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Education of family members to support weaning to solids and nutrition in later infancy in term-born infants (Protocol)

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[Intervention Protocol]

Education of family members to support weaning to solids and nutrition in later infancy in term-born infants

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ABSTRACT

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

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

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 (four to six months of age) to when the child is able to eat normal family food (around one year of age) (WHO 1988). The WHO decision to include anything except breast milk as complementary food is intended to emphasise the importance of exclusive breast feeding, however this may be misleading. Infants are frequently fed human milk substitutes such as infant formula even from the first week of life. Complementary feeding is generally used to describe any nutrient-containing foods or liquids other than breast milk, infant formula or follow-on formula (Agostoni 2008) and weaning as the process by which such complementary foods are introduced into the infant's diet.

While the WHO, UNICEF and the American Academy of Pediatrics recommend exclusive breast feeding for the first six months of life (AAP 2012; Kramer 2002; UNICEF 2005), most guidelines, particularly from high-income countries (World Bank 2015), recommend that weaning should not occur before 17 weeks, should not be delayed beyond 26 weeks and should be guided by the individual infant's nutritional needs and developmental abilities (Agostoni 2008). Weaning should be timely, safe, adequate in nutritional content and in the variety of food items offered, and should be offered to the infant at the correct frequency and in an appropriate manner (Weaver 2001). Adequate renal, gastrointestinal, immunological and neurodevelopmental maturation should have been achieved to make the transition from milk to solid foods. Delaying weaning or weaning with low en-

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ergy density foods can unintentionally reduce nutrient intake and expose the infant to faltering growth and specific nutrient deficiencies (Cohen 1994) such as an increased risk of iron deficiency and iron deficiency anaemia in late infancy (Hopkins 2007). Furthermore, inappropriate weaning has been linked to several other health problems, such as increased risk of allergic disorders, dental caries, and poor neurocognitive outcomes. At the other end of the spectrum, early weaning, particularly with inappropriately high energy food, can increase the risk of childhood obesity and cardiovascular illness in later life. In high-income countries, where feeding practices are mainly determined by parental beliefs and understanding of infant feeding, observational evidence demonstrates that early weaning onto solid foods is significantly associated with overweight or obesity at three years (Baughcum 2001; Hawkins 2009).

The nutritional challenges faced by populations in middle- and low-income countries may differ from those in high-income countries. In low- and middle-income countries, gains attained by promoting exclusive breast feeding for the first 6 months of life need to be sustained by encouraging appropriate weaning, as it is well recognised that between 6 and 24 months of age children are particularly vulnerable to malnutrition due to limitations in the quality and quantity of foods (Lassi 2013). Families are faced with limitations in availability and access to food along with a lack of information about the correct choices around weaning. In high-income countries, parents face anxieties and challenges despite the adequate availability of food for weaning (Redsell 2010).

Parents make infant feeding choices based on a variety of influences including advice from family members and health professionals, leaflets, magazines and, increasingly, information from the Internet (Gage 2012). Evidence suggests that compliance with weaning guidelines is low and mothers often experience conflict in deciding when and how to wean their infants (Arden 2010; Moore 2012). Surveys of parents demonstrate that they feel unsupported and experience anxiety due to a variety of factors such as inadequate knowledge and understanding of the physiological needs of the infant, and confusing information from multiple commercially-oriented sources, as well as social pressures, controversial cultural patterns and expectations, a lack of information about healthy diet, and apprehension about cooking even the simplest weaning foods (Redsell 2010).

Weaning practices impact on long-term eating habits of children. Parental anxieties about infant feeding also manifest as controlling feeding practices and attempts to impose the amount or type of foods the infant eats. Studies demonstrate that parents who lack awareness of infant hunger cues are more likely to force their child to eat more (pressure/control feeding) or restrain certain foods or limit amounts due to anxieties about weight gain (restriction for weight) (Musher-Eizenman 2007). Such practices have been shown to be associated with food neophobia (the avoidance and rejection of novel foods) which is associated with reduced dietary quality and lower nutrient intake in later life (Cassells 2014). Empowering parents with the knowledge to recognise and respond to their infant's hunger cues may reduce the use of controlling feeding practices and improve lifelong dietary habits.

Despite the differences in opinion and lack of consensus among experts, parents and families need information and support while weaning their infants. Parents are receptive to advice but need better support in accessing and understanding the best practices around infant feeding (Redsell 2010). Inadequate nutrition may be caused by limited access to sufficient food, however, caregivers may not be able to make the best use of available resources because of lack of knowledge and inappropriate beliefs and advice. Education of caregivers may have an impact and improve nutritional status in children by empowering parents/caregivers to provide the best possible diet and use the most appropriate feeding styles to wean their infants.

Description of the intervention

Nutrition education has been defined as "any combination of educational strategies, accompanied by environmental supports, designed to facilitate voluntary adoption of food choices" (Contento 2010). Educational interventions may be provided to the individual parent or caregiver or may be delivered via community-based programmes, and could include nutritional counselling of caregivers, dissemination of information via verbal, written or audio-visual aids, and/or any other strategy that provides information about weaning practices to families.

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 changes in behaviour that may impact nutritional practices thereby improving nutrition, growth and long-term metabolic health outcomes in children (Lassi 2013). Dietary supply of specific nutrients may influence the maturation of cortical function. Feeding breast 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 outcomes such as an increase in the Bayley Psychomotor Developmental Index (Morgan 2004), visual acuity (Hoffman 2003) and higher behavioural indices (Krebs 2006). In older children, nutrition education modifies eating behaviour and optimises growth, and parental education can have a positive impact on child nutrition (Luepker 1996).

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Why it is important to do this review

Previous systematic reviews have evaluated the impact of nutrition education and demonstrated improvements in both weight and linear growth (Dewey 2008; Imdad 2011).However, both of these reviews concentrated on populations in low- and middle-income countries only and included non-randomised studies as well as those studies that included children older than 12 months of age. This review will collate the current evidence to determine if the use of nutrition educational interventions to support families during the weaning process optimises growth and nutrition in infants born at term gestation in all parts of the world.

The need for educational programmes to improve infant nutrition has been highlighted by several studies (Hoare 2002; Redsell 2010), particularly as infant nutrition is subjected to strong pressures by commercial and self-help groups. The double threat of childhood undernutrition and obesity and their potential long-term impact on health has prompted attention on effective interventions that improve the nutritional status of children in all parts of the world (Black 2013). Nutrition education has the potential to improve child health at both ends of the malnutrition spectrum. It is imperative that parents and families have access to nutrition education with scientifically-correct, culturally-sensitive and economically-appropriate advice about healthy diet for infants (Caroli 2012). It is also vital to ensure that such interventions are effective, as significant resources could be saved by eliminating time- and resource-intensive educational programmes which prove to be of no benefit.

OBJECTIVES

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

METHODS

Criteria for considering studies for this review

Types of studies

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

Types of participants

Parents and families of infants born at term gestation (37 to 42 weeks of gestation and up to 1 year of age).

Types of interventions

We will include studies comparing any nutrition education intervention for parents or families of infants born at term (37 to 42 weeks gestation) with conventional management for weaning up to one year of age. We will include studies that use any form of nutrition education intervention such as 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 nutrition education provided to families. We will look at nutritional educational messages which place emphasis on the importance of breast feeding duration, initiation of weaning food, frequency of feeding, or composition of food (in terms of protein, energy and micronutrient content). Conventional management is defined as standard clinical support and/or appointments without a nutrition education focus.

Types of outcome measures

Primary outcomes

1. 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.
2. Neurodevelopmental scores in children aged 12 months of age or older using validated assessment tools, using neurological examination and Bayley Scale Index II (Black 2000). These scores will be considered abnormal if Bayley II Mental Developmental Index is < 70, Psychomotor Developmental Index is < 70, or if there is visual impairment, and/or hearing impairment. Neurological examination will be considered abnormal if there are impaired motor and/or sensory functions.

Secondary outcomes

1. Duration of exclusive breast feeding.
2. Compliance with advice regarding timing of weaning.
3. Cognitive ability in children at five, six or seven years of age, using validated assessment tools such as the Weschler intelligence scale for children (Wechsler 1974) and school examinations.
4. Long term growth: weight, height, skinfold thickness or body mass index at five, six or seven years of age.
5. Serum ferritin (< 12microg/L) and haemoglobin (< 110g/L) levels in children 6 months of age or older (WHO 2011).
6. Parental stress when the child is aged 6 months of age or older, measured using validated assessment tools such as the Parenting Stress Index (Grotevant 1989).

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7. Infant quality of life when the child is aged 6 months of age or older measured using the Infant and Toddler Quality of Life Questionnaire (ITQOL) (Bowling 2004).
8. Prevalence of atopic conditions in childhood.
9. Prevalence of food neophobia or 'picky/fussy eating'.
10. Death before one and five years of age.

Search methods for identification of studies

Electronic searches

We will use the standard search strategy of the Cochrane Neonatal Review Group, including electronic searches of the Cochrane Central Register of Controlled Trials (CENTRAL, *Cochrane Library*), MEDLINE (1966 to present), EMBASE (1980 to present), CINAHL (1982 to present) and PsycINFO (1978 to present). There will be no language restrictions.
See Appendix 1 for search terms.

Searching other resources

We will examine reference lists of included studies and previous reviews. We will search the proceedings of the annual meetings of the Paediatric Academic Societies (1993 to present), 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 will be eligible for inclusion if sufficient information is available from the report, or from contact with the authors, to fulfil the inclusion criteria. Clinical trials registries will also be searched for relevant studies using the search words 'wean' and 'solid foods'.

Data collection and analysis

We will use the standard methods of the Cochrane Neonatal Grou

Selection of studies

The principal review author will screen the title and abstract of studies and potentially-relevant reports identified from the above search. Two review authors will independently assess the full articles for all potentially-relevant trials and any disagreements will be resolved by discussion.

Data extraction and management

Three review authors will independently extract data from the full text articles of included studies using a data collection form for details of design, methodology, participants, interventions, outcomes and educational effects from each included study. We will cross-check information and resolve any discrepancies by discussion until agreement is reached.
Study authors will be contracted if additional information is required.

Assessment of risk of bias in included studies

The Cochrane Neonatal Group criteria and standard methods will be used to assess the methodological quality of included trials. Two authors will conduct the assessment of risk of bias, and disagreements will be resolved by discussion with a third author. Additional information will be requested as necessary from trial authors to clarify methodology. We will evaluate and report the following issues in 'Risk of bias' tables.
Random sequence generation - the method used to generate the allocation sequence will be categorised 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; and
- unclear risk - no or unclear information provided.

Allocation concealment - the method used to conceal the allocation sequence will be categorised as:

- low risk: e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes;
- high risk: open random allocation, e.g. unsealed or non-opaque envelopes, alternation; date of birth; and
- unclear: no or unclear information provided.

Blinding of participants (performance bias i.e. bias due to knowledge of the allocated intervention by participants during the study) will be assessed separately for each included study and categorised as:

- low risk of bias: no blinding or incomplete blinding but the outcome is unlikely to be influenced by lack of blinding of participants, and not likely that the blinding could have been broken.
- high risk of bias: no blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; i.e. blinding of study participants attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
- Unclear risk: no or unclear information provided.

Blinding of outcome assessment (detection bias i.e. bias due to knowledge of the allocated interventions by clinicians and outcome assessors)
for each included study, will be assessed separately and the methods categorised as:

- low risk of bias: no blinding or incomplete blinding but the outcome is unlikely to be influenced by lack of blinding of outcome assessors, and not likely that the blinding could have been broken.

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- high risk of bias: no blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; i.e. blinding of outcome assessors attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
- Unclear risk: no or unclear information provided.

Incomplete outcome data - the completeness of data including attrition and exclusions from the analysis for each outcome and any reasons for attrition or exclusion will be described where reported. Whether missing data are balanced across groups or are related to outcomes will be assessed. Where sufficient information is reported or supplied by the trial authors, missing data will be reinstated in the analyses. Completness will be categorised as:

- low risk: adequate (less than 10% missing data);
- high risk: inadequate (more than 10% missing data); and
- unclear risk: no or unclear information provided.

Selective reporting bias - for each included study where the protocol is available (through a trials register), we will describe how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- low risk: adequate (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review had been reported
- high risk: inadequate (where not all the study's pre-specified outcomes had been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported
- unclear risk: no information about pre-specified outcomes provided

Other potential types of bias (Other bias)
We will describe any important concerns we had about other possible sources of bias, for each included study (such as, whether there was a potential source of bias related to the specific study design used).
For each included study, will be assessed separately and the methods categorised as:

- Low risk: the study is likely to be free of other sources of bias;
- High risk: the study had at least one important risk of bias (for example, the study had a potential source of bias related to the specific study design used or whether the trial was stopped early due to some data-dependent process);
- Unclear risk: there may be a risk of bias, but there is either: no information provided to assess whether an important risk of bias exists; or insufficient rationale or evidence that an identified problem will introduce bias.

A 'Risk of bias ' graph will be used to illustrate risk across studies. Any disagreements will be resolved by discussion and, if necessary, by adjudication with a third review author (MGC).

Overall risk of bias - explicit judgements about whether studies are at high risk of bias will be made, according to the criteria suggested in the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins 2011). The magnitude and direction of the bias and its likely impact on the findings will be assessed. The impact of the level of bias will be tested in sensitivity analyses.

Measures of treatment effect

Educational interventions' effects in the individual trials will be analysed using Review Manager 5.3 (RevMan 2014). We will report risk ratio (RR) and risk difference (RD) for dichotomous data and mean difference (MD) for continuous data, with respective 95% confidence intervals (CIs). The number needed to treat for an additional beneficial outcome (NNTB) or an additional harmful outcome (NNTH) for analyses with a statistically significant difference in the RD also will be reported.
For categorical outcomes typical estimates for relative risk, RD, NNTB and NNTH will be calculated. We will use 95% CIs.

Unit of analysis issues

The unit of analysis will be the participating infant in individually randomised trials. An infant will be considered only once in an analysis. Infants with multiple enrolments will be excluded from analysis unless data from the report or investigators relating to the first episode of randomisation are obtained. If data from the first randomisation cannot be identified, we will exclude the study as we will not be able to address the unit of analysis issues that arise from multiple enrolments of the same infant. Infants from multiple births will be included.
We intend to conduct intention-to-treat analyses. The participating health organisation will be the unit of analysis in cluster-randomised trials. We will analyse these trials 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-randomised trials we will conduct the analysis at the same level as the allocation, using a summary measurement from each cluster which will be the unit of analysis.

Dealing with missing data

If data are missing or reported unclearly, we will request additional data on important outcomes from trial authors. Where data are still missing, we will 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 will be examined between trial results by inspecting the forest plots. The I

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^{2} statistic will be calculated for each RR analysis to quantify inconsistency across studies and describe the percentage of variability in effect estimates that may be due to heterogeneity rather than to sampling error. Degree of heterogeneity will be classified according to the I^2 statistic: < 25%: none, 25% to 49%: low, 50% to 74%: moderate, 75% or higher: high heterogeneity.
If moderate or high heterogeneity is detected (I^2 > 50%), we will explore the possible causes (for example, differences in study design, participants, interventions, or completeness of outcome assessments). In addition, we will employ a Chi^2 test of homogeneity to determine the strength of evidence that heterogeneity is genuine.

Assessment of reporting biases

If more than ten trials are included in a meta-analysis, a funnel plot for asymmetry will be used to assess potential reporting bias.

Data synthesis

The fixed-effect model in Review Manager 5.3 (RevMan 2014) will be used for meta-analyses (as per Cochrane Neonatal Group recommendations). We will use the standard methods of the Cochrane Neonatal Review Group to synthesise data using RR, RD, NNTB, NNTH, MD, and 95% CIs. Where substantial heterogeneity exists, the potential causes will be tested in subgroup and sensitivity analyses.

Quality of evidence

We will assess the quality of evidence for the main comparison at the outcome level using the Grading of Recommendations Assessment, Development and Evaluation approach (GRADEpro 2008; Guyatt 2011a). This methodological approach considers evidence from randomised controlled trials as high quality that may be downgraded based on consideration of any of five areas: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates and the presence of publication bias (Guyatt 2011a). 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 (Schünemann 2013).

The review authors will independently assess the quality of the evidence found for outcomes identified as critical or important for clinical decision making:

- 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;
- Cognitive development assessed with Bayley Mental Development Index > 70 during follow up at 12 months;
- Iron deficiency assessed with serum ferritin < 12 microgram/l during follow up at 6 months.

In cases where we consider the risk of bias arising from inadequate concealment of allocation, randomised assignment, complete follow-up or blinded outcome assessment to reduce our confidence in the effect estimates, we will downgrade the quality of evidence accordingly (Guyatt 2011b). Consistency will be evaluated by similarity of point estimates, extent of overlap of CIs and statistical criteria including measurement of heterogeneity (I^2). The quality of evidence will be downgraded when inconsistency across studies' results was large and unexplained (i.e. some studies suggest important benefit and others no effect or harm without a clinical explanation) (Guyatt 2011d). Precision will be assessed using the 95% CI around the pooled estimate (Guyatt 2011c). When trials were conducted in populations other than the target population, we will downgrade the quality of evidence because of indirectness (Guyatt 2011e).
Data (i.e. pooled estimates of effects and corresponding 95% CI) and explicit judgements for each of the above aspects assessed will be entered into the Guideline Development Tool, the software used to create 'Summary of findings' (SoF) tables. All judgements involving the assessment of the study characteristics described above will be explained in footnotes or comments in the SoF table.

Subgroup analysis and investigation of heterogeneity

We will perform the following subgroup analyses, if data are available:

1. Infants and families living in middle- and low-income countries.
2. Infant and families living in high-income countries.

Sensitivity analysis

Sensitivity analyses will be performed to determine if the findings are 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.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search methodology

PubMed search terms (to be modified for subsequent databases):

(Weaning OR Wean* Weaning[MeSH] OR (Feed* NEAR complementary) OR (Food NEAR complementary) OR (Feed* NEAR supplementary) OR (Food NEAR supplementary)) AND (Family[MeSH] OR Parent[MeSH] OR mother OR father OR parent* OR famil* OR carer OR caregiver) AND (program* OR education* OR training OR intervention*)

Plus database-specific terms:

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 randomized [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 (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)

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)

WHAT'S NEW

Date	Event	Description
10 February 2017	Amended	Added source of support

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