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TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
PLAIN LANGUAGE SUMMARY 2
BACKGROUND 2
OBJECTIVES 4
METHODS 4
RESULTS 7
Figure 1. 8
DISCUSSION 9
AUTHORS' CONCLUSIONS 10
ACKNOWLEDGEMENTS 10
REFERENCES 10
CHARACTERISTICS OF STUDIES 14
APPENDICES 16
CONTRIBUTIONS OF AUTHORS 18
DECLARATIONS OF INTEREST 18
SOURCES OF SUPPORT 18
DIFFERENCES BETWEEN PROTOCOL AND REVIEW 19

[Intervention Review]

Education of family members to support weaning to solids and nutrition in infants born preterm

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ABSTRACT

Background

Weaning refers to the period of introduction of solid food to complement breast milk or formula milk. Preterm infants are known to acquire extrauterine growth restriction by the time of discharge from neonatal units. Hence, the postdischarge and weaning period are crucial for optimal growth. Optimisation of nutrition during weaning may have long-term impacts on outcomes in preterm infants. Family members of preterm infants may require nutrition education to promote ideal nutrition practices surrounding weaning in preterm infants who are at high risk of nutritional deficit.

Objectives

To investigate the role of nutrition education of family members in supporting weaning in preterm infants with respect to their growth and neurodevelopment compared with conventional management.

Search methods

We used the standard search strategy of Cochrane Neonatal to search the Cochrane Central Register of Controlled Trials (CENTRAL 2018, Issue 5), MEDLINE via PubMed (1966 to 26 June 2018), Embase (1980 to 26 June 2018), and CINAHL (1982 to 26 June 2018). We also searched clinical trials databases, conference proceedings, and the reference lists of retrieved articles for randomised controlled trials (RCTs) and quasi-RCTs**.**

Selection criteria

RCTs and quasi-RCTs were eligible for inclusion if they examined the effects of nutrition education of family members as compared to conventional management for weaning of preterm infants up to one year of corrected gestational age. We defined prematurity as less than 37 completed weeks of gestation.

Data collection and analysis

At least two review authors independently screened potential studies for inclusion and planned to identify, extract data, and assess the quality of eligible studies. We resolved any differences in opinion through discussion with a third review author and consensus among all three review authors.

Main results

No eligible trials looking at the impact of nutrition education of family members in weaning of preterm infants fulfilled the inclusion criteria of this systematic review. Two studies investigating the ideal timing for weaning in premature infants reported conflicting results,

Authors' conclusions

We were unable to assess the impact of nutrition education of family members in weaning of preterm infants as there were no eligible studies. This may be due to the lack of evidence to determine the ideal weaning strategies for preterm infants with regards to the time of initiating weaning and type of solids to introduce. Trials are needed to assess the many aspects of infant weaning in preterm infants. Long-term neurodevelopment and metabolic outcomes should also be assessed in addition to growth parameters.

PLAIN LANGUAGE SUMMARY

Education of family members to support weaning to solids and nutrition in infants born preterm

Review question

We wanted to find out whether providing education to family members on weaning premature babies would improve their growth and development. We defined premature babies as babies born more than three weeks before their due date.

Background

Weaning refers to the introduction of solid food in babies to complement their milk intake. Weaning is an important period of time for the growth of premature babies. They are normally smaller than expected for their age at this time. Hence, good nutrition during weaning can improve their growth and brain development, besides preventing future cardiovascular diseases. Nutrition education to family members may be needed to achieve good nutrition practices during weaning.

What we found

We examined the evidence available up to the 26 June 2018. No studies could be included in this review. The lack of eligible studies in this review is likely due to the scarce evidence in identifying the ideal weaning strategy for premature babies. We found two studies that investigated the ideal timing for weaning in premature babies. These, however, found conflicting results.

What does it mean?

As there were no eligible studies, impact of nutrition education in weaning of premature babies is unknown. .

BACKGROUND

Description of the condition

The World Health Organization (WHO) defines weaning or the introduction of complementary feeding as the period when the diet changes from complete breast feeding to when the child is able to eat normal family food. This transition usually starts at four to six months of age and finishes at around one year (WHO/UNICEF 1988). More broadly, the term is used to describe the period of the introduction of solid foods to complement human or formula milk.

The WHO, UNICEF, and the American Academy of Pediatrics (AAP) recommend that infants should be breast fed for the first six months of life, with weaning to solid foods thereafter (AAP 2012; Kramer 2004; UNICEF 2005). In 2008, the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition Committee concluded that, in high income countries (World Bank), complementary feeding should be introduced no earlier than four months and no later than six months of age (Agostoni 2008). Similarly, the AAP advises that: infants should be exclusively fed mother's breast milk or infant formula up to four months of age; solids may be introduced in formula-fed infants, if the infant is physically ready, after four months of age; and all infants should be

given solid foods after six months of age (Gartner 2005). However, these recommendations apply to infants born at full term and are not appropriate for those born preterm. Despite a lack of evidence on weaning infants born preterm, the British Association of Paediatric Medicine (BAPM) has published a joint consensus statement on weaning in this population (BAPM 2011). This statement suggests that infants born preterm should be weaned between five and eight months from the date of birth, on recognition of appropriate readiness cues from the child.

Inadequate nutrition during the first two years of life can affect the child's growth and development. It has been noted that malnutrition rates increase between 6 and 18 months, which includes the period of weaning (Imdad 2011). With increasing recognition of the importance of post-discharge nutrition and weaning as a crucial dietary event (Whitehead 1985), debate has focused on the optimum time and method to wean infants born preterm (Fewtrell 2003; King 2009).

Preterm birth is associated with immaturity of the gastrointestinal tract (Sangild 2006), including digestion, absorption, and endocrine, exocrine, and immune functions. Immaturity of the gut, fear of necrotising enterocolitis, and feeding intolerance are major factors that inhibit enteral feeding (Neu 2007). Therefore, infants born preterm often grow slowly in early life and many are significantly undernourished by discharge (Ehrenkranz 1999). This growth deficit often persists through early childhood and into later life (Griffin 2002). Impaired growth from birth to hospital discharge, and possibly up to two years of age, is associated with cognitive and motor developmental delay (Ehrenkranz 2006; Franz 2009). In addition to effects on growth and neurodevelopment in childhood, recent evidence suggests that, in infants born preterm, both high and low nutrient intakes as well as fast or slow rates of growth in infancy could have long-term adverse effects on metabolic health (Greer 2007; Whitehead 1985).

Providing specific nutrients may influence the maturation of cortical function. Feeding human milk has often been associated with better later cognitive outcome; however, some studies have shown that certain foods provided during weaning are also associated with an improvement in cognitive outcomes, such as in the Bayley Psychomotor Developmental Index (Morgan 2004), visual acuity (Hoffman 2003), and higher behavioural indices (Krebs 2006). Inappropriate timing and method of weaning could therefore introduce further problems in the already fragile nutritional status of the preterm infant. Delaying weaning or weaning with low energy density foods can unintentionally reduce nutrient intake and expose the infant to further deficiencies (Cohen 1994). In addition, delayed introduction of solid food after six months of age can increase the risk of iron deficiency and iron deficiency anaemia for infants (Hopkins 2007; Jonsdottir 2012). This is especially the case for infants born preterm who require additional iron to compensate for increased consumption for rapid growth and relatively low stores at birth (Hågå 1980). In addition, earlier weaning could be unsafe for developmentally immature infants due to lack of head control, truncal instability, and underdeveloped oro-motor function (Thoyre 2005). Early weaning may also be associated with an increased risk of developing eczema or other allergic diseases, or both (Morgan 2004); childhood obesity; and potentially long-term detrimental effects on nutritional programming (Ong 2000).

Current recommendations for weaning infants born preterm are based on expert opinion and observation due to a scarcity of evidence, lack of randomised trials of interventions, and heterogeneity among the few studies performed to date. Nevertheless, current feeding practices in infants born preterm vary widely and are not consistent with recommendations (Fanaro 2007; Norris 2002). In addition, evidence suggests that parents and families of infants born preterm are confronted not only with a lack of clarity on when and how to start weaning, but also with social and family pressures to wean early and provide unhealthy foods, gaps in understanding about healthy diet and the myth of pre-prepared commercially-available foods, and anxiety about cooking the simplest weaning foods (Redsell 2010). In this scenario, nutritional education may improve the dietary intake and growth outcomes of young children. However, the effectiveness of this type of intervention needs to be assessed systematically.

Preterm infants who are small for gestational age (SGA), defined as birth weight less than 10th centile, may present different challenges compared to preterm infants who are appropriative for gestational age in terms of weaning. SGA infants may undergo foetal adaptation to the adverse intrauterine environment, causing the low birth weight as suggested by the 'thrifty' phenotype (Hales 2001). These adaptations may become maladaptive during the postnatal period when there is increased nutrient availability coupled with excessive weight gain. This may potentially lead to obesity and metabolic disorders in adulthood (Mericq 2017). Hence, there may be an argument that nutritional education during the weaning period is even more important in this group of infants and whether a different weaning method should be employed.

Description of the intervention

Despite the lack of consensus among experts in infant nutrition, parents and families need information about best practice and support while weaning their infants who were born preterm (Fanaro 2007). Ideally, such an intervention should be specifically tailored to the needs of infants born preterm to enable families to give appropriate weaning foods that will provide optimal nutrition at the correct time (Wilson 1998). Parents are receptive to advice but need better support in best practices around infant feeding (Redsell 2010).

Nutrition education either combined with or without other strategies can improve the dietary intake of young children and may improve growth (Imdad 2011), particularly in areas where access to food is not a limiting factor (Penny 2005). Nutrition education has been defined as "any combination of educational strate-

gies, accompanied by environmental supports, designed to facilitate voluntary adoption of food choices and other food and nutrition" (Contento 2010). The need for nutrition education, such as dissemination of booklets on child-feeding guidance, and demonstration of preparing enhanced recipes to improve infant nutrition practices, has been highlighted by some studies (Hoare 2002; Kwavnick 1999; Redsell 2010; Zhang 2013). Randomised trials, mostly from low- and middle-income countries (LMICs) (World Bank), have demonstrated that providing culturally-suitable nutritional education may improve growth rates, decrease the prevalence of malnutrition (Lutter 1990; Roy 2007; Zhang 2013), and may also improve cognitive development (Vazir 2013). Although a variety of strategies, such as group training sessions and individual counselling, were used in these studies to disseminate nutrition education to parents and caregivers, all suggest that the intervention improved caregivers' knowledge, food selection, and children's physical growth.

Although the existing literature suggests that nutrition educational interventions delivered to parents and caregivers can improve nutritional intake and growth in infants, and global evidence indicates the need for this support (Fanaro 2007; Kwavnick 1999; Redsell 2010), there is a lack of evidence backing these practices and the particular usefulness of such strategies for high-risk groups such as infants born preterm.

How the intervention might work

Nutrition education is an essential component of health promotion and disease prevention. Several theories of behaviour change, such as the theory of planned behaviour (Ajzen 1980), and social cognitive theory (Bandura 2004), explain the complex relationship between knowledge, beliefs, and perceived social norms and how nutrition education can induce behaviour changes in a given set of circumstances. Interventions that provide relevant information and education to parents and caregivers could induce change in behaviour impacting nutritional practices which could improve nutrition, growth, and potentially also neurodevelopmental and long-term metabolic health outcomes (Lassi 2013). In older children, nutrition education modifies eating behaviour and optimises growth, and parental education can have a positive impact on child nutrition (Luepker 1996).

Why it is important to do this review

To our knowledge, no systematic reviews are available on the effect of nutrition education for weaning infants born preterm. A systematic review of the impact of parents' and caregivers' education for weaning and provision of complementary foods on child growth in LMICs concluded that nutrition educational interventions alone are effective in improving weaning practices, and have a significant effect on growth in food-secure populations (Imdad 2011). However, this study focused on LMICs and did not differentiate between infants who were born at term and those born preterm.

This Cochrane Review examines the existing literature to determine if the use of nutrition education to support parents and caregivers for weaning improves the nutrition, growth, and development of infants born preterm. We focus on studies involving the provision of support for parents and families with nutrition educational packages alone compared with conventional management around the period of weaning. We defined conventional management as standard clinical support without a nutrition education focus. We evaluated the evidence of effects of nutrition education internationally, sought to understand whether such interventions can be applied to benefit the population of infants born preterm, and evaluated studies for any evidence of harm from such interventions. It is vital to ensure that such interventions are effective as significant resources could be saved by eliminating time- and resource-intensive educational programmes that prove to be of no benefit.

OBJECTIVES

To assess the effects of family nutrition educational interventions to improve the growth and development of infants born preterm, for weaning, compared with conventional management.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include published RCTs and quasi-RCTs, including cluster-RCTs where baseline characteristics and outcome measurements were similar (i.e. not statistically significantly different) between clusters in both groups. We excluded non-randomised trials, such as controlled before-and-after studies. The review was not limited to any particular region or socioeconomic category and included studies published in any language.

Types of participants

Parents and families of infants born preterm (at less than 37 weeks of gestation), up to the age of one year of corrected gestational age (CGA).

Types of interventions

Studies that compared any nutrition education intervention for parents or caregivers of infants born preterm (at less than 37 weeks of gestation) with conventional management for weaning up to one year of CGA were eligible. This included nutritional counselling, face-to-face sessions, audio-visual packages, support groups, additional input from health visitors or other allied professionals, and any other form of support involving education provided to families in determining the best time and method of weaning as well as improving the nutrition of their infant who was preterm at birth. We looked at nutritional educational messages placing emphasis on the importance of breast feeding duration, initiation of weaning food, frequency of feeding, and composition of food (in terms of protein, energy, and micronutrients). Any nutrition educational strategies, such as dissemination of booklets on child feeding guidance and demonstration of preparing enhanced recipes, were eligible for inclusion in this review. We defined conventional management as standard clinical support or appointments without a nutrition education focus.

Types of outcome measures

Primary outcomes

- Growth rates (weight gain, linear growth, and head growth) in the first two years of life; change in weight, height/length or head circumference z-scores;
- neurodevelopmental scores in children aged 12 months or older of CGA, measured using validated assessment tools, using neurological examination and Bayley Scale Index II (Black 2000). We considered these scores to be abnormal if Bayley II Mental Developmental Index was < 70, Psychomotor Developmental Index was < 70, or if there is visual or hearing impairment. We considered neurological examination abnormal if there were impaired motor or sensory functions, or both.

Secondary outcomes

- Duration of exclusive breast feeding;
- adherence to weaning advice;
- cognitive ability at five years of age and beyond, using validated tools such as Weschler intelligence scale for children (Wechsler 1974), and school examinations;
- long-term growth: weight, height, skinfold thickness, or body mass index assessed at five years of age and beyond;
- serum ferritin (< 12 μg/L) and haemoglobin (Hb) levels (< 110 g/L) in children aged six months or older of CGA (WHO 2011);
- parental stress when the child is aged six months or older of CGA, measured using validated assessment tools such as the Parenting Stress Index (Grotevant 1989);
- infant quality of life when the child is aged six months or older of CGA, measured using the Infant and Toddler Quality of Life Questionnaire (ITQOL) (Bowling 2005);
- death before one and five years of age;
- blood pressure at five years of age and beyond.

Search methods for identification of studies

We used the criteria and standard methods of Cochrane and Cochrane Neonatal. We did not limit the search to any particular geographical region, language, or timing of publication.

Electronic searches

We conducted a comprehensive search including the Cochrane Central Register of Controlled Trials (CENTRAL 2018, Issue 5) in the Cochrane Library, MEDLINE via PubMed (1966 to 26 June 2018), Embase (1980 to 26 June 2018), and CINAHL (1982 to 26 June 2018) using the following search terms: ("Weaning"[Mesh] OR wean* OR ((Feed*[tiab] OR food[tiab]) AND (complementary[tiab] OR supplementary[tiab]))) AND ("Education"[MeSH] OR program*[tiab] OR education*[tiab] OR training[tiab] OR intervention*[tiab] OR counseling[tiab] OR support[tiab] OR information[tiab] OR recommendation[tiab] OR guideline[tiab] OR advice[tiab]), plus database-specific limiters for RCTs and neonates (see Appendix 1 for the full search strategies for each database). We did not apply language restrictions.
We searched clinical trials registries for ongoing or recently completed trials (clinicaltrials.gov; the WHO International Clinical Trials Registry Platform (ICTRP; www.whoint/ictrp/search/en/), and the ISRCTN Registry (www.isrctn.com/). Clinical trials registries were searched for relevant studies using the search words (feeding AND education AND infant) OR (weaning AND education AND infant).

Searching other resources

We examined reference lists of studies that underwent full-text screening and of previous reviews. We searched the European Society for Pediatric Research (1995 to present), the Royal College of Paediatrics and Child Health (2000 to present), and the Perinatal Society of Australia and New Zealand (2000 to present). Trials reported only as abstracts were eligible for inclusion if sufficient information was available either from the report or from contact with the authors.

Data collection and analysis

We used the standard methods of the Cochrane Neonatal Group.

Selection of studies

Two review authors (ZE, TCK) screened the titles and abstracts of studies and potentially-relevant reports identified from the above search. Three review authors (ZE, SO, and TCK) independently assessed the full-text articles for potentially-relevant trials and resolved any disagreements through discussion and input from the fourth author (JD).

Data extraction and management

Three review authors (ZE, SO, and TCK) planned to independently extract data from the full-text articles of potentially included studies using Covidence for details of design, methodology, participants, interventions, outcomes, and educational effects from each included study (Covidence 2015). We cross-checked information and resolved any discrepancies by discussion until we reached agreement.

Assessment of risk of bias in included studies

We planned to independently assess the risk of bias (low, high, or unclear) of all included trials using the Cochrane 'Risk of bias' tool for the following domains (Higgins 2011) (Appendix 2):

- sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and personnel (performance bias);
- blinding of outcome assessment (detection bias);
- incomplete outcome data (attrition bias);
- selective reporting (reporting bias);
- any other bias.

Measures of treatment effect

We planned to perform analysis of the effects of educational interventions in the individual trials using Review Manager 5 (RevMan 2014). Risk ratio (RR) and risk difference (RD) for dichotomous data and mean difference (MD) for continuous data, with respective 95% confidence intervals (CIs) would have been reported. We also planned to report the number needed to treat for an additional beneficial outcome (NNTB) or the number needed to treat for an additional harmful outcome (NNTH) for analyses with a statistically significant difference in the RD.
For categorical outcomes we would have calculated typical estimates for relative risk, RD, NNTB, and NNTH and presented these with 95% CIs.

Unit of analysis issues

The unit of analysis was the participating infant in individually randomised trials, with an infant only being considered once in an analysis. We planned to exclude infants with multiple enrolments from analysis unless we obtained data from the report or investigators relating to the first episode of randomisation. If data from the first randomisation could not be identified, we would have excluded the study as we would not be able to address the unit of analysis issues that arose from multiple enrolments of the same infant. We planned to include infants from multiple births.
We planned to conduct intention-to-treat analyses. The participating health organisation was the unit of analysis in cluster-RCTs. We analysed them using an estimate of the intra-cluster correlation coefficient (ICC) derived from the trial (if possible), or from another source as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).
In cluster-RCTs we planned to conduct the analysis at the same level as the allocation, using a summary measurement from each cluster which was the unit of analysis.

Dealing with missing data

If data were missing or reported unclearly, we planned to request additional data on important outcomes from trial authors. Where data were still missing, we planned to examine the impact on effect size estimates in sensitivity analyses using the 'best-worst case scenario' technique.

Assessment of heterogeneity

Intervention effects of individual trials and heterogeneity were to be examined between trial results by inspecting forest plots.
We planned to assess statistical heterogeneity using the I^2 statistic (Higgins 2011), a quantity that describes the proportion of variation in point estimates that is due to variability across studies rather than sampling error. We planned to interpret the I^2 statistic as described by Higgins 2003:

- < 25% no heterogeneity;
- 25% to 49% low heterogeneity;
- 50% to 74% moderate heterogeneity; and
- ≥ 75% high heterogeneity.

Where we detected moderate or high heterogeneity (I^2 statistic > 50%), we planned to explore the possible causes (for example, differences in study design, participants, interventions, or completeness of outcome assessments).
We planned to use Chi^2 tests of homogeneity to determine the strength of evidence that heterogeneity is genuine.

Assessment of reporting biases

If more than 10 trials were included in a meta-analysis, we would have used a funnel plot for asymmetry to assess potential reporting bias (Higgins 2011).

Data synthesis

We planned to use the fixed-effect model in Review Manager 5 for meta-analyses (as per Cochrane Neonatal Group recommendations) (RevMan 2014). We planned to use the standard methods of the Cochrane Neonatal Group to synthesise data using RR, RD, NNTB, NNTH, MD, and 95% CIs. Where substantial heterogeneity existed, the potential causes were to be tested in subgroup and sensitivity analyses.

Quality of evidence

We planned to use the GRADE approach, as outlined in the GRADE Handbook (Schünemann 2013), to assess the quality of evidence for the following (clinically relevant) outcomes: growth rates (weight gain, linear growth, and head growth) in the first two years of life; change in weight, height or head circumference z-scores; neurodevelopmental scores in children aged 12 months or older of CGA, including: Bayley II Mental Development Index > 70; Bayley Psychomotor Development Index > 70; motor functions; sensory functions.

We planned for two review authors to independently assess the quality of the evidence for each outcome. We planned to consider evidence from RCTs as high quality, but to downgrade the evidence one level for serious (or two levels for very serious) limitations based upon the following: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates, and presence of publication bias. We intended to use the GRADEpro GDT Guideline Development Tool to create a 'Summary of findings' table to report the quality of the evidence (GRADEpro GDT 2017).

The GRADE approach results in an assessment of the quality of a body of evidence to one of four grades:

- high: we are very confident that the true effect lies close to that of the estimate of the effect;
- 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;
- low: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- 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 data were available, we planned to perform the following subgroup analyses:

- infants born at ≤ 27 weeks' gestation versus infants born at > 27 weeks' gestation;
- infants born ≤ 1000 g versus infants born at > 1000 g birth weight;
- infants who were SGA at birth (birth weight less than 10th centile) versus infants ≥ 10th centile reference population birth weight.

Sensitivity analysis

We planned to undertake sensitivity analyses to determine if the findings were affected by including only studies of adequate methodology (low risk of bias), defined as adequate randomisation and allocation concealment, blinding of intervention and measurement, and less than 10% loss to follow-up.

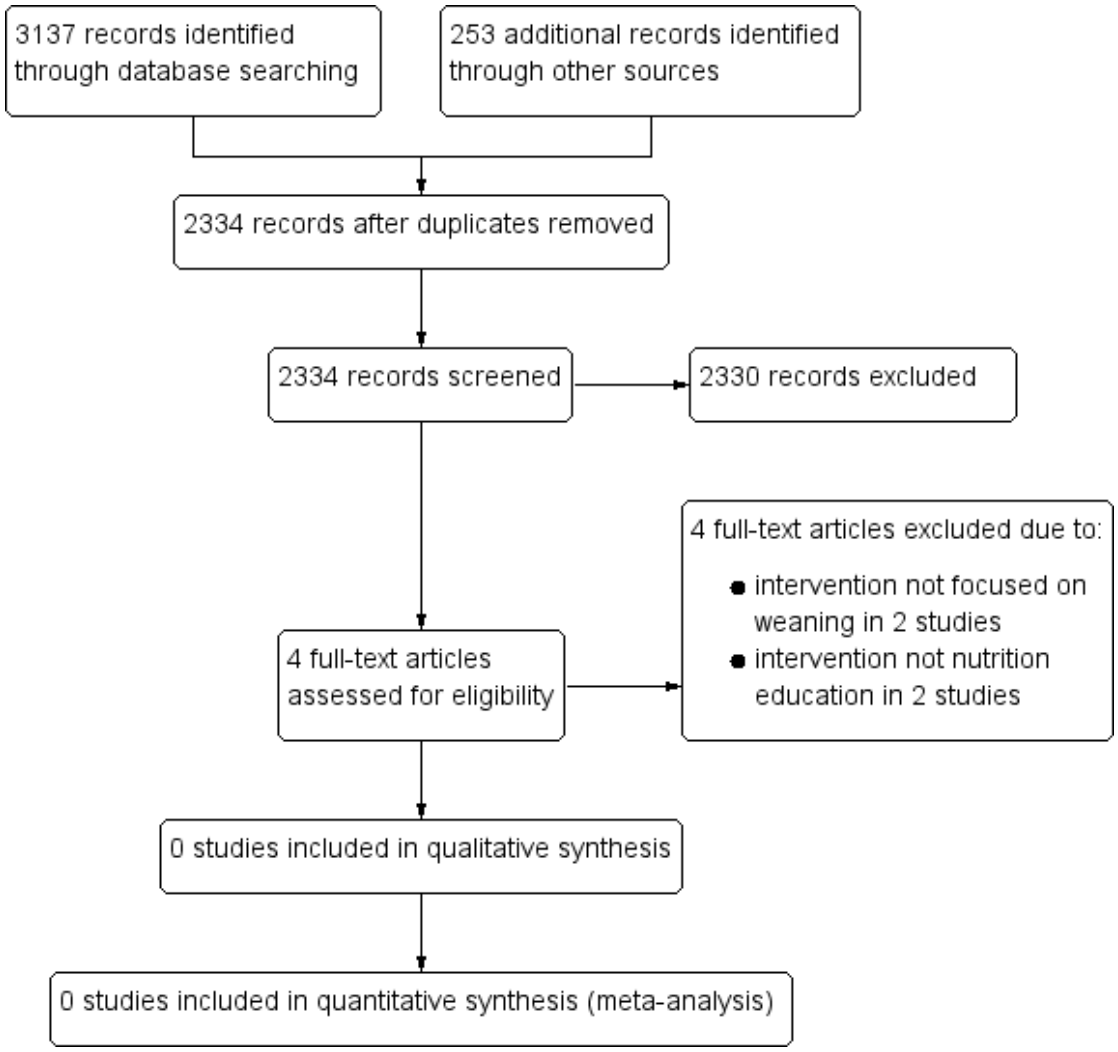
RESULTS

Description of studies

Results of the search

Our search strategy yielded 2334 records. Based on their titles and abstracts, we examined the full-text reports of four publications (Gupta 2017; Hoffenkamp 2015; Marriott 2003; Wu 2014). However, we excluded all four potential studies as the interventions proposed in these studies were not nutrition education. The search and screening results are depicted in Figure 1.

Figure 1. Study flow diagram.



Excluded studies

We exluded four studies (Gupta 2017; Hoffenkamp 2015; Marriott 2003; Wu 2014)(see Characteristics of excluded studies). We excluded two studies as the interventions were not focused on weaning of preterm infants (Wu 2014; Hoffenkamp 2015). Although the other two studies focused on weaning of preterm infants, the interventions proposed were not nutrition education (Gupta 2017; Marriott 2003). Instead, these two studies compared two different weaning regimes in terms of the child's age at introduction of solids (Gupta 2017; Marriott 2003), as well as the type of solids to introduce without a difference in how parents were educated to achieve the different weaning regimes (Marriott 2003). Although the intervention in Marriott 2003 included a component of nutrition education, the intervention also included weaning at an earlier age and lesser infant weight than in the control group. It was therefore difficult to attribute the differences between the two groups to nutrition education alone.

Marriott 2003 was a prospective, single-centre, parallel randomised controlled trial carried out at the Royal Hampshire County Hospital, UK between February 1998 to July 1999. Sixty-eight preterm infants with birthweight less than 2200 g were recruited and randomly randomised into either the preterm weaning strategy group or the control group. The randomisation was stratified by sex and birthweight below 1500g. Only the first infant from a set of twin or triplet was included.

Infants in the preterm weaning strategy group were recommended to be weaned earlier after 13 weeks of CGA if weighing above 3500 g, compared to after 17 weeks of CGA if weighing above 5000 g in the control group. In addition, infants in the preterm weaning strategy group were also recommended to consume solids with higher energy density, higher protein, iron, and zinc content compared to infants in the control group. The main outcome measures were growth parameters (weight, length, and head circumference) measured at 0, 6, and 12 months of CGA as well as serum ferritin and haemoglobin measured at 0 and 6 months of CGA.

We excluded the study as the intervention included different ages and weights at weaning along with some elements of nutrition education in both groups.

Wu 2014, a three-armed RCT from Taiwan, recruited 178 preterm, very low birth weight infants who were randomised to either a clinic-based early intervention programme; or home-based early intervention programme; or a control group (usual care) between 2006 to 2008. Usual care was based on synactive theory (Als 1986), with an emphasis on children-focused services to minimise the adverse impact of newborn environment. Apart from the synactive theory, the two intervention arms of clinic-based and home-based early intervention programmes were guided by Family-Centred Care with emphasis on building parent-professional partnerships to involve parents early in the care giving routines of their infants. The two intervention arms were also offered after-discharge interventions supporting parents to enhance neurodevelopment. Neurodevelopmental and behavioural outcomes were assessed at 24 months of CGA. We excluded this study as the focus of the intervention was on development and behaviour rather than nutrition education.

Hoffenkamp 2015 was a RCT that recruited 150 families of preterm infants from seven hospitals in the Netherlands between 2009 to 2012. Familes were randomly assigned to either the video-interaction guidance group to support parent-infant relationship, or to the control group who were given standard hospital care. Parent interactive behaviour was assessed at six months follow-up. We excluded this study as the intervention of video-interaction guidance was primarily behavioural focused at changing behavior and improving parental bonding, The intervention did not provide nutrition education.

Gupta 2017 was an open-label RCT, which recruited 403 preterm infants below 34 weeks of gestation, and was conducted in India between March 2013 and April 2015. Infants were randomly assigned to initiate complementary feeding either at four months of CGA, or at six months of CGA using pre-recorded audio-visual sessions and one-to-one counselling conducted in the local language. The instructions were based on WHO guidelines on complementary feeding of the breastfed child.The primary outcome measure was weight for age Z-score at 12 months of CGA. We excluded this study as nutrition education was provided to infants in both the control and intervention groups. The intervention examined in this study was the timing of complementary feeding introduction.

Risk of bias in included studies

There were no eligible studies that fulfilled the inclusion criteria of this systematic review.

Effects of interventions

There were no included studies in this review investigating the use of nutrition education of family members to support weaning in preterm infants.

DISCUSSION

Summary of main results

There were no clinical trials that looked at the impact of nutrition education of family members to support weaning in preterm infants. Studies have been conducted in term infants but, as infants born preterm are at higher risk of feeding and nutritional problems, caution should be applied in extrapolating the results to this group. More research on nutritional education is needed in infants born preterm.

Overall completeness and applicability of evidence

Despite the methodological and extensive search method employed in accordance with Cochrane guidance (Higgins 2011), we could not locate any published studies on the subject matter, This potentially raised the possibility of publication bias. However, there is an ongoing RCT in Taiwan (NCT01807533), which is investigating the impact of parental education including nutritional education on growth and neurodevelopmental outcomes in preterm infants. Further information on NCT01807533 can be found in the 'Characteristics of ongoing studies' section.

This lack of guidance and paucity of evidence-based strategies for weaning preterm infants is concerning as these infants are at high risk of extrauterine growth restriction. By the time they reach a corrected age corresponding to term gestation, 59% to 89% of preterm infants are smaller than expected as compared to 14% to 16% at birth (Lemons 2001; Radmacher 2003; Schanler 2005). This suggests that, despite neonatal intensive care, most preterm infants suffer extrauterine growth restriction. Hence, the post-discharge and weaning periods are crucial periods for growth of preterm infants, Optimisation of the nutrition during these periods may impact long-term outcomes (Wauben 1998). There is a need to identify the ideal weaning strategy for preterm infants

in terms of growth, neurodevelopment, and long-term metabolic outcomes. This may also aid in alleviating the anxiety of parents who often receive conflicting advices from healthcare professionals.

Agreements and disagreements with other studies or reviews

To the best of our knowledge, there are no reviews looking at the role of nutrition education of family members to support weaning in preterm infants. The recently published Cochrane Review found moderate- to very low-quality evidence that nutritional education can improve weaning practices but insufficient evidence that it impacts growth in term infants (Arikpo 2018). The review mainly focused on term infants rather than preterm infants, which is the focus of this review.

There is only one published guidance on weaning of preterm infants (BAPM 2011), which is the 2007 joint consensus statement from UK and Irish paediatric dietitians and speech and language therapists based on a literature review and Delphi questionnaire. The joint consensus was updated in 2011 by a subset of the original group (BAPM 2011). The consensus suggests that weaning can be safely initiated in preterm infants between 5 and 8 months of chronological age (i.e. 5 to 8 months from the date of birth rather than CGA) on recognition of readiness cues from the infants. Gupta 2017 suggested that initiation of weaning at six months of CGA (mean (standard deviation (SD)) of chronological age of 7.9 (0.4) months) is preferable to four months of CGA (mean (SD) of chronological age of 5.7 (0.3) months) in preterm infants less than 34 weeks of gestation. Chronological age was not reported in the Marriott 2003 study. The consensus, BAPM 2011, also recommends that preterm infants who are thriving should have similar dietary intake during weaning as healthy term infants.

AUTHORS' CONCLUSIONS

Implications for practice

At present, the impact of nutrition education of family members in weaning of preterm infants cannot be assessed as there were no eligible studies in this Cochrane Review.

Implications for research

Before studies looking at the impact of nutrition education in weaning of preterm infants are carried out, more clinical trials are needed in determining the ideal weaning strategy for preterm infants in terms of the time to initiate weaning and the type of solids to introduce during weaning from the perspective of energy, protein, and nutrient contents. Future studies should report growth parameters in the form of z-scores to allow the results to be comparable to other studies. Apart from growth parameters, these studies should also look at long-term neurodevelopment, as well as metabolic outcomes. An international collaborative effort would be needed as the differences in healthcare settings may impact on the outcome measures.

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The Methods section of this review is based on a standard template used by Cochrane Neonatal.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Gupta 2017	Nutrition education was provided to both intervention and control groups. The intervention examined in this study was the timing of complementary feeding introduction
Hoffenkamp 2015	The study intervention of video-interaction guidance was primarily behaviour-focused to improve parental bonding, The intervention did not provide nutrition education
Marriott 2003	Nutrition education was provided to both intervention and control groups. The intervention examined in this study was the timing of complementary feeding introduction as well as the type of solids to introduce during weaning
Wu 2014	Interventions were focused primarily on neurodevelopment and behaviour rather than nutrition education.The intervention groups received family-centred care, with an emphasis on building parent-professional partnerships, and after-discharge interventions to support parents to enhance neurodevelopment

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

NCT01807533

Trial name or title	A family-centered intervention program for preterm infants: effects and their biosocial pathways
Methods	**Study design:** randomised controlled trial **Study grouping:** parallel group
Participants	**Inclusion criteria** • Birth body weight < 1500 g; • gestational age < 37 weeks; • parents of Taiwan nationality, married or together at delivery, and northern family residing in greater Taipei and southern family residing in greater Tainan, Kaohsiung, or Chiayi. **Exclusion criteria** • Severe neonatal and perinatal diseases (e.g. seizures, hydrocephalus, meningitis, grade III-IV intraventricular haemorrhage, and grade II necrotising enterocolitis); • congenital or chromosome abnormality; • mother < 18 years of age, with mental retardation or history of maternal substance abuse at any time (smoking, alcohol, and drug). **Terminated criteria** • Diagnosis of brain injury (e.g. periventricular leukomalacia, stage IV retinopathy of prematurity or greater); • severe cardiopulmonary disease requiring invasive or non-invasive ventilator use at hospital discharge; • hospital discharge beyond 44 weeks' post-menstrual age.

NCT01807533 (*Continued*)

Interventions	Five sessions of in-hospital intervention will emphasize modulation of the neonatal intensive care unit: teaching of child developmental skills, feeding support, massage, interactional activities, and parent support and education The 7-session after-discharge intervention will consist of 4 clinic visits and 3 home visits with specific care in modulation of home environment, teaching of child developmental skills, feeding support, teaching of interactional activities, and parent support and education
Outcomes	**Primary outcomes** • Change of growth from baseline at 1, 4, 6, 12, 18, and 24 months of corrected age; • neurodevelopment using Bayley Scales of Infant and Toddler Development III at 12 and 24 months of corrected age
Starting date	May 2012
Contact information	**Name:** Professor Suh-Fang Jeng **Institution:** School and Graduate Institute of Physical Therapy, National Taiwan University
Notes	**Estimated study completion date:** December 2016 **Country:** Taiwan **Setting:** 3 medical centres in northern and southern Taiwan **Sponsorship source:** National Taiwan University Hospital, National Health Research Institutes, Taiwan **Note:** although study completion date was set in December 2016, the study has not been published yet

APPENDICES

Appendix 1. Standard search methodology

PubMed

((infant, newborn[MeSH] OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or infan* or neonat*) AND (randomised controlled trial [pt] OR controlled clinical trial [pt] OR randomised [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) 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 (randomised controlled trial or controlled clinical trial or randomised 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 (randomised controlled trial OR controlled clinical trial OR randomised OR placebo OR clinical trials as topic OR randomly OR trial OR PT clinical trial)

Cochrane Library

(infant or newborn or neonate or neonatal or premature or preterm or very low birth weight or low birth weight or VLBW or LBW)

Appendix 2. 'Risk of bias' tool

We planned to use the standard methods of Cochrane and Cochrane Neonatal to assess the methodological quality of the trials. For each trial, we planned to seek information regarding the method of randomisation, blinding, and reporting of all outcomes of all the infants enrolled in the trial. We planned to asses each criterion as being at either low, high, or unclear risk of bias. Two review authors separately planned to assess each study and resolve any disagreements through discussion. We planned to add this information to the 'Characteristics of included studies' table. We planned to evaluate the following issues and enter the findings into the 'Risk of bias' table.

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

For each included study, we planned to categorize the method used to generate the allocation sequence as:

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

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

For each included study, we planned to categorize the method used to conceal the allocation sequence as:

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

3. Blinding of participants and personnel (checking for possible performance bias). Was knowledge of the allocated intervention adequately prevented during the study?

For each included study, we planned to categorize the methods used to blind study participants and personnel from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or class of outcomes. We categorized the methods as:

- low risk, high risk or unclear risk for participants; and
- low risk, high risk or unclear risk for personnel.

4. Blinding of outcome assessment (checking for possible detection bias). Was knowledge of the allocated intervention adequately prevented at the time of outcome assessment?

For each included study, we planned to categorize the methods used to blind outcome assessment. Blinding was to be assessed separately for different outcomes or class of outcomes. We we planned to categorize the methods as:

- low risk for outcome assessors;
- high risk for outcome assessors; or
- unclear risk for outcome assessors.

5. 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 planned to describe the completeness of data including attrition and exclusions from the analysis. We planned to note whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported or supplied by the trial authors, we planned to re-include missing data in the analyses. We planned to categorize the methods as:

- low risk (< 20% missing data);
- high risk (≥ 20% missing data); or
- unclear risk.

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

For each included study, we planned to describe how we investigated the possibility of selective outcome reporting bias and what we found. For studies in which study protocols were published in advance, we planned to compare prespecified outcomes versus outcomes eventually reported in the published results. If the study protocol was not published in advance, we planned to contact study authors to gain access to the study protocol. We planned to assess the methods as:

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

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

For each included study, we planned to describe any important concerns we had about other possible sources of bias (for example, whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We planned to assess whether each study was free of other problems that could put it at risk of bias as:

- low risk;
- high risk;
- unclear risk.

If needed, we planned to explore the impact of the level of bias through undertaking sensitivity analyses.

CONTRIBUTIONS OF AUTHORS

ZE, SO, and JD contributed to writing the protocol. ZE, TCK and SO screened studies. The final manuscript was written by ZE, SO, and TCK, and was assessed and edited by JD.

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ZE has no known conflicts of interest.

TCK has no known conflicts of interest.

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- Vermont Oxford Network, USA.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

T'ng Chang Kwok joined the review author team.

There was no deviation from the methods in the published study protocol (Elfzanni 2017).