Evidence Tables 6 – 24 Months

Evidence is presented to answer the following questions:

1. What interventions effectively promote the timely introduction of appropriate solid/family foods?
2. What interventions effectively promote uptake of recommended vitamin and micronutrient supplements?

   (No studies that addressed this question were identified in the literature search).
3. What dietary strategies effectively reduce the risk of food allergies and intolerance?
4. What dietary interventions help to prevent diet-related dental caries in infants and young children?
5. What interventions effectively help mothers continue breastfeeding after 6 months, both at home and out of the home, for example, during return to paid employment?

   (A number of studies have been identified that examine interventions that aim to increase the duration of breastfeeding (these are included in the 0-6 month review). Only one study specifically aimed to support breastfeeding in women who planned to return to paid employment.)

Introduction of family foods

First author Year	Research Question	Study populations	Study quality	Intervention	Main results	Applicability to UK populations and settings Comments
Elkan et al 2000 UK SR 2+	The review objective was to examine the effectiveness and cost-effectiveness of home visiting by health visitors. This also included an assessment of home visiting in improving children's diet.	1. Studies that reported home visiting outcomes relevant to British health visitors were included 2. The personnel involved in carrying out the programme had to have responsibilities that were within the remit of British health visitors, and could not be members of a professional group other than health visiting 3. At least one home visit was made 4. Studies had to include a comparison group (RCTs, non-RCTs and controlled before-and-after comparisons) Four of 102 studies in the SR were included relevant to improving	Quality of individual studies was assessed using a standardised quality checklist – an adapted Reich scale, which included randomisation, concealment of allocation, blinding, power calculation and ITT analysis. Reich scores: Gutelius 1977 0.59 RCT moderate i.e. 1+ Barker 1988 0.46 RCT borderline i.e. 1- Barker 1994 0.46 non-RCT borderline i.e. 1- Johnson 1993 0.25 RCT weak i.e. 1-	Gutelius The intervention in the US study was 9, 6 and 4 home visits in the 1st, 2nd and 3rd years of life, respectively (minimum 1 h per visit) by a paediatrician or nurse, using a mobile coach parked outside the home, from 7 months pregnant to 3 y old versus no home visits. Additionally, 16 group events, usually discussion sessions, for 1 year. (Advice was based on Dr Benjamin Spock's book 'Baby and Child Care') Also 8-16 mg Fe daily for ≥1st year of life. Evaluation at 6, 12, 24 and 36 months. (No details of dietary assessment given.) 6% loss to follow-up (2 infants excluded due to retardation) For the 2 Barker studies (Barker 1988 and 1994), the intervention was monthly health visitor home visits versus no home visits. Evaluation at 12 and 36 months. Maternal self report for dietary assessment. Johnson study	Elkan et al. summary and conclusion: The authors reported that 3 of the 4 studies (excluding Barker 1994) reported better nutritional outcomes among home-visited children. They also conclude that the studies relied on maternal self-reports to assess diet and may thus be subject to bias. The author's state that there is insufficient evidence to make any conclusions. (Johnson concluded that the 'community mothers' programme was effective but it was not clear whether it was as cost effective as using professionals.) Results taken from data extraction tables: Results for Gutelius 1977 and Barker 1988 and 1994 Milk/weaning related outcomes Appropriate daily milk at 12 months (%) Int 55% Con 27% p<0.01 Gutelius % with an adequate milk intake Int 95% Con 94% at 12 months Barker 1994 Int 92% Con 98% at 36 months Barker 1994 Feeding self at 24 months (%) Int 71% Con 48% p<0.05 Gutelius Results for individual foods/nutrients % with >1 daily serving of fruit or fruit juice Int 51% Con 33% p<0.05 at 24 months Gutelius Int 57% Con 38% p<0.05 at 36 months Gutelius % with an adequate fruit intake at 12 months Int 63% Con 68% at 12 months Barker 1994 Int 76% Con 76% at 36 months Barker 1994 % with an adequate vegetable intake Int 73% Con 76% at 12 months Barker 1994	The results appear to be applicable to the UK. Three of the 4 studies were in the UK. Limitations of included studies: many were too small to detect effects, some were unrandomised with unblinded or self-reported outcome assessment . The Child Development Programme for 'community mothers' implemented in the Johnson study in 1983/4 (Johnson 1993) was an extension of the CDP developed at the Early Childhood Development Unit,

[1] Int= Intervention; Con=Control

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		children's diet (3 RCTs and 1 non-RCT). Two studies considered children of 1st time mothers: Gutelius 1977, a Washington, US, RCT of low income black infants in the 1st 3 years born to normal unmarried schoolgirls aged 15-18 y with normal births (n=97: Int n=49; Con n=48); and Johnson 1993, an Irish RCT in Dublin of disadvantaged infants in their 1st year (n=262: Int n=141; Con n=121). Gutelius Int and Con groups only differed in 6 of >90 variables, of these 5 favoured the Con group. The 2 remaining studies concerned 3-27 month old infants on normal health	Additional quality information (where available in the systematic review) Johnson 1993 Random allocation using consecutively numbered sealed envelopes. Group allocation known before consent sought. Gutelius 1977 (from original paper) Randomisation using random numbers	Intervention: monthly visits by non-professional 'community mothers' for the infant's 1st year versus routine care (visit at birth, at 6 weeks and then as required by the public health nurse). Each community mother had 4 weeks' training and worked under the guidance of a family development nurse. Maternal self report for dietary assessment. 11% loss to follow-up	Int 77% Con 77% at 36 months Barker 1994 % with >1 daily serving of meat at 6 months Int 88% Con 75% p<0.05 Gutelius % with an adequate animal protein intake Int 87% Con 87% at 12 months Barker 1994 Int 92% Con 90% at 36 months Barker 1994 % with an adequate non-animal protein intake Int 82% Con 84% at 12 months Barker 1994 Int 89% Con 83% at 36 months Barker 1994 % with an adequate whole food intake Int 70% Con 79% at 12 months Barker 1994 Int 80% Con 78% at 36 months Barker 1994 % with an adequate energy intake Int 87% Con 92% at 12 months Barker 1994 Int 94% Con 88% at 36 months Barker 1994 Results for vitamins and minerals % of children with <50% of RDA Barker 1988 At age 12 months At age 36 months Int Con Int Con Iron 10 5 5 5 Zinc 5 3 22 54 Calcium 0 0 0 0 Vitamin C 21 11 36 27 Total folate 2 0 18 35 Results for the Johnson 1993 study Milk/weaning related outcomes Cow's milk given before 26 weeks (%) Int[1] 24% Con 49% p<0.001	Bristol and described in the 2 included studies by Barker 1988 & 1994. The Johnson study was curtailed early due to lack of funding. Review funded via the Health Technology Assessment NHS R&D HTA Programme (UK).

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		visitor caseloads: Barker 1988, in NW and NE England, W Glamorgan and Dublin (health visitors) (n=1051; Int n=678; Con n=373) and Barker 1994 (non-RCT), in Northern Ireland (public health and family development nurses (n=606:Intn=384; Con n=222,). Search of electronic databases included Medline (1966-1997), CINAHL (1982-1997), EMBASE (1980-1997), the Internet, the Cochrane Library, relevant journals and references lists. Key individuals and organisations were also contacted and advertisements made in journals.			Mean ±SD length of time on formula feeds (weeks) Int 38.1 ± 13.5 Con 28.0 ± 15.2 p<0.001 Results for individual foods/nutrients % whose mothers gave vegetables appropriately Int 88% Con 62% p<0.001 at 12 months % whose mothers gave animal protein appropriately Int 83% Con 42% p<0.001 at 12 months % whose mothers gave non-animal protein appropriately Int 84% Con 51% p<0.001 at 12 months % whose mothers gave whole foods appropriately Int 86% Con 46% p<0.001 at 12 months % who had an appropriate energy intake Int 92% Con 56% p<0.001 at 12 months Significant results were reported for the studies by Gutelius and Johnson but no estimations of significance were reported for the Barker studies. It appears that many of the results of the Barker 1994 study were unlikely to be significant.	

First author, Year,	Research Question	Study population	Study quality: Including study design and grade	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Tedstone et al. 1998 UK SR 2++	To review interventions designed to promote healthy feeding of infants under one year of age	Inclusion criteria: Published or unpublished reports of interventions with evaluated outcomes that promoted healthy eating for 0-1- year old infants Exclusion criteria: Observational studies Studies published before 1984 Studies that targeted high-risk or diseased populations Childs 1997, an RCT of 6 week old children in 2 inner city areas of Birmingham with high social deprivation and low income, where 34.7% children were anaemic Characteristics: Asian 75%, Afro-Caribbean and White, low level of breastfeeding. N=1000 (Int, n=500; Con, n=500) No significant difference in socioeconomic status at baseline, iron intake or anaemia Johnson 1993, an Irish RCT of first time mothers in Dublin of disadvantaged	Quality assessment included sample size and power, comparability of intervention and control groups, rates of attrition, validity of method of assessing outcome, blinding of outcome assessment, treatment of potential bias and treatment of potential confounding factors. Poorer quality studies excluded, however some poorly UK studies retained, based on relevance of setting and type of intervention Graded poor to good Childs 1997,	Interventions in the home environment: 2 studies Childs 1997 Intervention - Home visits from health visitors at 3, 6 and 9 months of age giving specific dietary advice via audiotapes in relevant language + discussion + culturally appropriate leaflets. Main focus: improved intake of iron and vitamin C - rich foods. Additionally breastfeeding encouraged and good weaning practice. Controls: current practice Follow-up until 18 months Johnson 1993 Intervention: monthly visits by non-professional 'community mothers' for the infant's 1st year versus routine care (visit at birth, at 6 weeks and then as required by the public health nurse). Each community mother had 4 weeks' training and worked under the guidance of a family development nurse. Controls – routine care (routine home visits from public health nurse at birth and 6 weeks).	Nutritional outcomes: Childs 1997 No effect on the level of anaemia, blood haemoglobin and iron intake at 9 months Int Con Anaemia at 9 months 27.7% 26.8% Johnson 1993 (moderate) showed improved intake in terms of dietary recommendations for animal protein, non-animal protein, whole foods, milk, fruit and vegetables (p<0.001) resulting from a home-based peer support 'community mothers' programme. Infants in the Con group were significantly more likely to be given cow's milk before 26 weeks (p<0.001). Griffiths 1995 Int Con Anaemia at baseline (age 6-12m) 28% 37% Anaemia after 12m (age 18-24m) 24% 50% Haemoglobin g/dL at baseline 11.2 10.0 Haemoglobin g/dL after 12m 11.6 10.9 Diet score at baseline (age 6-12m) 5.9 5.2 Diet score after 12m (age 18-24m) 5.4 4.9 Significance not given but results unlikely to be sig due to small nos. (Tedstone Comments: 24 h food frequency estimates of diet intake are considered to be unreliable) McEnery and Rau 1986 Int Con (n=16) (n=27?) Haemoglobin g/dL after 12m 11.1 11.9 Vitamin supplements given 94% 86% Intervention relatively unsuccessful. Lapinleimu 1995/Niinikoski 1996	The Child Development Programme for 'community mothers' implemented in the Johnson study in 1983/4 (Johnson 1993) was an extension of the CDP developed at the Early Childhood Development Unit, Bristol Three studies with anaemia outcomes (McEnery 1986, Griffiths 1995, Childs 1997) were undertaken in the UK Anaemia may be affected by factors other than diet Childs 1997: A shortage of resources lead to incomplete delivery of the intervention

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		infants in their 1st year (n=262: Int n=141; Con n=121). No difference between groups in sex, mother's age, marital status, social class and housing but more parents were employed in the Int group. Griffiths 1995, a non-randomised trial of children aged 6-12 m in 2 inner city Bolton areas of mainly Asian families with high social deprivation. Int from adjacent GPs practices, n=34, Con from a GP's practice in another part of town, n=?. Groups similar for social class, ethnicity and age. McEnery and Rau 1986, an RCT of pregnant Asian women at a health clinic in Waltham Forest, East London n-69 (Int, n=35: Con, n=34) Only maternal data collected at baseline Lapinleimu 1995, Niinikoski 1996, a randomised prospective trial of infants at well baby clinics in Turku, Finland,	RCT moderate 1+ Griffiths 1995, non-randomised trial moderate 2+ Johnson 1993 non-randomised trial moderate 2+ No power calculation McEnery and Rau 1986 RCT poor 1- Lapinleimu 1995, Niinikoski 1996 RCT prospective good 1+	Assessment by family development nurse at birth and 1 year. 24 h dietary recall at 1 y 11% loss to follow-up: Int 10%; Con 13% Intervention set at hospital or clinic and home in postnatal period Griffiths 1995 Intervention: health promotion display focussing on diet and prevention of anaemia. Weaning leaflets in appropriate language with advice and recipes explained by health visitor, with translation if needed. Children visited by health visitor bimonthly to reinforce message for 12 m Controls: standard health care Assessment: 24 h food frequency questionnaire bimonthly, giving a diet score. Blood samples at baseline and after 12 m Loss to follow-up: Int, 9 (27%); Con 5 Intervention set at a health clinic in prenatal period McEnery and Rau 1986 Intervention: 12 week	Significant reduction in total intake of dietary fat, saturated fat intake, polyunsaturated/saturated fat ratio (P/S ratio) and cholesterol intake and increased polyunsaturated fat intake. Mean baseline adjusted serum lipids and cholesterol were only significantly reduced in boys. Boys Int Con p Energy intake (Kcal) 1234 1285 ns Fat % energy 30.8% 32.8 <0.0001 P/S ratio 0.48 0.38 <0.0001 Cholesterol intake (mg/1000Kcal) 118 137 0.002 Serum cholesterol mmol/l 0.32 0.56 <0.0001 Serum non-HDL cholesterol 0.17 0.35 <0.0001 Girls Int Con p Energy intake (Kcal) 1170 1199 ns Fat % energy 31.1% 33.7 0.001 P/S ratio 0.48 0.34 0.0001 Cholesterol intake (mg/1000Kcal) 123 137 0.008 Serum cholesterol mmol/l 0.23 0.37 ns Serum non-HDL cholesterol 0.09 0.20 ns . The 3 UK studies that intervened with high-risk groups (McEnery 1986 (poor), Griffiths 1995 (moderate), Childs 1997 (moderate)) failed to reduce their incidence of anaemia.	Griffiths 1995 Study too small to give sig results. McEnery and Rau 1986 Study seriously compromised by intervention subjects being moved to the control group i.e. a self-selected intervention group. The authors concluded that a home intervention might be a better option. Lapinleimu 1995, Niinikoski 1996 gave no details of socioeconomic status of subjects. Dietary regime of controls already shown to give a polyunsaturated/saturated fat ratio of 0.3-0.4 in young children

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		(STRIP Baby Project) recruited at 5 month visit 1990-2. 1054 families with 1062 children (56% of eligible families) Int, n=540; Con, n=522 At baseline, age 7 months, blood samples showed no sig differences in nutrient intake or serum lipid level and similar growth measurements. Search of 17 electronic databases including Medline, Science Citation Index, Social Science Citation Index, Embase, Unicorn, ASSIA and CINAHL, plus hand-searching, searching for grey literature and contacting organisations and specialists in the field 5 of 26studies evaluated interventions designed to promote good feeding practice in the weaning and post-weaning period but only 5 had follow-up data for age >6 months: Childs 1997, Griffiths 1995, Johnson 1993, McEnery and Rau 1986 and {Lapinleimu 1995,		intervention with 12 culturally specific prenatal 1.5h lectures at a health clinic from a health visitor, midwife or nutritionist – with a translator and appropriate literature. Controls: appropriate prenatal care including mothercraft classes (in English) at a hospital maternity unit Assessment: children examined at 1 y of age for growth, blood analysis and dietary history Follow-up: Only 16 women attended >4 classes so all the remaining women were moved to the control group! Data for 16+ 27 children at age 1 y. Loss to follow-up= 38% Intervention set at a health clinic in postnatal period Lapinleimu 1995, Niinikoski 1996 Intervention: intensive health education with specific dietary counselling to modify and reduce dietary fat intake (also encourage physical activity and avoid passive smoking). 10 meetings with paediatricians,		Although the Lapinleimu 1995/Niinikoski 1996 STRIP intervention reduced the total intake of dietary fat - the outcome noted by Tedstone not to be appropriate for this age group according to UK recommendations. Only the boys' blood lipid levels were affected but they are more at risk of CHD. Both HDL and LDL cholesterol were reduced, which diminished the effect of reducing LDL cholesterol. Tedstone concluded that the studies reported by Johnson 1993, and Lapinleimu 1995/Niinikoski 1996 provided an inadequate basis

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		Niinikoski 1996}		dieticians and nurses at 7,8,10,13,15,18,21,24,30 and 36m Individual advice for 20-45 min at every visit related to dietary records. 3-4 day dietary records at 8, 13, 24 and 36 months. Aim: 30-35% energy from fat and a polyunsaturated/monounsaturated/saturated fat ratio of 1/1/1, a cholesterol intake of <200 mg/day, energy from protein and carbohydrate to be 15% and 55%, respectively. Breast or formula milk up to age 1y, then 0.6L skimmed milk/day. Use of vegetable oil or margarine in food preparation Controls: routine health care at well baby clinic. Breast or formula milk up to age 1y, then cow's milk with ≥1.9% fat. (No detailed discussion of dietary fat and only brief discussion of dietary issues.) Infant blood samples at 7, 13, 24 and 36 m Follow-up to age 36 m: 70% for blood lipids and 31% for dietary records		for planning future interventions due to design limitations and overall paucity of data Review funded by the Health Education Authority

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				Three UK health promotion interventions aimed to reduce the prevalence of anaemia in vulnerable groups (McEnery 1986, Griffiths 1995, Childs 1997)		

Probiotics

First author Year	Research Question	Study population	Study Quality Power Calculation	Intervention	Main results	Comments Applicability to UK populations and settings Funding
Kalliomaki et al. 2001; 2003 Finland RCT 1+	Are probiotics (Lactobacillus GG) effective in the prevention of early atopic disease in children at high risk?	A single study with follow-up at 12 and 24 months (Kalliomaki 2001) and 4 years (Kalliomaki 2003) Inclusion criteria: Mothers with at least one 1st degree relative (or partner) with atopic eczema, allergic rhinitis or asthma Sample size n=159 Participant characteristics: No differences in infants' mean weight at birth or gestation in 2 groups. Infants mean weight: Int 3631±483 g, Plac 3612±466 g Gestation time: Int 39±1.3 weeks Plac 39±1.4 weeks Both groups had similar numbers of boys and girls: Boys: 64% Int: 32% Plac	Power calculation required 159 to be randomised. Expected frequency of atopic disease 50% in placebo group. With ≥56 subjects in each group, a reduction of 25% would be detected at a 5% level of significance with 80% power. Loss to follow-up was 17%. Double-blind placebo RCT. (Treatment codes retained by the supplier until data had been collected and analysed.	Intervention mothers (n=77) received 2 capsules of $1x10^{10}$ colony-forming units of Lactobacillus rhamnosus (Lactobacillus GG, ATCC 53103) daily for 2 weeks before delivery. After delivery, breastfeeding mothers either took the capsules or gave them to their children for 6 months, in which case the capsule contents were diluted with water and given with a spoon. Control: placebo (n=82) children examined in the neonatal period and at ages 3, 6, 12, 18 and 24 months for atopic disease. Atopic eczema was the primary study endpoint; SCORAD index used to assess eczema severity. Skin prick tests, serum total IgE and antigen-specific IgE in	Lactobacillus GG N=64 / Placebo n=68 / p Atopic eczema At 24 months 23% 46% RR (95% CI) 0.51 (0.32-0.84) 0.008 SCORAD Mean (95% CI) 9.8 (8.2—11.8) 10.4 (9.3-11.6) 0.60 Total IgE (kU/L) mean (95% CI) At 12 months 11.2 (8.0-15.7) 9.7 (7.0-13.4) 0.55 At 24 months 31.3 (22.8-43.0) 32.7 (22.6-47.3) 0.85 Increased RAST readings[2] At 12 months 16/62 (26%) 15/66 (23%) 0.68 At 24 months 17/62 (27%) 16/64 (25%) 0.76 Prick test reaction[3] At 12 months 17/63 (27%) 12/68 (18%) 0.20 At 24 months 11/61 (18%) 9/65 (14%) 0.52 Follow-up at 4 years N=53 n=54 Atopic eczema At 4 years 26% 46% RR (95% CI) 0.57 (0.33-0.97) Prick test reaction[2]	Reason for discontinuation with study was non-compliance i.e. failure to attend at study visits. Dropouts showed no signs of atopic disease before discontinuation Respiratory allergic diseases usually manifest themselves at an older age than 4 years so this is not a final assessment of any effect on such diseases The intervention is applicable to the UK population but the mode of delivery and long time of

[2] Number (%) with at least one increased (by >0.35 kU/L) antigen specific IgE concentration in radioallergosorbent (RAST) assay.
[3] Number (%) with at least one positive skin prick test reaction.
[4] Marker of bronchial infection. Excluding 4 children with asthma and 19 children with signs of acute respiratory infection.

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		Parental smoking characteristics: 12% Int; 21% Plac Furry pet at home: 21% Int; 11% Plac Both groups had similar mean (95% CI) times (months) of exclusive and total time of breastfeeding: Exclusive bf: Int 3.0 (2.6-3.4); Plac 2.7 (2.2-3.1), p=0.28 Total bf: Int 7.2 (6.4-8.1); Plac 6.4 (5.4-7.5), p=0.24	Randomisation by computer. The number needed to treat was 4.5 (2.6-15.6).	radioallergosorbent (RAST) assay also carried out. Overall 132 (83%) completed the study at 2 y Intervention 64 (83%) Placebo 68 (83%)	At 4 years 10/50 (20%) 9/50 (18%) 0.80 Seasonal allergic rhinitis At 4 years 19% 9.3% 0.15 Asthma At 4 years 5.7% 1.9% 0.30 Exhaled nitrous oxide[4] (ppb) mean (95% CI) N=25 n=32 At 4 years 10.8 (8.6-13.0) 14.5 (12.0-17.1) 0.03 The frequency of atopic eczema at 24 months was significantly reduced in the infants given probiotics compared with those on the placebo but there were no significant differences in the other measured indicators of atopic disease. The number needed to treat was 4.5 (2.6-15.6). The preventive effect on atopic eczema extended to 4 years. At 4 years there was no significant effect on the development of respiratory allergic disease but exhaled nitrous oxide was significantly higher in the placebo group. This indicated the possibility of more under-diagnosis or subclinical cases of respiratory allergic disease in the placebo group Most mothers chose to give the capsules to their infants: 56% (36/64) of Lactobacillus GG group and 57% (36 of 64) of placebo group, p=0.9. The preventive effect did not depend on mode of administration; in the intervention group, where infants took the probiotic 9 of 36 (25%) developed atopic eczema at 24 months and where mothers took the probiotic 6 of 28 (21%) developed atopic eczema, p=0.74.	administration of the probiotic should be noted Funded by the Finnish Foundation for Paediatric Research, the National Technology Agency of Finland and the Allergy Research Foundation in south west Finland.

Formula Milk and allergenic food

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Arshad et al. 1992& Hide et al. 1994 Isle of Wight, UK RCT 1+	To assess whether avoidance of food and inhaled allergens in infancy protects against the developme nt of allergic disorders in high-risk infants	Inclusion criteria: Infants with a family history of atopy and high (>0.5 kU/l) total IgE cord-blood concentrations were allocated randomly to prophylactic and control groups. Exclusion criteria: Not stated Sample size n=120 Participant characteristics The two groups were similar in hereditary characteristics, cord blood IgE distribution, home environments, rates of breastfeeding, formula feeding and introduction of solid foods	Power calculation not reported Mothers were prenatally randomised via computer-generated random numbers. The allergy specialist was not aware of the allocation group. Loss to follow-up 12%. All subjects were used in the final analysis.	Intervention group (I) (n=58) A dual approach was used: breastfeeding mothers avoided allergenic foods (milk, egg, fish and nuts) Infants' diets were free of dairy, egg, wheat, unhydrolysed soya, orange, fish and nuts up to 12 months. Up to 9 months breastfeeds were supplemented if necessary with a soya-based protein hydrolysate (Aptamil HA). Formula fed infants received Aptamil HA from birth. Cow's milk and soya were introduced at 9 months, wheat at 10 months, and egg at 11 months. A dietitian explained the dietary restriction in detail to all intervention mothers at birth. Written instructions were also given to mothers with a list of foods to take. In addition, the infants' bedrooms and living rooms were treated with an acaricidal powder and foam (benzyl benzoate, a chemical agent used to kill	Follow-up at 10-12 months (reported in both Arshad 1992 and Hide 1994) One or more allergic symptoms: p<0.005 I: 8/58 (14%), C 25/62 (40%) OR: 6.34, 95% CI: 2.0, 20.1 Asthma: p<0.05 I: 4/58 (7%), C: 12/62 (19%) OR: 4.13, 95% CI: 1.1, 15.5 Eczema: p<0.05 I: 4/58 (7%), C 12/62 (19%) OR: 3.6, 95% CI: 1.0, 12.5 Food intolerance: not significant I: 2/58 (3%), C: 7/62(11%) OR: 3.29, 95% CI: 0.6, 17.3 Parental smoking was a significant risk factor for total allergy at 12 months whether only one parent smoked or both parents smoked (OR: 3.97, 95% CI: 1.2, 13.6, p<0.05 and OR: 4.72, 95% CI: 1.2, 18.2, P<0.05, respectively). At 12 months, infants from a low socio-economic group had a higher risk of developing allergy than infants from high socio-economic group (OR: 3.30, 95% CI: 1.1, 10.2, p<0.05). Follow-up at 2 years (reported in Hide 1994) One or more allergic symptoms: I: 15/58 (26%) asthma 9, eczema 8, food intolerance 7, allergic rhinitis 2 C: 29/62 (47%) asthma 17, eczema 15, food intolerance 11, allergic rhinitis 7 At 2 years infants in the control group remained more likely to manifest any allergy (p<0.005), and eczema (p=0.008), but the enhanced risk of asthma shown at 1 year was no longer significant The authors concluded that the intervention (reduced exposure to allergens in food and in house dust) lowered the frequency of allergic disorders in the first years of life. Passive smoking is an important risk factor that should also	301 women were randomised before the birth of the infant. 136 met the inclusion criteria. 16 of the infants did not complete follow-up (11 in the intervention group and 5 in the control group) Of the 120 remaining, 8 mothers gave up the diet, and 3 infants were introduced to cow's milk. These infants were included in the final analysis It appears that this study was conducted in the UK (not explicitly stated) and is therefore directly applicable Supported by

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				mites) in the first week of life and then every 3-9 months, and all infants used polyvinyl-covered mattresses with vented head area Control group (C) (n=62): the diet of the mothers was unrestricted and presumed to be the normal diet as recommended by health workers There was no acaricidal treatment All lactating mothers were given 1000 mg calcium/day supplementation and vitamin supplements. Assessment Data on allergic manifestations were compared. The same paediatric allergy specialist examined all children for allergic diseases and was unaware of the allocation group. Skin prick tests were also carried out. Dermatophagoides pteronyssimus antigen (Der p 1) in house dust was measured at 9 months in both groups and during the	be addressed in any prophylactic programme	Milupa (UK), Crawford Chemicals (UK), the Isle of Wight Health Authority Trustees, the Wessex Medical Trust and the National Asthma Campaign (Isle of Wight Branch)

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				first week after birth for the Intervention group. Follow up of 120/136 (88%) (see comments) at 10-12 months and 2 years (100%)		

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Odelram et al. 1996 Sweden and Finland RCT 1-	To compare ultra filtered whey hydrolysate formula (eH) with cow's milk formula (CMF) to prevent atopy developme nt in infants at high risk of developing atopy	Inclusion criteria Infants were recruited if there were at least two atopic family members, or one atopic parent, and cord blood total IgE >0.5 kU/l Exclusion criteria Gestational age below 37 weeks, complicated delivery, neonatal illness, severe birth defects, and documented non-compliance with diet prescriptions were reasons for exclusion Study population N=91 (71 randomised) Recruited at well-mother clinics in Turku, Finland and Motala, Sweden Participant characteristics Turku 72; Motala 19 48 boys, 43 girls Mean birth weight: 3542g (2280-4700 g) No significant differences between groups with regard to family members with atopy, age of	Power calculation not reported Randomisation of 82 infants after breastfeeding for 0-12 months only for 2 intervention groups in blocks of 4, separately for infants at the 2 centres. 71 of these infants were exclusively breastfed for ≤9 months and included in the study analysis. 3rd group created due to its high level of long >9 months breastfeeding. Concealment was not addressed. Blinding was only addressed at the physical examination at	Intervention A: infants were given hydrolysed ultra filtered cow's milk whey formula (Profylac) (n=32) Intervention B: infants were given ordinary cow's milk formula (n=39) Control: infants who were exclusively breast-fed for more than 9 months (n=20) For all families, allergy prophylactic advice was given, including discouraging tobacco smoke, and pets. No fish or egg products were advised for the first 12 months of life, and all cow's milk products were to be avoided. Mothers were advised to avoid cow's milk, egg and fish from 10 days before expected day of delivery and throughout breastfeeding. Breastfeeding was encouraged, with other foods to be introduced from about 4 months. Mothers given a calcium carbonate supplement, 1000 mg Ca	At 18 months. Atopy before/after formula introduction . n/n %after Int A 7/10 31% Int B 7/15 39% 'Control' 7/3 35% These differences were not statistically significant, nor were those for skin prick tests or elevated levels of serum total-IgE and CM IgE	Study methodology was well reported but outcome data/results were less clearly reported Duration of breastfeeding in the Swedish/Finnish families was higher than in Britain Funded by the Swedish Medical Research Council, the Swedish National Association of the Prevention of Asthma and Allergy, the Medical Research Fund of the County of Ostergotland, the King Gustav Vth 80-year Anniversary Fund, the Odd Fellows Foundation, and

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		introduction of solid foods, environmental tobacco smoke exposure or house pets	18 months	daily When women decided to stop breastfeeding (before 9 months), they were randomised to one of the intervention groups The families completed questionnaires on symptoms of atopic disease and allergy when the infants were 3, 6, 9, 12 and 18 months old, including skin prick tests and determination of serum total IgE and cow's milk specific IgE. Parents also completed daily diaries recording symptoms and feeding changes including dietary mistakes. The infants had a blinded physical examination at 18 months,		the Swedish Association for Allergology

First author Year	Research question	Study population	Study quality	Intervention	Main results	Comments Applicability to UK populations and settings Funding
Oldaeus et al. 1997 Sweden RCT 1-	To compare the incidence and severity of atopic disease and allergic sensitisation during the first 18 months of life in infants at risk who were fed either an extensively hydrolysed formula milk a partially hydrolysed formula milk or a standard formula milk from	Inclusion criteria Infants of pregnant women attending well mother clinics in three towns in southeast Sweden. Infants with two or more family members with significant atopic disease (asthma, allergic rhinitis, or atopic dermatitis, diagnosed by a doctor) or one family member and cord blood IgE concentration of at least 0.5 kU/l (or food allergy with an immediate reaction or a positive oral challenge), were included Exclusion criteria Clear maternal risk of non-compliance with diet or follow-up, birth defects, severe chronic disease, birth at <35 weeks, mechanical ventilation, single heredity, breastfed for >9 months. Urticaria alone not accepted. 155 infants were randomised as weaning began	Power calculation: 55 per group for 80% power to detect a 25% reduction of allergic disease in the intervention group from the expected 40%. The cumulative incidence of atopic disease was also higher than expected: 60% in RM cf 40% in N group and the reduction smaller (20%). The study was therefore underpowered as it would require 107 instead of 55 subjects in each group to have 80% power Randomisation at weaning	One of 3 formulas to be given from start of weaning to age 9 months: N (n=55): extensively hydrolysed casein formula (Nutramigen) PH (n=51): partially hydrolysed formula whey: casein ratio 60:40 RM (n=49): standard formula milk (Enfamil) For all families, allergy preventive measures recommended, including discouraging smoking and furry animals in the home. All mothers were asked to eliminate cows' milk, eggs and fish from their diet from one week before the birth was expected until breastfeeding ended. Mothers were asked to exclude the following from their infants' diet: milk (to 9m), eggs, fish and citrus fruits (to 1y), other solid foods (to 4m). All mothers were given a 1 g/day calcium supplement during the diet period.	Wheezing during first 18 months: N 13%, PH 16% and RM 33% Significantly higher rates in RM than N group (p=0.031). Differences at 6, 9 and 12 months, and differences between N and PH group, not significant Atopic dermatitis in first 9 months: Significantly higher rates in PH 44% (p=0.004) and RM 41% (p=0.006) than N group 17%. Intergroup differences not significant at 6, 12 and 18 months Cumulative atopic symptoms: Significantly less in N than RM at 6, 9, 12 and 18 months (p=0.013-<0.001) Significantly less in N than PH group at 6 months (p=0.025) and 9 months (p=0.018) Significantly less in PH than RM group at 18 months (p=0.039) At 18 months: N 51%, PH 64% and RM 84% Yet non significant data also given for final cumulative diagnosis of atopy and obvious atopic disease at 18 months: N 29%, PH 44% and RM 33% Positive skin prick test for eggs: At 9 months, significantly fewer in N group (10%) than in PH group (33%) (p=0.006) otherwise no sig result. Other results are reported. Summary The extensively hydrolysed formula (N) had an allergy preventive effect but not the partially hydrolysed formula (PN) during the first 18 months of life of high risk infants.	Most of the differences in morbidity emerged at 3-6m, in line with other studies Authors report that analysis of confounding factors gave no difference between the groups or study sites. These conclusions may be applicable in the UK Funded by Bristol-Myers Inc, the Swedish Medical Research Council, the National Association for the Prevention of Asthma and Allergy, the Queen Sylvia's Jubilee Fund, and the Division of Research, Jonkoping City

	the start of weaning until 9 months of age	Study population There were no sig differences between the groups for: Birthweight, sex ratio, Furry animals in the home initially: N 22%, PH 6%, RM 16% and at the end of 1 year: N 27%, PH 8%, RM 16% Mean age at formula introduction (months) N 3.6, PH 3.8, RM 3.3 Mean age when weaning completed (months): N 5.1, PH 5.6, RM 5.1	stage, stratified according to age at starting weaning/giving formula – method not given. The formula tins had the same design but the RM formula was not masked. Authors report the challenge testing as being double blind. Follow-up 91% overall. ITT analysis - not clear	Infants seen by a nurse at 3,6,9,12 and 18 months, who recorded growth, formula acceptance, clinical symptoms (using a scoring system for atopic dermatitis) and challenge procedures e.g. skin prick tests, specific IgE RAST at 9,12, 18 months. Follow-up 50/55 (91%) N, 45/51 (88%) PH, 46/49 (94%) RM 141/155 (91%) overall Results are also given in the paper for the group which continued breastfeeding after 9 months, which were not randomised.		Council. The three formulae were provided by the manufacturer, Mead Johnson USA.

First author Year	Research question	Study population	Study quality	Intervention	Main results	Comments Applicability to UK populations and settings Funding
Von Berg et al. 2003 Germany RCT 1-	To investigate the allergy-preventive effect of 3 differently hydrolyzed infant formulae compared with a conventional cow's milk formula	Inclusion criteria Healthy newborn infants with at least one family member (mother, father, or biological sibling) with an allergic disease recruited in obstetric units in 2 areas of Germany (Wesel, North Rhine Westphalia, and Munich, Bavaria) Exclusion criteria Severe acquired or congenital diseases, gestational age <37 weeks, birth weight <2500g, age >14 days, intake of any cow's milk based formula before inclusion, incapability of the parents to comply with the study protocol 2252 randomised to four groups Control (C) (n=556) Conventional cow's milk formula (Nutrilon Premium) casein: whey ratio 40:60	Power calculation: A loss caused by drop out and exclusive breastfeeding of 50% was expected Prevalence of allergic disease in the cow's milk group was expected to be 30% A sample size of at least 313 infants per formula was needed. Infants randomised with a computer-generated list stratified by single or double (parents only) heredity of atopy and study region. Blinding of parents and	Infants randomised at birth to one of four standard formula milks. Study formula provided until infant 6 months old All mothers received written recommendations for feeding the infants – encouraged to exclusively breastfeed for 4 months (strict intervention period) and preferably 6 months No dietary restrictions during lactation were recommended The time of weaning and introduction of study formula was left to the mother Mothers were asked not to feed solid food during the first 4 months and thereafter to add not more than one food per week and to avoid milk and dairy products, hen's eggs, soy products, fish, nuts, tomatoes and citrus fruits in the first year Mother's kept a weekly infant feeding diary, which included health problems. Infants examined at 1, 4, 8	First year incidence of AD, allergic urticaria, FA-GIT and AM C pHF-W eHF-W eHF-C No of infants 256 241 238 210 AD n 38 22 31 15 % 14.8 9.1 13.0 7.1 Urticaria n 1 0 1 3 % 0.4 0 0.4 1.4 FA-GIT n 1 5 2 4 % 0.4 2.1 0.8 1.9 AM n 40 26 34 19 % 15.6 10.8 14.3 9.1 Crude OR 1 0.65 0.90 0.54 95%CI (0.39-1.1) (0.55-1.5) (0.30-0.96) P value 0.114 0.677 0.036 AD: atopic dermatitis FA-GIT: food allergy with manifestation in gastrointestinal tract AM: allergic manifestation Outcomes are reported at one year for infants who received formula according to protocol (n=945) The incidence of allergic manifestation was significantly reduced by using eHF-C compared with conventional cow's milk formula. The reduction in incidence of AM in both groups fed whey hydrolysate was not statistically significant.	This intervention was only for mothers who gave formula to their infants before 4 months 42% of infants randomised were exclusively breastfed for 4 months so were excluded from the study post-randomisation 15% of infants randomised were exclusively formula fed Family history of AD was a significant risk factor and modified the preventive effect of the hydrolysates Male infants were significantly more likely to develop AMs than female

First author Year	Research question	Study population	Study quality	Intervention	Main results	Comments Applicability to UK populations and settings Funding

		pHF-W (n=557)
		Partially hydrolysed whey formula (Beba HA) casein: whey ratio 0:100
		
		eHF-W (n=559)
		Extensively hydrolysed whey formula (Hipp HA) casein: whey ratio 0:100
		
		eHF-C (n=580)
		Extensively hydrolysed casein formula (Nutramigen) casein: whey ratio 100:0
		
		Baseline characteristics for infants remaining at end of follow-up:
		C, n=256; pHF-W, n=241; eHF-W, n=238; eHF-C, n=210
		
		Male n (%)
		C=139(54);
		pHF-W=129(54);
		eHF-W=128(54);
		eHF-C=103(49)
		p=0.669
		
		Mean (SD) birthweight (g)
		C=3469(515);
		pHF-W=3465(473);
			study team by using identically labelled tins of formula coded with 4 different letters.
			At 4 weeks, 114 (5%) were lost to follow-up and 889 (42%) of the remainder exclusively breastfed and data was not reported for this group. Of the remainder (1249), 166 (13%) dropped out and a further 138 (13%) did not comply with the study. i.e. total loss to follow-up, 58%, or 31% excluding those exclusively breastfed
			Data for a total of 945 infants
			There were sig more dropouts in the eHF-C
				and 12 months with a structured interview on health problems carried out by study physician
				
				Follow-up 945/2252 (42%) (see note in comments column about post-randomisation exclusions)
						infants.
						Neither parental education, nationality nor study centre influenced the incidence of AM
						
						Funding:
						Federal Ministry for Education, Science and Research.
						Child Health Foundation.
						Formulae provided by Nestle, Hipp, Milupa, Numico, Mead Johnson

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		eHF-W=3511(479); eHF-C=3441(454) p=0.502 Mean (SD) length (cm) C=52.4(2.6); pHF-W=52.3(2.6); eHF-W=52.2(2.4); eHF-C=52.1(2.4) p=0.552 Study formula during 1st 4 weeks C=168(66); pHF-W=160(66); eHF-W=165(69); eHF-C=149(71) p=0.576 13-16 week of study formula feeding C=126(49); pHF-W=113(47); eHF-W=123(52); eHF-C=96(46) p=0.589 Exclusive study formula feeding C=45(18); pHF-W=32(13); eHF-W=32(13); eHF-C=30(14) p=0.493 One family member with history of allergy n (%)	group: 18% vs. 10-12%, p=0.02 ITT analysis not described in detail but authors reported that an ITT analysis carried out on those with a 4 week follow-up (2138 (95%)) confirmed the results although they were less prominent.			

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		C=188(73);
		pHF-W=168(70);
		eHF-W=164(69);
		eHF-C=147(70)
		NS
		Two family members with history of allergy n (%)
		C=68(27); pHF-W=73(30);
		eHF-W=74(31);
		eHF-C=63(30)
		NS
		
		Parental education <10y n(%)
		C=32(13); pHF-W=20 (8);
		eHF-W=25(11);
		eHF-C=18(9)
		NS				

Dietary interventions and dental caries

<table>
<tr><th>First author Year</th><th>Research Question</th><th>Study population</th><th>Study quality</th><th>Intervention</th><th>Main results</th><th>Applicability to UK populations and settings Comments</th></tr>
<tr>
<td>Holm et al.

2002

Sweden

SR

2-</td>
<td>What interventions prevent dental caries?</td>
<td>1. RCTs and CCTs were included. Retrospective studies were excluded
2. Studies with follow-up times <2 y (for permanent teeth) were excluded. The follow-up time was less stringent for primary teeth, root surfaces or caries in patients receiving radiotherapy
3. Studies that did not use caries as an endpoint were excluded

The authors searched Medline (1966-2001)

A total of ~900 articles were reviewed but no details of those related to individual exposures were provided

The studies included data from children and adults</td>
<td>Evidence was graded from 1 to 4, i.e. from strong to insufficient scientific support (detailed criteria of these grades were not reported in detail)</td>
<td>Many interventions were discussed but most related to the use of fluoride and there were no included studies giving dietary information.</td>
<td>Data are not provided in the English summary of the review. The conclusions were summarised in table format. Relevant data included:

Effects of interventions to prevent caries

<table>
<tr><th>Intervention</th><th>Effect</th><th>Grade</th><th>Comments</th></tr>
<tr><td>Sorbitol in sweets and chewing gum</td><td>Uncertain effect</td><td>Insufficient scientific support</td><td>Insufficient documentation</td></tr>
<tr><td>Xylitol in sweets and chewing gum</td><td>Uncertain effect</td><td>Insufficient scientific support</td><td>Insufficient documentation</td></tr>
<tr><td>Dietary information</td><td>Uncertain effect</td><td>Insufficient scientific support</td><td>No studies</td></tr>
</table>

Sorbitol and xylitol are sugar substitutes. The authors note that the dietary interventions reviewed chiefly related to a reduction of sugar in the diet.</td>
<td>This report is an English language summary of a Swedish SR.

Evidence is insufficient to be applicable

High risk groups for caries in children and adolescents in Sweden include many immigrants and refugees and families with low educational level and no cash margin. Insufficient evidence indicated that there were too few studies of suitable quality to draw reliable conclusions not that the intervention had no clinical effects. Swedish sugar consumption is relatively high. For the previous 10 y it was 40</td>
</tr>
</table>

First author Year	Research Question	Study population	Study quality	Intervention	Main results	Applicability to UK populations and settings Comments
						kg/person/year. The review was carried out by the Swedish Council on Technology Assessment in Health Care (SBU) which appears to be government funded

Dental Caries

First author, Year,	Research Question	Study population	Study quality	Intervention	Main results	Applicability to UK populations and settings Comments
SIGN[5] 2005 UK SR 2+ included Valaitis et al. 2000 SR 2+ Reisine & Psoter 2001 SR 2+		Inclusion/exclusion criteria not supplied - apparently all relevant material including studies of adults and children. Included studies (only those studies that were used to develop guidelines [relevant to this NICE review], and that apply to children aged 6 to 24 months are included in this table) Systematic reviews: Burt & Pai 2005, Lingstrom 2003, Reisine & Psoter 2001, Valaitis 2000 RCTs: Gedalia 1994 Intervention studies: (Rodrigues & Sheiham 2000); Other studies: Gibson & Williams 1999 (large cohort study), Hallett 2002, Mohan 1998, a large US prospective study (Marshall 2003, Levy 2003) Initial search for guidelines: Embase and	Levels of evidence (1++ to 4 (expert opinion)) and grades of recommendation (A-D) were presented (see results) No other information on quality reported, except for the following: The Iowa study, Marshall 2003, Levy 2003, had a high level of attrition 67-85%	Few details given of specific interventions in review. Additional information includes the following: Rodrigues & Sheiham 2000: conducted in Brazilian children in nurseries with and without guidelines restricting the sugar consumption Burt & Pai 2005: a systematic review of observational studies Gibson & Williams 1999: large NDNS UK study of children aged 1.5-4.5 y	The SIGN Guidelines were developed using studies of subjects of any age. Data from studies was not provided in SIGN review and some additional data from original papers is presented in this table. Guidelines given a grade B Free sugars in food • Children attending a nursery which restricted the consumption of sugar consumed lower amounts of sugar at lower frequencies and had a substantially lower risk of caries. 2++ (Rodrigues & Sheiham 2000) • The systematic review found a weak to moderate association between sugar consumption and dental caries, which was weaker in the presence of fluoridation. 2+ (Burt & Pai 2005) Relevant guideline: Parents and carers should be advised that foods and confectionary containing free sugars should be minimised, and if possible, restricted to meal times. Guidelines given a grade C Free sugars in fluids A large US study (Marshall 2003, Levy 2003) found the strongest links with consumption in the 1st year: • Total non-water drinks intake at age 1-4 y, especially fizzy drinks milk, was strongly associated with dental caries at age 4-7 y (Marshall 2003). 2+ • Total water intake at age 1-4 y was highly protective against dental caries at age 4-7 y (Levy 2003). (The authors noted this is likely to be because the water was fluoridated) 2+ Two studies found: • A high risk of colonisation by streptococci mutans or caries with having sweetened bottle contents (Mohan 1998, Hallett 2002) In a further UK study in children aged 1.5-4.5 y (NDNS, Gibson & Williams 1999), the effect of sugar consumption on caries was found to be reduced in	The Guidelines were directly applicable to the UK The guidelines were developed because pre-school children in Scotland have the highest rates of tooth decay in Europe. The intention is to consider the guidelines for review in 2008. The Brazilian study (Rodrigues & Sheiham 2002) adjusted for many confounders e.g. tooth brushing, fluoride use, home sugar consumption. The review acknowledged that chewing gum

[5] SIGN is a collaborative network of clinicians, other healthcare professionals and patient organisations and is part of NHS Quality Improvement Scotland.

First author, Year,	Research Question	Study population	Study quality	Intervention	Main results	Applicability to UK populations and settings Comments
		Medline (1996-2003), the following websites: American Dental Association, Canadian Dental Association, Canadian Practice Guidelines Info Base, National Guidelines Clearinghouse, New Zealand Guidelines Group, National Health and Medical Research Council – Australia, Swedish Council on Technology Assessment in Health Care (SBU), UK Health Technology Assessment Programme and US Agency for Healthcare Research and Quality. Searches for systematic reviews, RCTs, meta-analyses and observational studies 1999-2004 on Embase, Medline and the Cochrane Library. Grey literature not included. Additional material from members of the group.			children that brushed their teeth twice daily. The association of caries with sugar confectionery (both in amount and frequency) was only present among children whose teeth were brushed less than twice a day. Relevant guideline: Parents and carers should be advised that drinks containing free sugars, including natural fruit juices, should be avoided between meals. Water or milk may be given instead. <u>Other foodstuffs</u> • Three studies found evidence that cheese might be protective against caries 2++ (Gedalia 1994) (the other two were conducted in older children/adults) • Whole fruit consumption did not appear to be cariogenic when eaten at normal levels. 3 Relevant guideline: Parents and carers should be advised that cheese is a good high energy food for toddlers as it is non-cariogenic and may be actively protective against caries. <u>Breastfeeding beyond one year</u> • Inconsistent evidence of an association between breastfeeding beyond one year and the development of early caries 2+ (Valaitis 2000) Relevant guideline: Members of the dental team should support and promote breastfeeding according to current recommendations. <u>Bottle feeding</u> • A high risk of colonisation by streptococci mutans with having sweetened bottle contents (Mohan 1998) • An increased risk of early childhood caries (OR=4.29, CI 2.9-6.38) sweetened bottle content, (OR=1.73, CI 1.49-2.0) sleeping with a bottle, (1.58, CI 1.49-2.0) (Hallett 2002, 2+) • A review (Reisine and Psoter 2001, 2+) found only weak evidence of an association of bottle contents with caries but the reviewers noted the very poor quality of most studies	should not be applicable to pre-school children but that chewable sweets would be applicable. The SIGN review suggests that the results of the Burt & Pai review 2005 should not give false reassurance about the role of sugars in dental caries.

First author, Year,	Research Question	Study population	Study quality	Intervention	Main results	Applicability to UK populations and settings Comments
					• The same review again based on poor quality studies found no evidence that duration of bottle use is not significantly related to caries risk Relevant guideline: Parents and careers should be advised that drinks containing free sugars, including natural fruit juices, should never be put in a feeding bottle	

Continuing Breastfeeding after 6 Months

First author, Year,	Research Question	Study population	Study quality	Intervention	Main results	Confounders/ Comments Applicability to UK populations and settings Funding
Jones 2004 Stone and Stoke-on-Trent, Staffordshire, UK RCT 1-	Objective: to support continued breastfeeding for mothers who plan to return to work and to ascertain the numbers of mothers who continued to breastfeed exclusively after returning to work	Inclusion Women who wished to breastfeed and planned to return to work were invited to participate Women who were successfully breastfeeding at 2 – 4 weeks and still planned to return to work were randomised. Exclusion Antenatal or postnatal complications Mothers contacted antenatally for consent, then 2-4 weeks post partum 75 randomised Mainly first time mothers, all singleton pregnancies Participant characteristics not reported	Randomisation using random permuted blocks gave rise to unbalanced numbers. 61% lost to follow-up. Reasons: did not or delayed return to work, weaned before work, postnatal depression, Blinding/concealment not addressed Power calculation not reported	Intervention group (I) n=44 Intervention 2001-2003 Specialist lactation advice by the researcher regarding return to work and milk expression: One hour evidence-based session and written leaflet (content included principles and technique of expression, handling and storage of breast milk, management of milk supply, emphasis on eliciting the milk ejection reflex and managing milk leakage and preventing mastitis; 'back to work' set (breast pump, storage bottles, gel pack, breast pads and shoulder bag) Control group (C) n=31 Standard support from community midwives and health visitors: Advice (ad hoc, some given leaflets, information not comprehensive); 'back to work' set (as above) Follow-up: mothers were	Mothers returned to work 2-6 months after the birth (not reported by intervention group) Full time work: I 47%, C 40% I (n=19) C (n=10) p value Expressed at work 12 5 NS Infant exclusively fed expressed milk while at work 9 7 NS (Infant fed breast milk and formula 10 3 Worked full time 9 4 NS Practised milk expression prior to returning to work 12 5 (p=0.04) Stockpiled expressed milk prior to returning to work 15 4 NS Lactation problems at work Engorged 4 2 NS Leaked 4 3 NS None 11 4 NS No refrigerator available for milk storage at work 4 4 NS NS: not statistically significant (Women who were still breastfeeding at 2-4 weeks post partum received significantly more support from health professionals and family than those who had not (p<0.001).)	This was a pilot study Authors state women reported practising how to express their milk prior to returning to work was beneficial to their success Many found the barriers they experienced at work insurmountable and were unable to express milk while at work Funded by the North Staffordshire Medical Institute. Cannon-Avent donated the 'Back to Work' milk expression sets

First author, Year,	Research Question	Study population	Study quality	Intervention	Main results	Confounders/ Comments Applicability to UK populations and settings Funding
				contacted at the time they originally anticipated returning to work, and received postal questionnaires one month and three months after returning to work Follow-up rates: I 19/44 (43%), C 10/31 (32%) Overall 29/75 (39%)		

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