

## **Evidence Tables Post Partum**

### **Evidence is presented to answer the following questions:**

1. What diet and/or physical activity programmes effectively aid postpartum weight loss?
2. What is the effectiveness of dietary counselling on improving postpartum nutrition?
3. What methods of delivering supplements in the postpartum period are effective?

No studies were identified in the literature that addressed the effectiveness of ways of delivering supplements in the postpartum period to improve maternal nutrition.

4. What supplements effectively improve maternal nutritional status?

**Diet and/or physical activity programmes**

First author Year	Research question	Study population	Research Quality	Intervention	Main Results	Applicability to UK populations and settings Comments Funding
Leermakers 1998 Pittsburgh, USA RCT 1-	Can a behavioural weight control intervention delivered in the postpartum year via correspondence help women return to their pre-pregnancy weight?	<u>Inclusion:</u> women aged $\geq 18$ years, gave birth in study hospital 3-12 months before recruitment, at least 6.8kg above pre-pregnancy weight, with body mass index (BMI) $\geq 22\text{kg/m}^2$ <u>Exclusion:</u> lactating women 90 women randomised 47 to intervention group 43 controls  Intervention group older than controls (mean 32.4y vs. 30.3y, $p < 0.05$ ) More of intervention group married (93.5% vs. 79.1%, $p < 0.05$ ) No other significant	Power calculation not reported  Method of randomisation is not reported	<u>Intervention group</u> received behavioural weight loss programme delivered over 6 months, comprising 2 group sessions (beginning of intervention and month 2), correspondence material (16 written lessons including homework, about nutrition, exercise and behaviour change strategies, tailored to special needs of new mothers) and telephone contact from program staff (1-2 calls per week lasting 5-15m focusing on eating and exercise progress, goal-setting and problem-solving). Behaviours aimed for were: Diet 1000-1500 kcal/d with fat restricted to 20% of caloric intake and an aerobic exercise programme (mainly walking), consistent with exercise guidelines for all adults recommended by the American College of Sports Medicine. Women were asked to monitor their calorie and fat intake and their exercise daily and return their records by mail  <u>Control group</u> was given written information about healthy eating and exercise. They did not receive the programme, but provided measurements <u>Measures taken</u> at pre-treatment and 6 months later	There was a significantly higher loss of excess post partum weight among women in the correspondence group (-7.8 kg, 79% of excess post partum weight) than controls (-4.9 kg ( $p < 0.03$ ), 44% excess pp weight ( $p = 0.01$ )) This result was still significant after adjustment for confounders. 33% of the intervention group returned to or below their pre-pregnancy weight compared to 11.5% controls $p < 0.05$ .  Dietary data and physical activity data were only available for 30 intervention subjects and 16 controls. Information on weekly energy expenditure, daily calorie intake and percent intake from fat was available for 30 subjects in the correspondence group and 16 in the control group at post-treatment. Physical activity did not change in either group. Both groups reduced their energy intake and % energy calories from fat by a similar extent after 6 months. The intakes were higher in the control group but differences were not significant.  Weight, height, physical activity, eating behaviour (using 60-item Block Food Frequency Questionnaire, modified to ask about intake over the past 6 months. Level of physical activity was assessed using the Paffenbarger Physical Activity Questionnaire, a	The post partum year is a particularly high risk period for weight gain. This correspondence weight loss intervention was effective and this appears relevant for the UK. However both study groups seemed to contain women who were particularly motivated to lose weight (23% controls reported joining Weight Watchers or another formal weight loss programme during the 6 month intervention). Return of self-monitoring forms correlated with weight lost. Completed homework and phone contacts did not and authors suggest that dropping these

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		differences found between groups at baseline Employed 62% Education beyond school 83% Caucasian 97% Mean kg over pre-pregnancy weight 12.3 Pregnancy weight gain by group (kg): mean ± SD (range) I: 17.5 ± 5.7 (4.6-29.6) C: 19.8± 6.7 (9.1-36.4) Mean BMI 29.8 kg/m <sup>2</sup> Pre-treatment BMI by group (kg/m <sup>2</sup> ) mean ± SD (range) I: 29.1±3.7 (23.4-42.0) C: 30.6±5.0 (23.4-43.5) Mean months since birth 8.2±2			measure which estimates weekly energy expenditure from self-reports of stairs climbed, blocks walked and other recreational activities performed in the past week.  Compliance measured by number of self-monitoring records and homework assignments returned and number of phone contacts completed  Length of follow-up 6 months Data from 36/47 of the intervention group (77%) and 26/43 of the control group (61%) Overall follow-up 62/90 (69%)  No infant or lactation outcomes reported	elements would improve the programme's cost-effectiveness Likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted. Mean time intervention delivered was 8.2-14.2 months post partum (i.e. took longer than the postpartum year to complete) 5 women who dropped out had become pregnant again Dropouts were significantly heavier P<0.05 and retained significantly more weight pre-treatment than completers p<0.05 Funding from The Obesity/Nutrition Research Centre

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Lovelady 2000  North Carolina, USA  RCT  1-  Additional information from Lovelady 2006	To evaluate the effect of weight loss in overweight lactating women on the growth of their infants	<u>Inclusion:</u> Healthy, sedentary, non-smoking, BMI 25-30 kg/m <sup>2</sup> , exclusively breastfeeding mothers of babies born vaginally at term with birth weight ≥2500g  48 randomised (27 intervention, 21 control)  Mean age 32 y White 82.5% Black 17.5% Parity 1, 25%; ≥2, 75% Mean BMI 27.8 Mean pre-pregnancy weight 70.3 kg Mean weight gain during pregnancy 15.6 kg Maximal oxygen consumption 35.1 ml/kg/min	Power calculation not reported  Method of randomisation is not reported	Intervention: 10-week (4-14 weeks postpartum) restriction of energy intake plus aerobic exercise programme, aiming for weight loss 0.5-1 kg/week. Energy intake restricted by 500 kcal/day (to ≥1800 Kcal/day). Aerobic exercise 45 min/day 4 times/week under supervision.  Control: no restriction of energy intake, vigorous aerobic exercise not more than once a week  Anthropometric measurements and cardiovascular fitness measured by professionals at 4, 9 and 14 weeks. At the same time intervals the women kept records of 3-day weighed dietary intakes. 10 week follow-up 40/48 (83%)  All participants given a daily multivitamin supplement containing 50% of recommended daily allowances for lactating women.  Calculation of energy requirements for the intervention group allowed 630 kcal to compensate for lactation.	Weight loss of ~0.5 kg/week of lactating overweight women by decreasing energy intake by 500 kcal/day and increasing exercise by 4x45 min/week is feasible for those who are exclusively breastfeeding. It does not appear to affect infant growth but the study may not have been powered to discriminate.  Possibly applicable, assuming appropriate adaptation, to women who want to and can commit to an intensive weight loss programme early in the postnatal period For the intervention group (21) vs. the control group (19), there were significantly larger decreases (all p<0.01) in: <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Intervention</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Weight (kg)</td> <td>-4.8±1.7</td> <td>-0.8±2.3</td> </tr> <tr> <td>BMI (kg/m<sup>2</sup>)</td> <td>-1.8±0.6</td> <td>-0.3±0.9</td> </tr> <tr> <td>Body fat (% body weight)</td> <td>-3.3±1.8</td> <td>-0.2±1.8</td> </tr> <tr> <td>Fat mass (kg)</td> <td>-4.0±2.0</td> <td>-0.3±1.8 kg</td> </tr> </tbody> </table> Skin-fold thickness of triceps, subscapular area, midaxillary line, abdomen, suprailiac area and thigh  Energy intake decreased by a non-significant -544±471 vs. -236±508 kcal/day Maximal oxygen consumption increased significantly (p<0.01) 4.5±4.9 vs. 0.6±3.8 ml/kg/min  At baseline no statistically significant differences in dietary intake between the groups were found except that women in the diet and exercise group consumed fewer fat servings (2.5±1.0 vs. 4.1±2.5, p<0.05).		Intervention	Control	Weight (kg)	-4.8±1.7	-0.8±2.3	BMI (kg/m <sup>2</sup> )	-1.8±0.6	-0.3±0.9	Body fat (% body weight)	-3.3±1.8	-0.2±1.8	Fat mass (kg)	-4.0±2.0	-0.3±1.8 kg	Reasons for exclusion of 8 women: stopped exclusive breastfeeding (6) and/or non-completion of dietary records (5) and/or personal (2). These 8 women were significantly heavier before pregnancy and at the beginning of the study and had a lower level of cardiovascular fitness.  This rate of weight loss (2kg/month) achieved is that recommended by the Institute of Medicine in: Nutrition during lactation (1991) Washington, D.C.: National Academy Press. in the US for lactating women.  Funded by the
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					<p>At the end of the study, women in the diet and exercise group reported consuming significantly (all <math>p &lt; 0.05</math>) fewer servings of; starches with fat (<math>0.4 \pm 0.5</math> vs. <math>1.5 \pm 1.4</math>), high-fat meat/meat substitutes (<math>0.4 \pm 0.5</math> vs. <math>1.0 \pm 1.2</math>), fats (<math>1.2 \pm 0.9</math> vs. <math>3.4 \pm 2.3</math>), sweetened drinks (e.g. 12oz cola) (<math>0.4 \pm 0.4</math> vs. <math>1.0 \pm 1.2</math>), sweets and desserts (<math>1.0 \pm 1.1</math> vs. <math>2.0 \pm 1.3</math>) and snack foods (<math>0.0 \pm 0.0</math> vs. <math>0.3 \pm 0.5</math>), and significantly (<math>p &lt; 0.05</math>) more servings of fruit (<math>2.3 \pm 1.5</math> vs. <math>1.2 \pm 1.1</math>).</p> <p>Gains in weight and length among the women’s infants during the 10-week study period (mean <math>\pm</math> SD) Gain in weight (g): All infants: <math>1925 \pm 500</math> vs. <math>1821 \pm 576</math> Female infants: <math>1869 \pm 483</math> vs. <math>1667 \pm 486</math> Male infants: <math>1968 \pm 530</math> vs. <math>2036 \pm 618</math></p> <p>Gain in length (cm) All infants: <math>7.8 \pm 2.0</math> vs. <math>7.3 \pm 1.7</math> Female infants: <math>7.7 \pm 1.1</math> vs. <math>6.8 \pm 1.5</math> Male infants: <math>7.9 \pm 2.7</math> vs. <math>7.8 \pm 1.8</math></p> <p>Authors state there were no significant differences between the groups</p> <p>No other infant outcomes reported</p> <p>Effects of the intervention on milk output not reported</p>	<p>National Institutes of Health and the North Carolina Agricultural Research Service.</p>

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McCrary 1999  Davis, California, USA  RCT  1-	What are the short-term effects of dieting compared to dieting plus aerobic exercise on (lactation performance), weight loss, fat mass and body fat?	Inclusion: exclusively breastfeeding women 8-16 weeks postpartum, no chronic illnesses, no regular medication, non-smokers, willing to take exercise before the study, single healthy infant born at term  68 randomised to diet group (n=22), diet + exercise group (n=23) or control (n=23) Mean age 32 y Mean y education 16.3 White 79%, Hispanic 10%, Black 4.5%, Asian 6% Mean BMI at baseline 25.2kg/m <sup>2</sup>  Baseline BMI by group (mean ± SD) Diet: 25.3±4.8 Diet+exercise:25.4±4.1	Power calculation, related to calculation of change in milk output only, required 23 subjects in each group  Paper states women were randomly assigned.  Method of allocation not described.	10-12 day baseline period then 11 day intervention period  Baseline: 4-day weighed food diary, 4-day detailed activity record; resting metabolic rate (RMR) determined. On 2 mornings during baseline RMR was determined with a portable metabolic cart (CPX/Max/D; Medgraphics, Minneapolis) by using standard procedures described previously. Total energy requirement (TER) at baseline determined by averaging energy expenditure (including breastmilk output and exercise) and intake  Interventions:  Diet group – 35% energy deficit diet (calculated as 0.65xTER), no change to baseline exercise. Diets individualised, food and multivitamin/mineral supplements provided  Diet + exercise group – 35% net energy deficit, 60% by dietary restriction + 40% by additional exercise. Diet as above. Exercise prescribed as target heart rate range/time via any aerobic exercise activity and was self-supervised  Control: Usual diet, no change to baseline exercise (but see Comment about exercise before study began)	Maternal outcomes that compare diet (D) with diet + exercise (D&E) groups:  Dietary energy intake and % energy from fat, carbohydrate and protein did not differ significantly at baseline and did not change significantly from baseline for the 2 intervention groups  An average 34% energy deficit was achieved in the 2 intervention groups, for which the diet + exercise group exercised an average of 86 min/session on 9 of the 11 days. Their change in number of times exercise was taken, exercise duration (min/week) and energy expended in exercise (MJ/day) for the diet + exercise group was significantly different from that of the other 2 groups p<0.0001. At the end of the intervention the mean exercise duration in min/week was 499 for the diet + exercise group (8h 19m) and 126 (2h 6m) for the diet group (135, 2h 15m, for the control group).  Milk energy output (MJ/d) mean ± SD (range) Diet: 2.29±0.41 (1.59-3.25) Diet + exercise: 2.49±0.45 (1.83-3.77) Paper states energy output did not differ significantly among the 3 groups  Change in milk volume (g/d) mean±SD Diet: -1±76 Diet + exercise: -16±84 Paper states change in milk volume did not differ	Research intervention not meant to be applied in other settings/populations The subjects did not appear to be more than a little overweight  Of 135 eligible women 67 chose not to participate (49.6%). Women not willing to exercise 3 d/wk for the month before the study (to prepare in case they were randomly assigned to the group with intensive exercise) were excluded  One woman withdrew from the diet and exercise group because she had difficulty completing the baseline assessments.

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		<p>Control: 24.9±3.8</p> <p>Pregnancy weight gain by group (kg) Diet: 15.2 ±5.0 Diet+exercise:16.1 ±4.8 Control: 16.4 ±6.0</p> <p>Pre-pregnancy weight by group (kg) Diet: 67.3±14.0 Diet+ exercise: 64.9±14.2 Control: 66.4±8.7</p> <p>Parity 1 37%, ≥2 63%</p> <p>Mean pre-pregnancy wt 66.2 kg Pregnancy wt gain 15.9 kg No significant differences found at baseline</p>		<p>Anthropometric measurements made at baseline and end of study. Heart rate monitors worn by all subjects throughout the study to determine energy expenditure</p> <p>Changes in weight, fat-free mass, fat mass and % body fat, also energy intake and output</p> <p>Length of follow-up 11 days Follow-up rate 67/68 (98.5%)</p>	<p>significantly among the 3 groups</p> <p>Infant weight gain (g) Diet: 194±139 Diet + exercise: 229±122 Paper states infant weight gain did not differ significantly among the 3 groups.</p> <p>None of the infants was below the 5<sup>th</sup> percentile of the National Center for Health Statistics weight-for-age reference at either the baseline or intervention time points.</p> <p>No other infant outcomes are reported.</p> <p>The American Institute of Medicine recommends a weight loss of 0.5 kg/week for overweight lactating women.</p> <p>This study investigated the effect of a relatively large energy deficit on lactating women and concluded that a short term weight loss of ~1kg/week using a combination of dieting and aerobic exercise was safe and preferable to weight loss by dieting alone because the latter reduced maternal lean mass.</p>	<p>Another in the same group developed asthma after exercise and stopped the intervention. Her incomplete data was included in the analysis.</p> <p>Re. lactation performance, the only difference found was that in the diet group only, milk energy output increased in fatter women and decreased in leaner women In the diet group. There was a significant positive association between percentage body fat at baseline and change in milk energy output. Such an association did not exist for the diet &amp; exercise or control groups. These results persisted even after differences in milk</p>

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						energy output at baseline were controlled for, either within or between groups'.  Funding from the National Institutes of Health, USA

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O'Toole 2003  St Louis, Missouri, USA  RCT  1-	To determine the impact of a structured intervention (diet and physical activity) initiated during the first 6 months postpartum on weight retention in overweight post partum women	Inclusion: 6 weeks - 6 months post partum, overweight (self-reported BMI 25-29.9) before pregnancy, gained >15 kg during pregnancy, >5 kg heavier than pre-pregnancy at enrolment Exclusion: currently participating in a regular exercise programme, enrolled in a formal weight loss programme, medical contraindications for participation in a diet and exercise programme  40 women randomised to a structured diet and physical activity intervention (STR) (n=21) or self-directed intervention (SELF) (n=19)	Power calculation not reported  Paper states participants were randomly assigned (blinded drawing of labels containing group assignment)	Goal for both groups was a calorie deficit of 500 kcal/day via both reduced calorie intake (-350 kcal/day) and increased energy expenditure (+150 kcal/day)  Intervention: STR subjects received individualised diet and physical activity prescriptions, kept daily food and activity diaries, and met for group educational sessions dealing with nutrition and physical activity strategies (weekly for first 12 weeks, fortnightly for the next 2 months and monthly up to 1 year post partum). Heart rate monitors were provided for this group to help establish the relationship between heart rate and energy cost (kcal/min)  Control: SELF subjects had a single 1-hour educational session about diet and activity with a physiologist and a dietician and received written information about nutrition and exercise  Measurements made at baseline, after 12 weeks participation and at 12 months post partum including weight, % body fat, cardiorespiratory fitness (VO <sub>2</sub> peak), index scores for physical activity (using the self-report Yale Physical Activity Survey (YPAS) and caloric intake (using 3-day food records).  Mean length of follow-up 40 weeks (12-52 weeks post partum)	Body weight did not change in SELF group. Mean weight loss from baseline in STR group was 5.6 kg at 12 weeks and 7.3 kg at 1 year (p<0.001, and p<0.05 for difference from SELF group)  % body fat lower in STR group than SELF group at all times points, including baseline (p<0.05) and decreased in STR group over time (p<0.001) but not in SELF group  No statistically significant within-group or between-group differences in weight loss by breastfeeding status were found at 12 weeks or 1 year.  In both groups, calorie intake at baseline stated to be significantly greater than estimated needs, and to reduce significantly with no between group differences to levels not significantly different from estimated calorie needs at both 12 weeks and 1 year post partum.  No difference in physical activity levels at baseline but exercise (kcal/week) and vigorous activity showed increases from baseline at 12 weeks and 1 year in STR group p<0.001 (p<0.05 for exercise at 12 weeks). STR group vigorous activity greater than SELF group (p<0.05) at 12 weeks and 12 months. Walking score in STR group higher from baseline to 12 weeks (p<0.05) and sitting score lower from baseline to 1 year for SELF group (p<0.05).  Cardiovascular fitness similar at baseline and when reported as VO <sub>2</sub> peak in ml/min showed no significant	Likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted Retention was low in this study compared with lifestyle interventions involving similar low to moderate physical activity that did not study postpartum women  Authors discuss barriers to lifestyle change in postpartum women  Supported by American Heart

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		Mean age 31.5 y Well educated (75% college graduates) Predominantly Caucasian (1/40 African-American) Mean BMI 29.9 kg/m <sup>2</sup> Mean parity 2.3 Breastfeeding 57% Mean time since delivery 13 weeks No significant differences found at baseline between the groups		Follow-up rate 23/40 58% at 12 months postpartum (STR 13/21 62%, SELF 10/19 53%)	<p>changes for either group. However when VO<sub>2</sub> peak indexed to body weight as ml/kg/min, STR group only showed significant increases from baseline (p&lt;0.001) at 12 weeks and 1 year post partum, which were significantly higher than SELF group (p&lt;0.05) at both 12 weeks and 1 year.</p> <p>Weight loss strongly correlated with % body fat (p&lt;0.001). Weight loss and decrease in % body fat were strongly correlated at both 12 weeks (r=0.865, P&lt;0.01) and one year postpartum (r=0.923, p&lt;0.01) and for STR group weight loss correlated with average physical activity kcal/week estimated from daily activity logs at 12 weeks (r=-0.64, p&lt;0.05). For all subjects weight loss correlated with vigorous activity score at 12 weeks and 1 year but not with caloric intake, VO<sub>2</sub> peak or other measures of physical activity.</p> <p>Infant outcomes not reported</p> <p>Effects of the intervention on lactation not reported</p> <p>A positive relationship has been found between weight gain during pregnancy and weight retention after pregnancy especially in women overweight prior to pregnancy.</p> <p>Overweight post partum women in this study were more likely to lose weight with participation in a formal structured diet and exercise programme.</p> <p>All participants reported reduced calorie intake.</p>	Association Heartland Affiliate

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					Increased physical activity seems to have been the programme component that mostly contributed to weight loss seen in this study.	

**Dietary counselling**

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Lagstrom 1999 Turku, Finland RCT 1-	To evaluate the impact of child-targeted, individualised, repeated dietary counselling on food consumption, nutrient intakes and serum cholesterol concentrations of the parents in a child-targeted coronary heart disease (CHD) intervention trial	<u>Inclusion:</u> Mothers of children participating in The Special Turku Coronary Risk factor Intervention Project (STRIP) Children attending well-baby clinics recruited aged 5m. At age 6m 1062 children from 1054 families were randomised  Intervention group 540 children Control group 522 children  Mean [range] age (y) of mothers 30.3 [17.9-45.1]	Power calculation not reported  Paper states the families and infants were allocated by random numbers to the intervention or control groups	<u>Intervention:</u> individual families met paediatrician and nutritionist at 1-3 month intervals from age 7m to 2y (therefore at least 3 sessions by age 13m) for counselling on how to reduce child's intake of saturated fats and cholesterol <u>Control:</u> standard care, met same team twice a year with no detailed input on dietary fats <u>Comparisons:</u> Consumption of selected foods and nutrients, BMI and serum cholesterol  Data from 314 intervention mothers and 307 control mothers at 7m visit (621/1054 families randomised, 59%) <u>Six month follow-up:</u> Data from 259 intervention and 238 controls at age 13m visit (47% of families randomised, 80% of those providing data at 7 months)	Mothers of intervention and control group children consumed almost equal amounts of total dietary fats and milk products during the whole study period (to child's age 5y) but the qualities of the dietary fats and milk products already differed at 6 mo after intervention (child's age 13 months). The intervention group ate less butter and milk with $\geq 1.9\%$ fat and more margarine and skimmed milk. There were no differences in intakes of cereals, fruits, vegetables or berries  Energy intake and energy from fat intake were slightly lower in the intervention group and they consumed less saturated fat and more polyunsaturated fat but there were similar intakes of monounsaturated fat, carbohydrate energy and protein energy  Mothers' cholesterol intakes (intervention group $132.7 \pm 69.1$ mg/1000 kcal, control group $135.4 \pm 64.5$ mg/1000 kcal) (table 3) and serum cholesterol concentrations (intervention group $4.80 \pm 0.86$ mmol/L, control group $5.11 \pm 1.06$ mmol/L) (table 5) were slightly lower in the intervention group when children were aged 13 months.  The majority of these trends were not significant at age 13 months Individual child-orientated family dietary counselling can be effective in reducing the mother's saturated fat and cholesterol intake when initiated 6 months post	Likely to be applicable across a broad range of populations and settings, assuming it is appropriately adapted The intervention continued 6-monthly until the child's age 5y and outcomes were further assessed yearly until age 5  The overall group effect of the intervention after 4.5 years duration were shown to be significant at 5 years post partum  Sponsored by the Ministry of

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					partum	Social Affairs and Health, Finnish Cultural Fund

**Multivitamin-mineral and fish oil supplementation**

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Doyle 2001  Additional information from Rees et al 2005  East London, UK  RCT  1-	To evaluate whether micronutrient supplementation improved the nutritional status of women with poor diets during the inter-pregnancy interval for women with low-birthweight babies.	English-speaking mothers with live low-birthweight ( $\leq 2.5$ kg) babies, intending to have further pregnancies, living in deprived inner city area of London, without chronic illnesses, not already taking supplements (n=124), completed 7-day diet diary and found to have an inadequate diet (meeting $<4$ of 16 dietary reference values, n=44), consented to have blood taken (n=34) 17 randomised to intervention and 17 to control Sample characteristics reported only for those who completed the study (n=27)	Power calculation not reported  Paper states that mothers were randomly allocated to supplements or no supplements using shuffled envelopes sub-stratified by ethnic origin	All participants received written dietary advice based on analysis of their diet diaries and general lifestyle advice on preparing for pregnancy. All were invited to keep a second 7-day diet diary at 9 months – completed with nutritionist  Intervention: daily multivitamin-mineral supplement and docosahexaenoic supplement (fish oil) 150 mg/day from 3-9 months after delivery. Compliance checked 3-weekly  Serum and erythrocyte folate, serum ferritin and haemoglobin at 3 and 9 months compared between groups  Overall follow-up rate 27/34 (79%) Intervention: 11/17 (65%). Dropouts (n=6) did not like the supplements. The 11 remaining mothers took the supplements 5 or more times per week Control: 16/17 (94%)	Mean serum folate ( $p<0.001$ ), mean erythrocyte folate ( $p<0.001$ ) and mean serum ferritin ( $p<0.01$ ) increased significantly from 3-9 months postpartum in the supplemented group only  Mean $\pm$ SD levels in the supplemented group at 9 months were: serum folate $12.5 \pm 3.34$ nmol/L; erythrocyte folate $346 \pm 91.3$ nmol/L; and serum ferritin $36.0 \pm 27.3$ $\mu$ mol/L.  Mean haemoglobin levels did not change significantly in either the supplemented or the non-supplemented group  With supplementation the proportion of mothers with low or marginal erythrocyte folate and/or low iron stores (serum ferritin) fell  Authors state supplementation has no side effects at this dosage; was partially effective; detailed dietary assessment in this population is difficult. They recommend routine folate and iron supplementation at least to women with a small baby planning further pregnancies	Younger mothers tended to have an inadequate diet Mothers whose diets were assessed as inadequate were younger than those in the adequate diet group ( $p<0.05$ ) but there was no significant difference in the proportion of ethnic minorities, cigarette smokers and non-smokers, non-manual occupations and manual or unemployed, or marital status, in the adequate and inadequate

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		<p>Mean age 29y, range 16-43y                      White 52%, Black 37%, Asian 11%                      Non-manual work 41%                      Smokers 16%                      All formula fed their babies</p> <p>Rees et al 2005 combined baseline data from Doyle's two nutrition intervention studies (Doyle 1999, Doyle 2001) to present Nutrient intakes of mothers of low birth weight babies-a comparison of ethnic groups in East London, UK.</p> <p>Dietary records from 165 (English-speaking) mothers of approximately 380 low-birthweight singleton births were analysed.                      Caucasian 63 (38%)</p>				<p>diet groups.</p> <p>Only 6 mothers (one from the intervention group and 5 controls) completed the 2<sup>nd</sup> diet diary at 9 months post partum</p> <p>Funded by Joint Research Board of St Bartholomew's hospital, The Mother and Child Foundation, Nutricia Ltd., UK and Numico Research, The Netherlands</p>

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		<p>African-Caribbean 40 (24%)                      African 36 (22%)                      Asian 26 (16%)                      Mean age varied significantly between ethnic groups with Asians having lowest mean age                      Mean BMI also varied significantly with Africans having highest BMI                      Babies were preterm (58%), below 10<sup>th</sup> centile for gestational age (52%) or both (13%). African mothers had 92% of the preterm births in this sample.                      Folate and iron intakes were low in all ethnic groups compared to RNI (half did not meet the RNI for folate and 88% did not meet the RNI for iron).                      Mean vitamin D and calcium intakes were</p>				

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		<p>significantly different between the groups. African women had the highest Vitamin D intakes and Caucasians and Asians the lowest. Over two thirds of African, Asian and African-Caribbean women did not meet the RNI for calcium. The authors acknowledge limitations in their sampling. They suggest their data could be used to target specific appropriate dietary advice to ethnic minorities for the prevention or repetition of LBW.</p>				

**Fatty acids**

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Jensen 2000 Houston Texas, USA RCT 1-	To determine the effect of docosahexaenoic acid (DHA) supplementation of lactating women on DHA contents of (breastmilk, infant plasma phospholipids and) maternal plasma phospholipids	<u>Inclusion:</u> Women in last trimester or at time of delivery, planning to breast-feed exclusively for ≥8 weeks <u>Exclusion:</u> Aged <19 or >35y at delivery, history of diabetes or suggesting egg allergy, baby born at gestational age <37 weeks or birth weight <2.5 or >4.2 kg  26 randomised to four groups Intervention groups: Gp 1 (n=7), Gp 2 (n=6) Gp 3 (n=6) Control group: Gp 4 (n=7)  Mean age 29y (25-35) Mean parity 1.5 (0.7-2.2) Mean height 163cm (152-172) Mean weight 2 weeks	Power calculation not reported  Method of randomisation is not reported	Assigned to receive, from 2-8 weeks postpartum: Gp 1: an algae-produced triacyl glycerol with a high DHA content Gp 2: 2 eggs per day with high DHA content Gp 3: a low-EPA, high DHA fish oil Gp 4 (controls): 2 regular eggs per day DHA received was <230, 170, 260 and <35 mg/day for groups 1-4 respectively.  Maternal n-3 and n-6 polyunsaturated fatty acids in maternal plasma phospholipids at 2 and 8 weeks postpartum  24/26 women followed up, 6 in each group (92%). Two partially breastfeeding women (<75% of intake) were excluded	No significant differences in total saturated or total monounsaturated fatty acid levels in maternal plasma phospholipids were found.  The only significant inter-group difference for change in n-3 fatty acids in maternal plasma phospholipid from baseline to 8 weeks post partum was for DHA (22:6n-3) with higher levels for all the supplemented groups than for the control group (p<0.05).  The highest DHA level was for Gp 1, who received the highest level of DHA supplementation  The only significant difference for change in maternal plasma n-6 fatty acid phospholipid concentrations from baseline to 8 weeks post partum was for eicosapentaenoic acid (EPA 22:5n-6) (usually found in fish oil). there were significantly lower levels in Gp 2 (high DHA eggs) than in the other groups and the highest level in Gp 4 (regular eggs)  The main aim of the paper is to determine the effect of supplementation on the content of breast milk and not the health of the mother.  DHA supplementation appears to increase maternal plasma DHA in a dose-related way.	Although the fish oil used as a supplement for Gp 3 was low-EPA, it appeared to contain some EPA. If the aim was to compare the use of different supplements containing DHA, it would have been better to use supplements containing identical DHA contents.  Funding from the US Department of Agriculture, Agricultural Research Service; the National Institutes of Health; the Mead-Johnson Nutritional Group; The Foundation Supporting Blindness;

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings
						Comments
						Funding
		postpartum 72.5 kg (53-102)  Baseline DHA intake/status of the study population/ the population of the USA are not reported.				Research to Prevent Blindness Inc; and Retina Research Foundation

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Helland 1998  Oslo, Norway  RCT  1-	What are the effects of cod liver oil consumption and general food intake on breast milk fatty acid composition?	Healthy, lactating women, 3-8 weeks postnatal, not daily smokers, not taking regular supplements after the birth/ at least 6 weeks before the study 28 randomised 22 completed the study Gp 1: No supplementation n=6 Gp 2: 2.5ml cod liver oil daily n=5 Gp 3: 5ml cod liver oil daily n=5 Gp 4: 10 ml cod liver oil daily n=6 Median age 29 (21-38) years BMI 24.1 (18.8-38.1) kg/m <sup>2</sup> Other details not reported Baseline fatty acid intake/status of the study population/ the population of Norway are not reported.	Power calculation not reported  Method of randomisation is not reported	Cod liver oil supplements for 14 days between 3 and 8 weeks postpartum  The cod liver oil contained 7.7g EPA (eicosapentaenoic acid 20:5n-3), 10.2g DHA (docosahexaenoic acid 22:6n-3), and 22.9g n-3 fatty acids per 100 ml  Median and range of fatty acid levels in maternal plasma phospholipids (and milk) for each of the four groups reported before and after the intervention  Venous blood samples taken on days 0 and 14. Follow-up at 14 days 22/28 (79%)	Large variations in reported dietary intake  Statistical significance set at (p <= 0.05)  Statistically significant increases were found in plasma DHA in Gp 4, plasma EPA in Gps 1 and 4, and sum of n-3 fatty acids in Gps 1 and 4  A statistically significant decrease in the ratio n-6/n-3 fatty acids was found in Gp 4  The concentration of EPA in breast milk increased in the groups supplemented with 5 or 10ml cod liver oil (p<0.05), whereas the concentration of arachidonic acid (AA, 20:4n-6) did not change in any of the supplemented groups. The concentration of tocopherol did not change during the supplementation period, neither in plasma nor in breast milk'.  The focus of this study is composition of breastmilk as nutrition for babies.  Authors conclude 'our study shows that supplementation with cod liver oil during lactation increases the content of DHA in breast milk in a dose-dependent way. This may be of practical importance for women and their infants, since mothers may lose DHA during several pregnancies, and infants need large amounts of DHA for development of the central nervous system'.	Data not normally distributed  Funding source not reported

**Iron**

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Krafft 2005  Zurich, Switzerland  RCT  1++	To assess the benefits of postpartum iron supplementation in non-anaemic iron-deficient women	<u>Inclusion:</u> antenatal iron deficiency (serum ferritin <15µg/L) combined with absence of ante or postpartum anaemia (haemoglobin [Hb] .11.0 g/dL up to 48 hours before delivery, and postpartum Hb >10.0 g/dL <u>Exclusion:</u> pregnancy anaemia, peripartum blood transfusion, a history of haematological disease, iron intolerance, malabsorption or inflammatory bowel disease, treatment interfering with Hb (e.g. plasma expanders), refusal to discontinue medication containing iron (e.g. multivitamin	Power calculation not reported  Paper states participants were randomised in blocks of four according to a computer-generated list by the sponsor's Clinical Pharmacy Department (who also held the master randomisation list)	Oral iron sulphate 80 mg daily or placebo for 12 weeks starting 24-48 hours after delivery  Measures of iron status, erythropoiesis and inflammatory response compared pre-treatment and at 1, 4, 6 and 12 weeks postpartum  100% follow-up at 12 weeks	Compared with placebo group, at 12 weeks the intervention group had: increased ferritin (P=0.0004) increased transferrin saturation (P=0.03) decreased soluble transferrin receptors (P=0.02) increased haemoglobin (P=0.02) decreased hypochromic red cells (P=0.04) with no differences in other red cell or reticulocyte parameters  Authors conclude that haemoglobin levels and iron stores in women with term gestational iron deficiency benefit significantly from iron supplementation compared with placebo, even in an industrialised population  Clinical importance for postpartum mothers of this finding is not clear	Mean [SD] blood loss (mL) at delivery reported: 301 [93.7] in the intervention group and 402.5 [252.2] in the control group. Assuming normal distribution, this would indicate that a third or more of the control group, and something less than a sixth of the intervention group, were judged by the birth attendant to have had a postpartum haemorrhage (blood loss >500 mL)  Stage at which postpartum Hb was measured is not stated but can be assumed to be

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		<p>preparations) after delivery, treatment with intravenous iron prior to delivery, haemosiderosis (iron overload syndrome) and participation in another clinical trial within the previous 3 months</p> <p>52 randomised. They were randomised after meeting the inclusion criteria, i.e. when the results of the postpartum Hb were reported as &gt;10.0g/dl. Paper does not state when the sample used to estimate postpartum Hb was taken.</p> <p>Supplementation was started 24-48 hours after delivery .</p> <p>28 to the intervention and 24 controls</p> <p>Mean age 28y</p> <p>Prepartum baseline haematology(mean (SD) range):</p> <p>Ferritin (µg/L)</p> <p>10.2(3.5) 2-18</p>				<p>before intervention began at 24-48 hours.</p> <p>Supplementation started at some point between 24 and 48 hours after the birth.</p> <p>Accuracy of Hb estimation at this stage is clinically questionable</p> <p>Robapham (Groupe Pierre Fabre) provided the study drug and gave financial support</p>

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings
						Comments Funding
		Hb (g/dL) 12.1 (0.7) 11-14-4 Postpartum Hb (g/dL) 11.7 (1.2) 10.2-14.3 in the intervention group versus 11.6 (0.8) 10.0-13.4 in the control group				

First Author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Mara 2001  Czech Republic  RCT  1-	To examine the occurrence of iron deficiency anaemia in women after spontaneous delivery, changes in clinical and laboratory indicators of anaemia in postpartum period and their possible control by administration of per oral anti-anaemics	Women in the third trimester of pregnancy Inclusion: baseline haemoglobin >10 g/dl, baseline haematocrit >0.30 Exclusion: women who had been treated with per oral anti-anaemicshaematinics, women who had ever had transfusion, delivery by caesarean section or forceps, and women who did not comply (missed any of the blood tests or did not use iron medication properly) 90 women randomised to 3 groups, 30 in each group Characteristics of 60/90 who completed the trial: Group T Mean age 27.10 y Proportion of	Power calculation not reported  Method of randomisation: Ninety cards were put into a white envelope. Each of the 90 women entering the trial after giving signed consent took a card from the envelope and was assigned to group T, F or C according to the letter written on the card	Group T: oral iron (Tardyferon = 256.3mg FeSO <sub>4</sub> i.e. 80 mg elemental iron, + 80mg mucoprotease + 30mg ascorbic acid) one tablet /day from day 4 to the end of the second month after the birth  Group F: oral iron (Tardyferon Fol = Tardyferon + 0.35mg folic acid) one tablet /day for the same period  Group C: no medication  Five data collection points, at 35-9 weeks of pregnancy, and after the birth at day 4 and the end of the first, second and third months  Tests included blood count, serum folic acid, vitamin B12, erythropoetin and soluble transferrin receptor, markers of iron metabolism and reserves, and total protein serum concentration. Women's self-ratings of fatigue, weakness/vertigo, tolerance for physical load, dyspnoea and palpitation on a 20 point scale (the higher the score, the better the feeling)  30 women, 10 from each group, did not complete the trial 14 delivered by caesarean section or forceps 6 blood transfusions 10 did not comply	Sideropenia is defined in the paper as ferritin concentration <30ng/ml and named as the 'only sovereign marker of iron deficiency anaemia in the early postpartum period'  Haemoglobin (g/dl) Day 4 1 month 2 months 3 months T 10.64 12.30 12.43 12.43 F 10.30 12.32 12.71 12.63 C 10.69 11.25 11.90 12.69 P<0.0001 for both treated groups compared with control group during the first month  Haematocrit Increase stated to be statistically significant at the same level between the same groups over the same period as for haemoglobin but numbers are not reported in the paper  Ferritin concentration Stated to have continually increased in all the groups, with a statistically significant increase only in group T (p<0.05)  Sideropenia (ferritin concentration <30ng/ml) At 35-9 weeks gestation: 53% (not reported by group) 3 months after delivery: T 3/20 (15%) F 6/20 (30%) C 7/20 (35%)  Women's ratings of their health	Applicable to UK women  BMI at recruitment seems low for women in the third trimester of pregnancy  This was not a placebo-controlled trial  Folic acid fortification is not mentioned in the paper  Both preparations used in the study were made by Pierre Fabre Medicament. Funding source not reported

First Author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		primiparae to multiparae 10/10 BMI 24.54 Mean blood loss at delivery 240ml Group F Mean age 27.35 y Proportion of primiparae to multiparae 14/6 BMI 25.63 Mean blood loss at delivery 310ml Group C Mean age 26.95 y Proportion of primiparae to multiparae 9/11 BMI 25.00 Mean blood loss at delivery 282.5ml Differences between groups not significant		Follow-up rate 66.67% in each group and overall	Significantly higher rating at one month ( $p < 0.01$ ) and two months postpartum for both intervention groups compared with control group. No differences between the groups detected at 3 months.	

**Folic Acid**

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Keizer 1995  Southern Ontario, Canada  RCT  1+	To assess the impact of (lactation on folate status and) ingestion of a low dose postpartum folic acid supplement on maternal folate and zinc status (and milk composition) in adolescent mothers	<u>Inclusion:</u> age 14-19 y, haemoglobin (Hb) $\geq 110$ g/L at 36 weeks gestation, singleton term delivery  <u>Exclusion:</u> discouraged by physician, baby for adoption, anaemic/ took supplements post partum  71 pregnant adolescents recruited and randomised if breastfeeding on delivery (n=29), 14 for intervention and 15 for placebo  White 92%, Native Canadian/white 4%, Black 3%, Asian/white 1% Married 0%, living with partner 14% 56% with main	Power calculation not reported.  Paper states a random numbers table was used to assign treatments	<u>Intervention:</u> 1x 300 $\mu$ g/capsule folic acid per day for 4 weeks, starting within 1 week of delivery  <u>Control:</u> placebo  Dietary intake estimated using 2x24h dietary recalls at 4, 8 & 12wks postpartum Blood samples taken at 36 wks gestation and 4, 8 and 12 wks post partum. Hb, haematocrit, plasma and erythrocyte folate, plasma vitamin B12, plasma ferritin, plasma alkaline phosphatase and plasma zinc determined  Hair zinc determined from samples taken at 36 weeks gestation and 4 and 12 weeks post partum.  Length of follow-up ~12 weeks  Follow-up rate 29/29, 100%	Total energy, fat, protein and carbohydrate intakes similar in both groups and close to recommended amounts except for % energy derived from fat (higher than recommended).  Dietary intakes (excluding the supplement) of folate, zinc, iron and vitamin B12 also similar but participants (59%, 46%, 36% and 59% respectively) consumed <67% of Canadian RNI of these micronutrients. Blood and hair analyses indicated that the mothers were not at immediate risk of folate, vitamin B-12 or zinc deficiency, but they were at risk of depleted iron stores since 37% had plasma ferritin levels <26.2 pmol/L, the normal limit.  Average erythrocyte folate concentrations for all groups were well above cut-off value (368nmol/L) indicative of folate depletion. Significant differences between the groups were evident only at 4 weeks postpartum (supplemented group 796.0 $\pm$ 48.2 nmol/L, placebo 1023.2 nmol/L). No significant change from 4 to 8 to 12 weeks noted in the supplemented group but a significant decline from 4 to 12 weeks seen in the placebo group ( $p < 0.05$ ).  Biochemical indexes measured did not differ by treatment group and most, including zinc (zinc or plasma zinc throughout), did not differ from wk4-wk12	82% of subjects took supplements containing folic acid during pregnancy. All were instructed not to use additional supplements postpartum (77% intervention group complied)  Serum zinc concentration is a very poor measure of status.  Funded by the Natural Sciences and Engineering

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		<p>source of income from government, 39% from parents and 5% from employment Negligible self-reported alcohol and drug use</p> <p>Baseline folate/zinc intake/status of study population/country not reported</p>			<p>postpartum</p> <p>Adolescent mothers, particularly those of low socioeconomic status, are thought to be at risk of folate deficiency due to poor dietary habits. Supplementation with folic acid was found to prevent a decline in erythrocyte folate in adolescent mothers. However, mean levels did not differ between the intervention and control groups.</p> <p>There were no significant differences in either plasma folate or plasma zinc levels in either group.</p>	<p>Council of Canada</p>

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Mackey 1999  Pennsylvania, USA  RCT  1-		<p><u>Inclusion:</u> Healthy, non-smokers, no pregnancy complications, successfully breastfeeding and planning to do so for <math>\geq 6</math> months, infant born at full-term (37-40 weeks), no unusual dietary practices, not using oral contraception</p> <p>42 lactating women randomised at 3 months postpartum, 21 to intervention and 21 to control Mean age [range] y: 34 [26-42] S/E status: middle to high income households White 100%; Mean weight 67 kg; Mean BMI <math>25 \pm 1</math> kg/m<sup>2</sup> Mean parity 2; Mean y education 16 Mean prenatal</p>	<p>Power calculation not reported</p> <p>Paper states the study was a double-blind, randomised trial with assignment to groups balanced for parity. Method of randomisation is not reported</p>	<p>All participants received a multivitamin/ mineral supplement <u>Intervention:</u> 1 mg folic acid supplement per day from 3-6 months post partum. <u>Control:</u> Placebo.</p> <p>2-day dietary records at 3 and 6 months post partum. Blood samples at 3 and 6 months post partum analysed for plasma folate, erythrocyte folate, plasma homocysteine, haemoglobin (Hb), haematocrit, mean corpuscular volume (MCV) and reticulocytes.</p> <p>Length of follow-up 3 months (100%)</p>	<p>Plasma folate concentrations at 3 months were similar. At 6 months plasma folate in the supplemented group was <math>47.6 \pm 6.5</math> nmol/L and in the control group <math>36.8 \pm 4.2</math> nmol/L (not statistically significant). Erythrocyte folate concentrations at 6 and 3 months were positively associated (<math>p &lt; 0.02</math> in both groups), and were significantly higher in the supplemented group at 6 months (<math>p &lt; 0.05</math>).</p> <p>There was an increase in plasma homocysteine level from 3 to 6 months in both groups, significant in the non-supplemented group only (<math>p &lt; 0.05</math>). In folic acid-supplemented women only, an inverse relationship between plasma homocysteine and plasma folate at 6 months was found (<math>p &lt; 0.01</math>).</p> <p>At 6 months, Hb was significantly higher in supplemented women (140 g/L) than controls (134 g/L) <math>p &lt; 0.02</math>. At 6 months, folic acid-supplemented women had significantly higher haematocrit values <math>p &lt; 0.02</math> and significantly lower nos. of reticulocytes <math>p &lt; 0.05</math>. No differences in MCV were found.</p> <p>This study found that folic acid supplementation in lactating women increased erythrocyte folate and haemoglobin concentrations and led to an inverse relationship between plasma folate and plasma homocysteine. They conclude dietary folate needs during lactation are greater than previously estimated (and <math>&gt; 380</math> <math>\mu\text{g/d}</math>).</p>	<p>Globally up to one third of pregnant and lactating women are thought to have some degree of folate deficiency linked to neural tube defects, low birth weight etc. and also precancerous lesions of the cervix and colon and elevated plasma homocysteine – an independent risk actor for cardiovascular disease.</p> <p>Compliance with taking tablets was 80%.</p> <p>Overall dietary intake of folate for all subjects (<math>\mu\text{g/d}</math>) at 6 months was</p>

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		<p>supplementation with folic acid 650 µg/day (11/42 of the participants (26%) did not take prenatal supplements during pregnancy and the early postpartum period before enrolment). Baseline mean folate intake from self-selected diets (µg/d) 390±21</p> <p>No significant differences found between the groups</p>				<p>372±19 (no significant differences between the groups)</p> <p>Funding in part from the US Department of Agriculture</p> <p>The paper does not report when the data was collected whether it was before or after fortification of grain, introduced in the US in 1998. The most recent references in the paper's reference list are dated 1998. The reported intakes look quite high if before, as mean in NHANES III was 275 µg /d).</p>

## Calcium

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
Cross 1995  Columbia, Missouri, USA  RCT  1-	To determine the effects of lactation and supplementation by 1 g of calcium on bone remodelling including markers for bone turnover, calcium homeostatic hormones and bone mass	<u>Inclusion:</u> healthy women intending to breastfeed for at least 3 months  <u>Exclusion:</u> non-Caucasian, <22 or >37 years old, use of alcohol except on special occasions, smoking, history of medical conditions or medications altering calcium (Ca) or bone metabolism  12 women randomised to 1g Ca/day 10 to placebo  Mean age 28.2 y Mean Ca intake at baseline 1308 mg/day  Calcium intake in USA not reported	Power calculation not reported  Paper states the study design was a randomised double-blind clinical intervention trial. Method of randomisation is not reported	All participants were provided with a (prenatal) supplement containing 250 mg Ca as CaCO <sub>3</sub> and 400 IU vitamin D. Intervention Ca group took 500mg Ca as CaCO <sub>3</sub> twice a day from ≤2 weeks post partum through the post-weaning study (when they stopped taking the tablets is unclear). Control group took placebo.  6-day food record kept at baseline and after weaning.  Measurements at baseline (≥2 weeks post partum), after 3 months lactation and 3 months post weaning (mean 10.3 months post partum).  Measurements of bone mineral density (BMD) (radius, ultradistal radius (UD), lumbar spine (L2-L4), total body), bone remodelling indices (serum bone specific alkaline phosphatase, procollagen I carboxypeptides (PICP), tartrate-resistant acid phosphatase (TRAP), osteocalcin), hormone levels (prolactin, parathyroid hormone (PTH), 25-OH-vitamin D (25-OH-D) and 1,25-dihydroxy-vitamin D (1,25- diOH-D) and mineral levels (serum and urine Ca, Mg and P and creatinine) Length of follow-up mean ~10 months, wide range (post weaning assessment carried out mean 2.7 months after weaning)  Follow-up rate 15/22 (68%)	All but 3 participants were breastfeeding exclusively at 3 months (these 3 provided at least 50% of the baby's milk as breastmilk). Six participants were breastfeeding exclusively at 6 months post partum. Mean length of breastfeeding 7.6 months, range 3-17 months.  Mean dietary intake of Ca at baseline was 1125±82 mg/day for Ca group vs. 1047±77 for P group ( ~2400 vs. ~1300 mg/day including supplements). Post weaning Ca intakes were lower by ~300 mg.  No differences were found between the Ca group and the placebo group for BMD, biochemical indicators or serum or urine minerals  Changes related to lactation and weaning. BMD: baseline to lactation - lumbar spine -4.3% (P) p<0.04 and -6.3% (Ca) p<0.01; UD radius +5.7% (Ca) p<0.04. Lactation to post weaning – all sites of radius and ulna -6% to -11% (Ca, P) p<0.04; lumbar spine +3% (Ca) p<0.03. Baseline to post weaning - UD radius -5.2% (P) p<0.03; UD radius and ulna -6% to -8% (Ca, P) p<0.04 but no statistically significant loss of lumbar or total BMD.  Bone turnover markers were higher at lactation than post weaning (PICP, osteocalcin, TRAP) and prolactin. Indicators of Ca metabolism were higher post weaning than lactation for PTH, 25-OH-D but not	After randomisation subjects excluded due to very low spinal BMD (1), unable to complete post weaning studies (6) (due to pregnancy (2), extended breastfeeding (2), non-attendance (2)  At baseline both the intervention and placebo groups had a mean total Ca intake greater than the RDA of 1200 mg/day  Funded by the National Dairy Promotion and Research Board

First author, Year,	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
					<p>1,25-diOH-D.</p> <p>An increase in markers of bone turnover and a loss of BMD of the spine during lactation appear to be part of the physiological changes of lactation and are not prevented by increasing Ca intake above the recommended daily allowance.</p>	

First author  Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings  Comments  Funding
Kalkwarf 1997  (also see Kalkwarf 1998, Kalkwarf 1999 and Wosje 2004)  Cincinnati, Ohio, USA  RCT  1-	Does calcium supplementation prevent bone loss during lactation; does it augment bone gain after weaning	<u>Inclusion:</u> Postpartum women with low-to-moderate baseline calcium intake ( $\leq 800\text{mg/day}$ ), who took vitamins in pregnancy and gave birth at term to singleton infants  <u>Exclusion:</u> Women with disorders affecting metabolism of calcium or bone, taking regular medications or hormonal contraceptives <u>Lactation study cohort</u> (the first six months, starting mean [SD] $16\pm 2$ days postpartum) n=196 Lactating women 97  Non-lactating women 99 Randomised to calcium 101 Randomised to placebo 95 <u>Weaning study cohort</u> (the second 6	Power calculation not reported  Paper states the study was a randomised, double-blind, placebo-controlled trial. Method of randomisation is not reported	All participants received multivitamin including 400 IU vitamin D. For lactation study only, these included iron.  Women randomised to calcium received 2 x 500 mg calcium carbonate tablets to be taken one with morning meal and one with evening meal  Women in control group received placebo (primarily lactose)  Participant monitoring included infant feeding frequency and method, menstrual cycle. Food consumption for calcium intake and physical activity assessed after 3 months for both cohorts  Bone mineral content of whole body, lumbar spine, ultradistal radius and distal third of radial shaft of left arm measured at enrolment and after 3 and 6 months by dual-energy x-ray absorptiometry  Follow-up at 6 months (lactation study) 168/196 (86%)  Follow-up after 6 months, at 12 months (weaning study) 158/187 (85%)  Overall follow-up 326/383 (85%)	<ul style="list-style-type: none"> <li>• Pill counts showed 92% of women took at least 80% of their pills</li> <li>• Dietary calcium intake was higher in the lactating women than in the non-lactating women in the lactation study both before and during the study (<math>p &lt; 0.05</math>)</li> <li>• Dietary calcium intake was higher in the lactating women than in the non-lactating women in the weaning study at baseline (<math>p &lt; 0.05</math>) but not after weaning</li> <li>• In the lactation study, lactating women lost significantly more lumbar spine mineral density than non-lactating women. Calcium supplementation had a positive effect on lumbar spine mineral density that was statistically significant among non-lactating women (<math>p &lt; 0.01</math>) but not in lactating women (<math>p = 0.38</math>). Authors state lack of statistical interaction between the lactating group and the calcium group indicates that calcium supplementation was not more beneficial in one group than in the other</li> <li>• In the lactation study, neither calcium supplementation nor lactation was found to affect bone mineral density of the radius</li> <li>• In the weaning study, bone density in the lumbar spine increased independently of calcium supplementation in both the lactating and non-lactating women, with increases noted at 9 months and greater increases at 12 months. Bone density in the lumbar spine increased significantly more in the two calcium groups than in the two placebo groups (<math>p &lt; 0.05</math> for both</li> </ul>	These findings would need to be applied in the light of mean calcium intake among postpartum women in the UK  Data on which sub-groups if any have lower than average intake of dietary calcium would be useful All mean % changes in bone mineral content and density were adjusted for initial bone mass or density, height, weight, change in weight, dietary calcium intake and physical activity. Authors state these adjustments had little effect on the results.  The paper reports results from milk that are not

First author  Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings  Comments  Funding
		months, starting mean [SD] 5.6±0.8 months postpartum) n=187  Lactating women 95 Non-lactating women 92 Randomised to calcium 90 Randomised to placebo 97 <u>Mean age [range]:</u> 30.5[26-34] <u>S/E status:</u> not stated <u>Ethnicity:</u> data from 5 black women in each cohort and 3 Asian women in the weaning cohort, all other data from white women <u>Mean weight [range] kg:</u> 65.3 [48.7-78.4] <u>Mean height [range] cm:</u> 164.4 [157-171.2] <u>Parity:</u> 2±1 <u>Method of infant feeding:</u> In lactation cohort,			lactating and non-lactating women) <u>Authors conclude:</u> <ul style="list-style-type: none"> <li>• Supplemental calcium does not prevent total body bone mass loss during lactation and does not benefit lactating women more than non-lactating women</li> <li>• Bone density increases after weaning both in women who receive calcium supplementation and in those who do not</li> </ul> Findings from this study demonstrate that postpartum women with moderate dietary calcium intake may improve their lumbar spine BMD with calcium supplements; however it does not benefit lactating women more than non-lactating women.	included here  Supported in part by grants from General Clinical Research Centers Program, National Center for Research Resources. Medela Company provided universal pumping systems for the electronic breast pumps, Abbott Laboratories provided multivitamin supplements, and Marion Merrell Dow provided calcium supplements and placebo compounds

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		<p>lactating women intended to breastfeed for at least 6 months and to provide no more than one formula feed per day; non-lactating women fed their infants exclusively with formula.</p> <p>In weaning cohort, lactating women were breastfeeding more than 4 times a day at enrolment and weaned their infants during the next 2 months; non-lactating women had not breastfed (86/92) or had breastfed for 2 weeks or less (6/92).</p> <p>Baseline dietary calcium intake (mg/day) median (25<sup>th</sup>, 75<sup>th</sup> percentile):  <u>Lactation cohort</u>                      Lactating women 614 (472, 753)                      Non-lactating women 510 (371, 644)</p>				

First author Year	Research question	Study population	Research Quality	Intervention	Main results	Applicability to UK populations and settings Comments Funding
		P<0.05 <u>Weaning cohort</u> Lactating women 699 (571, 792) Non-lactating women 578 (478, 704) P<0.05				

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