total (95% CI)	**151**		**105**			**100.0 %**	**-9.01 [-10.30, -7.71]**

Heterogeneity: $Chi^2 = 5.31$, df = 4 (P = 0.26); $I^2 = 25\%$

Test for overall effect: Z = 13.63 (P < 0.00001)

Test for subgroup differences: Not applicable



(1) Data for two intervention groups were combined

(2) Data for three intervention groups combined

Analysis 2.2. Comparison 2 Comparison 2. Oral stimulation versus non-oral intervention, Outcome 2 Total hospital stay (days).

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 2 Comparison 2. Oral stimulation versus non-oral intervention

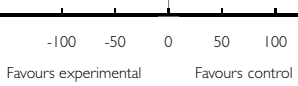
Outcome: 2 Total hospital stay (days)

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Asadollahpour 2015 (1)	21	27.0448 (12.2177)	11	33.45 (13.46)		2.2 %	-6.41 [-15.92, 3.11]
Fucile 2002	16	65 (16)	16	70 (22)		1.1 %	-5.00 [-18.33, 8.33]
Fucile 2011	55	53.1382 (4.0628)	20	55.3 (2.6)		82.4 %	-2.16 [-3.73, -0.60]
Lessen 2011	10	41.8 (7.2)	9	44.4 (4.8)		6.8 %	-2.60 [-8.05, 2.85]
Pimenta 2008	47	41.81 (17.7)	49	52.37 (19.51)		3.6 %	-10.56 [-18.01, -3.11]
Rocha 2007	49	41.9 (17.4)	49	52.3 (19.5)		3.8 %	-10.40 [-17.72, -3.08]
Total (95% CI)	**198**		**154**			**100.0 %**	**-2.94 [-4.36, -1.51]**

Heterogeneity: $Chi^2 = 9.58$, df = 5 (P = 0.09); $I^2 = 48\%$

Test for overall effect: Z = 4.05 (P = 0.000052)

Test for subgroup differences: Not applicable



(1) Data for two intervention groups combined

Analysis 2.3. Comparison 2 Comparison 2. Oral stimulation versus non-oral intervention, Outcome 3 Duration (days) of parenteral nutrition.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 2 Comparison 2. Oral stimulation versus non-oral intervention

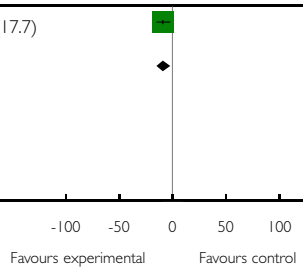
Outcome: 3 Duration (days) of parenteral nutrition

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Rocha 2007 (1)	49	38.5 (16.4)	49	47.2 (17.7)		100.0 %	-8.70 [-15.46, -1.94]
Total (95% CI)	**49**		**49**			**100.0 %**	**-8.70 [-15.46, -1.94]**

Heterogeneity: not applicable

Test for overall effect: Z = 2.52 (P = 0.012)

Test for subgroup differences: Not applicable



(1) Reports days of life at full oral feeding (independent oral diet)

Analysis 2.4. Comparison 2 Comparison 2. Oral stimulation versus non-oral intervention, Outcome 4 Exclusive direct breast feeding at discharge.

Review: Oral stimulation for promoting oral feeding in preterm infants

Comparison: 2 Comparison 2. Oral stimulation versus non-oral intervention

Outcome: 4 Exclusive direct breast feeding at discharge

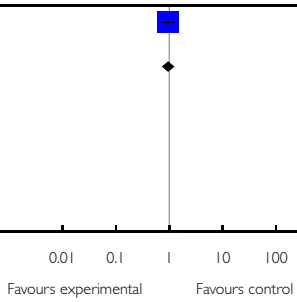
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Pimenta 2008	47/98	49/98		100.0 %	0.96 [0.72, 1.28]
Total (95% CI)	**98**	**98**		**100.0 %**	**0.96 [0.72, 1.28]**

Total events: 47 (Experimental), 49 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.29 (P = 0.78)

Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. Comparison groups: RCT allocation

RCTs in Comparison group 1	RCTs in Comparison group 2
Bala 2016	Asadollahpour 2015
Boiron 2007	Fucile 2002
Gaebler 1996	Fucile 2011
Harding 2006	Fucile 2012
Harding 2014	Lessen 2011
Lyu 2014	Pimenta 2008
Neiva 2006	Rocha 2007
Younesian 2015	
Zhang 2014	

APPENDICES

Appendix 1. Database search strategy

We used the search strategy recommended by the Cochrane Neonatal Review Group to find relevant studies for the review (http://www.neonatal.cochrane.org/en/index.html). We will use search terms and synonyms for 'oral stimulation', 'preterm infants' and filters to include clinical trials. We searched each database from inception to June 2013. We will search the following databases with specific search terms as outlined below:

ERIC, PsycINFO, PsycARTICLES, ASSIA, Linguistic and Language Behaviour Abstracts via CSA:

DE=(oral or stimulation or sucking) or DE=(feeding) or (pacifier) or (oral motor) or KW=(oromotor) or (enteral nutrition) or (parenteral nutrition) or DE=(motor manipulation) or (programme) or (myofunctional therapy) and KW=(premature or infant or neonate) or KW=(NICU) or (Intensive Care) or (low birthweight) DE = descriptors KW = Keywords

Academic Search Complete, CINAHL Plus, AMED, UK/EIRE Reference Centre via EBSCO:

AB Oral motor or SU feeding or SU sucking or SU pacifier or SU stimulation or SU mouth or SU rehabilitation or SU treatment or SU programme or SU oromotor AND SU neonatal or Su preterm infants or SU intensive care unit and SU Clinical trials

Science Direct and SCOPUS:

Oral stimulation OR feeding OR sucking OR oral motor exercises OR pacifiers OR stimulation OR treatment OR manipulation OR enteral feeding OR parenteral feeding AND premature infants OR neonate OR neonatal intensive care units OR health care costs

Social Science Citation Index via ISI Web of Science:

Topic=(oral) OR Topic=(stimulation) OR Topic=(feeding) OR Topic=(sucking) OR Topic=(pacifiers) OR Topic=(programme) OR Topic=(oral motor) OR Topic=(oromotor) OR Topic=(orofacial myology) OR Topic=(treatment) AND Topic=(preterm infant) OR Topic=(newborn infant) OR Topic=(neonate) OR Topic=(very low birth weight) OR Topic=(neonatal intensive care unit) Refined by: Subject Areas=(NEUROSCIENCES & NEUROLOGY) AND General Categories=(SOCIAL SCIENCES)

Highwire (Stanford University, http://highwire.stanford.edu/)

using the following key words; sucking stimulation, pacifiers, preterm, neonates, oral motor stimulation, feeding, neonatal intensive care,

REHABDATA (http://www.naric.com/research/rehab/)

using the following free text terms; oral stimulation, oral motor, feeding, sucking, infants, training programs, programs, rehabilitation, intervention, intensive care unit.

Searching other resources

We checked published conference proceedings of the following organisations:

- American Academy of Pediatrics.

- American Society for Parenteral and Enteral Nutrition.
- American Speech-Hearing-Language Association.
- British Association of Perinatal Medicine.
- Canadian Pediatric Society.
- Dysphagia Research Society (1992 to 2016).
- European Academy of Paediatrics.
- European Society for Paediatric Research.
- Neonatal Nurses Association.
- Royal College of Speech and Language Therapists (1999 to 2016).
- The Neonatal Society.
- Conference on Feeding and Eating in Infancy and Early Childhood (2010 to 2012).
- Personal communication with other relevant groups will be considered if appropriate.

Appendix 2. Standard search methods

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 (randomized controlled trial [pt] OR controlled clinical trial [pt] OR Clinical Trial[ptyp] OR randomized [tiab] OR placebo [tiab] OR clinical trials as topic [mesh: noexp] OR randomly [tiab] OR trial [ti] OR comparative study) NOT (animals [mh] NOT humans [mh]))
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 (randomized controlled trial or controlled clinical trial or randomized or placebo or clinical trials as topic or randomly or trial or clinical trial)
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 (randomized controlled trial OR controlled clinical trial OR randomized OR placebo OR clinical trials as topic OR randomly OR trial OR PT clinical trial)
The Cochrane Library: (infant or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW)

CONTRIBUTIONS OF AUTHORS

All review authors contributed to the development of this review.

DECLARATIONS OF INTEREST

Review authors have declared no conflicts of interest.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol and the review differ in the following ways.

- The title of the review has changed from 'Effects of oral stimulation for oral feeding in preterm infants' to 'Oral stimulation for promoting oral feeding in preterm infants'.

- Review authors have redefined 'oral stimulation intervention' to provide a specific focus and to narrow the remit of the review for clearer reporting. Initial searching under the original definition (Greene 2012) resulted in an extremely heterogeneous group of studies describing a wide spectrum of incomparable interventions including semi-demand gavage feeding, use of a pacifier with gavage feeds/direct active stimulation with pacifier, finger stimulation protocols before feeds (gavage or oral) with or without other supports, a device delivering timed electronic pulses via a nipple before feeds, body stroking protocols with or without oral stimulation, listening to music and sucking on a pacifier before feeds and sweet tastes on a pacifier with gavage feeds. Consultation among the Cochrane Neonatal Review Group Editors and the review authors resulted in agreement on narrowing the focus of this review to include only studies that described a 'finger stimulation' intervention. Additionally, several subsequent Cochrane reviews have addressed some of these interventions, for example, non-nutritive sucking (Pinelli 2005) and semi-demand feeding (Watson 2015), so these data have been examined elsewhere. Therefore, this current review has a narrower focus, and the definition of oral stimulation has been refined to reflect this change.

- We have excluded preterm populations with defined respiratory disease. We identified in our search several studies involving preterm populations with defined respiratory disease. We agreed to exclude these participants, as this group is at increased risk of feeding and swallowing problems. We had not directly specified in the original protocol that we would exclude them. We believe that making comparisons between this group and healthy preterm infants would be difficult.

- We added methods and a plan for Summary of findings tables and GRADE recommendations; these were not included in the original protocol.